1. CALL TO ORDER

2. TOPICS
   A. Discuss Minimum Age to Purchase Tobacco
   B. Set future Study Sessions

3. ADJOURN
Council has expressed an interest in reconsidering the minimum age to purchase tobacco in the community. The City has the ability to affect the age through its tobacco licensing authority. The Council discussed the concept of increasing the age to purchase tobacco at a study session on September 26, 2017.

When the Council last met, it asked for additional information. Specifically:

- Sample ordinances from other communities.
- Feedback from retailers and other interest groups.
- Information from industry on the health impacts of vapor.

Staff has received a significant amount of information from advocates of a policy change – but has received very little from retailers and industry. In discussion with a representative from one of these groups, opponents to the ordinance may wait to submit information or weigh in until the public hearing which the Council scheduled for November 28, 2017.

As the Council considers its ordinances related to tobacco, there are a few broad policy questions that merit discussion:

- What is the City’s role in establishing and regulating the minimum age to buy tobacco?
- Should the City establish a minimum age above the age prescribed in State Statute or should this be a prerogative of the State?
- How can local ordinances alter youth access to tobacco?

The options discussed on September 26, 2017 included more study of the matter, creation of an ordinance increasing the age, or defer this regulation to the State. If the third option is preferred, the Council may choose to add language to its legislative priorities to increase the age.

Staff has included copies of the Edina and St. Louis Park ordinances which have been enacted and an ordinance drafted by the City Attorney for Plymouth.
ORDINANCE NO. 2017-03

AN ORDINANCE AMENDING CHAPTER 12 OF THE
EDINA CITY CODE CONCERNING TOBACCO

THE CITY COUNCIL OF EDINA ORDAINS:

Section 1. The following definitions in Section 12-189 of the Edina City Code are amended to provide as follows:

Compliance checks means the system the city uses to investigate and ensure that those authorized to sell tobacco or tobacco-related products, and tobacco-related devices are following and complying with the requirements of this article. The term "compliance checks" also means the use of persons under 21 years of age who attempt to purchase tobacco or tobacco-related products, or tobacco-related devices, for education, research and training purposes as authorized by state and federal laws. Compliance checks may also be conducted by other units of government for the purpose of enforcing appropriate federal, state or local laws and regulations relating to tobacco or tobacco-related products, and tobacco-related devices.

Tobacco-related device means any tobacco product as well as a pipe, rolling papers or other device intentionally designed or intended to be used in a manner which enables the chewing, sniffing, smoking, or the inhalation of vapors of tobacco or tobacco-related products. The term "tobacco-related device" includes electronic delivery devices and nicotine or lobelia delivery products.

Section 2. Section 12-189 of the Edina City Code is amended by adding the following definitions:

Child-resistant packaging means packaging that meets the definition set forth in Code of Federal Regulations, title 16, section 1700.15(b), and was tested in accordance with the method described in Code of Federal Regulations, title 16, section 1700.20.

Nicotine or lobelia delivery product means any product containing or delivering nicotine or lobelia intended for human consumption, or any part of such a product, that is not tobacco or an electronic delivery device as defined in this section. Nicotine or lobelia delivery product does not include any product that has been approved or certified by the United States Food and Drug Administration for sale as a tobacco-cessation product, as a tobacco-dependence product or for other medical purposes, and is being marketed and sold solely for such an approved purpose.
Section 3. Section 12-217 of the Edina City Code is amended to provide as follows:

Sec. 12-217 Required.

No person shall keep tobacco, tobacco-related products or tobacco-related devices for retail sale or sell tobacco, tobacco-related products or tobacco-related devices at retail in the city without first obtaining a license from the city. No license shall be issued for the sale of tobacco, tobacco-related products or tobacco-related devices at a movable place of business or from a vending machine or to a person under the age of 21.

Section 4. Section 12-247 of the Edina City Code is amended to provide as follows:

12-247 Legal Age.

No person shall sell any tobacco, tobacco-related product or tobacco-related device to any person under the age of 21 and no person shall purchase or otherwise obtain such items on behalf of a person under the age of 21.

(1) Age Verification. Licensees shall verify by means of government-issued photographic identification that the purchaser is at least 21 years of age. Verification is not required for a person over the age of 30. That the person appeared to be 30 years of age or older shall not constitute a defense to a violation of this subsection.

(2) Signage. Notice of the legal sales age and the age verification requirement shall be posted at each location where tobacco, tobacco-related products or tobacco-related devices are offered for sale. The required signage, which will be provided to the licensee by the city, shall be posted in a manner so that it is clearly visible to anyone who is considering or making a purchase.

Section 5. Section 12-250 of the Edina City Code is amended to provide as follows:

12-250 Self-service merchandising.

No person shall sell any tobacco, tobacco-related product or tobacco-related device by means whereby the customer may have access to such items without having to request assistance from an employee of the licensed premises. The assistance or intervention shall entail the actual physical exchange of the tobacco, tobacco-related product or tobacco-related device between the customer and the licensee or employee. All tobacco, tobacco-related products or tobacco-related devices shall be stored or displayed behind a sales counter or in other rooms or display areas which are not freely accessible to customers. Provided, however, the requirements of this section shall not apply to establishments which:

(1) Prohibit persons under 21 years of age from entering the establishment at all times;

(2) Post notice advising of the prohibition at all entrances to the establishment; and
(3) Derive at least 90 percent of their revenues from the sale of tobacco and tobacco-related products.

Section 6. Section 12-251 of the Edina City Code is amended to provide as follows:

12-251 Liquid Packaging.

No person shall sell or offer to sell any liquid, whether or not such liquid contains nicotine, which is intended for human consumption and use in an electronic delivery device, in packaging that is not child-resistant. Upon request, a licensee shall provide a copy of the certificate of compliance or full laboratory testing report for the packaging used.

Section 7. Section 12-254 of the Edina City Code is amended to provide as follows:

12-254 Use of false identification.

No person under the age of 21 shall attempt to disguise his or her true age by the use of a false form of identification, whether the identification is that of another person or one on which the age of the person has been modified or tampered with to represent an age older than the actual age of the person.

Section 8. Section 12-255 of the Edina City Code is amended to provide as follows:

12-255 Compliance checks and inspections.

(a) All licensed premises shall be open to inspection by the city or other authorized official during regular business hours.

(b) From time to time, but at least once per year, the city shall conduct compliance checks by engaging, with persons over 15 years but less than 21 years, to enter the licensed premises to attempt to purchase tobacco, tobacco-related products or tobacco-related devices.

(1) Prior written parental consent is required for any minor who participates in a compliance check.

(2) Persons used for the purpose of compliance checks shall be supervised by designated law enforcement officers or other designated city personnel.

(3) Persons used for compliance checks shall not be guilty of the unlawful purchase or attempted purchase, nor unlawful possession of tobacco, tobacco-related products or tobacco-related devices when such items are obtained or attempted to be obtained as part of the compliance check.

(4) No person used in the compliance checks shall attempt to use a false identification misrepresenting the person's age, and all persons lawfully engaged in a
compliance check shall answer all questions about the person's age for which he or she is asked.

(c) Nothing in this article shall prohibit compliance checks authorized by state or federal laws for educational, research or training purposes, or required for the enforcement of a particular state or federal law.

Section 9. Section 12-282(3) of the Edina City Code is amended to provide as follows:

**Underage persons.** Persons under 21 years of age who use false identification to purchase or attempt to purchase, tobacco, tobacco-related products or tobacco-related devices shall be guilty of a misdemeanor and may be required to attend tobacco free education programs or court diversion programs.

Section 10. Section 12-283 of the Edina City Code is amended to provide as follows:

12-283 Exceptions and Defenses.

It shall be an affirmative defense to the violation of this article for a person to have reasonably relied on proof of age as described by state law.

Section 11. Sections 12-252 and 12-253 of the Edina City Code are deleted.

Section 12. This ordinance is effective July 1, 2017.

First Reading: April 18, 2017
Second Reading: May 2, 2017
Published: May 11, 2017

Attest
Debra A. Mangen, City Clerk
James B. Hovland, Mayor

Please publish in the Edina Sun Current on Thursday, May 11, 2017
Send two Affidavits of Publication
Bill to Edina Accounts Payable
ORDINANCE NO. 2521-17

ORDINANCE AMENDING CHAPTER 8 OF THE
ST. LOUIS PARK CITY CODE RELATING TO TOBACCO

THE CITY OF ST. LOUIS PARK DOES ORDAIN:

SECTION 1. Section 8-374(a) of the City Code shall be amended to read as follows:

(a) It shall be a violation of this subdivision for any person to sell or offer to sell any tobacco, tobacco-related device or electronic delivery device:
   (1) To any person under the age of 1821 years.
   (2) By means of any type of vending machine.
   (3) By means of self-service merchandising whereby the customer does not need to make a verbal or written request to an employee of the licensed premises in order to receive the tobacco, tobacco-related device or electronic delivery device. All such products shall be stored behind a counter or other area not freely accessible to customers.
   (4) Containing opium, morphine, jimson weed, bella donna, strychnos, cocaine, marijuana or other type of deleterious, hallucinogenic or toxic or controlled substance, except nicotine, and not naturally found in tobacco, tobacco-related devices or electronic delivery devices.
   (5) By any other means or to any other person prohibited by federal, state or other local laws, ordinances or other regulations.

SECTION 2. Section 8-377 of the City Code shall be amended to read as follows:

Sec. 8-377. Illegal acts.

Unless otherwise provided in this subdivision, the following acts shall be a violation of this subdivision:

(1) Illegal possession. It shall be a violation of this subdivision for any minor to possess any tobacco, tobacco-related device or electronic delivery device. This subsection shall not apply to minors lawfully involved in a compliance check on behalf of the city. Repealed

(2) Illegal use. It shall be a violation of this subdivision for any minor to smoke, chew, sniff or otherwise use any tobacco, tobacco-related device or electronic delivery device. Repealed

(3) Illegal procurement. It shall be a violation of this subdivision for any minor person to purchase or attempt to purchase, or otherwise obtain, any tobacco, tobacco-related device or electronic delivery device on behalf of a person under the age of 21 years; and it shall be a violation of this subdivision for any person to purchase or otherwise obtain such items on behalf of a minor. It shall also be a violation of this subdivision for any person to sell or otherwise provide such products to any minor person under the age of 21 years. It shall be a violation of this subdivision for any person to coerce or attempt to coerce a minor person under the age of 21 years to illegally purchase or otherwise obtain or use any tobacco, tobacco-related device or electronic delivery device.
device. This subsection shall not apply to minors lawfully involved in a compliance check on behalf of the city.

(4) Use of false identification. It shall be a violation of this subdivision for any minor person under the age of 21 years to attempt to disguise their true age by the use of a false form of identification, whether the identification is that of another person or one in which the age of the person has been modified or tampered with to represent an age older than the actual age of the minor person.

SECTION 3. Section 8-378(b) of the City Code shall be amended to read as follows:

(b) Criminal penalty. As set forth in M.S.A. ch. 609, it shall be a:
(1) Misdemeanor for anyone to sell tobacco, a tobacco-related device or electronic delivery device to a person under the age of 4821 years for the first violation. Whoever violates this subdivision a subsequent time within five years of a previous conviction under this subdivision is guilty of a gross misdemeanor.
(2) Misdemeanor to furnish tobacco, a tobacco-related device or electronic delivery device to a person under the age of 4821 years. Whoever violates this paragraph a subsequent time is guilty of a gross misdemeanor.
(3) Petty misdemeanor for anyone under the age of 18 years who possesses, smokes, chews, or otherwise ingests, purchases, or attempts to purchase tobacco, a tobacco-related device or electronic delivery device. Repealed.
(4) Petty misdemeanor for anyone under the age of 4821 years to sell, furnish or give away any tobacco, tobacco-related device or electronic delivery device. This subsection shall not apply to an employee of the license holder under the age of 18 years while such employee is stockling such products a person age 18-20 years while working as an employee of a business holding a license granted pursuant to this Subdivision.

SECTION 4. Section 8-378(c) of the City Code shall be amended to read as follows:

(c) Presumed penalties for Violations: The presumed penalties for violations are as follows (unless specified, numbers below indicate consecutive business days’ suspension):

<table>
<thead>
<tr>
<th>Type of Violation</th>
<th>1st Violation</th>
<th>2nd Violation within 36 months</th>
<th>3rd Violation within 36 months</th>
<th>4th Violation within 36 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Commission of a felony related to the licensed activity.</td>
<td>Revocation</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>2. Sale of tobacco, tobacco-related device or electronic delivery device while license is under suspension.</td>
<td>Revocation</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>3. Sale of tobacco, tobacco-related device or electronic delivery device to underage person.</td>
<td>$250</td>
<td>$750 and 1 day</td>
<td>$2,000 and 30 days</td>
<td>Revocation</td>
</tr>
<tr>
<td>4. Refusal to allow government inspectors or police admission to inspect premises.</td>
<td>5 days</td>
<td>15 days</td>
<td>Revocation</td>
<td>N/A</td>
</tr>
<tr>
<td>5. Illegal gambling on premises.</td>
<td>3 days</td>
<td>6 days</td>
<td>18 days</td>
<td>Revocation</td>
</tr>
<tr>
<td>6. Failure to attend mandatory education training.</td>
<td>$250</td>
<td>$750 and 1 day</td>
<td>$2,000 and 3 days</td>
<td>Revocation</td>
</tr>
</tbody>
</table>

**SECTION 5.** Section 8-378(j) of the City Code shall be amended to read as follows:

(j) Exceptions and defenses. Nothing in this subdivision shall prevent the providing of tobacco, tobacco products or tobacco related devices to a minor person under the age of 21 years as part of a bona fide religious, spiritual or cultural ceremony. It shall be an affirmative defense to a violation of this subdivision for a person to have reasonably relied upon proof of age as set forth by state law.

**SECTION 6.** This Ordinance shall take effect following its passage and publication on October 1, 2017.

| First Reading | June 26, 2017 |
| Second Reading | July 17, 2017 |
| Date of Publication | July 27, 2017 |
| Date Ordinance takes effect | October 1, 2017 |

Reviewed for Administration

Reviewed for Administration

Adopted by City Council July 17, 2017

Thomas K. BarronKing, City Manager

Jared Spano, Mayor

Attest:

Melissa Kennedy, City Clerk

Approved as to Form and Execution:

Soren Mattick, City Attorney
THE CITY OF PLYMOUTH ORDAINS:

SECTION 1. Section 1150 of the Plymouth City Code is amended to provide:

Section 1150 - Tobacco and Related Products

1150.01. Purpose and Intent. The City recognizes that young people are particularly susceptible to the addictive properties of tobacco products and are particularly likely to become lifelong users. National data show that about 95 percent of adult smokers begin smoking before they turn 21. The ages of 18 to 21 are a critical period when many smokers move from experimental smoking to regular daily use. Many persons under the age of 18 years purchase or otherwise obtain, possess and use tobacco, tobacco products, tobacco-related devices, and nicotine or lobelia delivery devices, and the sales, possession, and use are violations of both state and federal laws; and because studies, which the City hereby accepts and adopts, have shown that most smokers begin smoking before they have reached the age of 18 years and that those persons who reach the age of 18 years without having started smoking are significantly less likely to begin smoking; and because smoking has been shown to be the cause of several serious health problems which subsequently place a financial burden on all levels of government; this ordinance shall be intended to regulate the sale, possession and use of tobacco, tobacco products, tobacco-related devices, and nicotine or lobelia delivery devices for the purpose of enforcing and furthering existing laws, to protect persons under the age of 21 from the serious effects associated with the illegal use of tobacco, tobacco products, tobacco-related devices, and nicotine or lobelia delivery devices, and to further the official public policy of the state in regard to preventing young people from starting to smoke as stated in State Statute 144.391, as it may be amended from time to time. In making these findings, the City Council accepts the conclusions and recommendations of Center for Disease Control in their study “Selected Cigarette Smoking Initiation and Quitting Behaviors Among High School Students, United States, 1997,” and of the following medical professionals in these medical journals: Khuder SA, et al., “Age of Smoking Onset and its Effect on Smoking Cessation,” Addictive Behavior 24(5):673-7, September-October 1999; D’Avanzo B, et al., “Age at Starting Smoking and Number of Cigarettes Smoked,” Annals of Epidemiology 4(6):455-59, November 1994; Chen, J & Millar, WJ, “Age of Smoking Initiation: Implications of Quitting,” Health Reports 9(4):39-46, Spring 1998; Everett SA, et al., “Initiation of Cigarette Smoking and Subsequent Smoking Behavior Among U.S. High School Students,” Preventive Medicine, 29(5):327-33, November 1999, copies of which are adopted by reference.

1150.02. Definitions. For the purpose of this Section, the following definitions shall apply unless the context clearly indicates or requires a different meaning.

Subd. 1. Compliance Checks. The system the City uses to investigate and ensure that those authorized to sell tobacco, tobacco products, tobacco-related devices, and nicotine or lobelia delivery
devices are following and complying with the requirements of this ordinance. Compliance checks shall involve the use of persons under the age of 21 as authorized by this ordinance. Compliance checks shall also mean the use of persons under the age of 21 who attempt to purchase tobacco, tobacco products, tobacco-related devices, or nicotine or lobelia delivery devices for educational, research and training purposes as authorized by state and federal laws. Compliance checks may also be conducted by other units of government for the purpose of enforcing appropriate federal, state or local laws and regulations relating to tobacco, tobacco products, tobacco-related devices, and nicotine or lobelia delivery devices.

Subd. 2. Individually Packaged. The practice of selling any tobacco or tobacco product wrapped individually for sale. Individually wrapped tobacco and tobacco products shall include but not be limited to single cigarette packs, single bags or cans of loose tobacco in any form, and single cans or other packaging of snuff or chewing tobacco. Cartons or other packaging containing more than a single pack or other container as described in this definition shall not be considered individually packaged.

Subd. 3. Indoor Area. All space between a floor and a ceiling that is bounded by walls, doorways, or windows, whether open or closed, covering more than 50 percent of the combined surface area of the vertical planes constituting the perimeter of the area. A wall includes any retractable divider, garage door, or other physical barrier, whether temporary or permanent.

Subd. 4. Loosies. The common term used to refer to a single or individually packaged cigarette or any other tobacco product that has been removed from its packaging and sold individually. The term “loosies” does not include individual cigars with a retail price, before any sales taxes, of more than $2 per cigar.

Subd. 5. Minor. Any natural person who has not yet reached the age of 18 years.

Subd. 6. Moveable Place of Business. Any form of business operated out of a truck, van, automobile or other type of vehicle or transportable shelter and not a fixed address store front or other permanent type of structure authorized for sales transactions.

Subd. 7. Nicotine or Lobelia Delivery Devices. Any product containing or delivering nicotine or lobelia intended for human consumption, or any part of such a product, that is not tobacco as defined in this section, not including any product that has been approved or otherwise certified for legal sale by the United States Food and Drug Administration for tobacco use cessation, harm reduction, or for other medical purposes, and is being marketed and sold solely for that approved purpose.

Subd. 8. Retail Establishment. Any place of business where tobacco, tobacco products, tobacco-related devices, or nicotine or lobelia delivery devices are available for sale to the general public. The phrase shall not include but not be limited to grocery stores, convenience stores, restaurants, and drug stores.

Subd. 9. Sale. Any transfer of goods for money, trade, barter or other consideration.

Subd. 10. Self-Service Merchandising. Open displays of tobacco, tobacco products, tobacco-related devices, or nicotine or lobelia delivery devices in any manner where any person shall have access to the tobacco, tobacco products, tobacco-related devices, or nicotine or lobelia delivery devices, without the assistance or intervention of the licensee or the licensee’s employee. The assistance or intervention shall entail the actual physical exchange of the tobacco, tobacco product, tobacco-related device, or nicotine or
lobelia delivery device between the customer and the licensee or employee. Self-service sales are interpreted as being any sale where there is not an actual physical exchange of the product between the clerk and the customer.

Subd. 11. **Smoking.** Inhaling or exhaling smoke from any lighted or heated cigar, cigarette, pipe, or any other lighted or heated tobacco or plant product. Smoking also includes carrying a lighted or heated cigar, cigarette, pipe, or any other lighted or heated tobacco or plant product intended for inhalation.

Subd. 12. **Tobacco or Tobacco Products.** Tobacco and tobacco products includes cigarettes and any product containing, made, or derived from tobacco that is intended for human consumption, whether chewed, smoked, absorbed, dissolved, inhaled, snorted, sniffed, or ingested by any other means, or any component, part, or accessory of a tobacco product; cigars; cheroots; stogies; perique; granulated, plug cut, crimp cut, ready rubbed, and other smoking tobacco; snuff, snuff flour, Cavendish; plug and twist tobacco, fine cut and other chewing tobaccos; shrots; refuse scraps, clippings, cuttings and sweepings of tobacco; and other kinds and forms of tobacco. Tobacco excludes any tobacco product that has been approved by the United States Food and Drug Administration for sale as a tobacco cessation product, as a tobacco dependence product, or for other medical purposes, and is being marketed and sold solely for such an approved purpose.

Subd. 13. **Tobacco-Related Devices.** Tobacco-related devices includes any tobacco product as well as a pipe, rolling papers, ashtray, or other device intentionally designed or intended to be used in a manner which enables the chewing, sniffing or smoking of tobacco or tobacco products.

Subd. 14. **Vending Machine.** Any mechanical, electric or electronic, or other type of device which dispenses tobacco, tobacco products or tobacco-related devices upon the insertion of money, tokens or other form of payment directly into the machine by the person seeking to purchase the tobacco, tobacco produce or tobacco-related device.

1150.03. **License.**

Subd. 1. **License Required.** No person shall sell or offer to sell any tobacco, tobacco products, tobacco-related device, or nicotine or lobelia delivery device without first having obtained a license to do so from the City.

Subd. 2. **Application.** An application for a license to sell tobacco, tobacco products, tobacco-related devices, or nicotine or lobelia delivery devices shall be made on a form provided by the City. The application shall contain the full name of the applicant, the applicant’s residential and business addresses and telephone numbers, the name of the business for which the license is sought, and any additional information the City deems necessary. Upon receipt of a completed application, the City Clerk shall forward the application to the City Council for action at its next regularly scheduled City Council meeting. If the City Clerk shall determine that an application is incomplete, he or she shall return the application to the applicant with notice of the information necessary to make the application complete.

Subd. 3. **Action.** The City Council may either approve or deny the license, or it may delay action for a reasonable period of time as necessary to complete any investigation of the application or the applicant it deems necessary. If the City Council shall approve the license, the City Clerk shall issue the license to the applicant. If the City Council denies the license, notice of the denial shall be given to the applicant along with notice of the applicant’s right to appeal the City Council’s decision.
Subd. 4. **Term.** All licenses issued under this section shall be valid for one calendar year from the date of issue except that initial licenses shall expire on December 31 of the year they are issued.

Subd. 5. **Revocation or Suspension.** Any license issued under this Section may be revoked or suspended as provided in Section 1150.12.

Subd. 6. **Transfers.** All licenses issued under this Section shall be valid only on the premises for which the license was issued and only for the person to whom the license was issued. No transfer of any license to another location or person shall be valid without the prior approval of the City Council.

Subd. 7. **Moveable Place of Business.** No license shall be issued to a moveable place of business. Only fixed location businesses shall be eligible to be licensed under this Section.

Subd. 8. **Display.** All licenses shall be posted and displayed in plain view of the general public on the licensed premise.

Subd. 9. **Renewals.** The renewal of a license issued under this Section shall be handled in the same manner as the original application. The request for a renewal shall be made at least 30 days but no more than 60 days before the expiration of the current license.

Subd. 10. **Issuance as Privilege and Not a Right.** The issuance of a license issued under this Section shall be considered a privilege and not an absolute right of the applicant and shall not entitle the holder to an automatic renewal of the license.

Subd. 11. **Smoking.** Smoking shall not be permitted and no person shall smoke within the indoor area of any establishment with a retail tobacco license. Smoking for the purpose of sampling tobacco and tobacco related products is prohibited.

1150.04. **License Fee; Term; Date.** The fee for a license is set by Chapter X.

1150.05. **Prohibited Acts.**

A. It shall be a violation of this Section for any person to sell or offer to sell any tobacco, tobacco product, tobacco-related device, or nicotine or lobelia delivery device:

1. To any person under the age of 18 years.

2. By means of any type of vending machine.

3. By means of self-service methods whereby the customer does not need to make a verbal or written request to an employee of the licensed premise in order to receive the tobacco, tobacco product, tobacco-related device, or nicotine or lobelia delivery device and whereby there is not a physical exchange of the tobacco, tobacco product, tobacco-related device, or nicotine or lobelia delivery device between the licensee, or the licensee’s employee, and the customer.

4. By means of loosies.
5. Containing opium, morphine, jimson weed, bella donna, strychnos, cocaine, marijuana, or other deleterious, hallucinogenic, toxic or controlled substances except nicotine and other substances found naturally in tobacco or added as part of an otherwise lawful manufacturing process. It is not the intention of this provision to ban the sale of lawfully manufactured cigarettes or other tobacco products.

6. By other means, to any other person, on in any other manner or form prohibited by federal, state or other local law, ordinance provision, or other regulation.

1150.06 Other Illegal Acts. Unless otherwise provided, the following acts shall be a violation of this Section:

Subd. 1. Illegal Sales. It shall be a violation of this Section for any person to sell or otherwise provide any tobacco, tobacco product, tobacco-related device, or nicotine or lobelia delivery device to any person under the age of 21.

Subd. 2. Illegal Possession. It shall be a violation of this Section for any minor person under the age of 21 to have in his or her possession any tobacco, tobacco product, tobacco-related device, or nicotine or lobelia delivery device. This subdivision shall not apply to minor persons lawfully involved in a compliance check.

Subd. 3. Illegal Use. It shall be a violation of this Section for any person under the age of 21 to smoke, chew, sniff or otherwise use any tobacco, tobacco product, tobacco-related device, or nicotine or lobelia delivery service.

Subd. 4. Illegal Procurement. It shall be a violation of this Section for any minor person under the age of 21 to purchase or attempt to purchase or otherwise obtain any tobacco, tobacco product, tobacco-related device, or nicotine or lobelia delivery device, and it shall be a violation of this Section for any person to purchase or otherwise obtain those items on behalf of a minor person under the age of 21. It shall further be a violation for any person to coerce or attempt to coerce a minor person under the age of 21 to illegally purchase or otherwise obtain or use any tobacco, tobacco product, tobacco-related device, or nicotine or lobelia delivery device. This subdivision shall not apply to minor persons lawfully involved in a compliance check.

Subd. 5. Use of False Identification. It shall be a violation of this Section for any minor person under the age of 21 to attempt to disguise his or her true age by the use of a false form of identification, whether the identification is that of another person or one on which the age of the person has been modified or tampered with to represent an age older than the actual age of the person.

1150.07 Basis for Denial of License. Grounds for denying the issuance or renewal of a license under this Section include but are not limited to the following:

1. The applicant is under the age of 21.

2. The applicant has been convicted within the past five years of any violation of a federal, state, or local law, ordinance provision, or other regulation relating to tobacco, tobacco products, tobacco-related devices, or nicotine or lobelia delivery devices.
3. The applicant has had a license to sell tobacco, tobacco products, tobacco-related devices, or nicotine or lobelia delivery devices revoked within the preceding 12 months of the date of application.

4. The applicant fails to provide any information required on the application, or provides false or misleading information.

5. The applicant is prohibited by federal, state, or other local law, ordinance, or other regulation from holding a license.

1150.08. **Self-Service Sales.** It is unlawful for a licensee under this Section to allow the sale of tobacco, tobacco products, tobacco-related devices, or nicotine or lobelia delivery devices by any means where by the customer may have access to those items without having to request the item from the licensee or the licensee’s employee and whereby there is not a physical exchange of the tobacco, tobacco product, tobacco-related device, or nicotine or lobelia delivery device between the licensee or his or her clerk and the customer. All tobacco, tobacco products, tobacco-related devices, and nicotine or lobelia delivery devices shall either be stored behind a counter or other area not freely accessible to customers, or in a case or other storage unit not left open and accessible to the general public. Any retailer selling tobacco, tobacco products, tobacco-related devices, or nicotine or lobelia delivery devices at the time this Section is adopted shall comply with this Section within 90 days following the effective date of this Section.

1150.09. **Responsibility.** All licensees under this Section shall be responsible for the actions of their employees in regard to the sale of tobacco, tobacco products, tobacco-related devices, or nicotine or lobelia delivery devices on the licensed premises, and the sale of an item by an employee shall be considered a sale by the license holder. Nothing in this Section shall be construed as prohibiting the City from also subjecting the clerk to whatever penalties are appropriate under this Section, state or federal law, or other applicable law or regulation.

1150.10. **Compliance Checks and Inspections.** All licensed premises shall be open to inspection by the City policy or other authorized City official during regular business hours. From time to time, but at least once per year, the City shall conduct compliance checks by engaging, with the written consent of their parents or guardians, personminors over the age of 15 years but less than 21 years to enter the licensed premise to attempt to purchase tobacco, tobacco products, tobacco-related devices, or nicotine or lobelia delivery devices. MinorPerson under the age of 21s used for the purpose of compliance checks shall be supervised by City designated law enforcement officers or other designated City personnel. MinorPerson under the age of 21s used for compliance checks shall not be guilty of unlawful possession of tobacco, tobacco products, tobacco-related devices, or nicotine or lobelia delivery devices when those items are obtained as a part of the compliance check. No minor person under the age of 21 used in compliance checks shall attempt to use a false identification misrepresenting the personminor’s age, and all minorperson under the age of 21s lawfully engaged in a compliance check shall answer all questions about the personminor’s age asked by the licensee or his or her employee and shall produce any identification, if any exists, for which he or she is asked. Nothing in this Section shall prohibit compliance checks authorized by state or federal laws for educational, research, or training purposes, or required for the enforcement of a particular state or federal law.

1150.11. **Exceptions and Defenses.** Nothing in this Section shall prevent the providing of tobacco, tobacco products, tobacco-related devices, or nicotine or lobelia delivery devices to a person under 21.
minor as part of a lawfully recognized religious, spiritual, or cultural ceremony. It shall be an affirmative defense to the violation of this Section for a person to have reasonably relied on proof of age as described by state law.


A. Misdemeanors. Any person who violates this ordinance shall be guilty of a Misdemeanor unless the violation has a specific penalty designated by state law.

B. Administrative Civil Penalties; Individuals. An individual who sells tobacco to a person under the age of 21 years shall be subject to an administrative penalty of $50. No penalty may be imposed until the individual has received notice, served personally or by mail, of the alleged violation and an opportunity for a hearing before the Chief of Police or his/her designee. A decision that a violation has occurred must be in writing.

C. Administrative Civil Penalties; Licensee. If a licensee or an employee of a licensee is found to have sold tobacco to a person under the age of 21 years, the licensee shall be subject to an administrative penalty as follows:

<table>
<thead>
<tr>
<th>Offense</th>
<th>Minimum (State)</th>
<th>Presumptive Penalty (City)</th>
<th>Maximum (City/State)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Violation</td>
<td>$75 and/or 0 days suspension</td>
<td>$500 fine and 5-day suspension stayed</td>
<td>$2,000 and/or 60-days suspension</td>
</tr>
<tr>
<td>2nd Violation (within 24 mos)</td>
<td>$200 and/or 0 days suspension</td>
<td>$750 fine and 5-day suspension</td>
<td>$2,000 and/or 60-days suspension</td>
</tr>
<tr>
<td>3rd Violation (within 24 mos)</td>
<td>$250 and/or 7 days suspension</td>
<td>$1,000 fine and 10-day suspension</td>
<td>$2,000 and/or 60 days suspension</td>
</tr>
<tr>
<td>4th Violation (within 24 mos)</td>
<td>None listed</td>
<td>Revocation</td>
<td>Revocation</td>
</tr>
</tbody>
</table>

D. Defense. It is a defense to the charge of selling tobacco to a person under the age of 21 years, that the licensee or individual, in making the sale, reasonably and in good faith relied upon representation of proof of age described in State Statute section 340A.503, subdivision 6, paragraph (a).

E. Exemption. A person, no younger than 15 and no older than 2017, may be enlisted to assist in the tests of compliance, provided that written consent from the person’s parent or guardian has been obtained and that the person shall at all times act only under the direct supervision of a law enforcement officer or an employee of the licensing department, or in conjunction with an in-house program that has been pre-approved by the Police Department. A person who purchases or attempts to purchase tobacco-related products while in this capacity is exempt from the penalties imposed by subdivisions A and B above.

SECTION 2. This ordinance shall be effective _____________ following its enactment.

ADOPTED by the City Council of the City of Plymouth, Minnesota this ________ day of _________________, 2017.
ATTEST:

Sandra Engdahl, City Clerk

Kelli Slavik, Mayor
### 2017 Plymouth Tobacco Licenses

<table>
<thead>
<tr>
<th>Establishment</th>
<th>Address</th>
<th>Licensee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colony Liquor Store</td>
<td>15705 35th Ave. N.</td>
<td>Ken-Ebs, Inc.</td>
</tr>
<tr>
<td>Cub Foods</td>
<td>4445 Nathan Ln. N.</td>
<td>Plymouth 1998 LLC</td>
</tr>
<tr>
<td>Cub Foods</td>
<td>3550 Vicksburg Ln. N.</td>
<td>SuperValu Inc.</td>
</tr>
<tr>
<td>Cub Foods</td>
<td>10200 6th Ave. N.</td>
<td>Uppsala, LLC</td>
</tr>
<tr>
<td>Freedom Valu</td>
<td>16705 County Road 24</td>
<td>Supervalu, Inc.</td>
</tr>
<tr>
<td>Freedom Valu Center</td>
<td>4140 Berkshire Ln. N.</td>
<td>AMBE LLC</td>
</tr>
<tr>
<td>Herb's Servicenter</td>
<td>17435 Co. Rd. 6</td>
<td>Herbs Service Center Inc.</td>
</tr>
<tr>
<td>Holiday</td>
<td>4075 Vinewood Ln. N.</td>
<td>Vinewood Holiday Inc.</td>
</tr>
<tr>
<td>Holiday Stationstores Inc.</td>
<td>3020 Fernbrook Ln.</td>
<td>Holiday Stationstores, Inc.</td>
</tr>
<tr>
<td>Holiday Stationstores Inc.</td>
<td>10900 Hwy. 55</td>
<td>Holiday Stationstores, Inc.</td>
</tr>
<tr>
<td>Holiday Stationstores Inc.</td>
<td>189 Cheshire Ln. #140</td>
<td>Holiday Stationstores, Inc.</td>
</tr>
<tr>
<td>Holiday Stationstores Inc.</td>
<td>10100 Co. Rd. 9</td>
<td>Holiday Stationstores, Inc.</td>
</tr>
<tr>
<td>Holiday Stationstores Inc.</td>
<td>9700 Betty Crocker Dr.</td>
<td>Holiday Stationstores, Inc.</td>
</tr>
<tr>
<td>Holiday Stationstores Inc.</td>
<td>9705 Schmidt Lake Rd.</td>
<td>Holiday Stationstores, Inc.</td>
</tr>
<tr>
<td>Holiday Stationstores Inc.</td>
<td>2725 Campus Dr.</td>
<td>Holiday Stationstores, Inc.</td>
</tr>
<tr>
<td>Kwik Trip #411</td>
<td>1605 Annapolis Ln. N.</td>
<td>Kwik Trip, Inc.</td>
</tr>
<tr>
<td>MGM Wine &amp; Spirits</td>
<td>3900 Vinewood Ln. N., Unit 1</td>
<td>Montecore LLC</td>
</tr>
<tr>
<td>Paradise Liquors</td>
<td>12 Nathan Ln. N.</td>
<td>Ragma Inc. Corporation</td>
</tr>
<tr>
<td>Plymouth BP</td>
<td>3855 Plymouth Blvd.</td>
<td>KTCO Inc.</td>
</tr>
<tr>
<td>Plymouth Cigars and Tobacco</td>
<td>16605 Co. Rd. 24, Suite 203</td>
<td>Plymouth Cigars and Tobacco Inc.</td>
</tr>
<tr>
<td>Plymouth Liquor Barrel</td>
<td>11000 State Hwy. 55</td>
<td>JD Christensen Liquors, Inc.</td>
</tr>
<tr>
<td>Plymouth Station Holiday</td>
<td>16825 Co. Rd. 24</td>
<td>Jerry's Service, Inc.</td>
</tr>
<tr>
<td>Rockford Road BP</td>
<td>4090 Annapolis Ln. N.</td>
<td>Lan-Tay, Inc.</td>
</tr>
<tr>
<td>Sami's Stop</td>
<td>9605 36th Ave. N.</td>
<td>Ayani Gas Corporation</td>
</tr>
<tr>
<td>Sid's Discount Liquor</td>
<td>10200 6th Ave. N.</td>
<td>Applebaum Companies Inc.</td>
</tr>
<tr>
<td>Smokies</td>
<td>17405 Co. Rd. 6, Suite 100</td>
<td>Smokies U.S.A. Inc.</td>
</tr>
<tr>
<td>SuperAmerica</td>
<td>4325 Peony Ln. N.</td>
<td>Northern Tier Retail, LLC</td>
</tr>
<tr>
<td>Store Name</td>
<td>Address</td>
<td>Company Name</td>
</tr>
<tr>
<td>--------------------</td>
<td>----------------------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>SuperAmerica</td>
<td>5750 Nathan Ln. N.</td>
<td>Northern Tier Retail LLC</td>
</tr>
<tr>
<td>SuperAmerica</td>
<td>15805 61st Ave. N.</td>
<td>Northern Tier Retail LLC</td>
</tr>
<tr>
<td>Walgreens</td>
<td>3255 Vicksburg Ln. N.</td>
<td>Walgreen Co.</td>
</tr>
<tr>
<td>Walgreens</td>
<td>4005 Vinewood Ln. N.</td>
<td>Walgreen Co.</td>
</tr>
<tr>
<td>Walgreens</td>
<td>6025 Shenandoah Ln. N.</td>
<td>Walgreen Co.</td>
</tr>
</tbody>
</table>
2016 Minnesota Student Survey: Tobacco Findings

YOUTH SMOKING HITS HISTORIC LOWS, BUT TOBACCO PREVENTION AND HEALTH EQUITY EFFORTS MUST REMAIN STRONG.

Cigarette smoking fell dramatically among both 9th and 11th grade students.

Results from the 2016 Minnesota Student Survey showed that cigarette smoking among both 11th and 9th grade students fell by nearly one third since the survey was last conducted in 2013. These are the lowest rates ever recorded by the survey, with only 8.4% of 11th graders, and 4.3% of 9th graders reporting they had smoked cigarettes in the past 30 days.

Results also showed declines in 11th and 9th grade cigar product and smokeless tobacco use.

Statewide efforts are keeping kids from using tobacco.

These declines follow extensive statewide efforts to curb cigarette smoking. Price increases on tobacco are one of the most effective strategies for reducing youth use; in July 2013, Minnesota’s landmark tobacco excise tax increase raised the price of cigarettes by $1.60 per pack.

Minnesota also has a comprehensive clean indoor air law that doesn’t allow smoking in indoor public places like restaurants and workplaces. Additionally, Minnesota’s strong network of communities and partners across the state are actively working to raise awareness and further protect youth from the harms of cigarette use.

More needs to be done to achieve a generation free from the harms of tobacco.

The survey also showed a dramatic and concerning increase in the number of students using e-cigarettes; 11th and 9th graders are now using e-cigarettes at twice the rate of conventional cigarettes.
Products like e-cigarettes, e-hookahs and vape pens typically contain nicotine, and are currently unregulated. No amount of nicotine is safe for youth; it is highly addictive and may harm adolescent brain development. Damaging long-term effects may have implications for learning, memory, attention, behavior problems, and future addiction.

The survey also found that, despite declines in use among all groups, disparities still remain among some student populations. American Indian students, those experiencing economic hardship, identifying as bi, gay, or lesbian, experiencing suicidal thoughts, and those who also binge drink, smoke at significantly higher rates.

About the Survey

The Minnesota Student Survey is conducted every three years among populations of Minnesota public schools. The census-like survey asks questions about activities, experiences, and behaviors. Topics include: tobacco, alcohol and drug use, school climate, physical activity, violence and safety, health, connections with school and family, and other topics. In 2016, nearly 169,000 public school students participated in the survey.

Minnesota Department of Health
Tobacco Prevention and Control
PO Box 64882,
St. Paul, MN 55164-0882
612-651-3535
tobacco@state.mn.us
www.health.state.mn.us/tobacco

10/28/2016

To obtain this information in a different format, call: 651-201-3535. Printed on recycled paper.
Additional Point of Sale Actions to Reduce Youth Access to Tobacco Products

Local communities can pursue additional point of sale regulations to further limit youth tobacco access and exposure to tobacco marketing practices, and reduce tobacco use. The U.S. Surgeon General and the Institute of Medicine recommend implementing evidence-based, point-of-sale strategies as part of comprehensive tobacco control.

Control the Cost of Tobacco

Limiting tobacco industry marketing tactics that lower tobacco prices and counteract tobacco tax increases is an effective strategy to prevent tobacco use by youth (who are especially sensitive to tobacco prices) and adult populations that typically experience higher rates of health disparities. Options include:

- Require a minimum pack size and/or price for cheap cigar products such as little cigars or cigarillos. (Brooklyn Center, Minn.; Boston and roughly 30 other Massachusetts cities; and New York City)
- Prohibit price-discounting strategies by retailers, such as multi-pack offers and coupon redemption. (Providence, R.I.; and New York City)

Regulate Sales of Flavored Products

Limiting the sale of specified products to adult-only tobacco product shops is an effective strategy to discourage youth tobacco use. Flavored products are increasingly popular with youth and widely available in stores where they shop.

- Limit flavored, non-cigarette tobacco products to adult-only tobacco establishments. (Providence, R.I.; New York City; and the state of Maine)
- Limit the sale of flavored tobacco products within 500 feet of primary and secondary public and private schools, excluding adult-only tobacco establishments. (Chicago)
- Menthol products are included in the Chicago ordinance and Maine law, but were excluded from the Providence and New York ordinances.

Increase Age Requirements Related to Age of Purchase or Sales Clerks

Regulating other aspects of the point-of-sale environment would further reduce youth access.

- Increase the minimum age required to purchase tobacco products to 21. (New York City; Englewood, N.J.; Hawaii County, Hawaii; and at least 10 towns and cities in Massachusetts)
- Require tobacco sales clerks to be at least 18.

Regulate the Number, Density, and Location of Tobacco Retailers

Reducing the number and density of tobacco retailers and controlling their location reduces the overall availability of tobacco products in the community, especially to youth. Options include:

- Regulating the location and/or density of tobacco retail outlets by prohibiting licenses for stores within a certain distance of places where youth gather (e.g., schools or parks), in certain neighborhood commercial districts, or within a specific distance of other tobacco retailers. (Brooklyn Park, Hopkins, Minneapolis, and Rock County, Minn.)
- Reduce or prevent increases in the number and/or density of tobacco retail outlets by capping the number of tobacco licenses. The cap could be set at the current number of licenses and reduced over time as attrition occurs. It also could be set at a lower number than the current number of licenses, with no new licenses granted until the number decreases appropriately. (Rock County, Minn., and Arlington, Massachusetts)
- Make stores with pharmacy licenses and educational institutions ineligible for tobacco licenses. (Boston and about 80 other Massachusetts communities; and Richmond and San Francisco, Calif.)

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1 Cities in parentheses have successfully passed similar policies.
Additional Point of Sale Actions to Reduce Youth Access to Tobacco Products

Updated information on where these policies have been adopted.

Increase Minimum Legal Age Requirements Related to the sale of tobacco
Increase the minimum age required to purchase tobacco products to 21.
- **Minnesota:** Edina, St. Louis Park.
- **Nationally:** States of California, Hawaii, Maine, New Jersey and Oregon; over 260 individual communities across the country.

Control the Cost of Tobacco
Require a minimum pack size and/or price for cheap cigar products such as little cigars or cigarillos.
- **Minnesota:** Bloomington, Brooklyn Center, Minneapolis, Richfield, Maplewood, St. Paul and 11 cities and 9 counties in greater MN.
- **Nationally:** Boston and 68 municipalities in Massachusetts, New York City

Regulate Sales of Flavored Products
Limit the sale of flavored, non-cigarette tobacco products to adult-only tobacco establishments.
- **Minnesota:** Minneapolis, St. Paul and Shoreview implemented laws restricting sale of flavored tobacco products (excluding menthol, mint and wintergreen) to tobacco product shops where 90% of gross revenues are from tobacco and related products, and those under age 18 are excluded. Minneapolis recently removed the exemption for menthol, mint and wintergreen products (implementation August 2018).
- **Nationally:** Those restricting all flavors include Chicago, IL, 6 cities and 2 counties in California. Those restricting flavors, exempting menthol products include Providence, RI, New York, NY, Boston, MA, 83 municipalities in Massachusetts, and Manhattan Beach and Sonoma, CA.
September 12, 2017

The Honorable Kelli Slavik and Members of the Plymouth City Council
3400 Plymouth Boulevard
Plymouth, MN 55447-1482

Sent electronically to: council@plymouthmn.gov
CC: Dave Callister dcallister@plymouthmn.gov & Luke Fischer lfischer@plymouthmn.gov

Dear Mayor Slavik and Councilmembers:

On behalf of the over 27,000 employees at Allina Health, we strongly support your consideration to raise the tobacco sales age to 21. Allina Health is a not-for-profit network of hospitals, clinics and other health care services, providing care throughout Minnesota and western Wisconsin. We are dedicated to the prevention and treatment of illness, as well as enhancing the greater health of individuals, families and communities. Here in Plymouth, we are proud to offer a full complement of primary and specialty care, including 24/7 emergency and urgent care services at Abbott Northwestern, WestHealth Campus.

We see first-hand the negative impact of tobacco use on the health of Minnesotans. Smoking costs Minnesota more than $3 billion annually in excess health care costs, and each year the tobacco industry spends millions of dollars marketing to youth and recruiting replacement customers. Besides premature death, many Americans who use tobacco live with chronic diseases such as lung, oral and pharyngeal cancer.

The tobacco industry actively markets to young people with fruit and candy flavored tobacco products. Increasing the tobacco sales age would reduce youth access to these harmful products and prevent a lifetime of addiction. Tobacco 21 also prevents youth smoking by creating barriers to getting tobacco products from social sources. Most kids get cigarettes from older friends. Raising the tobacco sale age to 21 will help get cigarettes out of high schools, where there are plenty of 18-year-olds but no 21-year-olds. Ultimately, a Minnesota-specific study found that if the age of sale was raised to 21, it would prevent at least 30,000 youth from smoking over the next 15 years.

We fully support the Plymouth City Council in moving forward with this ordinance and commend you for leading the state in this bold tobacco prevention initiative.

Sincerely,

Erin Huppert
Public Policy Specialist
Allina Health

Mailing Address: PO Box 43, Mail Route 10811, Minneapolis, MN 55440-0043
September 5, 2017

Mayor Kelli Slavik
Plymouth City Council
3400 Plymouth Boulevard
Plymouth, MN 55447

RE: Raising the Tobacco Sales Age to 21

Dear Mayor Slavik and members of the Plymouth City Council,

The American Cancer Society Cancer Action Network supports raising the minimum age for sale of all tobacco products to age 21. For years, tobacco use has been the number one preventable cause of death in our country and our state. Smoking kills over 6,300 Minnesotans each year and costs the state more than $3 billion annually in excess health care costs. Despite this, we continue to let the tobacco industry addict young people to their deadly products.

Roughly 95% of adults who smoke started smoking before the age of 21. Increasing the sale age may prevent more youth from starting to use tobacco products. The tobacco industry has designed products such as cherry chewing tobacco, strawberry kiwi cigarillos, and cotton candy e-juice to get children addicted and keep them as customers throughout their life. The addictive properties of nicotine can lead adolescents to heavier daily tobacco use and a difficult time quitting later in life.

A national consensus is growing to protect young people from a lifetime of addiction and health problems caused by tobacco. A 2014 national survey shows that 75 percent of adults favor increasing the age of sale for tobacco products to 21. In fact, 70 percent of current smokers and 65 percent of those ages 18-24 support raising the tobacco sales age. By implementing such an ordinance, Plymouth will lead the way for other communities in Minnesota.

We hope Plymouth will consider this bold tobacco prevention policy. Strong and effective tobacco prevention and cessation policies contribute to a reduction in nicotine addiction, tobacco use rates, and therefore a reduction in cancer cases and deaths. I have included a fact sheet on raising the minimum age of sale of tobacco products to 21. Please feel free to reach out to me directly with any questions you may have.

Sincerely,

Ellie Beaver
Minnesota Government Relations Director
American Cancer Society Cancer Action Network
WHY RAISE THE TOBACCO SALE AGE?

The tobacco industry heavily targets young adults ages 18-21 in order to recruit new tobacco users and guarantee profits. Approximately 95 percent of current adult smokers started before they were 21. In Minnesota, no one under 18 years old is allowed to buy tobacco. Youth get tobacco from several sources, including social sources. A 16-year-old has more contact with and access to 18-year-olds who can buy tobacco. However, it is less likely a 16-year-old would ask a 21-year-old for tobacco. Increasing the age gap between young people and those who can legally buy tobacco will reduce youth access to tobacco.

A 2015 report from the Institute of Medicine (IOM) found that increasing the legal age to purchase tobacco to 21 would decrease smoking initiation among 15-17-year-olds by 25 percent. A Minnesota-specific study looked at the impact of raising the tobacco age and found that 25 percent fewer 15-year-olds would start smoking by the time they turn 18 and 15 percent fewer 18-year-olds would start smoking by the time they turn 18. This translates into 30,000 young people not becoming smokers over the next 15 years. If youth don't smoke by the time they are 21, they likely never will.

WHAT IS THE IMPACT OF NICOTINE ON ADOLESCENT BRAIN DEVELOPMENT?

Nicotine is harmful to the development of the adolescent brain. Evidence suggests that nicotine interferes with brain maturation and can have a long-term effect on cognitive development and mental health. Even brief or intermittent nicotine exposure during adolescence can cause lasting damage. The addictive properties of nicotine can lead adolescents to heavier daily tobacco use and a more difficult time quitting later in life. Nicotine exposure can also increase the risk of addiction to other harmful substances. The long-term effects of nicotine on the adolescent brain is a significant public health concern.

WHO SUPPORTS RAISING THE TOBACCO SALE AGE TO 21?

A 2014 national survey shows that 75 percent of adults favor increasing the minimum sale age for tobacco to 21. A national consensus is growing to protect young people from a lifetime of addiction and health problems caused by tobacco by raising the tobacco sale age. In addition, 70 percent of current smokers and 65 percent of those age 18-24 support raising the minimum tobacco sale age.
IS YOUTH TOBACCO USE STILL A PROBLEM?

The percent of students who smoke cigarettes is declining, but the 2016 Minnesota Student Survey found that 9th and 11th graders in Minnesota are now using e-cigarettes at twice the rate of regular cigarettes. Increasing the sale age to 21 would reduce youth access to all harmful tobacco products, including e-cigarettes, cigars and hookah.

WHAT CAN STATE AND LOCAL GOVERNMENTS DO?

Hawaii and California and a growing list of more than 260 cities in the United States have raised the tobacco sale age to 21. New York City, Boston, Kansas City, Saint Louis and Chicago lead that list.

The city of Needham, Mass., raised the legal tobacco sale age to 21 in 2005. Within five years, tobacco use among high school students decreased by nearly half.

California, Hawaii, New Jersey, Maine and Oregon raised the minimum legal sale age for tobacco products to 21 since 2016.

More than 250 localities in the United States have raised the minimum legal sale age for tobacco products to 21.

Some organizations who support raising tobacco sale age to 21 include:

- American Cancer Society Cancer Action Network
- American Heart Association
- American Lung Association
- ClearWay Minnesota™
- Minnesota Academy of Family Physicians
- Service Employees International Union Minnesota State Council

SOURCES

From: Judy Johnson
Sent: Monday, July 10, 2017 3:55 PM
To: Dave Callister <dcallister@plymouthmn.gov>; Luke Fischer <lfischer@plymouthmn.gov>; caitlin.devos@gmail.com; Kelli Slavik <KSlavik@plymouthmn.gov>
Subject: Fwd: Reaching out with Tobacco 21 Information

Mayor, Dave, Luke, and Chief,

FYI see below - raising the age to 21 for tobacco. Please keep Caitlin informed (copied on this email) about our study session on this in September - can't recall the date off the top of my head.

She sent information - see attached. She would like to be engaged in this discussion as the council considers this issue.

Thanks!

Judy

Sent from my iPhone

Begin forwarded message:

From: Caitlin DeVos < Caitlin.devos@gmail.com >
Date: July 10, 2017 at 3:42:11 PM CDT
To: johnson@plymouthmn.gov
Subject: Reaching out with Tobacco 21 Information

Hi Judy,

I hope you're having a wonderful start to your week! My name is Caitlin DeVos and I live at 13225 34th Ave N. in Plymouth. I'm the one on Twitter who has tagged you in a few posts about the Tobacco 21 movement that is starting to gain momentum in Minnesota cities. It passed in Edina a few months ago and St. Louis Park is now considering it and will have their second vote in July that would approve the policy if they vote yes.

I'm passionate about raising the legal tobacco age from 18 to 21 in cities throughout the state, and hopefully at the state level in the next few years, because it will prevent youth tobacco use and save lives. Almost 95 percent of addicted adult smokers started smoking by age 21, according to the U.S. Department of Health and Human Services. Research shows that raising the age will stop more young people from starting smoking and in turn, stop them from the harmful social and health effects of tobacco later in their lives. Most middle and high school students have access to a 18 year old as a social source for tobacco, but very few have access to a
21 year old to give them tobacco. This age increase truly can save lives from all of the diseases and health issues tobacco causes and I would love to see our city be a leader in this movement.

Attached, you'll find more details on Tobacco 21 and the facts behind it. My goal of reaching out to you is two-fold:

1. To make sure you had all of the facts about this public policy change and were informed on the benefits it has for our young people if Plymouth was to raise the age of sale for tobacco from 18 to 21.
2. Because I am curious to know from your perspective and role on the City Council what you think the chances are of the Plymouth City Council passing this policy in the future. I would want to know your honest thoughts on the plausibility of our community and our City Council supporting this policy, before taking any next steps to propose we pursue it. There are many cities across Minnesota that have strong public support for this policy and I wouldn't want to harm their efforts by working on it in Plymouth if now is not the right to pursue this.

Thank you for reviewing and for your thoughts around the potential of Tobacco 21 in Plymouth!

Warm regards,
Caitlin

Caitlin DeVos
T | 763.447.0374
E | caitlin.devos@gmail.com
INCREASE THE TOBACCO AGE TO 21

Minnesotans agree: We can do more to prevent kids from becoming addicted. A national consensus is growing to prevent addictions and future health problems by ensuring that those who sell tobacco products do so to adults who are 21 and older. Minnesotans for a Smoke-Free Generation supports this movement.

RAISING THE TOBACCO AGE TO 21 WILL PREVENT YOUTH TOBACCO USE AND SAVE LIVES.

ALMOST 95 PERCENT OF ADDICTED ADULT SMOKERS STARTED SMOKING BY AGE 21.2

- Increasing the age gap between kids and those who can legally buy tobacco will help remove access to tobacco products from the high-school environment.

BIG TOBACCO ACTIVELY RECRUITS REPLACEMENT SMOKERS TO GUARANTEE PROFITS.

- The tobacco industry heavily targets 18-to-21-year-olds with menthol and candy flavoring, magazine advertisements, product design and packaging, and event sponsorships and promotions.3,4

ADULTS SUPPORT RAISING THE TOBACCO AGE TO 21.

- A national survey shows that 75 percent of adults favor increasing the minimum sale age for tobacco to 21.3
- 70 percent of smokers are in support of raising the minimum legal age.3

Research shows a 25 percent reduction in smoking initiation among 15-to-17-year-olds following such an increase.1
STATE AND LOCAL GOVERNMENTS ARE TAKING ACTION TO PROTECT YOUTH.

- California, Hawaii and more than 200 localities in the United States have raised the sale age of tobacco to 21, including New York City, Boston and Kansas City.
- Needham Massachusetts found that tobacco use among high-school students fell by nearly half after raising the age to 21.5

NICOTINE CAN CAUSE ADDICTION AND DISRUPT ATTENTION AND LEARNING IN ADOLESCENTS?

- Nicotine is addictive, and adolescents are especially vulnerable to the health impacts of tobacco use.6
- The adolescent brain is negatively impacted by nicotine, and its long-term effects are a significant public health concern.7

Minnesotans for a Smoke-Free Generation is a coalition of Minnesota organizations that share a common goal of saving Minnesota youth from a lifetime of addiction to tobacco. The coalition supports policies that reduce youth smoking, including keeping tobacco prices high, raising the tobacco sale age to 21, limiting access to candy-, fruit- and menthol-flavored tobacco and funding future tobacco control programs. Find out more at www.smokefreeegenmn.org.

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October 16, 2017

Mayor Slavik and Plymouth City Councilmembers,

My name is Jodi Radke. I am the Regional Director with the Campaign for Tobacco-Free Kids. Our organization works within the United States and around the world to advocate for public policies proven to prevent kids from using tobacco, help tobacco users quit and protect everyone from secondhand smoke. For more information about our policy priorities, please visit our website, www.tobaccofreekids.org.

It is public health heroes, such as yourself, who help achieve the outcomes mentioned above. Thank you for leading the way in protecting Minnesota’s kids by considering raising the age of sale on tobacco in Plymouth from 18 to 21.

About 95 percent of adult smokers began smoking before they turned 21. Policies, such as the one being considered, are a critical part of impacting the rate of initiation by kids, and will help to eliminate a critical point of access. This policy will have a positive impact on public health and will save lives.

The tobacco industry continues to target Minnesota kids with its deceptive marketing practices. We therefore must continue to be vigilant in protecting Minnesota’s kids from the tobacco industry’s outreach and efforts to addict them.

I really appreciated the dialogue and thoughtful discussion during the September work session, which I was able to attend, and want to address some of the concerns reflected that evening.

We understand part of your consideration is the penalization of kids for purchase, use or possession of tobacco, and whether this ordinance should include ecigarettes. Please note that penalizing children has not been proven to be an effective strategy for reducing youth smoking and could actually detract from more effective enforcement measures and tobacco control efforts.

We strongly oppose this approach and its stigmatization of children, many of whom become addicted at a young age as a result of aggressive marketing by the tobacco industry.

Additional Concerns about PUP (Purchase, Use, Possession) Laws

- Penalizing youth can divert enforcement officials’ attention from stopping retailers from illegally selling tobacco to kids in the first place. PUP laws are more difficult to systematically enforce than sanctions against retailers, especially since PUP laws rarely provide additional enforcement resources. It is easier and more effective to conduct compliance checks of retailers, who are fewer in number compared to youth and whose locations are both known and constant.

- The ease of discretely possessing and using some tobacco products makes PUP laws more challenging to enforce than laws restricting sales to minors. Similarly, the perceived risk among youth of getting caught and punished is likely too low to have a meaningful impact on deterring tobacco use. In fact, there is little evidence showing that PUP laws have been enforced well enough to reduce youth smoking.
• Tobacco companies and their allies have a history of supporting PUP laws as alternatives to other laws that would promote greater declines in youth smoking, such as increasing the price of cigarettes. Tobacco companies have also promoted the passage of PUP laws to get additional provisions enacted that make implementing or enforcing additional tobacco control measures more difficult (e.g., preemption of strong local laws/ordinances).

• Despite the fact that many youth smokers are addicted, making it difficult for them to quit, few PUP laws include provisions ensuring that quit smoking resources are made available to them. Some research even suggests that penalizing youth could deter them from seeking support for cessation. Promoting interventions that provide cessation resources for youth interested in quitting could be a more beneficial alternative.

Ecigarettes... For the first time in decades, in 2014, overall nicotine and tobacco use increased among U.S. high school students. This is almost entirely due to an explosion in teen use of e-cigarettes, hookahs and vaping. E-cigarettes have become the perfect addiction machine enticing a new generation of young people to lifelong nicotine dependence.

They are brazenly sold in fanciful and sweet flavors that include candy apple, bubble gum, cherry cola, marshmallow, orange soda, s’mores, chocolate, and taffy. There are over 7,000 unique flavors of e-liquid available online, many of which can be purchased easily by minors. **Exempting products such as these is an oversight in the efforts to safeguard our kids from a lifetime of addiction.**

Thus far, five states and more than 260 localities across the United States have passed policies to raise the age of sale to 21. We **strongly** advise states and localities to exclude punishing youth for purchase, use or possession of tobacco products, and to keep the focus on establishing a higher age of sale for retailers and enforcing it, which has been **proven** to reduce use rates amongst kids. Lastly, we only support policy changes that deliver outcomes, by including all products being marketed to our kids, which includes ecigarettes.

If you have any questions, please feel free to contact me directly.

Thank you again for your leadership and partnership to protect Plymouth’s kids. I work with many cities in outlying states that do not have that privilege, and are preempted from making such critical, public health decisions. Your privilege, and leadership on this issue, will save lives for generations to follow.

Respectfully,

**Jodi L. Radke**

Jodi L. Radke
Regional Director
Campaign for Tobacco-Free Kids
970-214-4808
jradke@tobaccofreekids.org
Research shows that youth access laws successfully reduce youth tobacco use when they are well enforced and disrupt the sale of tobacco products to minors. Today, all 50 states and the District of Columbia have laws that restrict the sale of tobacco products to minors. But in addition to restricting the sale, 45 states and the District of Columbia have laws that also prohibit the purchase, use, and/or possession (PUP) of tobacco products by underage persons. Penalties for youth who violate a PUP law typically include a fine but may also include other penalties like community service, attending mandatory smoking education or cessation programs, or the suspension of a driver’s license or permit. Only five states—Maryland, Massachusetts, Nevada, New Jersey, and New York—do not have PUP laws.

Some states passed PUP laws with the intention of reducing youth smoking by making kids more personally responsible for buying and using tobacco products. Penalizing children, however, has not been proven to be an effective strategy for reducing youth smoking; and some experts argue that PUP laws could actually detract from more effective enforcement measures and tobacco control efforts.

PUP laws also unfairly punish and stigmatize children, many of whom became addicted at a young age as a result of the tobacco industry’s aggressive marketing to kids. In this way, PUP laws shift the blame away from the industry’s irresponsible marketing and retailers’ irresponsible sales, to its victims. Penalties against youth become even more unreasonable when little is done to counter the tobacco industry’s targeted marketing to kids. Rather than treat children as the wrongdoers, youth access laws should focus on limiting access to tobacco products by conducting ongoing retailer compliance checks with strong penalties for sales to underage persons.

Additional Concerns about PUP Laws

- Penalizing youth can divert enforcement officials’ attention from stopping retailers from illegally selling tobacco to kids in the first place. PUP laws are more difficult to systematically enforce than sanctions against retailers, especially since PUP laws rarely provide additional enforcement resources. It is easier and more effective to conduct compliance checks for retailers, who are fewer in number compared to youth and whose locations are both known and constant.

- The ease of discreetly possessing and using some tobacco products makes PUP laws more challenging to enforce than laws restricting sales to minors. Similarly, the perceived risk among youth of getting caught and punished is likely too low to have a meaningful impact on deterring tobacco use. In fact, there is little evidence showing that PUP laws have been enforced well enough to reduce youth smoking.

- Tobacco companies and their allies have a history of supporting PUP laws as alternatives to other laws that would produce greater declines in youth smoking, such as increasing the price of cigarettes. Tobacco companies have also promoted the passage of PUP laws in order to get additional provisions enacted that make implementing or enforcing additional tobacco control measures more difficult (e.g., preemption of strong local laws/ordinances).

- Despite the fact that many youth smokers are addicted, making it difficult for them to quit, few PUP laws include provisions ensuring that quit smoking resources are made available to them. Some research even suggests that penalizing youth could deter them from seeking support for cessation. Promoting interventions that provide cessation resources for youth interested in quitting could be a more beneficial alternative.

Youth Access Laws Should Emphasize Restricting Sales to Minors

Youth access laws that restrict sales to minors are better supported by research as a way to reduce youth smoking than laws that focus primarily on penalizing youth for purchase or possession of tobacco.
PUP laws may have some potential if combined with laws banning sales to minors, evidence of their effectiveness still is lacking, and many concerns about how to effectively implement them remain.

Regardless of whether a state chooses to implement PUP provisions as part of its youth access law, rigorous enforcement of restrictions against sales to minors is critical to minimizing the accessibility of tobacco products and, ultimately, reducing youth tobacco use. The most successful youth access programs incorporate routine retailer compliance checks which use minors to attempt tobacco purchases.\(^\text{11}\)

\textit{Campaign for Tobacco-Free Kids, March 28, 2016/ Becca Knox}

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1 DiFranza, JR, “Which interventions against the sale of tobacco to minors can be expected to reduce smoking?” Tobacco Control, doi:10.1136/tobaccocontrol-2011-050145, published online first October 12, 2011.
2 Most states set the age for sale of tobacco products at 18. As of 3/28/16, Alabama, Alaska, New Jersey, and Utah set the age at 19, and Hawaii sets it at 21.
11 DiFranza, JR, “Which interventions against the sale of tobacco to minors can be expected to reduce smoking?” Tobacco Control, doi:10.1136/tobaccocontrol-2011-050145, published online first October 12, 2011.
September 19, 2017

The Honorable Kelli Slavik and Members of the Plymouth City Council
Plymouth City Hall
3400 Plymouth Boulevard
Plymouth, MN 55447

Dear Mayor Slavik and Council Members:

I am the Chief Executive Officer of ClearWay Minnesota, an independent nonprofit organization that works to reduce tobacco’s harm in our state. I am writing to urge you to consider and support raising Plymouth’s tobacco age to 21.

The devastating harms of tobacco addiction are well documented. For elected leaders such as yourselves, the question is not “What does smoking do?” but “What can we do to stop it?” Tobacco 21 policies address that question in the best possible way: by preventing kids from starting.

The vast majority of addicted smokers start at very young ages. About 95 percent of adult smokers begin before age 21. That means everything possible should be done to stop young people from smoking before they reach that age.

Tobacco 21 also prevents youth smoking by creating barriers to getting tobacco products from social sources. Most kids get cigarettes from older friends. Raising the tobacco sale age to 21 will help get cigarettes out of high schools, where there are plenty of 18-year-olds but no 21-year-olds.

Five U.S. states and more than 260 municipalities across the country have already raised the age. Already there are studies showing youth smoking reductions from Tobacco 21, and Minnesota research projects huge declines in youth smoking if these policies are adopted statewide here.

Stopping youth smoking doesn’t just prevent future disease and death, it also reduces excess medical costs, which are an enormous burden on individuals, families and taxpayers. I hope Plymouth will consider and pass this life-saving policy. Thank you.

Sincerely,

David J. Willoughby, M.A.
Chief Executive Officer
ClearWay Minnesota™
Coalition of Neighborhood Retailers

DATE:
September 25, 2017

TO:
Plymouth City Council

The five retail trade associations that make up the Coalition of Responsible Retailers are writing to you to share concerns on raising the legal age to purchase tobacco to 21. Please see the attached letter and accompanying documents, including the news article link in the letter about the Detroit Lakes City Council recent vote against the age 21 ordinance.

We appreciate you taking the time to read our letter and consider our concerns.
Coalition of Neighborhood Retailers

September 25, 2017

Mayor Kelli Slavik
Council Member Judy Johnson
Council Member Jeffry Wosje
Council Member Jim Davis
Council Member Jim Prom
Council Member Ned Carroll
Council Member Jim Willis
3400 Plymouth Boulevard
Plymouth, MN 55441-1482

Re: The Issue of Raising the Legal Age to Purchase Tobacco

Dear Mayor Slavik and City Council Members:

The retail trade associations that comprise the Coalition of Neighborhood Retailers and our respective retail store members located in Plymouth appreciate the opportunity to share concerns about the city council potentially raising the legal age to purchase tobacco products. Our collective concerns about raising the legal age are outlined below. We urge you not to consider changing the age of adulthood regarding the right to purchase tobacco products.

Detroit Lakes City Council Votes Not to Proceed with Age 21 Ordinance

Earlier this month, after several hours of debate on both sides of this issue, the City Council in Detroit Lakes voted against the Age 21 ordinance that would have prohibited 18, 19 and 20-year-old adults from having the right to purchase legal tobacco products, which include products that fall in the harm reduction category such as electronic cigarettes that can help many adults transition away from combustible tobacco products.

Pasted below is a news article link from the September 12, 2017 Detroit Lakes hearing and vote including footage of the testimony:


Social Sources Are the Real Problem that Raising the Legal Age Will Not Solve

In 2016, the U.S. Food and Drug Administration (FDA) published the findings of the agency’s Population Assessment of Tobacco and Health Study which demonstrate that the vast majority of underage youth obtain access to tobacco from non-retail sources, also referred to as “social sources.” These social sources include older friends, adult age siblings, parents and even strangers.
As shown on the accompanying chart provided by the FDA and summarized in the table below, minors rely on social sources and use various methods to obtain access to cigarettes 86.1% of the time, to obtain access to electronic cigarettes 89.5% of the time, and to obtain access to cigars 75.6% of the time.

<table>
<thead>
<tr>
<th>Product</th>
<th>Gave Someone Money to Buy</th>
<th>Bought From Someone Else, Stole From a Person or Store</th>
<th>Asked Someone for a Tobacco Product or Someone Offered a Tobacco Product</th>
<th>Other or Don’t Know or Refused to Answer</th>
<th>Social Sources Percentage</th>
<th>Bought at a Retail Store</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cigarettes</td>
<td>32%</td>
<td>6.6%</td>
<td>42.5%</td>
<td>5%</td>
<td>86.1%</td>
<td>13.8%</td>
</tr>
<tr>
<td>E-Cigarettes</td>
<td>17.3%</td>
<td>5.8%</td>
<td>56.7%</td>
<td>9.7%</td>
<td>89.5%</td>
<td>10.5%</td>
</tr>
<tr>
<td>Cigars</td>
<td>34.2%</td>
<td>4.1%</td>
<td>37.3%</td>
<td>NA</td>
<td>75.6%</td>
<td>21%</td>
</tr>
</tbody>
</table>

Raising the legal age to purchase tobacco does not address the problem of youth obtaining tobacco through social sources. Until all levels of government focus on solving the social sources problem, then there will not be a significant reduction in youth access to tobacco products. A societal attitude change needs to occur so that adults understand that it is not permissible to provide tobacco to underage youth.

**Raising the Legal Age to Purchase Tobacco to 21 is a Catch 22**

A “Catch 22” is a problematic situation caused by mutually conflicting or seemingly contradictory conditions. Considering raising the legal age to purchase tobacco products is a Catch 22 and also allows the social sources problem to perpetuate itself.

The dialogue around raising the legal age to 21 centers on whether to make it illegal for 18, 19 and 20 year olds to possess and use tobacco products in addition to prohibiting the sale to these young adults. Those advocates who are proposing to raise the legal purchase age to 21 claim that there will be a health benefit because 18, 19 and 20 year olds would then not use tobacco products nor serve as a social source for underage youth.

However, if 18, 19 and 20-year-old adults are not prohibited from possessing and using tobacco products, these adults will simply drive to a neighboring or nearby city or town, purchase their preferred tobacco products, and then legally possess and use them in their hometown. This also means that these adults can continue to be a social source of tobacco for minors. In other words, the public health benefit claimed will be marginal to non-existent, but your local retailers would suffer the financial loss of tobacco sales to legal age adults along with reduced gasoline, snack and beverage sales when these adults drive to nearby towns to patronize other retailers.

If your city council decides to proceed with an age 21 ordinance that would also ban the possession and use of tobacco products, then local police departments generally oppose an ordinance because the police would be tasked with enforcing the ordinance by citing and/or arresting 18, 19 and 20-year-old adults for possessing and/or using legal tobacco products. At a Bloomington City Council workshop session held on August 14, 2017, a representative of ClearWay Minnesota (the anti-
tobacco organization formed as a result of the 1998 tobacco litigation settlement in Minnesota), informed the Bloomington City Council that if an age 21 ordinance included a prohibition on the possession and use of tobacco by 18, 19 and 20 year olds, then the organizations that make up the Tobacco 21 movement would likely withdraw their support for the ordinance.

This opposition to prohibiting the possession and use of tobacco, while at the same time raising the legal age to 21 to purchase tobacco, creates a conflicting double standard. Minnesota Statutes Section 340A.503 makes it illegal for anyone under the age of 21 to buy, possess or use alcohol (copy of statute accompanies this letter). However, these advocate groups apparently oppose uniformity with the state liquor laws and, instead, want to allow 18, 19, and 20-year-old adults to be able to possess and use tobacco.

Here is the Catch 22: On the one hand, the supporters of an age 21 ordinance claim a health benefit if the age to purchase tobacco is raised, but fail to acknowledge that there will little if any health benefit because 18, 19 and 20 year olds could still possess and use tobacco and that social sources will remain the leading access point to tobacco for underage youth. On the other hand, when the possibility of also prohibiting possession and use of tobacco is raised to be in line with the state liquor possession and use law, the advocates publicly state that support for raising the legal age will likely be withdrawn. These positions are contradictory and demonstrate the difficulty presented by considering a policy that changes the legal of adulthood.

If the goal is to benefit the public health, then an age 21 ordinance that does not ban possession and use will not reach that goal. If possession and use of tobacco by 18, 19 and 20-year-olds are prohibited, then the very advocacy groups that proposed this idea of raising the legal age to 21 will no longer support the ordinance and your local police departments may also withhold their support.

**Significant Reduction in Youth Tobacco Use Without an Age 21 Ordinance**

The annual Minnesota Student Survey reports that smoking among 9th graders decreased from 19.6% in 2001 to 4.3% in 2016, an 80% decline. In addition, the smoking rate among 11th graders decreased 75% over this same time period. These declines were achieved by retailers preventing sales to minors, better health education, and all in the absence of raising the age to 21.

The advocate groups lobbying for the passage of an age 21 ordinance may reference the Town of Needham, Massachusetts which experienced a 50% reduction in smoking rates among high school students after an age 21 ordinance was adopted. However, it is important to understand that Minnesota has seen even more significant declines in youth smoking rates than in Needham without the adoption of an age 21 law.

**Overwhelming Negative Public Reaction to Edina Age 21 Ordinance**

The adoption of an age 21 ordinance is not necessarily an accurate reflection of the public’s opinion about raising the legal age. Accompanying this letter are actual comments posted on-line in response to a Minneapolis Star Tribune newspaper story about Edina’s adoption of its age 21 ordinance. The overwhelming majority of posted comments did not support the action of the Edina City Council. We urge you to read the sample comments as they are a barometer of this strong negative public opinion toward an age 21 ordinance.
Personal Rights Still Matter

The personal rights of 18, 19 and 20-year-old adults to decide for themselves whether to purchase tobacco products will be curtailed even though these same young adults can vote, serve in the military, get married, take out loans for college, and make their own health care decisions. The protection of personal rights is still important in our society and we ask that you weigh the rights of all adults before considering whether to restrict the freedom of 18, 19 and 20 year olds to decide what legal products they are allowed to purchase.

We appreciate you considering our concerns and urge you to not consider an ordinance that would raise the legal age to 21 to purchase tobacco products.

Sincerely,

Lance Klatt, Executive Director
Minnesota Service Station Association

Jamie Pfuhl, President
Minnesota Grocers Association

Kevin Thoma, Executive Director
Minnesota Petroleum Marketers Association

Brian Carr, Deputy Executive Director
National Association of Tobacco Outlets

Bruce Nustad, President
Minnesota Retailers Association
Sample of Comments in Response to Edina Age 21 Ordinance Passage

Source: Minneapolis Star Tribune (www.startribune.com), May 2-3, 2017

“All Edina has done is make cigarettes more of a ‘forbidden fruit’ to their teenagers and won’t do much, if anything to do with reducing smoking rates. It’s already proven that education, not prohibition, is the best way to reduce smoking (and drinking).”

“Since Edina doesn’t seem to believe 18 year olds can make a good decision when it comes to tobacco use, I assume they’ll want to raise the age of legal majority to 21 along with the voting age and the age for military service?”

“When are the citizens going to say enough is enough? A City Council enacting a law prohibiting the sale of a legal product seems like overreach. Hopefully these 18-20 year olds will vote against these folks for infringing on their rights.”

“I would not have voted for the 2 new members of the city council had I known they would bring to life and vote for this. It’s a waste of my city tax dollars and a loss of more tax dollars.”

“This is a no brainer…just go elsewhere…how dumb are the council people of Edina?”

“What principle does this establish? That they don’t trust 18 year olds to make decisions about their own personal consumption choices?”

“Do you trust them enough to allow them to march into battle overseas with a machine-gun in their hands?”

“I’m a non-smoker and well over 21 so I have no dog in [t]his fight. But I don’t think it’s a good idea to make cigarettes illegal to purchase for young adults. They’re legal adults. They can make their own decisions.”

“What an amazingly superficial and useless action. Military personnel aside, is there any true reason to be a legal adult when others are making your personal decisions for you?”

“Self-righteous do-nothingness. And no, I do not smoke-I just don’t believe in arbitrarily taking away the rights of legal adults.”

“Brilliant! Leave it up to Edina to lead the way to show the rest of us how another symbolic, do nothing law will only hurt local businesses and effectively lower tax revenues for their city.”

“Nanny state.”

“I loathe smoking, but the only thing more insufferable than smokers is people on their high horse telling adults what they can’t do.”

“Each day we are getting closer to living in a totalitarian society. This is supposed to be a free country. We are losing more and more of our freedoms with each legislative session, with each city council meeting and each new law that is put on the books. Tragie and sad.”
YOUTH ACCESS TO TOBACCO PRODUCTS AMONG PAST 30-DAY USERS: WHERE DO YOUTH GET TOBACCO?

Source of access to tobacco product among 15-17 year old current users

- **Cigarettes (n=533)**
  - Bought myself: 13.8%
  - Gave someone else money to buy: 32.0%
  - Bought from someone/took from store or another person: 6.6%
  - Asked for or someone offered: 42.5%
  - Other/missing/don’t know/refused: 5.0%

- **E-cigarettes (n=342)**
  - Bought myself: 10.5%
  - Gave someone else money to buy: 17.3%
  - Bought from someone/took from store or another person: 5.8%
  - Asked for or someone offered: 56.7%
  - Other/missing/don’t know/refused: 9.7%

- **Cigarillos (n=257)**
  - Bought myself: 21.0%
  - Gave someone else money to buy: 34.2%
  - Bought from someone/took from store or another person: 4.1%
  - Asked for or someone offered: 37.3%
  - Other/missing/don’t know/refused: #

- **Hookah (n=189)**
  - Bought myself: 12.0%
  - Gave someone else money to buy: 17.3%
  - Bought from someone/took from store or another person: 4.8%
  - Asked for or someone offered: 56.9%
  - Other/missing/don’t know/refused: 9.0%

- **Smokeless (n=154)**
  - Bought myself: 23.2%
  - Gave someone else money to buy: 37.0%
  - Bought from someone/took from store or another person: 4.9%
  - Asked for or someone offered: 31.2%
  - Other/missing/don’t know/refused: #

*# Estimate suppressed because it is statistically unreliable; it is based on a sample size of less than 50, or the coefficient of variation of the estimate is larger than 30 percent.*

April 21, 2016 | NATO
340A.503 PERSONS UNDER 21; ILLEGAL ACTS.

**Subdivision 1. Consumption.** (a) It is unlawful for any:

(1) retail intoxicating liquor or 3.2 percent malt liquor licensee, municipal liquor store, or bottle club permit holder under section 340A.414, to permit any person under the age of 21 years to drink alcoholic beverages on the licensed premises or within the municipal liquor store; or

(2) person under the age of 21 years to consume any alcoholic beverages. If proven by a preponderance of the evidence, it is an affirmative defense to a violation of this clause that the defendant consumed the alcoholic beverage in the household of the defendant's parent or guardian and with the consent of the parent or guardian.

(b) An offense under paragraph (a), clause (2), may be prosecuted either in the jurisdiction where consumption occurs or the jurisdiction where evidence of consumption is observed.

(c) As used in this subdivision, "consume" includes the ingestion of an alcoholic beverage and the physical condition of having ingested an alcoholic beverage.

**Subdivision 2. Purchasing.** It is unlawful for any person:

(1) to sell, barter, furnish, or give alcoholic beverages to a person under 21 years of age;

(2) under the age of 21 years to purchase or attempt to purchase any alcoholic beverage unless under the supervision of a responsible person over the age of 21 for training, education, or research purposes. Prior notification of the licensing authority is required unless the supervised alcohol purchase attempt is for professional research conducted by postsecondary educational institutions or state, county, or local health departments; or

(3) to induce a person under the age of 21 years to purchase or procure any alcoholic beverage, or to lend or knowingly permit the use of the person's driver's license, permit, Minnesota identification card, or other form of identification by a person under the age of 21 years for the purpose of purchasing or attempting to purchase an alcoholic beverage. If proven by a preponderance of the evidence, it shall be an affirmative defense to a violation of clause (1) that the defendant is the parent or guardian of the person under 21 years of age and that the defendant gave or furnished the alcoholic beverage to that person solely for consumption in the defendant's household.

**Subdivision 3. Possession.** It is unlawful for a person under the age of 21 years to possess any alcoholic beverage with the intent to consume it at a place other than the household of the person's parent or guardian. Possession at a place other than the household of the parent or guardian creates a rebuttable presumption of intent to consume it at a place other than the household of the parent or guardian. This presumption may be rebutted by a preponderance of the evidence.
September 14, 2017

The Honorable Mayor Slavik and Members of the Plymouth City Council
Plymouth City Hall
3400 Plymouth Blvd
Plymouth, MN 55447-1482

Dear Mayor Slavik and Members of the City Council:

On behalf of the 24,500 employees at HealthPartners, many of whom live or work in the city, we want to express our strong support for the proposed ordinance to raise the age for tobacco sales to 21 in Plymouth. As you may know, it is HealthPartners’ mission to improve health and well-being in partnership with our members, patients and the community.

Approximately 95 percent of adult smokers started before they were 21. For years tobacco use has been the number one preventable cause of death in our country and our state. Smoking costs the state more than $3 billion annually in excess health care costs and each year more than 6,000 Minnesotans die from tobacco-related diseases. And as you know, increasing health care costs are frequently cited as a top concern by both businesses and citizens.

18-21 is a critical time when young people move from intermittent smoking to daily use. In addition to the countless long-term negative health effects of tobacco, nicotine itself is known to be particularly harmful to the development of the adolescent brain. Research suggests that nicotine interferes with brain maturation and can have long term effects on development and mental health. A recent report from the Institute of Medicine found that increasing the tobacco sales age to 21 would also mean that smoking initiation among 15-17-year-olds would be reduced by 25 percent.

Thank you for you for being a leader in our state and taking a positive step towards keeping tobacco out of the hands of our children.

Sincerely,

Dr. Thomas Kottke, M.D.
HealthPartners Medical Director, Well-being
Health Risks of Nicotine for Youth
8/25/2017 - Health Advisory: Nicotine Risks for Children, Teens, and Pregnant Women (PDF)

Nicotine is a chemical commonly found in cigarettes, e-cigarettes, and other tobacco products. **Nicotine is highly addictive and can be toxic.**

**No amount of nicotine is safe for youth.**
Nicotine can harm brain development as teens grow. Animal research has found that even in small doses, nicotine exposure in adolescence causes long-lasting changes in brain development, which could have negative implications in human adolescents for learning, memory, attention, behavior problems, and future addiction.

Nicotine is harmful to the health of unborn children. Evidence shows that fetal exposure to nicotine can have negative long-term effects, including sudden infant death syndrome (SIDS), impaired fetal brain and lung development, hearing problems, effects on behaviors and obesity, and deficits in attention and cognition. Studies also indicate that fetal nicotine exposure is associated with nicotine dependence in adolescence.

**Nicotine can be toxic, even deadly, in high doses.**
Eating, drinking, or otherwise absorbing large amounts of nicotine can lead to nicotine poisoning, especially in children. Symptoms of poisoning include nausea, vomiting, seizures, and respiratory depressions. In high enough doses nicotine can be deadly.

**For poison emergencies or questions call the Minnesota Poison Control System at 1-800-222-1222.** Service is available 24/7, free of charge, and is confidential.

**E-cigarettes expose Minnesota teens to the dangers of nicotine.**
Among 11th grade students, e-cigarette use is now more than double conventional cigarette use. Nearly all e-cigarettes contain nicotine.

Learn more about [E-cigarettes and Other Vaping Products](http://www.health.state.mn.us/divs/hpcd/tpc/topics/ecigarettes.html).

Learn more
[http://www.mnpoison.org]
• Health Advisory: Nicotine Risks for Children, Teens, and Pregnant Women (PDF)
  (http://www.health.state.mn.us/divs/hpcd/tpc/topics/nicotine_docs/2017nic_advisory.pdf)
• Infographic: Nicotine - More Harmful than You Think (PDF)
  (http://www.health.state.mn.us/divs/hpcd/tpc/topics/nicotine_docs/2017nic_infographic.pdf)
• American Lung Association: Is it safe to use electronic cigarettes while pregnant?
  (http://lethallure.org/is-it-safe-to-use-electronic-cigarettes-while-pregnant-2/)
• Minnesota Poison Control System http://www.mnpoison.org/ (http://www.mnpoison.org/)
  Call 1-800-222-1222 for poison emergencies.

This information is also available as a PDF: Health Risks of Nicotine for Youth (PDF)
(http://www.health.state.mn.us/divs/hpcd/tpc/topics/nicotine_docs/nicotine.pdf)

Updated Friday, August 25, 2017 at 08:42AM
City of Plymouth
Tobacco environmental scan, 2017

Youth tobacco use is still a problem
• Smoking is the greatest cause of preventable death and disease in Minnesota.¹
• Nearly nine out of 10 smokers start smoking by age 18, and 99% start by age 26.²
• 2,800 kids in Minnesota become new daily smokers each year; 102,000 now under age 18 will die prematurely from smoking.³
• The tobacco industry spends over $300,000 a day marketing tobacco, most of which is spent in retail stores—the most important channel for reaching kids.⁴
• Annual health care costs in Minnesota directly caused by smoking exceed $3.2 billion in excess medical costs. This does not include the cost of lost productivity and other costs indirectly attributed to smoking.⁵

Tobacco retailers (Sources: City of Plymouth; FDA Compliance Check Inspections database)

<table>
<thead>
<tr>
<th>Tobacco retailers</th>
<th>35, or 0.45 per 1,000 residents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tobacco or e-cigarette shops/lounges</td>
<td>1*</td>
</tr>
<tr>
<td>Compliance check violations in 2014, 2015, 2016</td>
<td>2, 3, 0 (includes 2 repeat violations)</td>
</tr>
<tr>
<td>Frequency of local compliance checks</td>
<td>2 per year</td>
</tr>
<tr>
<td>FDA violations in 2014, 2015, 2016</td>
<td>2, 0, 2**</td>
</tr>
</tbody>
</table>

* Uncertain if this store restricts minors from entering.
**2014 violation for self-serve display; 2016 violation for sale of electronic liquid to a minor.

Youth tobacco use (Sources: Minnesota Student Survey 2010, 2013, and 2016, Robbinsdale and Wayzata School Districts)

<table>
<thead>
<tr>
<th>Percentage of youth who reported using the following products within the past 30 days:</th>
<th>Robbinsdale School District</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>9th Grade</td>
</tr>
<tr>
<td></td>
<td>2010</td>
</tr>
<tr>
<td>Conventional tobacco**</td>
<td>10%</td>
</tr>
<tr>
<td>Any tobacco use (also includes e-cigarettes)</td>
<td>NA***</td>
</tr>
<tr>
<td>Cigarettes</td>
<td>7%</td>
</tr>
<tr>
<td>Cigars, cigarillos, little cigars</td>
<td>5%</td>
</tr>
<tr>
<td>Electronic cigarettes</td>
<td>NA</td>
</tr>
<tr>
<td>Flavored tobacco</td>
<td>NA</td>
</tr>
<tr>
<td>Menthol cigarette</td>
<td>NA</td>
</tr>
</tbody>
</table>

*Data is not available for 11th grade in 2010.
**Conventional tobacco use includes cigarettes, chewing tobacco/snuff/dip, or cigars/cigarillos/little cigars.
***NA = Not Asked.

Key findings from Robbinsdale and Wayzata School Districts’ MN Student Survey
• Use of conventional tobacco products continues to decline, however, when e-cigarettes are factored in, tobacco use has remained the same in 9th grade and increased in 11th grade.
• 9th and 11th graders use e-cigarettes at a much greater rate than conventional cigarettes.
• Youth are using menthol and other flavored tobacco products, which are considered starter products. Some, such as menthol, are harder to quit.⁶

Sources:
¹ MN Department of Health Smoking fact sheet. https://apps.health.state.mn.us/mndata/smoking.
⁴ Ibid.
Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products

Over the past 50 years, tobacco control in the United States has led to an estimated 8 million fewer premature deaths. However, tobacco use continues to significantly affect public health, and more than 40 million Americans still smoke.

In 2009, the Family Smoking Prevention and Tobacco Control Act granted the U.S. Food and Drug Administration (FDA) broad authorities over tobacco products, though it prohibited FDA from establishing a nationwide minimum age of legal access—an MLA for tobacco products—above 18 years of age. It also directed FDA to convene a panel of experts to conduct a study on the public health implications of raising the minimum age to purchase tobacco products. At FDA’s request, the Institute of Medicine (IOM) convened a committee in 2013 for this purpose.

In the resulting report, Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products, the committee of experts reviews existing literature on tobacco use initiation, developmental biology and psychology, and tobacco policy and predicts the likely public health outcomes of raising the MLA for tobacco products to 19 years, 21 years, and 25 years. The committee also uses mathematical modeling to quantify these predictions. Of note, the report contains only conclusions regarding raising the MLA; as requested by FDA, the committee does not offer recommendations as to whether the MLA should be raised.
Lowering Initiation Rates

The initiation age of tobacco use is critical. Among adults who become daily smokers, approximately 90 percent report first use of cigarettes before reaching 19 years of age, and almost 100 percent report first use before age 26. As mentioned above, FDA cannot raise the MLA nationwide. However, states and localities can set a higher minimum age for their communities. Most states currently set the MLA at 18 years. Four states set it at 19 years, and several localities around the country have raised the minimum age to 21 years.

Based on its review of the literature, the committee concludes that overall, increasing the MLA for tobacco products will likely prevent or delay initiation of tobacco use by adolescents and young adults. The age group most impacted will be those age 15 to 17 years. The committee also concludes that the impact of raising the MLA to 21 will likely be substantially higher than raising it to 19. However, the added effect of raising the MLA from 21 to 25 will likely be considerably less.

The parts of the brain most responsible for decision making, impulse control, sensation seeking, and susceptibility to peer pressure continue to develop and change through young adulthood, and adolescent brains are uniquely vulnerable to the effects of nicotine. In addition, the majority of underage users rely on social sources—like family and friends—to get tobacco.

Raising the MLA to 19 will therefore not have much of an effect on reducing the social sources of those in high school. Raising the MLA to 21 will mean that those who can legally obtain tobacco are less likely to be in the same social networks as high school students. In the same vein, increasing the MLA from 21 to 25 is not likely to achieve additional notable reductions in social sources for those under age 15.

Reducing Prevalence, Decreasing Disease

Delaying initiation rates will likely decrease the prevalence of tobacco users in the U.S. population. To quantify this decrease in both prevalence of tobacco users and in related health concerns
Given a decline in the initiation rates of tobacco use by adolescents and lower prevalence in the population, it follows that tobacco-related disease would also decrease in proportion to the reduction in tobacco use. It is generally known that smoking-related diseases like cancer and heart disease develop over decades, and therefore, it could take many years to lower rates of these diseases; however, there could be immediate decreases in other tobacco-related health effects.

The committee concludes that raising the MLA will likely immediately improve the health of adolescents and young adults by reducing the number of those with adverse physiological effects such as increased inflammation and impaired immune functioning caused by smoking, as these could potentially lead to negative health consequences, including increased hospitalizations and lessened capacity to heal wounds. Adverse maternal, fetal, and infant outcomes—including preterm births, low birth weight, and sudden infant death—will also probably decrease due to reduced tobacco exposure in mothers and infants. Raising the MLA will also lessen the population’s exposure to secondhand smoke and its associated health effects, both now and in the future.

Over time, the committee concludes that raising the MLA will likely lead to substantial reductions in smoking-related mortality, though results from the models suggest that these results will not be observed for at least 30 years, assuming that the MLA increase occurs now. The CISNET model...
projected that if the MLA were raised now to 21 nationwide, there would be approximately 223,000 fewer premature deaths, 50,000 fewer deaths from lung cancer, and 4.2 million fewer years of life lost for those born between 2000 and 2019.

Conclusion

The public health impact of raising the MLA for tobacco products depends on the degree to which local and state governments change their policies. These decisions will depend on each state’s or locality’s balance between personal interests and the privacy of young adults to make their own choices versus society’s legitimate concerns about protecting public health.

The IOM committee makes conclusions about likely public health outcomes of raising the MLA for tobacco products. Overall, in the absence of transformative changes in the tobacco market, social norms and attitudes, or in the knowledge of patterns and causes of tobacco use, the committee is reasonably confident that raising the MLA will reduce tobacco use initiation, particularly among adolescents 15 to 17 years of age; improve the health of Americans across the lifespan; and save lives.
Dear Mayor Slavik and Council Members:

I am writing to express my support for increasing the tobacco age to 21 in Plymouth. I was very pleased to see that the Council is having a study session on the topic later this month. As a mother, I have always appreciated that Plymouth puts its kids first. Our city truly is a great place to raise families. Let’s join our neighboring cities in preventing kids from becoming addicted.

Increasing the tobacco purchase age to 21 will prevent youth tobacco use and save lives. I’m especially supportive of this policy because it will help keep tobacco products out of our schools. Younger students know plenty of 18 year olds, but they know far fewer, if any, 21 year olds. Increasing the age is another step our city can take to ensure our kids grow up in a healthy community.

Can I count on your support for this important policy? I look forward to hearing from you.

Best Regards!

Laurie

Laurie Lafontaine
11400 5th Ave. N.
Plymouth, MN 55441
laurielafa@msn.com
612/501-9307
Dear Mayor Slavik and Members of the City Council,

Thank you to Mayor Slavik, and Council Members Ned Carroll, Jim Prom and Jeffry Wosje for responding to my previous letter. I am a Plymouth resident and parent and businessperson concerned about youth tobacco use in Plymouth. I am excited to see that the City Council is considering raising the tobacco sales age to 21. I encourage you to put Plymouth Youth and the health of our community above profits.

Based on the last City Council study session, it sounds like the Council is concerned about local business impacts and wondering if it’s better for the State to act instead. Here are my responses to each of these concerns:

MN History has shown that local action is needed before statewide action happens. We have recent history with the MN Freedom to Breathe Act which started locally and moved to State Law. The expectation was that restaurant business would suffer but it did not. Only 2-4% of retail business is from 18-20 year olds. There are
organizations such as CVS that have determined they will not sell tobacco products and they have not suffered financially.

I would encourage Plymouth to lead in this important work. It’s important to note the 95% of current smokers started before age 21 and 60% of 18-19 year olds have been asked to buy cigarettes for younger kids. I have always been impressed with quality of life and support for youth in Plymouth – let’s not prioritize profits for business over the health of our community and our youth!

I am writing to express my full support in strengthening Plymouth’s tobacco ordinance. I am concerned about the raising rates of e-cigarette use among the young people in our community. Nicotine is dangerous for the developing adolescent brain and getting these products out of our high schools will go a long way in preventing future generation from a lifelong addiction.

A Tobacco 21 ordinance will have a positive impact on our youth and the health of our entire community. I strongly support you in raising the tobacco sales age to 21 in Plymouth.

I look forward to hearing from you!

Laurie.

Laurie Lafontaine
laurielafa@msn.com
612/501-9307
Increasing the Tobacco Sale Age to 21

WHY RAISE THE TOBACCO SALE AGE?

The tobacco industry heavily targets young adults ages 18-21 in order to recruit new tobacco users and guarantee profits. Approximately 95 percent of current adult smokers started before they were 21.1 In Minnesota, no one under 18 years old is allowed to buy tobacco. Youth get tobacco from several sources, including social sources. A 16-year-old has more contact with and access to 18-year-olds who can buy tobacco. However, it is less likely a 16-year-old would ask a 21-year-old for tobacco. Increasing the age gap between young people and those who can legally buy tobacco will reduce youth access to tobacco.

A 2015 report from the Institute of Medicine (IOM) found that increasing the legal age to purchase tobacco to 21 would decrease smoking initiation among 15-17-year-olds by 25 percent.2 A Minnesota-specific study looked at the impact of raising the tobacco age and found that 25 percent fewer 15-year-olds would start smoking by the time they turn 18 and 15 percent fewer 18-year-olds would start smoking by the time they turn 18. This translates into 30,000 young people not becoming smokers over the next 15 years.3 If youth don't smoke by the time they are 21, they likely never will.

WHAT IS THE IMPACT OF NICOTINE ON ADOLESCENT BRAIN DEVELOPMENT?

Nicotine is addictive and is particularly harmful to the developing adolescent brain. Evidence suggests that nicotine interferes with brain maturation and can have a long-term effect on cognitive development and mental health.4 Even brief or intermittent nicotine exposure during adolescence can cause lasting damage.5

The addictive properties of nicotine can lead adolescents to heavier daily tobacco use and a more difficult time quitting later in life.6 Nicotine exposure can also increase the risk of addiction to other harmful substances.5 The long-term effects of nicotine on the adolescent brain is a significant public health concern.7,8

WHO SUPPORTS RAISING THE TOBACCO SALE AGE TO 21?

A 2014 national survey shows that 75 percent of adults favor increasing the minimum sale age for tobacco to 21. A national consensus is growing to protect young people from a lifetime of addiction and health problems caused by tobacco by raising the tobacco sale age. In addition, 70 percent of current smokers and 65 percent of those age 18-24 support raising the minimum tobacco sale age.9
WHAT CAN STATE AND LOCAL GOVERNMENTS DO?

Hawaii and California and a growing list of more than 260 cities in the United States have raised the tobacco sale age to 21. New York City, Boston, Kansas City, Saint Louis and Chicago lead that list.

The city of Needham, Mass., raised the legal tobacco sale age to 21 in 2005. Within five years, tobacco use among high school students decreased by nearly half.11

IS YOUTH TOBACCO USE STILL A PROBLEM?

The percent of students who smoke cigarettes is declining, but the 2016 Minnesota Student Survey found that 9th and 11th graders in Minnesota are now using e-cigarettes at twice the rate of regular cigarettes.10 Increasing the sale age to 21 would reduce youth access to all harmful tobacco products, including e-cigarettes, cigars and hookah.

SOURCES

11 Kessed Schneider S et al. Community reductions in youth smoking after raising the minimum tobacco sales age to 21. Tob Control. 2015.

California, Hawaii, New Jersey, Maine and Oregon raised the minimum legal sale age for tobacco products to 21 since 2016.

More than 250 localities in the United States have raised the minimum legal sale age for tobacco products to 21.

Some organizations who support raising tobacco sale age to 21 include:
- American Cancer Society Cancer Action Network
- American Heart Association
- American Lung Association
- ClearWay Minnesota℠
- Minnesota Academy of Family Physicians
- Service Employees International Union Minnesota State Council

The Association for Nonsmokers-Minnesota is dedicated to reducing the human and economic costs of tobacco use in Minnesota. (February, 2017)

2395 University Avenue W, Suite 310, St. Paul, MN 55114 | 651-646-3005 | www.ansrmn.org
SF 2370

Minnesota State Legislature

Minnesota Senate

SF 2370 as introduced - 90th Legislature (2017 - 2018)  
Posted on 05/05/2017 09:56am

KEY: stricken = removed, old language. underscored = added, new language.

Version List  
Authors and Status

Jump to page/line # [eg. 2.1]

1.1  A bill for an act
1.2  relating to health; adding charter schools to the prohibition of tobacco in schools;
1.3  increasing the tobacco safe age; increasing administrative penalties; allowing
1.4  alternative penalties; amending Minnesota Statutes 2016, sections 144.4105;
1.5  144.4167, subdivision 4; 171.171; 461.12, subdivisions 2, 3, 4, 5, 6; 461.18;
1.6  609.645; 609.655; proposing coding for new law in Minnesota Statutes, chapter
1.7  461.
1.8  BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2016, section 144.4165, is amended to read:
1.10 144.4165 TOBACCO PRODUCTS PROHIBITED IN PUBLIC SCHOOLS.
1.11  No person shall at any time smoke, chew, or otherwise ingest tobacco or a tobacco
1.12  product, or inhale or exhale vapor from an electronic delivery device as defined in section
1.13  609.645, subdivision 1, in a public school, as defined in section 120A.05, subdivisions 9.
1.14  11, and 13, and no person under the age of 18 shall possess any of these items or in a charter
1.15  school, as defined in section 124E.05, subdivision 2. This prohibition extends to all facilities,
1.16  whether owned, rented, or leased, and all vehicles that a school district owns, leases, rents,
1.17  contracts for, or controls. Nothing in this section shall prohibit the lighting of tobacco by
1.18  an adult as a part of a traditional Indian spiritual or cultural ceremony. For purposes of this
1.19  section, an Indian is a person who is a member of an Indian tribe as defined in section
1.20  260.755, subdivision 12.
1.21  Sec. 2. Minnesota Statutes 2016, section 144.4167, subdivision 4, is amended to read:
1.22  Subd. 4. Tobacco products shop. Sections 144.414 to 144.417 do not prohibit the
1.23  lighting of tobacco in a tobacco products shop by a customer or potential customer for the
1.24  specific purpose of sampling tobacco products. For the purposes of this subdivision, a
1.25  tobacco products shop is a retail establishment with that cannot be entered at any time by
1.26  persons younger than 21 years of age that has an entrance door opening directly to the
1.27  outside, and that derives more than 90 percent of its gross revenue from the sale of loose
1.28  tobacco, pipes, or orbs and cigars, cigarettes, pipe, and other smoking devices for burning
1.29  tobacco and related smoking accessories, tobacco-related devices, and electronic delivery
1.30  devices, as defined in section 609.645, and in which the sale of other products is merely
1.31  incidental. "Tobacco products shop" does not include a tobacco department or section of
1.32  any individual business establishment with any type of liquor, food, or restaurant license.

Sec. 3. Minnesota Statutes 2016, section 171.171, is amended to read:
1.34  171.171 SUSPENSION; ILLEGAL PURCHASE OF ALCOHOL OR TOBACCO.
1.35  The commissioner shall suspend for a period of 90 days the license of a person who:
1.36  (1) is under the age of 21 years and is convicted of purchasing or attempting to purchase
1.37  an alcoholic beverage in violation of section 340A.303 if the person used a license, Minnesota
1.38  identification card, or any type of false identification to purchase or attempt to purchase the
1.39  alcoholic beverage;
1.40  (2) is convicted under section 171.22, subdivision 1, clause (3), or 240A.503, subdivision
1.41  2, clause (3), of lending or knowingly permitting a person under the age of 21 years to use
1.42  the person's license, Minnesota identification card, or other type of identification to purchase
1.43  or attempt to purchase an alcoholic beverage; or
1.44  (3) is under the age of 18 years and is found by a court to have committed a petty
1.45  misdemeanor under section 609.645, subdivision 2, or 609.655, subdivision 2, if the person used a license, Minnesota
1.46  identification card, or any type of false identification to purchase or attempt to purchase the
1.47  tobacco product or
1.48  (4) is convicted under section 171.22, subdivision 1, clause (2), of lending or
1.49  knowingly permitting a person under the age of 21 years to use the person's license, Minnesota
1.50  identification card, or other type of identification to purchase or attempt to
1.51  purchase a tobacco product, tobacco, a tobacco-related device, an electronic delivery device,
1.52  as defined in section 609.645, subdivision 1, or nicotine or heated delivery product, as
1.53  described in section 609.645, subdivision 1.

Sec. 4. Minnesota Statutes 2016, section 461.12, subdivision 2, is amended to read:
1.55  Subd. 2. Administrative penalties; licensees. If a licensee or employee of a licensee
1.56  sells, gives, or otherwise furnishes tobacco, tobacco-related devices, electronic delivery
1.57  devices, or nicotine or heated delivery products to a person under the age of 21 years,
1.58  or violates any other provision of this chapter, the licensee shall be charged an administrative
1.59  penalty of $50 to $500. An administrative penalty of $200 to $500 must be imposed for a second
1.60  violation at the same location within 34 months after the initial violation. For a third or any
3.8 subsequent violation at the same location within 24 months after the initial violation, an
administrative penalty of $500 to $1,000 must be imposed, and the license's authority to sell
3.10 tobacco, tobacco-related devices, electronic delivery devices, or nicotine or other delivery
3.11 products to that location must be suspended for not less than seven days and may be revoked.
3.12 No suspension, revocation, or other penalty may take effect until the license has received
3.13 notice, served personally or by mail, of the alleged violation and an opportunity for a hearing
3.14 before a person authorized by the licensing authority to conduct the hearing. A decision
3.15 that a violation has occurred must be in writing.
3.16
3.17 Sec. 5. Minnesota Statutes 2016, section 461.12, subdivision 3, is amended to read:
3.18 Subd. 3. Administrative penalty; individuals. An individual who sells, gives, or
3.19 otherwise furnishes tobacco, tobacco-related devices, electronic delivery devices, or nicotine
3.20 or other delivery products to a person under the age of 21 years must be charged an
3.21 administrative penalty of $50. No penalty may be imposed until the individual has received
3.22 notice, served personally or by mail, of the alleged violation and an opportunity for a hearing
3.23 before a person authorized by the licensing authority to conduct the hearing. A decision
3.24 that a violation has occurred must be in writing.
3.25
3.26 Sec. 6. Minnesota Statutes 2016, section 461.12, subdivision 4, is amended to read:
3.27 Subd. 4. Minors Persons under age 21. The licensing authority shall consult with
3.28 interested educators, parents, children persons under the age of 21 years, and representatives
3.29 of the court system to develop alternative penalties for minors persons under the age of 21
3.30 years who purchase, possess, and consume tobacco, tobacco-related
3.31 devices, electronic delivery devices, or nicotine or other delivery products using a driver's
3.32 license, permit, Minnesota identification card, or any other type of false identification to
3.33 misrepresent the person's age, in violation of section 609.685 and 609.6855. The licensing
3.34 authority and the interested persons shall consider a variety of options, including, but not
3.35 limited to, tobacco-free education, tobacco cessation programs, notice to schools, parents,
3.36 community service, and other court diversion programs.
3.37
3.38 Sec. 7. Minnesota Statutes 2016, section 461.12, subdivision 5, is amended to read:
3.39 Subd. 5. Compliance checks. A licensing authority shall conduct unscheduled
3.40 compliance checks at least once each calendar year at each location where tobacco,
3.41 tobacco-related devices, electronic delivery devices, or nicotine or other delivery products
3.42 are sold to test compliance with sections 609.685 and 609.6855. Compliance checks
3.43 must involve minors persons over the age of 15, but under the age of 21 years, who, with the prior
3.44 written consent of a parent or guardian, under the age of 18, attempt to purchase tobacco,
3.45 tobacco-related devices, electronic delivery devices, or nicotine or other delivery products
3.46 under the direct supervision of a law enforcement officer or an employee of the licensing
3.47 authority.
3.48
3.49 Sec. 8. Minnesota Statutes 2016, section 461.12, subdivision 6, is amended to read:
3.50 Subd. 6. Defense. It is an affirmative defense to the charge of selling tobacco,
3.51 tobacco-related devices, electronic delivery devices, or nicotine or other delivery products
3.52 to a person under the age of 21 years in violation of subdivision 2 or 3 that the licensee
3.53 or individual making the sale relied in good faith upon proof of age as described in section
3.54 340A.591, subdivision 6.
3.55
3.56 Sec. 9. Minnesota Statutes 2016, section 461.18, is amended to read:
3.57 461.18 BAN ON SELF-SERVICE SALE OF PACKS SALES: EXCEPTIONS.
3.58 Subdivision 1. Except in adult-only age 21 and older facilities. (a) No person shall
3.59 offer for sale tobacco or tobacco-related devices, or electronic delivery devices as defined
3.60 in section 609.685, subdivision 1, or nicotine or other delivery products as described in
3.61 section 609.6855, in open displays which are accessible to the public without the intervention
3.62 of a store employee.
3.63 [Repealed August 31, 1997]
3.64 [Repealed]
3.65 (b) (1) This subdivision shall not apply to retail stores which have an entrance door
3.66 opening directly to the outside and that derive at least 90 percent of their gross revenue from
3.67 tobacco, tobacco-related devices, and electronic delivery devices as defined in section
3.68 609.685, subdivision 1, and where the retailer ensures that no person younger than 21 years
3.69 of age is present, or permitted to enter, at any time.
3.70 Subd. 2. Vending machine sales prohibited. No person shall sell tobacco products,
3.71 electronic delivery devices, or nicotine or other delivery products from vending machines.
3.72 This subdivision does not apply to vending machines in facilities that cannot be entered at
3.73 any time by persons younger than 21 years of age.
3.74 Subd. 3. Federal regulations for cartons, multipacks. Code of Federal Regulations,
3.75 title 21, part 829, 1149.16(e), as amended by Code of Federal Regulations, volume
3.76 81, number 90 (May 10, 2016), and as otherwise amended from time to time, is incorporated
3.77 by reference with respect to cartons and other multipack units.
3.78 Sec. 10. 461.221 SIGNAGE REQUIRED.
3.79 At each location where tobacco, tobacco-related devices, electronic delivery devices, or
3.80 nicotine or other delivery products are sold, the licensee shall display a sign in plain view
3.81 to provide public notice that selling any of these products to any person under the age of
3.82 21 is illegal and subject to penalties. The notice shall be placed in a conspicuous location.
in the licensed establishment and shall be readily visible to any person who is purchasing
or considering a purchase of such products. The sign must provide notice that all persons
responsible for selling such products shall verify, by means of photostatic identification
containing the buyer's date of birth, the age of any person under 30 years of age.

Sec. 11. Minnesota Statutes 2016, section 609.685, is amended to read:

609.685 SALE OF TOBACCO TO CHILDREN PERSONS UNDER AGE 21.

Subdivision 1. Definitions. For the purposes of this section, the following terms shall
have the meanings respectively ascribed to them in this section:

(a) "Tobacco" means cigarettes and any product containing, made, or derived from
tobacco that is intended for human consumption, whether chewed, smoked, absorbed,
dissolved, inhaled, snorted, sniffed, or ingested by any other means, or any component,
part, or accessory of a tobacco product including but not limited to cigars; cheroots; stogies;
perique; granulated, plug cut, crimp cut, ready rubbed, and other smoking tobacco, snuff;
snuff flour; cavendish; plug and twist tobacco; fine cut and other chewing tobaccos; snort;
reese specialty, slippers, cuttings, or sweeping of tobacco; and other kinds and forms of

tobacco. Tobacco excludes any tobacco product that has been approved by the United States
Food and Drug Administration for sale as a tobacco-cessation product, as a
tobacco-dependence product, or for other medical purposes, and is being marketed and sold
solely for such an approved purpose.

(b) "Tobacco-related devices" means cigarette papers or pipes for smoking or other
devices intentionally designed or intended to be used in a manner which enables the chewing,
swallowing, smoking, or inhalation of vapors of tobacco or tobacco products. Tobacco-related
devices include components of tobacco-related devices which may be marketed or sold
separately.

(c) "Electronic delivery device" means any product containing or delivering nicotine,

tabacco, or any other substance intended for human consumption which can be used by a person
to simulate smoking or inhaling the delivery of nicotine or any other substance through
inhaling of vapor from the product. Electronic delivery device includes any component part of a
product, whether or not marketed or sold separately. Electronic delivery device does not
include any product that has been approved or certified by the United States Food and Drug
Administration for sale as a tobacco-cessation product, as a tobacco-dependence product,
or for other medical purposes, and is being marketed and sold for such an approved purpose.

Subd. 1a. Penalty to sell or furnish. (a) Whoever sells, gives, or otherwise furnishes
tobacco, tobacco-related devices, or electronic delivery devices to a person under the age
of 18 years is guilty of a misdemeanor for the first violation. Whoever violates this
subsection a subsequent time within five years of a previous conviction under this
subdivision is guilty of a gross misdemeanor.

(b) It is an affirmative defense to a charge under this subdivision if the defendant proves
by a preponderance of the evidence that the defendant reasonably and in good faith relied
on proof of age as described in section 340A.503, subdivision 6.

Subd. 2. Other offenses Use of false identification. (a) Whoever furnishes tobacco,
tobacco-related devices, or electronic delivery devices to a person under the age of 18 years
is guilty of a misdemeanor for the first violation. Whoever violates this paragraph a
subsequent time is guilty of a gross misdemeanor.

(b) A person under the age of 18 years who purchases or attempts to purchase tobacco,
tobacco-related devices, or electronic delivery devices and who uses a driver's license,
permit, Minnesota identification card, or any type of false identification to misrepresent the
person's age, is guilty of a petty misdemeanor.

Subd. 2a. Alternative penalties. Law enforcement and court system representatives
shall consult with interested parents, persons under the age of 21 years, educators, and others
to develop alternative penalties for persons under the age of 21 years who violate any
subdivision of this section. Law enforcement, court system representatives, and all interested
persons shall consider a variety of options including, but not limited to, tobacco-free
education programs, notice to schools and parents, community service, tobacco cessation
programs, and court diversion programs.

Subd. 3. Petty misdemeanor. Except as otherwise provided in subdivision 2, whoever
possesses, smokes, chews, or otherwise ingests, purchases, or attempts to purchase tobacco,
tobacco-related devices, or electronic delivery devices and is under the age of 18 years is
guilty of a petty misdemeanor.

Subd. 4. Effect on local ordinances. Nothing in subdivisions 1 to 2a shall supersede
or preclude the continuation or adoption of any local ordinance which provides for more
stringent regulation of the subject matter in subdivisions 1 to 2a.

Subd. 5. Exceptions. (a) Notwithstanding subdivision 2, an Indian may furnish tobacco
to an Indian under the age of 18 years if the tobacco is furnished as part of a traditional
Indian spiritual or cultural ceremony. For purposes of this paragraph, an Indian is a person
who is a member of an Indian tribe as defined in section 250.755, subdivision 12.

(b) The penalties in this section do not apply to a person under the age of 18 years
who purchases or attempts to purchase tobacco, tobacco-related devices, or electronic
delivery devices while under the direct supervision of a responsible adult for training,
education, research, or enforcement purposes.

Subd. 6. Seizure of false identification. A retailer may seize a form of identification
listed in section 340A.503, subdivision 6, if the retailer has reasonable grounds to believe
that the form of identification has been altered or falsified or is being used to violate any
law. A retailer that seizes a form of identification as authorized under this subdivision shall
deliver it to a law enforcement agency within 24 hours of seizing it.

https://www.revisor.mn.gov/bills/text.php?number=SF2370&version=0&session=ls90&se... 10/9/2017
Sec. 12. Minnesota Statutes 2016, section 609.6855, is amended to read:

609.6855 SALE OF NICOTINE DELIVERY PRODUCTS TO CHILDREN

PERSONS UNDER AGE 21.

Subdivision 1. Penalty to sell or furnish. (a) Whoever sells, gives, or otherwise furnishes to a person under the age of 21 a product containing or delivering nicotine or lobelia intended for human consumption, or any part of such a product, that is not tobacco or an electronic delivery device as defined by section 609.685, is guilty of a misdemeanor for the first violation. Whoever violates this subdivision a subsequent time within five years of a previous conviction under this subdivision is guilty of a gross misdemeanor.

(b) It is an affirmative defense to a charge under this subdivision if the defendant proves by a preponderance of the evidence that the defendant reasonably and in good faith relied on proof of age as described in section 340A.03, subdivision 6.

(c) Notwithstanding paragraph (a), a product containing or delivering nicotine or lobelia intended for human consumption, or any part of such a product, that is not tobacco or an electronic delivery device as defined by section 609.685, may be sold to persons under the age of 21 if the product has been approved or otherwise certified for legal sale by the United States Food and Drug Administration for tobacco use cessation, harm reduction, or for other medical purposes, and is being marketed and sold solely for that approved purpose as a drug, device, or combination product authorized for sale by the United States Food and Drug Administration, as those terms are defined in the Federal Food, Drug, and Cosmetic Act.

Subd. 2. Other offense Use of false identification. A person under the age of 21 who purchases or attempts to purchase a product containing or delivering nicotine or lobelia intended for human consumption, or any part of such a product, that is not tobacco or an electronic delivery device as defined by section 609.685, and who uses a driver's license, permit, Minnesota identification card, or any type of false identification to misrepresent the person's age, is guilty of a petty misdemeanor. This penalty does not apply to a person under the age of 21 who purchases or attempts to purchase such a product while under the direct supervision of a responsible adult for training, education, research, or enforcement purposes.

Subd. 3. Petty misdemeanor Alternative penalties. Except as otherwise provided in subdivisions 1 and 2, whoever is under the age of 18 years and possesses, purchases, or attempts to purchase a product containing or delivering nicotine or lobelia intended for human consumption, or any part of such a product, that is not tobacco or an electronic delivery device as defined by section 609.685, is guilty of a petty misdemeanor. Law enforcement and court system representatives shall consult with interested parents, persons under the age of 21 years, educators, and others to develop alternative penalties for persons under the age of 21 years who violate any subdivision of this section. Law enforcement, court system representatives, and all interested persons shall consider a variety of options including, but not limited to, tobacco-free education programs, notice to schools and parents, community service, tobacco cessation programs, and court diversion programs.
September 27, 2017

Dear Tobacco License Holder,

The Plymouth City Council will be conducting a study session on October 24 at 5:30 p.m. to discuss the minimum age to purchase tobacco and an ordinance amending the City Code to increase the age to purchase tobacco products from 18 to 21 in the City of Plymouth. In addition, the Council has scheduled a public hearing on November 28 at 7:00 p.m. on said ordinance.

The study session and public hearing will be held at City Hall, 3400 Plymouth Boulevard, Plymouth. You are encouraged to attend these meetings if you so desire.

If you have any questions, please feel free to contact me at sengdahl@plymouthmn.gov or (763) 509-5080.

Sincerely,

Sandy Engdahl
City Clerk
September 20, 2017

The Honorable Kelli Slavik and Members of the Plymouth City Council
Via E-mail: council@plymouthmn.gov

Dear Mayor Slavik and Members of the City Council:

On behalf of the Local Public Health Association of Minnesota (LPHA) and local government public health leaders from throughout the state, I write to commend the City of Plymouth on its efforts to prevent youth tobacco use and express our support for the Tobacco 21 ordinance being considered.

Despite the great progress that has been made, tobacco use among youth is still a problem. Each year tobacco companies spend more than $115 million to market their products to Minnesotans, and much of this marketing aggressively targets our youth with cheap prices and kid-friendly flavors to build a base of replacement smokers.

We know that nearly all adult smokers start smoking before the age of 21, and many kids turn to older friends and classmates as a source of cigarettes. In Hennepin County, 19% of eleventh graders report using a tobacco product in the last 30 days (2016 MN Student Survey). New strategies are needed to counter tobacco industry marketing and save youth from a lifetime of addiction.

Increasing the tobacco age to 21 is gaining momentum across the nation as an evidence-based policy that will help keep tobacco out of schools and save lives by reducing the number of kids who start smoking. Your consideration of this policy shows a strong commitment to fostering a healthier future for Plymouth’s youth and sets you apart as a leader in Minnesota’s efforts to prevent youth tobacco use.

LPHA looks forward to Plymouth becoming the next city in Minnesota to increase the tobacco age to 21. Your leadership will help pave the way for other communities to take action and bring us one step closer to achieving a Minnesota where all people are free from the harms of tobacco.

Best regards,

Lorna Schmidt, Director
Local Public Health Association of Minnesota

Lorna Schmidt
September 21, 2017

Mayor Slavik and Members of the Plymouth City Council
City of Plymouth
3400 Plymouth Boulevard
Plymouth, MN 55447-1482

Dear Mayor Slavik and Plymouth City Council Members,

On behalf of the March of Dimes, I would like to thank you for considering an ordinance that increases the tobacco sale age to 21. This is an important step to ensure that citizens and youth in Plymouth live in a safe and healthy community. The mission of the March of Dimes is to improve the health of babies by preventing birth defects, premature birth and infant mortality. Both smoking and exposure to secondhand smoke increase the risk for a wide range of negative pregnancy outcomes for women of childbearing age, pregnant women, and their babies.

As you are aware, the minimum age to purchase tobacco is 18 years old. On average, ninety percent of adult smokers begin smoking during teenage years. Raising the minimum age required to purchase tobacco products can significantly improve public health outcomes for women, children, and infants by delaying or preventing altogether the initiation of smoking or use of other tobacco products.

Nationwide, an average of one in every ten pregnant women smokes. For expecting mothers, tobacco use during pregnancy increases the risk of premature delivery in babies and directly affects fetal growth. According to the 2014 Surgeon General’s report, in the last 50 years, 10,000 babies have died from sudden infant death syndrome or complications of prematurity, low birthweight, and other conditions as a result of parental smoking.

Increasing the minimum age of access to tobacco will have significant public health benefits for women, children, infants and families by delaying the age at which people begin smoking and preventing them from ever starting. We thank you for your leadership on this important issue and look forward to working with you to ensure that all babies are given the best chance at a healthy start in life.

Sincerely,

Angie Thies
Director of Advocacy and Government Affairs
E-cigarettes and other Vaping Products

E-cigarettes are battery-powered devices that allow users to inhale, or vape, aerosolized liquid (e-juice). E-cigarettes, "vapes", vape or hookah pens, e-pipes, and other vaping products recently surpassed conventional cigarettes as the most commonly used tobacco product among youth[1] so it is critical that public health officials and the general public understand the potential risks of using them.

Youth e-cigarette use is an emerging public health threat.

Among Minnesota’s 11th grade students, e-cigarette use is now more than double conventional cigarette use.[2]

Additionally, nearly 6 percent of adults currently use e-cigarettes, compared to less than 2 percent in 2010; and, nearly 13 percent of adults age 18-24 use e-cigarettes.[3] The use of multiple tobacco products – dual use – is common: most adult e-cigarette users use cigarettes.[2]

E-cigarettes are not safe for youth.

Nearly all e-cigarettes contain nicotine.[4] Nicotine is highly addictive and can harm the developing adolescent brain.[1, 5, 6] Because the brain is still developing until about age 25, youth and young adult exposure to nicotine can lead to addiction and disrupt attention and learning.[1] No amount of nicotine is safe for youth.

Nearly one in four of Minnesota high school students who has tried e-cigarettes has never tried any conventional tobacco products.[7] A growing body of evidence indicates that young people who have never smoked cigarettes, but currently use e-cigarettes, are more likely to smoke cigarettes in the future than are young people who do not use e-cigarettes.[8-13]

Learn more about the harms of nicotine at www.health.mn.gov/nicotine.

E-cigarettes attract kids despite the dangers.

- E-cigarettes are available in fruit and candy flavors; flavored tobacco products appeal to youth.[14]
- E-cigarettes are sometimes advertised using celebrity endorsements. A majority of Minnesota high school students (57.4%) have seen ads for e-cigarettes on TV in the past 30 days.[7]
E-cigarettes and other vaping products

- E-cigarettes are available for purchase online.  

E-cigarettes are not proven to help people quit smoking.

E-cigarettes are not FDA-approved smoking quitting aids, and they are not proved to help people quit. Free quitting medications and counseling are available to all Minnesotans by visiting QUITPLAN® Services at www.quitplan.com or by calling 1-888-354-PLAN (7526).

For more free quit smoking resources visit www.health.mn.gov/quitsmoking.

Minnesota communities are taking action to protect kids.

Some schools, universities, and government and health care facilities prohibit e-cigarette use. Minnesota law also requires that e-cigarettes are taxed as tobacco products, and retailers in Minnesota cannot sell e-cigarettes to minors.

Cities and counties around the state have passed provisions restricting e-cigarette use indoors, protecting over half the state’s population from e-cigarette aerosols in bars, restaurants, and other public places.

Learn more at www.health.mn.gov/ecigarettes.

5/4/17
To obtain this information in a different format, call: 651-201-3535
Tobacco 21 movement gathers momentum in Minnesota

By Sarah Brandt | 08/23/17

"Under 21, No Tobacco. It’s the Law.”

The new, green signs have popped up in convenience stores and gas stations across Edina this summer. For some customers, the signs are a reminder of the change that made headlines as Edina broke from its neighbors and raised the legal age to buy tobacco products within its city limits from 18 to 21. For others, their trip into a store like Lang’s One Stop Market is the first time they learn of the new rule.

“I get a lot of reaction from customers that come through,” Anita Lang, co-owner and co-founder of Lang’s, told me. “Older people say ‘Oh, that’s good. They’ll probably thank you later.’ Younger people say ‘How can just one city do this?’ ”

The comments from Lang’s customers are two sides of the conversation about legislation that has been developing both within Minnesota and across the country. Edina became the first city in the state to join that conversation on May 2 when its City Council voted to raise the legal age for purchasing cigarettes and vaping products from 18 to 21.
Soon, however, Edina will not be alone. Just a few weeks after Edina’s ordinance went into effect July 1, the St. Louis Park City Council voted to raise its legal age of purchase to 21, effective Oct. 1. Further yet, city councils in towns like Detroit Lakes, Bloomington, Mankato and North Mankato have all been considering their own city ordinances, and state Sen. Carla Nelson, R-Rochester, introduced a bill (S.F. 2370) in the Minnesota Legislature proposing raising the age across the state.

These moves in Minnesota are a part of the Tobacco 21 movement nationwide that has been picking up speed in the past few years. More than 260 cities and counties in 18 states have raised the age of purchase to 21, and five states (Hawaii, California, Oregon, Maine and New Jersey) have made Tobacco 21 state law. Three of the five (Oregon, Maine and New Jersey) just passed their age increases this summer, all within less than three weeks of one another.

The roots of the Tobacco 21 movement
When Dr. Rob Crane’s father died from lung cancer after years of smoking, he made a silent vow to take on the tobacco companies responsible for his father’s addiction. Busy balancing his time as a family doctor and a professor at Ohio State University, Crane finally got the chance to take on the issue during a sabbatical in 1996. While looking around for ways to make a difference, he noticed that although drinking was not legal until 21, tobacco was still legal at 18. “It didn't make sense to me.”

Crane founded the Preventing Tobacco Addiction Foundation that same year, and took on Tobacco 21 as the group’s main campaign. Tobacco 21 policies aim to reduce the incidence of addiction by restricting youth access to tobacco products. Since nearly 95 percent of addicted adult smokers start before age 21, these policies aim to prevent addiction when it is most likely to develop.

As the group’s first action, Crane took up raising the legal age of purchase in the group’s home state, Ohio. But after legislation failed there in 1996, and then in a number of other states in 1997, the push for Tobacco 21 stalled for a number of years. After nearly 10 years without progress, though, that changed with one Boston suburb.

The movement takes off
In 2005, Dr. Crane received a phone call from Needham, Mass. The 30,000-person town just 30 minutes from Boston had decided to raise its legal age of purchase to 21. Six years later, Crane received another phone call from the Boston suburb, this time to report the effects of the law. Needham had completed a survey comparing smoking rates within its city limits to those in the
surrounding towns, and its findings were staggering. They found that frequent smoking in Needham had dropped 62 percent, a decrease nearly triple that in the surrounding cities.

“That was the beginning,” Crane said. “Then a couple of Harvard pediatricians took up the cry and, like Paul Revere, went city to city and managed to convince about half a dozen suburbs around Boston to adopt Tobacco 21 laws.”

With the movement gaining force in Massachusetts, cities and states elsewhere began to take notice. In Nov. 2013, New York City and the Big Island, Hawaii, adopted Tobacco 21 laws. A number of other cities followed in the next two years until what Crane calls “the real help” came in 2015.

That year, the Institute of Medicine released a study commissioned by the FDA on the public health implications of Tobacco 21. One of its key findings was that raising the age of purchase nationally would lead to a 25 percent decrease in smoking initiation among 15- to 17-year-olds. “That got everybody’s attention,” Crane said. “It made the scientific and medical fields sit up and take notice, because it predicted that if we went to 21 nationally, it would save 4.2 million lives.”

Since that report came out, Tobacco 21 legislation has expanded rapidly. The number of cities with Tobacco 21 legislation has more than doubled from 125 cities just one year ago to more than 260 cities today. Now, nearly 25 percent of the U.S. population lives in a city or state where the minimum legal age of tobacco purchase is 21.

**Tobacco 21 takes hold in Minnesota**

On March 7, Edina Mayor Jim Hovland gathered with the rest of the City Council to hear a presentation from Edina’s Community Health Commission. If Edina adopted a Tobacco 21 policy, they said, the city would reduce youth smoking rates and save lives. Hovland was so convinced by the presentation that he still remembers his surprise when he learned that no other city in the state had yet adopted Tobacco 21.

“It seemed to me hearing the data that we would be far from the first,” Hovland said. “But it didn’t matter whether we were first or tenth, what was important was that we were making a solid public health decision.”

Less than two months later, the council voted unanimously to be the first city in the state to raise its legal age.

Meanwhile, just across city limits, the same conversation went on at St. Louis Park’s City Hall. Before learning that Edina was considering Tobacco 21 laws, St. Louis Park’s City Council had also started discussing the issue. Not long after Edina’s law took effect July 1, the St. Louis Park Council voted 5-0 on July 17 to make its city the second in the state to pass legislation of this kind.

One of those votes in favor came from Susan Sanger, a 21-year veteran of the council, who said the reason she and her fellow council members supported the bill was twofold.

“One reason was to try to protect and improve the public health for the community,” Sanger said. “The second reason was to start to build the momentum to get other communities to pass the same kind of
ordinance with the hope that the Minnesota legislature would pass this state-wide.”

Though no other communities in the state have yet put Tobacco 21 to a vote, some are close.

Detroit Lakes has drafted an ordinance to be discussed Sept. 21; Bloomington is “looking favorably” at drafting an ordinance that would have the city adopting Tobacco 21, according to City Manager Jamie Verbrugge; Mankato and North Mankato are likely to pass Tobacco 21 ordinances, despite disagreements between the two cities that have delayed the voting process.

Elsewhere in Minnesota, these conversations are just beginning. Six cities in the greater St. Cloud area, for example, will open discussion on Tobacco 21 at an all-cities meeting Aug. 29.

Anne Mason Yoder, the senior public affairs manager for ClearWay Minnesota, a nonprofit that runs Quitplan® and works to reduce tobacco exposure, has noticed the recent increase in interest in Tobacco 21.

“We’ve supported the policy for a number of years, but we’ve really seen elected officials take action in the past few years,” Mason Yoder said.

At the state level, that action was spearheaded by Nelson when she introduced a bill May 4 to expand Edina’s policy statewide. Though her proposal came too late in the legislative session (the deadline for committees to act on bills was March 31), Nelson hoped to ride off the momentum generated by Edina’s move to spark serious conversations about implementing this statewide before the start of the upcoming legislative session next January.

The Republican senator from Rochester sees the age increase as a bipartisan issue supported by Minnesotans across party lines. In fact, a 2015 survey from the Centers for Disease Control and Prevention found that 75 percent of Americans, including 70 percent of smokers, would support Tobacco 21 legislation.

Erin Simmons, the senior manager of tobacco control for the American Lung Association in Minnesota said that in her experience advocating for Tobacco 21, the data behind these laws are what has been most convincing for people.

“When we look at a 25 percent reduction in youth use, that’s big and really has the potential to save lives,” Simmons said. “That number has really been compelling for people.”

Youth cigarette use rates have been on a continual decline to historic lows, according to 2016 surveys. Nationwide, 8 percent of high school students say they smoked in the past 30 days, and in Minnesota, the rate was at 8.4 percent.
High school use rates for electronic cigarettes, however, which are also covered by Tobacco 21 laws, have been increasing since 2011. At the national level, the electronic cigarette use rate was at 11.3 percent, while in Minnesota it was at 17.1 percent. Crane says that when it comes to youth tobacco use, nicotine, present both in cigarettes and electronic cigarettes, is the biggest concern because of its addictive nature.

In Minnesota, retailers adjust
In a quiet, residential neighborhood of Edina, the Edina Market & Deli sells hot foods, baked goods, and as of July 1, tobacco products to those aged 21 and up. Since the law went into effect last month, owner Asif Dawood has seen revenue go down in his store.

“I was actually just looking at my numbers for this month,” he said, motioning to a packet of charts on his desk in the store’s back office. Tobacco sales, he estimated, have gone down 10 to 15 percent, and with that, “we lost pop, candy, chips and food sales, because people would come in and buy those with their tobacco products.”

Nonetheless, Dawood sees the new law as a positive move. “Yeah, I might lose some sales, but our community will be healthier,” he said. “In the long run, we should be thinking about our community. Businesses — we will survive.”

There is one part of the law that Dawood disagrees with, though. By only implementing the age increase in one city, he sees the law as penalizing to Edina’s businesses.

When the Edina City Council was considering the city ordinance, Mayor Hovland said that they weighed the issue from both a public health and an economic standpoint.

“We had some small merchants that were concerned about it, and we were concerned about them as well, but we thought that on balance it was more important to address the public-health-related issues,” Hovland said. Plus, Hovland mentioned, the ordinance could have a positive economic impact on the city’s health care system in the long term by reducing the number of people engaging the health system with tobacco-related maladies.

About one mile from the Edina Market & Deli, Anita Lang said that though her bottom line hasn’t gone down since July 1, she is frustrated by the law for the same reason as Dawood.

“I find it discriminating against myself as a businessperson because you can go across the highway to Bloomington and buy your tobacco there,” Lang said. “If it was statewide, it would make more sense, and I’d support it wholly.”
Simmons agrees that a statewide policy is important, but thinks that it is more important that communities address the issue now, rather than wait for action from the state. “Why wait?” Simmons asked. “Let’s act now because it has such a tremendous potential to reduce tobacco’s harm.”

In fact, local legislation may need to predate statewide action. Tobacco restrictions in Minnesota have historically started as grassroots movements that progressed up to the state Capitol. Before the state passed the Freedom to Breathe Act, the law banning smoking in public places statewide, in 2007, cities from Duluth to the Twin Cities had been enacting their own smoking bans, starting with the small town of Moose Lake in 2000.

Tobacco 21 legislation nationwide has followed a similar pattern. In the states that have raised the legal age for purchasing tobacco so far, at least one major municipality has preceded state action. “Legislators takes notice when that happens,” Crane said.

In Minnesota, that would mean that an age increase in Minneapolis or St. Paul might make a big difference. At the moment, neither city is seriously considering Tobacco 21 legislation, though the idea was brought up when Minneapolis was discussing limiting sales of menthol-flavored tobacco to adult-only shops. Some opponents of the Minneapolis ruling felt that Tobacco 21 laws were a more appropriate way to curb youth smoking than the menthol flavor restrictions, which passed earlier this month.

**Criticisms of the legislation**
For a statewide age increase to be possible, the Tobacco 21 movement would need to overcome opposition from many of its critics. One critic is the Coalition of Neighborhood Retailers, a group of five retail trade associations in Minnesota that would be impacted by Tobacco 21 laws, including the National Association of Tobacco Outlets (NATO). The executive director of NATO, Thomas Briant, said that the biggest issue with Tobacco 21 ordinances is the fact that they police purchasing rather than possession.

“If you still allow use and possession, what benefit is there from a health perspective?” Briant asked. “There is none. It’s really disingenuous to say there’s going to be a health benefit when there’s really not going to be.”

Though proponents of Tobacco 21 point to Needham to defend the health benefits of the laws in practice, data still remain scarce. No city has conducted a thorough study to corroborate the findings in Needham, and no state has had its law in place long enough to meaningfully study the effects on youth smoking at the level of state law.

One early issue that has materialized in places with Tobacco 21 legislation in place is that of enforcement. Crane calls Hawaii a “shining light” when it comes to enforcing the laws, as the state pays police to ensure retailers aren’t selling to those underage. California, on the other hand, has “the best intentions but no enforcement activity planned.”

In Minnesota, though, Crane thinks enforcement will be less of an issue. Because of Minnesota’s “good record” of enforcing the 18-year-old age minimum, Crane calls Minnesota well-positioned to “do it right.”

Even if the policy is well-enforced, skeptics argue that youths could still have someone older purchase tobacco for them. Currently, however, 90 percent of those who buy tobacco for minors are between the ages of 18 and 21. Proponents like Sen. Nelson hope that by raising the legal age of purchase to 21, these laws will cut off social sources of tobacco, like the 18-year old classmate that an underage high school student sees every day in the hallways.

“When I was in high school, you could purchase alcohol at age 18, and the challenges that caused in the high school environment are very similar to what we are seeing right now with the purchasing of tobacco,” Nelson said. “It should be a statewide policy like what we’ve done for alcohol.”

For some people, regardless of whether these laws are effective in practice or not, the issue with Tobacco 21 ultimately comes down to a question of rights.

“These are adults who can vote, get married, go in the military, sign contracts, Briant said. “They have rights as adults, and they should be allowed to make a decision whether they purchase legal products or not.”

Though she was generally supportive of a statewide age increase, Lang said she would feel slightly uncomfortable with the law for the same reason. “You can graduate from high school, go into the
military, serve for two years, come in here in your uniform and I can say ‘Oh, I can’t sell to you.’ I think that's kind of stinky. It's kind of discriminatory.”

In fact, frustration with this aspect of the law in California drove lawmakers to include an exemption for military personnel between the ages of 18 and 21.

Although momentum is increasing behind these policies, failure rates are certainly still high. Twenty-three different state legislatures offered a Tobacco 21 bill this past year, 20 of which failed. Crane said one huge barrier that remains is overcoming the influence of tobacco lobbyists. And though the time to vote on Minnesota’s statewide bill is still some ways away, Gov. Mark Dayton issued a statement in May saying he was “undecided” about raising the legal age of purchase.

“I support the goal of reducing smoking by young Minnesotans,” Dayton said. “However, people who are 18, 19 and 20 years old are legally adults, who should generally be allowed to make the same personal decisions as older adults.”

Nevertheless, Mason Yoder remains optimistic. “I think it will start to fall like dominoes,” she said. “Hopefully by the next legislative session enough local action will have taken place, and we can all have a more educated discussion about the possibility for it statewide.”

Related Tags:

COMMENTS (4)

ALEC
SUBMITTED BY FRANK PHELAN ON AUGUST 23, 2017 - 12:24PM.
Five will get you ten ALEC has some model legislation to put a stop to this sort of local control non-sense. Anyone seen Mary Kiffmeyer or Pat Garofalo lately?
but but but ....

SUBMITTED BY HOWARD MILLER ON AUGUST 23, 2017 - 4:30PM.

When 70% of Minnesota kids started tobacco use 6 years or more before age 18, I am skeptical that raising the age for legal purchase or possession will do much good. It does, however, remove a freedom from adults based on age .... why not ban tobacco sale and use for everyone on Medicare, if you want to go there? Why can old Americans make lousy choices but young adults can't? No one should use tobacco, the evidence is crystal clear. But if we keep it legal, let's also respect equality before the law for all adults of voting age.

These data are 17 years old noting

Table 6. Age at Start of Tobacco Use: High School Students
Percentage of current cigarette smokers who started smoking cigarettes at:
10 years old or younger 20.1%
12 years old or younger 47.2%
Percentage of current smokeless tobacco users who started using at:
10 years old or younger 22.4%
12 years old or younger 42.0%
Percentage of current cigar smokers who started smoking cigars at:
10 years old or younger 15.7%
12 years old or younger 31.0%
Source: Minnesota Youth Tobacco Survey 2000
http://www.health.state.mn.us/divs/chs/tobacco/youthtob.pdf

adoption is the key

SUBMITTED BY ALAN STRAKA ON AUGUST 24, 2017 - 2:39PM.

The reason why young people and not older should be restricted is that most people who are addicted to smoking got addicted as youths. If you make it past those years, chances are you won't become a smoker. Reducing addiction is the prime motivation of raising the minimum age. If we accept age restrictions on alcohol, then why not tobacco? Will kids circumvent the law? Yes, but some will be deterred and that is reason enough to have the law. Maybe I am just still annoyed that the year I turned 21, 18 year olds got the right to vote.

Tobacco 21

SUBMITTED BY NANCY GIBSON ON AUGUST 25, 2017 - 9:57AM.

Well researched and written by someone who has seen her peers tempted by these addictions. I am proud of St. Louis Park to follow Edina's lead. At the very least this restriction will give the younger generation some pause.
In order to realize a future where smoking and its harms have been eliminated, we must find new ways to stop kids from starting at all.

Almost all current smokers started smoking when they were teenagers. But what if we could delay the uptake of smoking by young people and prevent their long-term addiction to nicotine? Existing smokers quitting is important, which is why it’s wonderful that Minnesota tobacco users can get free help to quit through QUITPLAN® Services. However, in order to realize a future where smoking and its harms have been eliminated, we must find new ways to stop kids from starting at all. The question is, how?

One new idea in this effort is to increase the sale age of tobacco products to 21. Almost all underage tobacco is sourced to teens by someone under 21. Raising the tobacco age will prevent older high-school students from buying for younger friends, and will change retail dynamics around who looks “old enough to buy.”
The evidence is compelling
In 2013, only 10 places around the country had raised the age of sale. Four years later, more than 200 localities and two states, Hawaii and California, have made 21 the legal tobacco age. The evidence to support this momentum is compelling, to the extent that a 2015 report from the National Academy of Medicine (formerly Institute of Medicine) estimated long-term effects would include fewer young people starting to smoke, fewer deaths from smoking, and long-term savings from lower healthcare costs.

In the January/February issue of Minnesota Medicine, I presented, with co-authors from the Minnesota Department of Health, an estimate of the effects we would expect to see on youth and young adult smoking in Minnesota should such a law be passed. The article was based on the calculations from the National Academy of Medicine report, using state-specific data from the Minnesota Adolescent Community Cohort and the Minnesota Adult Tobacco Survey, which included youth aged 15-18 and young adults aged 18-21, respectively.

Public-policy efforts work
The short-term result is that raising the tobacco age to 21 in Minnesota would have a one-time effect of preventing smoking among more than 3,300 young people. Within 15 years, Minnesota could expect 30,000 young people would not start smoking if the age of sale is raised to 21. This is a life-saving opportunity we can’t afford to miss.

The research adds to other Minnesota evidence we have showing that public policy initiatives — notably cigarette taxes and smoke-free laws — are the best tools for reducing smoking in our state. This is based on earlier research I coauthored that found that 70 percent of smoking reductions in Minnesota since 1993 were the direct result of public policies.

If Minnesota lawmakers take this opportunity and adopt a Tobacco 21 law, we will push that number even higher, and help make smoking what it properly should be: a thing of the past.

Raymond Boyle, Ph.D., is the director of research programs at ClearWay Minnesota.

WANT TO ADD YOUR VOICE?
If you’re interested in joining the discussion, add your voice to the Comment section below — or consider writing a letter or a longer-form Community Voices commentary. (For more information about Community Voices, email Susan Albright at salbright@minnpost.com.)
**INCREASING THE TOBACCO PURCHASE AGE TO 21**

**Minnesotans agree** that kids shouldn’t use tobacco products – and more can and should be done to make sure they don’t. A national consensus is growing to prevent addictions and future health problems by **raising the minimum age to purchase tobacco products to 21**. Minnesotans for a Smoke-Free Generation supports this movement.

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**RAISING THE PURCHASE AGE TO 21 WILL PREVENT YOUTH TOBACCO USE AND SAVE LIVES.**

- According to a 2015 report from the Institute of Medicine, increasing the legal age to purchase tobacco will mean fewer teenagers starting to smoke. For example, research predicts a 25 percent reduction in smoking initiation among 15-17-year-olds alone following such an increase.¹

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**THE BEST WAY TO REDUCE THE HARM OF TOBACCO IS TO PREVENT KIDS FROM STARTING**

- Almost 90 percent of addicted adult smokers started smoking by age 18.²
- Increasing the age gap between kids and those who can legally buy tobacco will help remove access to tobacco products from the high-school environment.

---

**BIG TOBACCO ACTIVELY RECRUITS REPLACEMENT SMOKERS TO GUARANTEE PROFITS.**

- The tobacco industry heavily targets 18-to-21-year-olds with menthol and candy flavoring, magazine advertisements, product design and packaging, and event sponsorships and promotions.³

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**ADULTS SUPPORT RAISING THE TOBACCO PURCHASE AGE TO 21.**

- A 2014 national survey shows that 75 percent of adults favor increasing the minimum purchase age for tobacco to 21.⁴
- Even 70 percent of smokers are in support of raising the minimum legal age.⁴
STATE AND LOCAL GOVERNMENTS ARE TAKING ACTION TO INCREASE THE MINIMUM LEGAL AGE AND PROTECT YOUTH.

- The state of Hawaii and at least 125 localities in the United States have raised the age to purchase tobacco to 21, including New York City, Boston and Kansas City.
- One city in Massachusetts found that tobacco use among high-school students fell by nearly half after raising the age to 21.5

NICOTINE MAY HARM ADOLESCENT BRAIN DEVELOPMENT.

- Nicotine is addictive, and adolescents are especially vulnerable to the health impacts of tobacco use.6
- The adolescent brain is negatively impacted by nicotine, and its long-term effects are a significant public health concern 7,8

Minnesotans for a Smoke-Free Generation is a coalition of Minnesota’s leading health and other interested organizations. We share a common goal of saving Minnesota youth from a lifetime of addiction to tobacco. Each year in Minnesota tobacco use is responsible for more than 5,100 deaths and almost $3 billion in preventable health care costs and 90 percent of adult smokers started before the age of 18. Minnesotans for a Smoke-Free Generation supports policies that reduce youth smoking and help end the death and disease associated with tobacco use.

5 Kessel Schneider S et al. Community reductions in youth smoking after raising the minimum tobacco sales age to 21. Tob Control. 2015.
Raising the Minimum Legal Sale Age for Tobacco to 21
The Estimated Effect for Minnesota

BY RAYMOND G. BOYLE, PHD, JOHN H. KINGSBURY, PHD, AND MICHAEL J. PARKS, PHD

A campaign to raise the minimum legal sale age for tobacco products from 18 to 21 years known as Tobacco 21 is having a nationwide impact, with at least 200 localities in 14 states having already implemented a Tobacco 21 policy. A 2015 report from the Institute of Medicine (IOM) estimated the effects of such policy on cigarette use at the national level; however, little is known about the expected effects for individual states. The purpose of this study was to consider the effect on smoking initiation in Minnesota if the minimum sale age were 21 in 2015. Estimates from the Minnesota Adolescent Community Cohort and Minnesota Adult Tobacco Survey were used to calculate the uptake of smoking in a hypothetical cohort of Minnesota adolescents 15 to 20 years of age. Expected reductions in initiation in the IOM report were used to calculate the effects of Tobacco 21 policy on smoking uptake in this cohort. Results revealed that raising the sale age to 21 in 2015 would prevent 3,355 young Minnesotans from starting to smoke.

Minnesota addresses tobacco use through a comprehensive approach that includes coordinating smoke-free policies, promoting normative changes in the social acceptability of tobacco use, establishing and expanding the reach of cessation programs, keeping the price of tobacco high and preventing young people from initiating tobacco use. The overall effect of these actions has been a 35% reduction in cigarette smoking in Minnesota since 1999;1 however, tobacco use remains popular among young adults in Minnesota and nationally.1,2

The persistence of tobacco use among young adults, coupled with an evolving marketplace that includes new flavored products (eg, flavored cigars and cigarillos) and new delivery methods (eg, electronic cigarettes), has led to a desire for increased regulation of tobacco. In 2009 the U.S. Congress granted authority to the Food and Drug Administration (FDA) through the Family Smoking Prevention and Tobacco Control Act to regulate the manufacture, distribution and marketing of tobacco products.3

Although this law prohibited the FDA from increasing beyond age 18 the national minimum sale age for tobacco products, state and local governments are able to raise the minimum sale age for tobacco. In addition, the law required a study of the health implications of a higher minimum age of legal access. The Institute of Medicine (IOM), now the National Academy of Medicine, conducted the study using national data to consider the effects of different minimum purchase ages (19, 21 or 25 years) and examine multiple outcomes, including preventing young people from starting and encouraging current smokers to quit smoking, and the health benefits from reduced smoking because of an increased purchase age. Nationally, increasing the purchase age to 21 would result in approximately 223,000 fewer premature deaths and 50,000 fewer deaths from lung cancer.4

Adolescents younger than age 18 frequently obtain tobacco from social sources who are older than 18 but younger than 21.5 If tobacco could not be sold to 18- to 20-year-olds, they would be far less likely to provide tobacco to younger teens. By age 21, young adults are likely to have friends older than high-school age and, therefore, less likely to provide tobacco to minors.

The IOM’s 2015 report is particularly important because it provides scientific guidance for state and local governments as they seek to protect public health. Although the report provided novel information on the expected effects of Tobacco 21 policy on a national level, it provided little...
information about the expected effects at a state level.

The purpose of this study was to consider the effects on smoking initiation in Minnesota if the legal minimum sale age for tobacco products were 21. The specific goal was to calculate how many young people ages 15 to 20 years would not start smoking if the assumptions from the IOM report were applied to Minnesota.

Methods and Assumptions

Age groups: The 2015 IOM report examined effects among specific age groups: under 15 years, 15- to 17-year-olds and 18- to 20-year-olds. In this analysis, we limited the consideration to ages 15 and older.

Initiation rate: Cohort studies that follow participants over time provide the best estimates of smoking initiation. The Minnesota Adolescent Community Cohort (MACC) study was a population-based study of Minnesota youth ages 12 to 16 in 2000 who were followed until 2008. In 2003, approximately 19% of the cohort reported smoking in the previous month. Smoking among Minnesota high school students has fallen to about 10% since 2003. Therefore, in this analysis we used 10% as the estimate of smoking initiation among youth 15 to 17 years of age.

In a later analysis of the MACC data, the cohort who did not start smoking in high school took up smoking (smoked in the past month) between the ages of 18 and 21. This estimate of smoking uptake is consistent with the prevalence of smoking among young adults in the Minnesota Adult Tobacco Survey. For this analysis we used 16% as the estimate of 18- to 20-year-olds who would initiate smoking.

Estimated effects of Tobacco 21 policy: An increase in the minimum sale age is expected to apply to all commercial tobacco products; however, for the purpose of estimating effects similar to those in the IOM report, the scope of this study was restricted to cigarette smoking. In addition, the expected reduction in smoking initiation is thought to vary by age. The effect is expected to be larger among youth 15 to 17 years of age, with an expected reduction in the uptake of smoking of 25%. Among those 18 to 20 years of age, the expected reduction is 15%.

Variation by demographic variables: Smoking rates vary substantially by population groups in Minnesota. For example, in 2014 the overall adult smoking rate was about 14%, but within the urban American Indian population the smoking rate was 59%. There is a lack of literature on how smoking initiation would be affected in population groups with higher smoking rates if the sale age were increased. Thus, the estimate here is not adjusted by gender or other demographic variables (eg, race/ethnicity, income).

Enforcement: States are required to enact and enforce laws prohibiting the sale or distribution of tobacco products to individuals younger than 18 years of age. A major assumption of Tobacco 21 policy is that the same level of current enforcement and retailer compliance would remain in effect. Although Minnesota has a high rate of retailer compliance with current law, retailer cooperation has been lower in other places. For example, in New York City, compliance has fallen over time after Tobacco 21 policy was implemented.

Calculation: In this analysis, we began with a cohort of Minnesota 15-year-olds in 2015—approximately 72,000. We estimated the smoking initiation rate in two periods: during high school (ages 15 to 17 years) and after high school (ages 18 to 20 years). Next, the reduction in smoking was calculated for each period if the sale age for tobacco were raised to 21 in 2015. We assumed that the smoking uptake in high school and after high school would not change in future years. The difference is reported as the number of young people 15 to 20 years of age who would not have started smoking.

Results

In 2015, the Minnesota population of those 15-year-olds was approximately 72,000. Of these, an estimated 7,200 will start smoking during their high school years. If the minimum legal sale age in 2015 were 21, an estimated 1,800 would not start smoking in high school.
Of those who finished high school without initiating smoking, 10,368 will begin smoking between ages 18 and 21. Under a Tobacco 21 policy, 1,555 fewer young people would start smoking after high school. Overall, 3,355 fewer young people would start smoking in this cohort of youth if a Tobacco 21 policy were in effect (see Figure). In other words, increasing the sale age to 21 would increase the proportion of nonsmokers in a cohort of 15-year-olds from 76% to 80%.

Discussion
Increasing the sale age to purchase tobacco products from 18 to 21 would have a positive effect on Minnesota, where tobacco use remains popular among young adults. Given that almost 95% of smokers start smoking by age 21, raising the age of sale to 21 years would prevent the vast majority of young people from becoming addicted to the nicotine in tobacco.

At least 200 localities in 14 states have raised the minimum legal sale age for tobacco products to 21 years. Notably, Hawaii was the first state (2015) followed by California (2016), and New York City (2013) is the largest city to adopt a Tobacco 21 policy. This policy has broad support and is viewed positively by both smokers and nonsmokers. In New York City, 60% of smokers and 69% of non-smokers have supported the age increase. In a national sample of adults, 70.5% supported the increase. And in an online survey, 77.5% of never smokers and 70% of current smokers either strongly favored or somewhat favored raising the legal purchasing age to 21.

We acknowledge that some young people will begin using tobacco at a later age. The amount is unknown; but even if 5% eventually take up smoking, this would not diminish the overall effect of Tobacco 21 policy. In addition, while we have highlighted how Tobacco 21 would inhibit more than 3,300 youth from initiating smoking, it is important to note the policy could have additional and more indirect benefits. Youth tend to respond more strongly to smoking bans than to other types of tobacco control in part because a ban is an unambiguous anti-tobacco message that indirectly influences social norms, creating a social environment that discourages health-risk behavior. Put differently, the effects of Tobacco 21 policy would extend into the future as new cohorts of young people do not start using tobacco.

Our analysis considered only cigarette smoking; but a Tobacco 21 policy would apply to all tobacco products. Whether the effects of raising the purchasing age to 21 would be similar across all demographic and racial/ethnic groups is not known. Similar to the IOM, we did not adjust the Minnesota estimate for any variation by demographics other than age. This question should be examined when there is sufficient data on communities that have implemented the policy.

Conclusion
Raising the minimum sale age for tobacco to 21 would prevent the uptake of smoking among youth and young adults, subsequently reducing smoking prevalence over time. Applying national estimates from the 2015 IOM report to Minnesota, we found that implementing a Tobacco 21 policy could have a marked impact on smoking initiation among Minnesota’s young people. Tobacco 21 should be considered an effective strategy for reducing smoking initiation. Preventing smoking among youth remains a primary focus for reducing morbidity and mortality as well as promoting health across the lifespan.

Raymond Boyle is director of research programs for ClearWay Minnesota. John Kingsbury and Michael Parks are research scientists for the Minnesota Department of Health.

REFERENCES
Friday, September 8, 2017

Plymouth City Council
3400 Plymouth Blvd.
Plymouth, MN 55447

Dear Mayor Slavik and Members of City Council,

I am writing on behalf of Partnership for Change, an organization comprised of youth, parents, schools, law enforcement, and community groups that are working together to reduce drug use among youth and young adults in northwest Hennepin County. Our focus is changing the community environment that leads to youth substance use by implementing strategies that will affect behavior around alcohol and other drugs. An effective strategy for reducing the burden of tobacco addiction would be to increase the tobacco age to 21.

Youth tobacco use is still a problem. E-cigarettes are particularly appealing to youth. They come in bright colors and an array of flavors like chocolate, cherry cola and grape. In the 2016 Minnesota Student Survey, nearly 11% of Robbinsdale 11th graders and 21% of Osseo 11th graders reported using e-cigarettes in the last 30 days. Increasing the gap between youth and those legally able to purchase tobacco products will help get e-cigarettes and other tobacco products out of the hands of our youth.

Smoking remains the leading preventable cause of death and disease in the state of Minnesota. In Minnesota, tobacco causes more than 6,000 deaths and costs more than $3 billion each year in healthcare and lost productivity.

We are glad to hear that the City Council will be considering this ordinance at an upcoming study session at the end of September. Thank you for your leadership and ensuring Plymouth is a healthy place to live.

Sincerely,

Amber Smith
Partnership for Change Coordinator
763-581-3739
Amber.smith@northmemorial.com
www.partnership4change.org
Dear Councilmember Johnson

Tobacco use is still the number one cause of preventable death and disease in Minnesota. Increasing the age gap between young people and those who can legally buy tobacco will reduce youth access to tobacco and ensure our youth don’t suffer from a lifetime of tobacco addiction.

By increasing the tobacco sale age to 21, you can help prevent addiction and tobacco-related diseases. Please act now to protect our community and our youth.

Sincerely,

[Signature]

Address: 17713 38th Ave N
City: Plymouth Zip: 55446

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Dear Councilmember Johnson

Tobacco use is still the number one cause of preventable death and disease in Minnesota. Increasing the age gap between young people and those who can legally buy tobacco will reduce youth access to tobacco and ensure our youth don’t suffer from a lifetime of tobacco addiction.

By increasing the tobacco sale age to 21, you can help prevent addiction and tobacco-related diseases. Please act now to protect our community and our youth.

Sincerely,

[Signature]

Address: 10540 43rd Ave N
City: Plymouth Zip: 55446

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Plymouth City Hall
C/O Councilmember
Jim From
3400 Plymouth Blvd
Plymouth, MN 55447
Dear Councillor Wosje,

Tobacco use is still the number one cause of preventable death and disease in Minnesota. Increasing the age gap between young people and those who can legally buy tobacco will reduce youth access to tobacco and ensure our youth don’t suffer from a lifetime of tobacco addiction.

By increasing the tobacco sale age to 21, you can help prevent addiction and tobacco-related diseases. Please act now to protect our community and our youth.

Sincerely,

Address: 620 Orchard Lane
Worth
Plymouth Zip 55447

Plymouth City Hall
C/O Councillor Wosje
3400 Plymouth Blvd.
Plymouth, MN 55447
Approximately 95% of current adult smokers started before they were 21. If youth don't smoke by the time they are 21, they likely never will.
Retail Tobacco Policy Analysis  
City of Plymouth - Hennepin County

Hennepin County asked the Public Health Law Center (PHLC) to assess the licensing and zoning regulations that impact tobacco retailers in the city of Plymouth. Plymouth’s licensing and zoning regulations were compared to licensing and zoning laws from other jurisdictions in Minnesota and across the U.S. Key findings are summarized below.

Plymouth’s Retail Tobacco Regulations

Minnesota cities have the authority to license retailers and regulate the sale of tobacco and related devices and products within their jurisdictions. Similar to most cities in Hennepin County, Plymouth has adopted its own tobacco licensing law. Regulating tobacco retailers through licensing is considered a best practice.

Plymouth’s licensing regulations include some good tobacco control practices. They include:

- A city license is required to sell nicotine or lobelia delivery products (consistent with state law).
- The transfer of a license to another person or location is prohibited, with exceptions determined by the city council.
- The sale of tobacco products and nicotine or lobelia products are prohibited by means of unattended self-service methods, vending machines, and loosies.
- Kiosks and other moveable places of business are ineligible for a city license.
- Open product (“self-service”) displays and vending machine sales are prohibited in all licensed locations.
- Indoor smoking is prohibited in all licensed establishments.
- A violation of any state, federal, or local tobacco control law is grounds for suspension, revocation, or other penalty.
- License holders are responsible for the conduct of their employees on the licensed premises; employee violations are considered acts of the licensee for penalty purposes.

Despite these strengths, there are elements that could be clarified, strengthened, or added, including:

Align with minimum standards in state and federal law

- Minnesota law requires a local license to sell “electronic delivery devices” – a broad term used to describe what are more commonly referred to as “e-cigarettes.” These products (whether they contain nicotine or not) are subject to the same sales regulations that apply to more conventional tobacco products and tobacco-related devices. Cities should update their ordinances to expressly and clearly incorporate all the minimum requirements of this state law.
- State law requires that any liquids sold for use in an electronic delivery device must be in child-resistant packaging. This requirement – as well as guidance to retailers on how they will demonstrate compliance - could be incorporated as well.
- Minnesota law also regulates “nicotine or lobelia delivery products” – a broad “catch-all” term that covers other “non-tobacco” or “non-electronic delivery device” products that contain nicotine and/or lobelia. These products are also subject to the same licensing and sales regulations and really should be specifically addressed in the licensing ordinance.
- State and federal law prohibits the distribution of most free samples. Local jurisdictions can prohibit the distribution and use of all free or nominally priced samples.
<table>
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<tr>
<th>Effective Administration and Enforcement</th>
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<td>o Minnesota law requires at least one youth access compliance check per retailer each year. Plymouth sets a minimum number of compliance checks each year (one), but allows for more. A city can require multiple checks, as well as re-inspections after violations. Performing additional compliance checks per year can help promote better compliance with youth access laws. Costs for additional-mandated compliance checks can be incorporated into the license fee, with the costs absorbed by the license holders themselves.</td>
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<td>o Some cities require retailers to train their employees on youth access laws and other licensing requirements. Plymouth could require training as a preventive measure for all licensees and/or as a consequence for underage sales or other violations.</td>
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<th>Fees &amp; Penalties</th>
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<td>o Fees should be periodically reviewed to ensure they cover all administration, implementation and enforcement costs, including compliance checks. Fees that do not reflect actual costs should be adjusted.</td>
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<td>o As written, a violation of Plymouth’s licensing ordinance results in a misdemeanor offense and/or an administrative fine for both the seller and the purchaser. There is little public health rationale for penalizing underage purchasers. Any license-related violation should be grounds for a penalty on the seller instead of the purchaser.</td>
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<td>o Plymouth’s licensing code creates a violation for underage use of false identification. State law already penalizes the use of false identification. A minor, then, could be charged for the same activity under city and state law. The equity and public health effects from these violations on the purchaser could be negative.</td>
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<td>o Strong consequences, like high administrative fines can help promote compliance. Establishing longer suspension terms, providing suspensions for first or second violations, and incorporating mandatory licensing revocations into the penalty structure can help encourage voluntary compliance and provide stronger tools to address repeat violators.</td>
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<th>Additional Licensing Options</th>
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<td>Through licensing regulations, Minnesota cities also have the opportunity to:</td>
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<td>o Raise the minimum legal sales age to 21.</td>
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<td>o Reduce or restrict the number, location, density, and types of retailers. A high prevalence of tobacco retailers is associated with increased use of tobacco; and a higher concentration of tobacco retailers in low income neighborhoods or around schools has negative consequences for public health. Retail outlets are also a source of exposure to tobacco marketing, which is designed to encourage initiation and use.</td>
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<td>o Increase product costs through non-tax approaches (such as minimum product pricing, minimum pack sizes, prohibiting coupon redemption, or other price discounting).</td>
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<td>o Restrict the sale of flavored products (this includes the sale of the menthol flavor).</td>
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<tr>
<td>o Establish a minimum age for clerks or other employees who sell tobacco and related devices and products.</td>
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**Other Laws that Impact Tobacco Retailers—Zoning Restrictions**

Plymouth’s zoning laws do not explicitly create tobacco-specific proximity/density restrictions within its zoning districts. The zoning code does limit the use of “tobacco and e-cigarette shops” to the C-2 and C-4 zoning districts. Despite this limitation, other licensed tobacco retailers that are not “tobacco and e-cigarette...
shops” are allowed to sell tobacco products in any zoning district. Zoning can be a tool to limit access and exposure to tobacco products, especially in areas where there are high concentrations of licensed tobacco retailers.

Signs that obscure windows and block sight lines into stores may not be aesthetically pleasing and can create public safety concerns. Many sign codes restrict the window and door space covered by signage. Plymouth’s signage regulations (Section 21155 of its zoning code) restricts the total amount area (by square footage) of walls, doors and windows that can be covered by signage, including a maximum percentage of certain window areas that may be covered by signs (e.g., fifty percent). Content-neutral signage laws that restrict the way signage is displayed on a business’ property can impact on the marketing and advertising of tobacco products at the point of sale.

August 2017

DISCLAIMER: The Public Health Law Center does not lobby, nor does it provide legal representation or advice. Based on our experiences with retail licensing and sales restrictions, we are able to provide our observations and other educational information for your own evaluation of these issues. This information is for educational purposes only; we do not request that a policymaker take any specific action in regard to our comments, nor should our comments be considered a replacement for legal advice. If you require a legal opinion, we encourage you to consult with local legal counsel.
Consider this: Just outlaw tobacco

Times Editorial Board Published 10:00 a.m. CT Sept. 30, 2017

The city of St. Cloud is considering whether to increase the age to buy tobacco in the city to 21.

Really, though, if elected and professional officials of any government wanted to do what's best for their constituents, they would simply outlaw tobacco.

Yes, admittedly, that seems extreme. Until you try to answer one fundamental challenge: Name one redeeming quality of tobacco.

The health evidence is overwhelmingly and unequivocally negative — even deadly.

The historical and cultural significance of tobacco in the United States — except for American Indian traditions — is built on marketing myths, nothing more.

And then, of course, there's the money — arguably the real reason an outright ban is seldom given serious consideration.

Economics rooted in tobacco and smoking production certainly benefit those directly involved — including governments, which tax the tar out of tobacco while simultaneously letting various elected officials collect lobbyists' cash.

But those narrowly targeted economic benefits pale in comparison to the costs tobacco products inflict on all of society — from health care to never-ending public policy debates, the age of purchase being just the latest example.

With all that in mind, the challenge remains: Name one redeeming quality of tobacco.

Raise the age

Of course, nobody expects St. Cloud's elected leaders to show that much political courage. Still, though, they are on the right track.

Crave the Change, a Central Minnesota organization that's spent the past decade fighting tobacco use, offers an array of statistics on why boosting the age to 21 makes sense. Among the most compelling:

http://www.sctimes.com/story/opinion/2017/09/30/consider/712104001/
Consider this: Just outlaw tobacco

- Nearly 90 percent of addicted smokers start by the time they turn 21.

- About 77,000 Minnesota kids use tobacco. While half those teens have tried to quit, 80 percent will become adult smokers.

- Overall about 118,000 of today’s Minnesota kids will die from smoking.

Raising the age makes even more sense when you look at what the tobacco industry continues to do to attract kids. Tobacco flavors include menthol as well as sweet flavors like fruits and candy. Not to mention the packaging and marketing of such items.

Of course, those tactics are nothing new. Crave the Change, along with similar groups nationwide, have long cited this research done more than 30 years ago by tobacco giant Phillip Morris and made public only in the past decade:

“Raising the legal minimum age for cigarette purchaser to 21 could gut our key young adult market (17-20) where we sell about 25 billion cigarettes and enjoy a 70 percent market share.”

A woman smoking tobacco blows a large cloud of smoke. *(Photo: Getty Images)*

Regional effort

Finally, as the St. Cloud City Council approaches a Nov. 9 public hearing on the matter, residents of neighboring cities Sartell, Sauk Rapids, St. Joseph, Waite Park and St. Augusta should urge their elected leaders to act, too.

Raising the age to 21 in just one city in a metro community made up of six communities will do little good.

Read or Share this story: [http://on.sctimes.com/2kd9R9a](http://on.sctimes.com/2kd9R9a)
City council pushes back public hearing on tobacco purchasing age

Alyssa Zaczek, azaczek@stcloudtimes.com  Published 10:03 a.m. CT Sept. 26, 2017

The St. Cloud City Council moved Monday night to temporarily postpone a public hearing on raising the tobacco purchasing age to 21.

City Council members were expected to schedule a public hearing on the matter for Oct. 9. Instead, council members will hold a study session on the issue in October in order to be better prepared for a public hearing in November.


To prepare for the study session, Council member Dave Masters requested that city administrator Matt Staehling reach out to the other cities in the area considering the ordinance change — including Sartell, Sauk Rapids, and Waite Park, among others — to determine where they are in the process and what, if any, changes those cities intend to make to the ordinance before voting upon it.

Staehling also added that “some language from the ordinance is pulled from the city of Edina ordinance” which was passed in May, making Edina the first in the state to raise the tobacco purchasing age to 21. (/story/news/local/minnesota/2017/05/03/edina-raises-age-buy-tobacco/101235334/) The change to the ordinance in Edina passed unanimously.

Currently, Minnesota law prohibits the sale of tobacco and tobacco-related products to people younger than 18.

Follow Alyssa Zaczek on Twitter @sctimesalyssa, email her at azaczek@stcloudtimes.com, or call her at (320) 255-8761.

Read or Share this story: http://on.sctimes.com/2yr7fH5
St. Cloud to schedule public hearing on raising tobacco buying age

TIMES STAFF REPORT   Published 12:17 p.m. CT Sept. 22, 2017 | Updated 3:09 p.m. CT Sept. 22, 2017

St. Cloud is considering raising the minimum age to purchase tobacco products to 21, according to St. Cloud City Council documents.

At the Sept. 25 city council meeting, council members will likely schedule a public hearing for Oct. 9 to discuss the issue.

READ MORE: Advocates aim to raise tobacco-buying age to 21 (/story/news/local/2017/07/14/advocates-aim-raise-tobacco-buying-age-21/440581001/)

Currently, Minnesota law prohibits the sale of tobacco and tobacco-related products to people younger than 18. But recently, Edina became the first in the state (http://www.startribune.com/edina-could-become-the-first-city-in-the-state-to-raise-tobacco-sales-age-to-21/421028233/) to raise the legal age to purchase tobacco products to 21.

READ MORE: Edina raises age to buy tobacco to 21 (/story/news/local/minnesota/2017/05/03/edina-raises-age-buy-tobacco/101235334/)

In late August, Dr. Julie Anderson and representatives from the CentraCare Health Foundation Crave the Change organization recommended that the joint area cities of St. Cloud, St. Augusta, St. Joseph, Sauk Rapids, Waite Park and Sartell all adopt ordinances raising the purchasing age to 21.

Read or Share this story: http://on.sctimes.com/2xnfGDG
Advocates aim to raise tobacco-buying age to 21

Published 1:34 p.m. CT July 14, 2017 | Updated 1:50 p.m. CT July 14, 2017

If he could, Sauk Rapids Mayor Kurt Hunstiger might single-handedly raise the tobacco-buying age to 21 in the St. Cloud area.

After seeing his father die from bladder cancer, he’s in favor of the campaign to raise the buying age, which has been shown to limit tobacco access to teenagers and thwart the start of lifelong nicotine addictions.

“My dad smoked since he was 16. He lived to be 72, but he died from it, too,” Hunstiger said. “(The doctors) told us 99 percent of bladder cancer is caused by cigarette smoking, so I have no problem raising (the legal age). I’d vote for it tomorrow morning.”

His comments come as cities elsewhere in Minnesota are raising the tobacco-buying age from 18 to 21. Several advocates for the change have been talking to leaders in the St. Cloud area, explaining that it could reduce the long-term costs of tobacco-related health issues.

Other area leaders aren’t as comfortable changing the legal age for buying tobacco.

“I can’t speak from a city perspective or a council perspective, but I can tell you my own viewpoint,” said Sartell Mayor Sarah Jane Nicoll. “Philosophically speaking, I think it is something that should be handled at the state level.”

St. Cloud Mayor Dave Kleis agreed tobacco regulations are a state responsibility, especially because regulations could impact commerce and local retailers. More important to Kleis is abiding by the 26th amendment of the U.S. Constitution, which reduced the voting age from 21 to 18 and established the “age of maturity,” he said.

“We pick an age which we determine an individual’s maturity, and it’s in the Constitution now where it’s 18,” Kleis said. “If you’re old enough to vote and select the people who make those decisions, you’re old enough to make those decisions.

“One of the most important things you do as an individual is determine who represents you. That’s an extremely important decision that we entrust in the public,” he said. “If we feel someone is mature enough and smart enough to make that decision, and if they’re old enough to fight for the country, I think we have to be consistent in that age.”

Kleis acknowledged the legal drinking age of 21 is a departure from that logic, but said he thinks if the age of maturity is 18, people should be able to purchase alcohol at that age, too.

Push to raise legal buying age

A local group advocating to raise the tobacco-buying age to 21 is hoping to bring together the six St. Cloud metro cities and start a community conversation on the initiative. Dr. Julie Anderson, a family physician with St. Cloud Medical Group, has already spoken to three local city councils about the initiative.

Also advocating for raising the tobacco age are Kasey Cable and Meghan Bown of Crave the Change, a tobacco-free initiative that’s part of Feeling Good MN, a nonprofit collaborative powered by CentraCare Health. The group hopes to present in August at the Joint Area Cities meeting, which brings together city representatives from St. Cloud, Sauk Rapids, Sartell, Waite Park, St. Joseph and St. Augusta.
Advocates aim to raise tobacco-buying age to 21

Despite Hunstiger's support of the idea of raising the tobacco-buying age, he thinks the effort will be ineffective if it is not implemented in all six cities.

"It's either all or none," he said. "I'm not going to put (Sauk Rapids') merchants at a disadvantage," he said.

There are 114 tobacco licenses in the six-city metro area. St. Cloud has about 53 percent of all the tobacco licenses in the metro. As of mid-July, St. Cloud had 60 tobacco licenses. Sartell and Waite Park each have 18 tobacco licenses, followed by Sauk Rapids with 10 tobacco licenses and St. Joseph with seven tobacco licenses. St. Augusta, where the county authorizes tobacco licenses instead of the city, has one establishment with a tobacco license.

Mayors from St. Augusta, St. Joseph and Waite Park support raising the tobacco-buying age locally, but are not sure if local city councils would vote in favor of the measure.

"I'm all in favor of it. I think we should ban smoking completely," said St. Augusta Mayor Bob Kroll.

Waite Park Mayor Rick Miller agreed.

"They could raise the smoking age to 100. I don't smoke. It doesn't make any difference to me," he said.

Waite Park City Council discussed the topic in a work session a few months ago, where the council was pretty evenly split on the issue, said Miller, who noted he thinks the topic should be addressed at an area cities meeting.

St. Joseph Mayor Rick Schultz said he was also personally in favor of raising the tobacco-buying age to 21.

"I don't know the economic impact to local stations. We would take that into consideration," he said. "But just like alcohol, I don't have any problem (increasing) the age to get tobacco to 21."

Other cities tackle tobacco

Local cities aren't the first to consider raising the tobacco-buying age to 21. In May, Edina became the first city in Minnesota to raise the tobacco age to 21 in an effort to curb teen tobacco use. More than 250 cities and counties in 18 states have passed similar laws, according to Tobacco 21, a national initiative. California, Hawaii and Oregon have statewide bans on selling tobacco to those younger than 21.

St. Louis Park is also considering raising the tobacco sales age to 21. Its city council is planning to vote on the topic on July 17; if approved, the new restrictions would go into effect in October.

Mankato and North Mankato have also been discussing raising the tobacco age. Because the cities are next to each other, officials
Advocates aim to raise tobacco-buying age to 21
to draft similar ordinances.

Kasey Cable, program specialist with Crave the Change, said she is following the Mankato and North Mankato conversations because it is a joint effort, similar to what local advocates hope to create in the St. Cloud metro.

Cable said she hopes the six joint cities can agree to raise the tobacco-buying age, then each city's council would approve its own ordinance.

High tobacco costs

While daunting, the effort is important, advocates say.

"What we spend on tobacco-related illnesses is high," Anderson said. "We've got to start having the conversation."

According to a report commissioned by Blue Cross and Blue Shield of Minnesota (http://www.ce.nerforpreventionmn.com/newsroom/press-releases/2017-cost-of-smoking-report), smoking is responsible for more than 6,300 deaths and $3.19 billion in excess medical costs each year. That costs equals about $554 for every man, woman and child in the state, Anderson said.

Anderson compared the logic in regulating tobacco use to seat belt and alcohol regulations, which are also public health concerns with solutions that favor safety over personal freedoms.

Increasing the legal tobacco age hinders access for children, Anderson said, noting that 18- to 20-year-olds purchase only 2 percent of the cigarettes sold, but supply 90 percent of tobacco to children. That's problematic because 95 percent of smokers begin before the age of 21.

For Anderson, the problem is in the nicotine. While e-cigarettes or other tobacco products might have fewer chemicals than traditional cigarettes, they still contain nicotine, which has been shown to alter brain development in young people and increase rates of mental illness. Nicotine exposure is also linked to cardiovascular diseases, heart problems and even conditions such as erectile dysfunction.

A study published by the Institute of Medicine (http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2015/TobaccoMinAge/tobacco_minimum_age_report_brief.pdf) in March 2015 showed that if the minimum legal age for tobacco was raised to 21 nationwide, there would be approximately 223,000 fewer premature deaths and 50,000 fewer deaths from lung cancer for those born between 2000 and 2019.

"The evidence out there shows you can have a 25 to 50 percent reduction in teen smoking by simply raising the age," she said.

Massachusetts town leads the way

Much research on raising the tobacco age to 21 is based on Needham, Massachusetts, which was the first town in the country to raise the tobacco sales age to 21 in 2005. Following the new law, a survey showed a 47 percent reduction in high school smoking rates from 2006 to 2010, according to a study published by BMJ Publishing Group (http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2015/TobaccoMinAge/tobacco_minimum_age_report_brief.pdf) in 2015.

In Needham, the smoking rate decreased from 13 to 7 percent, while the smoking rate in surrounding communities declined from 15 to 12 percent.

"It's all about access," Anderson said. "When you've got communities who are neighboring each other, even though they don't have as great of a reduction, they do have a reduction in their smoking because kids hang out with kids from neighboring communities."

A follow-up study (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4202949/), Cable said, checked back on retailers 10 years later and found all tobacco retailers were still in business in the area.

"I think that's important to know when we're talking about economic development," Cable said. "The ordinance update and the Tobacco 21 policy is not about restricting point-of-sale retailers to the point where they aren't able to stay in business."

Many local retailers are also affiliated with regional or national companies, many of which have experience with tobacco ordinances in other communities, Anderson said.

Advocates aim to raise tobacco-buying age to 21

Raising the tobacco-buying age also wouldn’t necessarily add cost to a city or county, Anderson said, because it would not need to police the possession or use of tobacco of those younger than 21. Police would instead only monitor vendors to make sure they are not selling tobacco to those younger than 21.

"It’s not really costing more because (cities and counties) already do compliance checks (/videos/news/2017/04/03/how-alcohol-compliance-checks-work/99995250/)," Anderson said.

Local efforts

Bown, the program coordinator with Crave the Change, has been working with local businesses and nonprofits to endorse the campaign. The group also plans to meet with area school districts and other organizations in the coming months.

"Ultimately our present goal is to educate and talk to people about it," Bown said. "It’s fairly new to the state of Minnesota and Central Minnesota."

This spring, a bill was introduced at the Legislature to raise the statewide tobacco selling age. Although the bill didn’t make it to the governor’s desk to be signed into law, Anderson expects the issue to come forth during next year’s legislative session.

In the meantime, the advocates are working to get the word out locally.

"Even if we just move the needle toward a discussion in our communities, I would be personally happy with that," Anderson said. "We are concerned about our specific community and need to place our efforts here."

For more information, visit feelinggoodmn.org/crave-the-change (http://feelinggoodmn.org/crave-the-change/).


Read or Share this story: http://on.sctimes.com/2us1mvi
St. Paul leaders say they support restriction of menthol tobacco sales but will wait a month

Council members plan to work with businesses before moving forward with regulations.

By Jessie Van Berkel Star Tribune  SEPTEMBER 27, 2017 — 9:58PM

The St. Paul City Council will wait a month before considering restrictions on the sale of menthol tobacco products.

St. Paul leaders emphasized Wednesday that they want to restrict the sale of menthol tobacco, but opted to hold off for a month to work with affected business owners.
Community groups and health organizations spurred the City Council to consider restrictions on menthol tobacco products, as well as mint- and wintergreen-flavored tobacco. The city already restricts fruit- and candy-flavored tobacco products.

The proposed regulations would allow only specialty tobacco shops — not other retailers like gas stations — to sell menthol tobacco products. Council Member Dan Bostrom proposed they go further and ban menthol tobacco sales at all retailers, but it was unclear Wednesday whether that proposal could gain enough council support to pass.

The emotional debate over restrictions has pitted health and neighborhood advocates against retailers.

Supporters of the change brought photos of family members killed by lung cancer to Wednesday’s public hearing and held them up for council members to see.

Meanwhile, gas station and convenience store owners and workers threw their keys down at public hearings, saying they could lose their businesses or jobs.

“These are the keys to my store, you are taking it from me,” Todd Knudten, who owns Capitol City Station on Shepard Road, said last week.

Council members opted to hold off on the vote for a month as they look at ways to ease the transition for businesses.

“This change is inevitable,” Council Member Amy Brendmoen said, but it could be better with more input from retailers.

Jessie.VanBerkel@startribune.com
 STATES AND LOCALITIES THAT HAVE RAISED THE MINIMUM LEGAL SALE AGE FOR TOBACCO PRODUCTS TO 21

States
Hawaii (effective 1/1/16)
California (effective 6/9/16)
New Jersey (effective 11/1/17)
Maine (effective 7/1/18)
Oregon (effective 1/1/18)

Localities
As of September 13, 2017, at least 260 localities have raised the minimum legal sale age for tobacco products to 21.

Arizonia (2)
Cottonwood
Douglas

Arkansas (1)
Helena/West Helena

California (3)
Healdsburg
San Francisco, City and County
Santa Clara County

Colorado (1)
Aspen

Hawaii (1)
Hawaii County

Illinois (11)
Berwyn
Buffalo Grove
Chicago
Deerfield
Evanston
Highland Park
Lake County
Lincolnshire
Maywood
Naperville
Oak Park

Kansas (18)
Bonner Springs
Garden City
Iola
Johnson County
Kansas City/Wyandotte Cty
Lansing
Leavenworth
Leawood
Lenexa
Merriam
Mission Hills
Olathe
Overland Park
Prairie Village
Roeland Park
Shawnee County
Westwood Hills
Westwood

Maine (1)
Portland

Massachusetts (153)
Acton
Adams
Amherst
Andover
Arlington
Ashland
Attleboro
Avon
Belchertown
Belmont
Blackstone
Boston
Braintree
Brewster
Bridgewater
Brimfield
Brockton
Brookline
Buckland
Cambridge
Canton
Carver
Charlestown
Chelsea
Chelmsford
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Chimham
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MA localities courtesy of the Municipal Tobacco Control Technical Assistance Program
New York (16)
Albany County
Baxter Estates
Cattaraugus County
Chautauqua County
Cortland County
Great Neck Plaza
Hempstead
New York City
North Hempstead
Orange County
Port North
Schenectady County
Suffolk County
Sullivan County
Tompkins County
Williston Park

Ohio (8)
Bexley
Cleveland
Columbus
Euclid
Grandview Heights
New Albany
Powell
Upper Arlington

Oregon (1)
Lane County

Rhode Island (2)
Barrington
Central Falls

Washington, DC
(not yet implemented)
Dear Mayor Slavik & City of Plymouth Council Members,

I am writing to you in regard to Tobacco 21. The language in this ordinance prevents adult access to tobacco harm reduction and carries with it some unintended negative consequences.

In a recently published National Bureau of Economic Research Working Paper titled "The Effects of E-cigarette Minimum Legal Sale Age Laws on Youth Substance Use", research supported by the National Institutes of Health concluded that laws banning sales of e-cigarettes to young adults actually pushes youth toward traditional cigarettes. The study concludes that strict enforcement of these laws is linked to an increase in youth smoking participation and that the unintended consequences of these laws are concerning and may have a negative impact on public health. Preventing 18 - 20-year-olds from access to smoke-free vaping products will result in continued smoking among the restricted age group, and cause unnecessary harm to these individuals, whereas vaping would prevent tobacco-related harm.

As evidence continues to mount, leading tobacco control experts both in the US and abroad are beginning to embrace supporting the many harm reduction benefits of vapor products. I encourage you to read the following reports, all released by recognized anti-tobacco organizations or government entities.

Liberating Nicotine From Smoke: This is a report released this year by leading tobacco control experts in the US. It stresses the need to embrace harm reduction technologies such as vapor, in an effort to reduce smoking rates.

Royal College of Physicians: The first organization to warn of the dangers of smoking in 1962 recently came out to embrace vaping as an alternative - and even reported that vapor is at least 95% safer than smoking, with very few if any demonstrable concerns for nonusers.

Public Health England: England’s National Health Department determined that vaping is a 95% - 98% safer than smoking, poses no risk of a "gateway to smoking", and vapor aerosols to pose no quantifiable risk to bystanders.
Last year the UK government AND all of the leading anti-smoking organizations issued a joint statement about vapor products, promoting them as a safe alternative to smoking.

The latest Minnesota Adults Tobacco Survey shows that while seeing an all-time low in smoking rates, and an all-time high for successful quit attempts, vapor products were not only the most popular option for people seeking to quit but that traditional methods such as gum or the patch saw a nearly 50% decrease. In other words, Minnesotans are successfully using vapor to stop smoking!

Please carefully read over this comprehensive Tobacco 21 research packet from Tobacco Harm Reduction 4 Life before making any final decisions. This packet will highlight how ‘raising the smoking age’ will actually INCREASE smoking. Prohibitive measures have a proven track record of failure. More information HERE.

I’d like to bring to your attention that Tobacco 21 laws do directly conflict with the Age of Majority rule as defined in Minnesota Statute 645.451. On June 19, a Michigan lawsuit challenged this conflict after Genesee County passed Tobacco 21, and the Genesee County Circuit Judge ruled that Tobacco 21 laws are unenforceable at a municipal level for this reason. I’m seeing lawsuits popping up all over the country challenging municipalities that pass Tobacco 21 law that conflict with the Age of Majority rule. It can become a costly mistake, and we don’t want to see Minnesota become another victim of a reckless tobacco control lobby.

Currently, only 2 MN cities have adopted these overreaching and harmful ordinance changes - St. Louis Park and Edina.

Hutchinson voted in May not to entertain Tobacco 21 policies.

Frazee decided this was a state issue and Tobacco 21 never made it past the Public Safety Committee in May.

Perham turned it down in June, stating it would give retailers within city limits an unfair disadvantage to those outside city limits.

Eagle Lake turned it down in July and South Bend has expressed firm disinterest in adopting such a policy, should the Mankato’s ever adopt it.

Elk River sent a letter to retailers on July 28 stating they would not be moving forward with Tobacco 21.

Detroit Lakes deliberated the issue for 4 months, resulting in a 6-2 vote not to adopt it, on Sept. 12th. The two council members that were interested in moving forward, wanted to do so by exempting vapor from the language.

Mankato/N. Makato have been very hesitant of the policy due to its ‘discriminatory nature”, and have set it for a second intergovernmental meeting after canceling an August public hearing. They are taking a “both cities
adopt it or no one does” approach. One thing they have been able to agree on so far is to drop all language that criminalizes possession and use of tobacco and vapor products by the targeting group of 18 - 20-year-old adults.

So far, of the MN cities that have been presented with Tobacco 21, more cities have stepped back from it, than have moved forward with it. An average of recent Minnesota public polls showed 71% of respondents were opposed to ‘raising the smoking age’.

*Raising the smoking age’ is a bad idea, may backfire

*Legislation To Raise Tobacco (And E-Cigarette) Age Is Unnecessary, Risky

*CITY REJECTS TOBACCO 21

*This short video is very informative and I highly recommend you give it a watch! Though it is regarding Tobacco 21 in Texas, the information is still applicable to us.

*Here is a short educational video explaining tobacco harm reduction through vaping.

Please do not enact these proposed policies that will discourage more adults from vaping and ending their addiction to cigarettes!

Vaping is not smoking, and preventing adult access to tobacco harm reduction will carry negative consequences for public health. We urge you to take the time and due diligence to study and understand tobacco harm reduction (THR) before making a decision to move forward with Tobacco 21 ordinance language.

My team and I would really appreciate the opportunity to present another side to this before any final changes are enacted.

Thank you very much for your time and attention to this important matter, and please let me know if you have any questions or would like more information!

Respectfully,
Jenny Hoban

Minnesota Tobacco Harm Reduction Advocate

Board of Directors

Tobacco Harm Reduction 4 Life (THR4Life) was established to help smokers regain control over their lives by providing balanced and accurate information about tobacco harm reduction. We believe that honesty and transparency in public health are imperative to the long-term well-being of our communities. We assert that the best way to protect future generations from the harms of tobacco is to begin with the adults in their lives. We advocate for the technological innovation of tobacco harm reduction as paving the way toward a smoke-free future, a healthier population, and a cleaner environment.

THR4Life is a Public Charity 501c3 and is Tax-Deductible for bequests, devises, transfers or gifts under Section 2055, 2106, or 2522 of the IRS.
The Effects of E-Cigarette Minimum Legal Sale Age Laws on Youth Substance Use
Dhaval Dave, Bo Feng, and Michael F. Pesko
NBER Working Paper No. 23313
April 2017
JEL No. D12,I12,I18

ABSTRACT

We use difference-in-differences models and individual-level data from the national and state Youth Risk Behavior Surveillance System (YRBSS) from 1991 to 2015 to examine the effects of e-cigarette Minimum Legal Sale Age (MLSA) laws on youth cigarette smoking, alcohol consumption, and marijuana use. Our results suggest that these laws increased youth smoking participation by 0.7 to 1.4 percentage points, approximately half of which could be attributed to smoking initiation. We find little evidence of higher cigarette smoking persisting beyond the point at which youth age out of the law. Our initial results also show little effect of the law on youth drinking, binge drinking, and marijuana use. Taken together, our findings suggest a possible unintended effect of e-cigarette MLSA laws—rising cigarette use in the short term while youth are restricted from purchasing e-cigarettes.

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1. Introduction

Teenage substance use and abuse continues to be a major public health concern. Although rates of youth smoking are declining, each day more than 3,200 youth initiate cigarette consumption and more than 2,000 transition into daily smoking (US Department of Health Human Services, 2014). Youth drinking and marijuana use is a prevalent and costly form of teenage substance use, which has been linked to poor academic performance, impaired cognitive development, and other severe health problems (National Institute on Alcohol Abuse and Alcoholism, 2016). In 2015, 33% of youth drank, 18% binge drank, and 22% used marijuana over the past month (Centers for Disease Control and Prevention (CDC), 2015). Since use of substances is often inter-related, policies reducing one form of substance use might also impact other forms.

The introduction of electronic cigarettes (e-cigarettes) presents youth with an alternative that could disrupt their use of cigarettes, marijuana, and alcohol. E-cigarettes are a particular type of vaping device within the broader class of electronic nicotine delivery systems (ENDS). They differ primarily from conventional cigarettes by permitting the inhalation of nicotine that is heated rather than combusted, substantially reducing the harm associated with combustion-related byproducts. Since their introduction into the U.S market, e-cigarettes have been advertised and positioned as alternatives to conventional cigarettes. Their popularity among adults and youth, in particular, has been rising exponentially. Within a four-year period (2011-15), e-cigarette use has increased from 1.5% to 16.0% among high school students and from 0.6% to 5.3% among middle school students, surpassing cigarettes as the most commonly used tobacco product among adolescents (Singh, 2016).1 The most recent estimates show that over 3 million middle and high school students currently use e-cigarettes (Singh, 2016).2

Examining the risks of e-cigarettes, and the relative risks between e-cigarettes and conventional cigarettes, has spurred a heated policy debate and has attracted significant academic interest. A recent report issued by the British government suggests that e-cigarettes

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1 E-cigarettes were not treated as tobacco products until 2016 when FDA finalized its deeming rule.
2 Among adults, the 2014 National Health Interview Survey shows that 12.6% had ever used e-cigarettes at least once and 3.7% currently use e-cigarettes (Schoenborn and Gindi, 2015).
are no more than five percent as harmful as conventional cigarettes (Tobacco Advisory Group of the Royal College of Physicians, 2016). Other studies have suggested that e-cigarettes can direct smokers away from smoking and possibly help them quit (Hampton, 2014, Abrams, 2014, Brandon et al., 2015, McNeill et al., 2015). However, the 2016 Surgeon General’s Report warns that e-cigarettes are dangerous to adolescents because they can interfere with cognitive development and can cause nicotine addiction (US Department of Health Human Services, 2016).

A particular concern raised by the public health community is that e-cigarettes may act as a gateway towards the use of other addictive substances, such as cigarettes, alcohol, and marijuana (Gostin and Glasner, 2014, Primack et al., 2015, Mammen et al., 2016). In response, state governments passed a wave of regulations limiting youth access to e-cigarettes. A popular initiative has been the adoption of Minimum Legal Sale Age (MLSA) laws on e-cigarettes analogous to those passed for conventional cigarettes decades ago. New Jersey became the first state to implement an e-cigarette MLSA law in March of 2010, followed by four other states later within the same year.³ Additional states adopted an e-cigarette MLSA law in each year subsequently: two in 2011, five in 2012, twelve in 2013, fifteen in 2014, eight in 2015, and two in 2016. By the time the Food and Drug Administration (FDA) mandated a federal e-cigarette MLSA law of 18 in August of 2016, all states but two had an e-cigarette MLSA law in place.

Canonical microeconomic theory suggests that youth vaping is likely to decline as costs and other components of the “full price” associated with the product rise. The magnitude of the decline in e-cigarette use caused by e-cigarette MLSA laws may be less pronounced to the extent that retailers do not abide by the law or youth bypass the law through online vendors. If e-cigarettes are economic substitutes with other tobacco products or other addictive substances, then e-cigarette restrictions may induce substitution toward smoking and other substance use, thus lessening the intended public health implication. However, relating to the public health community’s concerns about e-cigarettes being a gateway to other substances,

³ Utah, New Hampshire, Minnesota, and California enforced the law on May 11, July 31, August 1, and September 27, all in 2010, respectively.
complementarity is also possible. In this case, restricting e-cigarette access may reduce not only its own use but also the use of cigarettes, both today and in the near future, through a reduction in the addictive stock of nicotine.

In this study, we explore how e-cigarette MLSA laws affect youth smoking. Other studies exploring this question have arrived at mixed conclusions (Friedman, 2015, Pesko et al., 2016, Abouk and Adams, 2017), and our study attempts to provide further clarity to this question. Specifically, we examine the impact of these laws on youth smoking behaviors by exploiting the heterogeneity in the timing of states’ adoption of e-cigarette MLSA laws using a quasi-experimental difference-in-differences research design. These analyses inform whether youth, who are constrained from purchasing e-cigarettes, are currently more likely to use conventional cigarettes.

In addition to contemporaneous effects, by affecting the addictive nicotine stock, e-cigarette MLSA laws may also have dynamic effects. We therefore extend our analyses and provide some of the first evidence on the dynamic, intertemporal relationship between e-cigarette MLSA laws and youth smoking. Specifically, we provide estimates that inform whether a policy that makes vaping less attractive today makes future smoking more or less likely when youth are no longer subject to the MSLA-based restriction.

Finally, we broaden the lens to other addictive substances and provide some of the first evidence on potential spillover effects of e-cigarette MLSA laws on other substance use. Such spillover effects are plausible given the high prevalence of co-occurring alcohol, marijuana, and tobacco use among adolescents.\(^4\) The rest of the study is organized as follows. Section 2 provides a brief background and a review of current literature on this topic. Section 3 outlines a conceptual framework of the various channels through which e-cigarette MLSA laws may affect substance use, and also motivates our empirical specifications. Section 4 describes the dataset, and the construction of e-cigarette MLSA laws and other relevant policy variables, followed by our empirical approach in section 5. Section 6 presents the findings, followed by a discussion of the implications of our results.

\(^4\) Data from the 2014 National Survey of Drug Use and Health (NSDUH) suggest that, among youth ages 12-17 who have used tobacco products in the past year, 88% have also consumed alcohol and 56% have used marijuana over this period.
2. Literature

A. Cigarette MLSA Laws and Youth Smoking

Over recent decades, individual states have made several efforts to tighten tobacco control regulations by prohibiting retailers from selling tobacco products to minors. Several studies have examined the efficacy of cigarette MLSA laws adopted between the 1980s and early 1990s in curbing youth smoking. Though many of these studies suggest that the laws have been effective in reducing youth smoking (Chaloupka and Pacula, 1998, Gruber and Zinman, 2001, Ahmad and Billimek, 2007, DiFranza et al., 2009), some find limited effects. Chaloupka and Grossman (1996) find little effect of youth access restrictions on youth smoking, which they attribute to the weak enforcement of the laws. DeCicca and colleagues (2002), using indices of smoking restrictions that ranged from youth access restrictions to restrictions on smoking in public places, also find limited effects of the laws. A recent study by Yoruk and Yoruk (2015) revisits the effect of cigarette MLSA laws on youth smoking using a regression discontinuity design. They find that, although the law’s impact are imprecisely estimated, gaining legal access to tobacco products once youth have aged out is associated with a 2 to 3 percentage point increase in the probability of smoking. By focusing on a subsample where youth report smoking in the prior wave, the authors find that cigarette MLSA laws lead to a statistically significant increase in the probability of smoking (five percentage points) and frequency of smoking (25% increase) over the past month.

B. Relationship Between E-Cigarettes and Traditional Cigarettes

A few studies assessing the contemporaneous relationship between vaping and smoking have suggested substitutability. Using state-level aggregated data from the National Survey on Drug Use and Health (NSDUH), Friedman (2015) find that state e-cigarette MLSA laws are associated with an increase in youth smoking rate. Pesko and colleagues (2016) also analyze the effects of e-cigarette MLSA laws on adolescent smoking and other tobacco consumption using
state-level aggregated YRBSS data. In their main findings, e-cigarette MLSA laws are associated with a 0.8 percentage point increase in regular adolescent smoking, which slowed the downward trend of youth smoking. However, they do not find any strong evidence that e-cigarette MLSA laws affect use of other tobacco products in adolescents. Abouk and Adams (2017) find opposite results. Using individual-level data from Monitoring the Future (MTF), their estimates suggest that e-cigarette MLSA laws lead to a reduced smoking rates among high-school seniors. This suggests that e-cigarettes and cigarettes are economic complements, rather than substitutes as suggested by Friedman (2015) and Pesko and colleagues (2016). Abouk and Adams (2017) attribute their use of individual-level data as one possible reason for the opposite findings.

One study uses price changes\(^5\) as the mechanism to study whether e-cigarettes and cigarettes are economic substitutes or complements. Using Nielsen scanner data, Huang and colleagues (2014) find little evidence that consumers substitute toward cigarettes when e-cigarette price increases.

C. Relationship Between Smoking, Drinking and Marijuana Use

The relationship between youth e-cigarette use and marijuana and alcohol use has not yet been clearly established. Equipment that is used for delivering nicotine may also be used to vaporize marijuana (Budney et al., 2015, Mammen et al., 2016). A study using YRBSS data suggests no relationship between e-cigarette MLSA laws and adolescent marijuana use (Pesko et al., 2016). While little is known about the relationship between vaping and drinking, many studies have explored the relationship between smoking and drinking. Dee (1999) suggests that smoking and drinking are complements among high school seniors. By exploiting variation in state cigarette excise taxes and state’s adoption of minimum legal drinking age (MLDA) laws at different points in time, Dee finds that MLDA laws are negatively associated with youth smoking. However, the negative impact of cigarette taxes on youth drinking is imprecisely estimated. Using sales and household expenditure data on cigarettes and alcohol in Canada,

\(^5\) These are prices recorded during the actual transactions.
Gruber and colleagues (2003) find partial evidence supporting complementarity between smoking and drinking. Their estimates suggest that a ten percent increase in cigarette prices is associated with a one percent drop in alcohol sales, alluding to a cross-product price elasticity of -0.1. In the same study, cigarette prices are estimated to have a positive but statistically insignificant impact on household expenditure on total alcohol consumption. Focusing on the elderly population, Picone and colleagues (2004) find that complementarity and substitutability can co-exist. Higher cigarette prices are found to increase drinking, and yet smoking bans are found to decrease both smoking and drinking. Overall, the existing literature seems to lack a consensus on the relationship between smoking and drinking.

D. Summary and Contributions

As noted above, only a handful of studies have focused specifically on the impact of e-cigarette MLSA laws on youth smoking. Two of them (Pesko et al., 2016, Friedman, 2015) find that the laws increased smoking and the third (Abouk and Adams, 2017) find the opposite effect. Friedman (2015) is based on 2-year state aggregated data from the NSDUH (spanning 2002-2013) and Pesko et al. (2016) is based on the state-aggregated data from the Youth Risk Behavioral Surveillance System (YRBSS; spanning 2007-2013). Both studies indicated that e-cigarette MLSA laws increased youth smoking by 0.8 to 0.9 percentage points. Abouk and Adams (2017) focus on high school seniors and utilize micro-level data spanning 2007-2014 from the MTF. Their study suggests that e-cigarette MLSA laws led to reduced cigarette use by about 2-3 percentage points. It is unclear whether the divergence in findings stems from the use of more granular individual-level data or from the addition of one more study period.

Our study extends this seminal work by Friedman (2015), Pesko et al. (2016), and Abouk and Adams (2017), and contributes to this literature in several respects. First, we add to the prevailing evidence by incorporating micro-level data from both the national and the state YRBSS spanning up to 2015. This yields a substantially larger sample size (between 500,000 and 1,000,000 person-wave observations) relative to previous work. Utilizing data up to 2015, just prior to the FDA’s national ban on e-cigarette sales to minors, further maximizes policy
variation (8 additional states had adopted these laws in 2015) and extends the post-policy window for the other states to disentangle dynamic effects. Second-order policy responses on youth substance use (other than e-cigarettes) are likely to be small, and hence micro-level data with large sample sizes, more cleanly-defined affected groups, and longer time windows with greater policy variation may be necessary for maximizing precision.

Second, prior work has focused only on the contemporaneous effects of e-cigarette MLSA laws on smoking behaviors. Our study is the first to consider how these laws may affect youth smoking rates once they have aged out of the restrictions and are able to purchase e-cigarettes. This is particularly relevant for assessing long-term effects on smoking rates and addressing public health concerns. Finally, we also estimate the relationship that e-cigarette MLSA laws have on other substance use. With the exception of Pesko et al. (2016), who studied and found no effects on marijuana use, prior work has mainly focused on cigarette smoking.

3. Conceptual Framework

The overall effect of e-cigarette MLSA laws on smoking, drinking, and marijuana use depends on the marginal direct and indirect costs of youth obtaining e-cigarettes. Banning legal sales of e-cigarettes to minors will raise the indirect costs of obtaining the product through added inconvenience and/or associated time delays. It could also increase the direct costs of obtaining the product through additional markups or purchasers having to pay “friends” who can buy the product for them. E-cigarette MLSA laws will therefore raise the full price of e-cigarettes, which are expected to have first-order effects in the form of a decline in e-cigarette consumption. However, the predicted decrease in e-cigarette consumption may be moderated to the extent that retailers do not abide by the law or youth are able to bypass the law through online vendors.

A rise in the indirect or direct costs of purchasing e-cigarettes would also cause a relative increase in the cost of e-cigarettes in comparison to conventional cigarettes and other

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6 For the purpose of this paper, the substances we focus on are conventional cigarettes, alcohol, and marijuana. Ideally, we would want to incorporate e-cigarettes into the basket, but the lack of national datasets with sufficient information on e-cigarette use prevents us from doing so. Nevertheless, we present some preliminary evidence on the effects of e-cigarette MLSA laws on youth e-cigarette use later in the study to help frame our estimates on other substance use.
addictive substances. This increase in relative costs could have spillover second-order effects on the consumption of cigarettes, alcohol, and/or marijuana through complementarity or substitution.

A priori, the effects of e-cigarette MLSA laws on the use of conventional cigarettes, marijuana, and alcohol are ambiguous. One particular mechanism through which the laws may increase smoking is if e-cigarettes are being used for smoking cessation or reduction. Losing access to e-cigarettes could therefore reduce a smoker’s propensity to attempt cessation. In fact, many studies have documented the success of e-cigarettes in helping smokers quit (Etter and Bullen, 2011, Brown et al., 2014, Adkison et al., 2013). E-cigarettes could also lead to smoking initiation if they generate nicotine-induced cravings that cigarettes are then able to meet. E-cigarette MLSA laws could also raise youth interest in the motive underlying the legal change and encourage them to search for health information related to e-cigarettes and possibly other substances, which could in turn change their attitudes toward consumption.

The dynamic effects of e-cigarette MLSA laws on smoking, when youth have reached the age limit, are also a priori indeterminate. However, it should be noted that once youth turn 18, they are able to purchase both e-cigarettes and conventional cigarettes legally. In states that have passed an e-cigarette MLSA law, youth who age out of the laws will therefore experience a decrease in the relative cost of obtaining e-cigarettes, which could lead to an increase in e-cigarette use and a decrease in smoking. Hence, once youth are able to purchase e-cigarettes legally, they may substitute from smoking to vaping. However, if youth had turned to smoking when exposed to e-cigarette MLSA laws, the accumulation of the addictive stock of nicotine may make it difficult to cut down on smoking even when they are able to purchase e-cigarettes legally.

Ultimately, the impact of e-cigarette MLSA laws on smoking, drinking, and marijuana use is an empirical question, and one that we explore in this study.

4. Data

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7 In most cases, youth aged 18 are old enough to legally purchase e-cigarettes and conventional cigarettes except for a few cases where states set the minimum age at 19 or 21.
To study the impact of e-cigarette MLSA laws on youth use of cigarettes, alcohol, and marijuana, we draw on all available waves of the bi-annual national and state Youth Risk Behavior Surveillance System (YRBSS) spanning 1991–2015. The national YRBSS is conducted by the CDC and the state YRBSS is usually administered by state health departments. Many states have authorized the CDC to distribute their data for secondary analyses and for states that did not, we contacted each and received their permission to use the data. The data was limited to states that participated in the survey noting that data in a given year could be withheld from secondary analyses due to sample size constraints. Appendix Table 1 shows the observation count in each state from 1991 to 2015.

The YRBSS data collection typically starts in March and ends in early June for each state. Standard demographic characteristics are consistently collected and a battery of questions relating to youth risky behaviors such as smoking, drinking, and other drug use is also included in each wave. We identify youth as current smokers, drinkers, or marijuana users using questions in the data and conventional methods in the literature. To investigate the specific question of whether e-cigarette MLSA laws cause youth to newly initiate smoking, we infer initiation based on a series of responses. We first use a question in the data asking how old the individual was when he/she smoked a whole cigarette for the first time. We use that information to create a binary indicator for smoking initiation if the reported age of first cigarette smoking matches his/her current age at the time of the survey and zero otherwise. For all the following analyses, we restrict the sample to youth with no missing demographic information.

To isolate the ceteris paribus relationship between e-cigarette MLSA laws and youth substance use, we control for an extensive set of confounding policy shifts over this period: federal and state cigarette excise taxes, state beer taxes, an index for medical marijuana laws.

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8 A common reason that states do not distribute their data for secondary analyses is that sample size is not large enough to meet the minimum weighting requirement.
9 We define being a current smoker using a question “During the past 30 days, on how many days did you smoke cigarettes?” Youth are then defined as current smokers if any days of smoking are reported. Being a current drinker is defined using the question “During the past 30 days, on how many days did you have at least one drink of alcohol?” Being a current binge drinker is defined using the question “During the past 30 days, on how many days did you have 5 or more drinks of alcohol in a row, that is, within a couple of hours?” Being a current marijuana user is defined using the question “During the past 30 days, how many times did you use marijuana?”
(MML), state unemployment rates, and the natural logarithm of state per capita income.\textsuperscript{10} Our index for MML is created using the law’s three main provisions – overall legislative decision, home cultivation, and medical marijuana dispensary (Anderson et al., 2015, Pacula et al., 2015, Choi et al., 2016). The index equals one when states only grant the legal status of using marijuana for therapeutic purposes but not for home cultivation or marijuana dispensaries. It equals three when all dimensions are allowed. To proxy for anti-smoking sentiment at the state level, we control for an index (with a maximum value of 3) capturing the restrictiveness of indoor smoking in private workplaces in each state. We also account for anti-vaping sentiment by using an indicator for if vaping in private workplaces is banned.\textsuperscript{11} We do not use e-cigarette taxes as a control because only Minnesota has levied taxes on e-cigarettes over our study period. We also control for zero-tolerance laws to account for a general social perception of teenage drinking at the state level.

Table 1 reports the summary statistics for the variables investigated during our study period. Column 1, 2, and 3 present the means of each variable for the full sample, a subsample of individuals younger than 18, and a subsample of individuals 18 or above, respectively. While four states (Alabama, Alaska, New Jersey, and Utah) set the purchasing age of e-cigarettes at 19 years old during the study period, age in the YRBSS is top-coded at “18 or above” and we are unable to separate out youth who are 19 years of age.\textsuperscript{12}

As shown in Table 1, 19% of the sample were current smokers, 20% were marijuana users, 39% were current drinkers, and 23% percent were binge drinkers. The proportion of

\textsuperscript{10} The cigarette tax data comes from the CDC STATE System and the beer tax data comes from the National Institute on Alcohol Abuse and Alcoholism (NIAAA). We use the tax rates as of March for both variables to match the period of time over which the survey was conducted. Data for state’s medical marijuana laws come from the National Conference of State Legislatures (NCSL) and National Organization for the Reform of Marijuana Laws (NORML). We obtain state unemployment rates and per capita income from Bureau of Labor Statistics (BLS). Both cigarette and beer taxes are inflation-adjusted to 2005 values using the Consumer Price Index for All Urban Consumers (CPI-U), and we transform the per capital income using a natural logarithm.

\textsuperscript{11} No partial bans on vaping in private workplaces exist. We have also experimented with including smoke-free air laws in bars and restaurants to further control for state anti-smoking sentiment, which are highly collinear with private workplace laws. Our estimate of the impact of e-cigarette MLSA laws was not materially affected by adding these additional proxy variables for anti-smoking sentiment.

\textsuperscript{12} This will result in some individuals “18 and above” being subject to the e-cigarette MLSA laws, that is, some individuals in the control group may be treated. We found that moving these youth into column 2 does not at all change the summary statistics. Based on the 2016 American Community Survey, among current high-school enrollees nationally between the ages of 12-19, only about 2% are aged 19, and only 4.3% (based on the share of the population of the affected states, AK, AL, NJ and UT) of these 19 year olds would be misclassified as being not treated. Hence, any attenuation bias from this misclassification is negligible.
current smokers, drinkers, and marijuana users among those who are 18 or above is significantly higher than that among youth 17 or younger (10, 12, and 6 percentage points higher, respectively). Questions related to youth e-cigarette use are first included in the YRBSS in 2015. These questions indicated that 45% of high-school students have tried e-cigarettes in their lifetime, and 24% are current (past 30-day) vapors.

Figure 1 graphs the trend of youth smoking, drinking, and marijuana use over our study period from a sample restricted to those younger than 18 years of age. We use solid lines to represent states where laws were in place before or during February 2015 and dashed lines to represent states where laws have yet to be implemented. These figures suggest two things; first, the prevalence of youth smoking and drinking consistently declined over the past two decades while youth marijuana use spiked in the early 1990s, then decreased substantially, before trending slightly upwards again. Second, trends within both the treated states (solid line) and the non-treated states (dashed line) have been largely similar, yielding little graphical evidence on the impact of e-cigarette MLSA laws on youth smoking, drinking, or marijuana use. Limited graphical evidence notwithstanding, many confounding factors have not been taken into consideration in these graphical representations. Furthermore, second-order effects on smoking and other substance use may be small and difficult to disentangle from other confounding trends. For this reason, we turn to more rigorous quasi-experimental evidence to investigate the policy effects of e-cigarette MLSA laws on youth use of these substances.

5. Empirical Specification

Our baseline model employs the standard difference-in-differences (DD) framework, exploiting differences in the timing of policy adoption across states to identify the effects of the e-cigarette MLSA laws on youth substance use behaviors. Specifically, we estimate the following reduced-form demand function, relating substance use directly to the e-cigarette MLSA laws.

\[
p(D_{i,t} > 0) = \sum_{l} \Gamma_{l,t} + \beta_{1}M_{l,t} + \beta_{2}Z_{l,t} + \gamma_{1} \delta_{l,t} + \lambda_{l} \theta_{l,t} + \epsilon_{i,t}, \quad (1)
\]
In specification (1), $DV_{i,s,t}$ is one of the three indicators for youth substance use at the current time. For instance, when $DV_{i,s,t}$ indicates smoking, $P(DV_{i,s,t} > 0)$ denotes the probability that the youth is a current smoker. Our key variable of interest, $MLSA_{s,t}$, is an indicator for whether the state had an e-cigarette MLSA law in place. To reflect the typical data collection time in YRBSS, this variable is set equal to one if the law was effective by the end of February of that year and all the subsequent time periods and zero otherwise. The parameter of interest is $b_1$, which captures the average reduced-form effect of e-cigarette MLSA laws on youth smoking, drinking, or marijuana use, including through all reinforcing and/or competing pathways as discussed earlier. The vector $X_{i,s,t}$ contains a full vector of interactions across youth demographic characteristics, and the vector $Z_{s,t}$ represents the time-varying, state level policy variables (inflation-adjusted cigarette and beer taxes expressed in dollars, a three-value index for the medical marijuana law, restrictions on vaping and smoking in private workplaces, an indicator for the existence of zero-tolerance laws, state unemployment rate, and the natural log transformed state per capita income). We include state and year fixed effects, denoted by $\gamma_s$ and $\lambda_t$ respectively, to account for time-invariant state heterogeneity and unobserved national trends. In some specifications, we also add state-specific linear time trends, denoted by $\gamma_{s,t}$, to account for the unobserved state-level factors, evolving at a linear rate. All specifications are estimated as linear probability models via OLS.\(^{12}\) Standard errors are clustered at the state level where the variable of interest varies (Bertrand et al., 2004).

We extend the baseline specification in several ways to address specific issues. First, to examine dynamic impacts of the policy on youth substance use and explicitly assess the parallel trends assumption between the reform and non-reform states, we transform specification (1) into an event study design. In particular, we decompose $MLSA_{s,t}$ in model (1) into $MLSA_{s-3}$, $MLSA_{s-0}$, and $MLSA_{s,1}$ that capture a series of policy “leads”, or “placebo” laws. $MLSA_{s-3}$ takes the value of 1 if an e-cigarette MLSA law will be passed, but not within 3 years (0 otherwise). $MLSA_{s-0}$ takes the value of 1 in the year when the law is de facto effective (0 otherwise). $MLSA_{s,1}$ takes the value of 1 if a law has been in effect for one or more years (0 otherwise). Our results and conclusions are not materially affected if the specification is estimated via logit or probit regression.
omitted category, or the reference group, is an MLSA law coming into effect 1-2 years later. The new specification takes the form:

\[ P(DV_{i,s,t} > 0) = \sum \gamma X_{i,s,t} + \alpha_1 MSLA_{s,3} + \alpha_2 MSLA_{s,0} + \alpha_3 MSLA_{s,1} + b_2 Z_{s,t} + \gamma_f + \lambda_t + \lambda [+\gamma_s t] + \epsilon_{i,s,t} (2) \]

where all other variables besides the MLSA variable are defined as before. The parameter \( \alpha_2 \) captures the contemporaneous policy effect on teen substance use and \( \alpha_3 \) captures the lagged policy effect one or more years after the law’s implementation. Hence, \( \alpha_1 \) provides evidence of parallel or differential pre-treatment period time trends. If this coefficient is statistically distinguishable from zero, it would suggest that the treatment and control states had differential trends prior to policy adoption, which may undermine the interpretation of the DD effect as causal. Explicitly controlling for the lead effects as in the event study can also help to partly account for any non-parallel trends.

Second, we build upon the above specifications and assess the margin at which smoking is potentially affected. Specifically, we consider whether, and to what extent, e-cigarette MLSA laws have impacted youth smoking initiation and take-up.

Third, we further assess inter-temporal responses by estimating how being exposed to an e-cigarette MLSA law when underage affects smoking behaviors once youth have aged out and are able to purchase e-cigarettes. We do so by restricting the sample to those who are currently over the e-cigarette MLSA age limit and then follow three approaches.

In the first approach, we construct an indicator (denoted MSLA_MINOR) that is set equal to one if an e-cigarette MLSA law was effective when the individual was underage and to zero otherwise. For instance, an e-cigarette MLSA law was effective on January 1st, 2013 in the state of New York. Therefore, a youth aged 18 in 2014 from New York would have been exposed to the law in 2013. By the same analogy, a youth aged 18 or 19 in 2015 would have also been exposed to the law two years ago. Based on this construct, restricting the sample to youth who are not currently impacted by the law based on their age, we estimate the following specification:

\[ \text{For states where no e-cigarette MLSA laws were enacted during the study period, this variable also takes on value zero.} \]
\[ P(Smk_{i,s,t} > 0) = \sum l \Gamma X_{i,s,t} + b_1 \text{MLSA}_\text{Minor} + b_2 Z_{s,t} + \gamma_s + \lambda_t [+\gamma_{s,t}] + \epsilon_{i,s,t} \quad (3) \]

where the dependent variable denotes the probability that the youth is a current smoker, and the other variables are as defined above.

Alternately, we use the same sample of those currently aged out of e-cigarette MLSA laws, wherein MLSA_1Pass denotes an indicator for whether the e-cigarette MLSA law has been in effect in the youth’s state of residence for at least one or more years.\(^{15}\)

\[ P(Smk_{i,s,t} > 0) = \sum l \Gamma X_{i,s,t} + b_1 \text{MLSA}_1\text{Pass} + b_2 Z_{s,t} + \gamma_s + \lambda_t [+\gamma_{s,t}] + \epsilon_{i,s,t} \quad (4) \]

Building upon model (4), we further decompose MLSA_1Pass into responses to a law that has been in effect for one year and responses to a law that has been in effect for two or more years. In each of these specifications, parameter \( b_1 \) captures how youth exposure to the e-cigarette purchase restriction, at any point in time when the youth was underage (model 3) or when the law was passed one or more years ago when the youth was underage (model 4), affects their current smoking behaviors when the youth is no longer a minor.

In alternate specifications, we conduct additional checks to assess heterogeneous responses across gender and race. Finally, we implement a falsification check, assessing effects of the e-cigarette MLSA law on youth who should not be constrained or affected by the policy.

6. Results

A. Effects on Smoking

Table 2 presents estimates of the effects of e-cigarette MLSA laws on youth smoking among those under the age of 18. Panel A reports baseline effects from the difference-in-differences (DD) model specified in Equation (1). Model 1 suggests a 1.3 percentage point increase in smoking participation among youth exposed to an e-cigarette MLSA law, a 7% increase relative to the sample mean. The model utilizes the full sample window from the

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\(^{15}\) Using the same example as above, A 1 ass takes on value one in year 2014 and 2015.
YRBSS, spanning 1991-2015. Though maximizing the number of pre-policy periods\textsuperscript{16} can reduce the residual variance and improve the precision in estimating pre-policy trends within the DD framework, extending the pre-policy window too far back may introduce additional confounding. We therefore assess the sensitivity of the estimates to alternately restricting the sample window to 2005-2015 (Model 3), 2007-2015 (Model 5), and 2009-2015 (Model 7). The estimates remain quite robust and indicate a 1.0 to 1.1 percentage point increase in the probability of being a current smoker.

While all models control for additional tobacco, alcohol, and marijuana policies, we further control for state-specific linear trends in even-numbered models, in order to capture remaining time-varying state heterogeneity and potential policy endogeneity. The effect magnitudes in even-numbered models range from 0.7 to 1.4 percentage points and generally remain statistically significant. In some cases, standard errors become smaller, which may point to the presence of marked state trends, which once controlled reduces the residual variance (and hence the standard errors). One possible limitation of using state-specific trends is that it reduces the amount of identifying variation, which may be less credible (Neumark et al., 2014). Furthermore, fitting such state-specific linear trends may exacerbate bias, particularly for sample periods and pre-policy windows where trends in smoking (or other substance use) are far from linear. We therefore exercise care as the case warrants. Taking this into consideration, we continue to present models with and without state trends in all subsequent analyses.

Panel B decomposes the timing of the DD effects and presents estimates from a formal event study design. In keeping with the biennial sampling scheme of the YRBSS, these models control for indicators for the full year of policy enactment, 2 or more years post-adoption, 2 or more years pre-adoption (reference category) and 4 or more years pre-adoption. While we report models both with and without state-specific trends for completeness, we emphasize results from the latter. Wolfers (2006) cautions against adding state-specific linear trends in such timing analyses where the policy is modeled as pre-post implementation since such trends

\footnote{\textsuperscript{16}As noted earlier, NJ was the first state to enact an e-cigarette MLSA law in March of 2010.}
may confound both the state-specific time-varying unobservable as well as any dynamic effects of the policy itself. Nevertheless, both sets of specifications show largely similar patterns.

The results from the event study design underscore three points. First, e-cigarette MLSA laws appear to have a significant “contemporaneous” effect during the full year of enactment, about 1.3 percentage points on average. Owing to YRBSS’ biennial sampling frame, the enactment year indicator is defined such that it turns on if the policy took effect anytime since March of the previous wave and February of the current year. This ensures that the policy was active for at least 12 months, though it would also pick up some lag in the policy effect for up to 2 years. Second, as the lag increases, the response to policy becomes larger, on the order of 2-3 percentage points. This compounding of the policy effect over time is consistent with an interactive age response. Smoking participation generally increases with age among adolescents; current smoking participation among 16-year-olds is 10.2% compared to 5.0% among 14-year-olds. Hence, an e-cigarette MLSA law in effect when the adolescent was, for instance 14 years of age, would be expected to have a stronger “bite” as he/she ages and becomes more likely to contemplate smoking (or use other forms of tobacco) in the future. Third, the lead effects are generally small and insignificant, providing some validation of the research design and confirming that the policy is orthogonal to pre-adoption trends in smoking.

While our conceptual framework is agnostic about the direction of the effects given the potential for cigarette smoking to either substitute or complement e-cigarette use, the pattern of results that we find – suggesting an increase in smoking participation – is ex post validating when contrasted with unconditional declining trends in youth smoking over the sample period. As shown in Figure 1, unconditional trends suggest a decrease in youth smoking as e-cigarettes entered the market (2007) and e-cigarette MLSA laws proliferated across states (starting in 2010). Thus, if our models are simply reflecting this decline in smoking as states passing more e-cigarette MLSA laws, then the DD effects would have suggested (possibly spuriously) that the laws have reduced youth smoking. However, finding increases in smoking from the policy,

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17 Hence, it is not surprising that, in disentangling the timing of the effects and separating out the lead vs. lagged responses, the estimates are more sensitive to the inclusion of state-specific trends.

18 For instance, for respondents interviewed in the 2013 YRBSS, the enactment indicator would equal 1 in 2013 if the state they lived in adopted the policy anytime between March 2011 and February 2013.
despite this declining secular trend, adds some confidence that these estimates are not just reflecting the falling smoking rates.

Estimates in Table 2 suggest that when faced with e-cigarette MLSA laws, underage youth may be more likely to turn to cigarette smoking. This may prima facie seem counter-intuitive since they are also restricted from purchasing cigarettes; hence, it would appear that underage youth are turning from one restricted substance to another. However, since all youth face purchase restrictions for cigarettes over the sample period, the implementation of e-cigarette MLSA laws would increase the relative costs of accessing e-cigarettes (relative to cigarettes), affecting the demand for these substances. Because cigarettes have been in the market for a long time, most youth who smoke may have found alternative ways to bypass the purchase restrictions and obtain their cigarettes through secondary sources, such as “bumming” or borrowing from a friend or adult (Katzman et al., 2007, Hansen et al., 2013).\textsuperscript{19} Thus, it is conceivable that these youth are increasing their participation in the secondary cigarette market when purchasing e-cigarettes is prohibited. The secondary market for e-cigarettes, however, may be less well-developed, particularly when recent estimates suggest that only 3.7% of adults vape (Schoenborn and Gindi, 2015). That said, adults may be a less reliable source of e-cigarettes for teenagers in secondary markets than cigarettes.\textsuperscript{20}

In Table 3, we evaluate whether an increase in smoking persists after youth are no longer constrained by the purchasing restrictions. Thus, all models are estimated for youth who have aged out of the e-cigarette MLSA laws.\textsuperscript{21} For models reported in Panel A, we define an indicator for whether a youth was exposed to an e-cigarette MLSA law at any time while he/she

\textsuperscript{19} A dollar increase in cigarette taxes is estimated to decrease the probability of youth getting cigarettes through a secondary market by 5 or 6 percent, but cigarette taxes had little impact on youth obtaining cigarettes through borrowing or taking from a store or family member. This may suggest that they have alternative ways to bypass the rising costs of cigarettes.

\textsuperscript{20} See \url{https://www.cdc.gov/nchs/products/databriefs/db217.htm}. Furthermore, while it may be relatively easier for a youth to borrow or “bum” a combustible cigarette from a friend or adult, which by definition is disposed after use, the long-lasting properties of e-cigarettes (e.g. even one disposable e-cigarette can last up to 400 puffs or equivalent to one pack of cigarettes) makes it more difficult to borrow or bum from another user.

\textsuperscript{21} Age in the YRBSS is top-coded as 18 or above and four states (AL, AK, NJ, and UT) set the age for legally purchasing e-cigarettes at 19. We restrict the sample to youth with age top-coded as 18 or above, which may still include a few who are not old enough to buy e-cigarettes. We thus ran the same model by further excluding these four states. Our results for the variable of interest remained virtually the same.
was underage. There is little evidence from these specifications to suggest that exposure to an e-cigarette MLSA law when underage is associated with smoking behaviors when he/she has aged out. Models in Panels B and C are more explicit in specifying the timing of underage exposure. Specifically, Panel B separately assesses the effects of being exposed to an e-cigarette MLSA law both one year and two or more years ago (when the youth is below the e-cigarette MLSA age limit) on youth current smoking participation once they aged out of the law. Panel C assesses the combined effects of underage exposure to e-cigarette MLSA laws one or more years prior. Specifications that control for state-specific trends and are limited to shorter pre-policy windows (models 6 and 8) are weakly suggestive of some decline in smoking (about the same magnitude as Table 2 indicated, but in the opposite direction). However, large standard errors make the confidence intervals wide and difficult to rule out nil effects. In any case, we do not find any strong evidence that the increase in smoking persists as youth age out of e-cigarette MLSA laws. These models suggest that any effects on underage smoking, among youth exposed to an e-cigarette MLSA law, fade when they aged out of the law and are able to purchase e-cigarettes legally.

The smoking participation margin among adolescents combines first-time smoking, smoking experimentation, regular smoking, and use of multiple tobacco products including cigarettes. Table 4 presents a parallel set of models for smoking initiation to those presented in Table 3 for smoking participation. Panel A reports estimates for the baseline DD specification, and Panel B reports estimates from the event study design. We have restricted the sample to youth who have initiated smoking in the given year and youth who are non-smokers; thus youth who are current smokers but had initiated their smoking habits in prior years are excluded. As noted earlier, a youth is defined as a first-time smoker if his/her age at the time of interview matches the reported age when he/she first tried smoking. These results should be interpreted with care since smoking initiation in the YRBSS is likely coupled with recall errors in

22 Since the YRBSS is not longitudinal, this requires the implicit assumption that the youth has not changed their state of residence. Data from the 2001-2015 American Community Surveys show that, on average, about 1.3% of high-school students ages 14-18 change state of residence from one year to the next. Thus, any measurement error from assuming stable state of residence will be minimal; based on the average inter-state migration rate, only about 5% of 18 year olds may be misclassified when assigning a state of residence to when they were underage.

23 Most smokers initiate smoking during adolescence, with 16 years of age being the mode among ever-smokers (based on the 2013 National Survey on Drug Use and Health). Hence, accumulation of the addictive smoking stock is still relatively low.
the reported age at which smoking was initiated as well as the mismatch between age and wave year. These estimates are generally insignificant and imprecise, though we note that these estimates may be biased downwards from measurement error. At best, they may suggest some positive lagged effects on smoking initiation of about 1 to 2 percentage points, derived from models that control for state-specific linear trends. These magnitudes represent about half of the smoking participation effect identified in Table 2. Thus, the caveats regarding measurement error notwithstanding, it appears that the positive effects of e-cigarette MLSA laws on smoking among underage youth depicted Table 2 might have reflected some increase in initiation as well as movement across smoking and vaping in former initiates.

B. Magnitude of the Smoking Effect

Our estimates thus far suggest that when faced with e-cigarette MLSA laws, underage youth may be more likely to turn to cigarette smoking, at least until they age out of these laws. Models in Table 2 suggest a 1.0 to 1.4 percentage point increase in smoking post-policy adoption, which is consistent with findings reported by Friedman (2015) and Pesko et al. (2016). To place this magnitude in context, it should be noted that the DD effect we estimate is an intention-to-treat (ITT) effect. Most adolescents in the population would not be affected by e-cigarette MLSA laws, and thus the estimated reduced-form smoking response is an average across two groups – those who are potentially affected by e-cigarette MLSA laws and those who are not. It is unlikely that e-cigarette MLSA laws would have a direct effect on smoking behaviors, independent of their effect on e-cigarette use. If e-cigarette MLSA laws had no effect on e-cigarette use, we should expect no effects on other substance use behaviors as well.

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24 For instance, a 15-year-old surveyed in 2013 who reported that they initiated smoking at age 15 would be coded as having initiated smoking in 2013. However, the youth may have initiated smoking in 2012 while still 15 years of age.
25 It should be noted that adolescents aged 14-17 who are current smokers are likely to have initiated very recently; hence, any change in the smoking margin for this age group may still reflect initiation, experimentation, and trying out different substances.
26 Both studies find about a one percentage point increase in smoking among underage youth, based on data up to 2013. Our slightly larger estimate (up to 1.4 percentage points in some models) reflect the one additional wave of data (YRBS spanning up to 2015) in conjunction with the evidence from Table 3 that the lagged policy response is generally larger over time.
Hence, establishing the first-stage effect of how e-cigarette MLSA laws may have impacted youth e-cigarette use can help frame what the maximal effect should be for spillover responses into smoking (and other substance use) given that these individuals represent the affected group. However, estimating effects on e-cigarette use due to these policies has been a challenge because of data limitations; youth-based surveys, including the YRBSS and the MTF, have only recently started asking respondents regarding their e-cigarette use, yielding only one wave of data. Abouk and Adams (2017), for instance, estimate that the e-cigarette MLSA law is associated with a significant 10 percentage point decline in e-cigarette use among high school seniors, which may be an upper bound estimate given that it is based on cross-sectional evidence from only the 2014 MTF wave out of necessity.

The YRBSS started fielding questions on e-cigarette use in the latest 2015 wave. For suggestive evidence, we estimate a similar specification to equation (1) for outcomes related to e-cigarette use (ever use and current use) based only on the 2015 YRBSS. Appendix Table 2 suggests that, among underage youth, e-cigarette MLSA laws reduced current use by about 1.2 percentage points (6% decline relative to the sample mean of 21% vaping participation), and ever use (as a proxy for initiation) by about 4.4 percentage points (10% decline relative to the sample mean of 40% ever vaping). Similar to Abouk and Adams (2017), the effects (not shown) are somewhat larger for older adolescents (11th and 12th graders). We previously found evidence that the laws increased youth smoking by 1.0 to 1.4 percentage points, and so we calculate a back-of-the-envelope treatment-on-the-treated (TOT) effect of 0.3 using the law’s impact on ever vaping. We use ever vaping for this calculation to better match the longer duration of data available for smoking. In other words, about 1 in 3 youth may have increased their smoking as they reduced their e-cigarette use in response to the e-cigarette MLSA. These estimates should be interpreted with caution and are meant to be suggestive due to the inherent difficulties in obtaining the first-stage effect of the laws on e-cigarette use. Nevertheless, they can prove useful in gauging the credibility of the magnitudes on the second-order effects.

27 Given the single wave of data, we are not able to control for state fixed effects, and year fixed effects are not necessary. Instead, we include census region fixed effects to account for unobserved heterogeneity at this geographic level. Models are saturated with all other state-level policy controls.
C. Effects on Drinking and Marijuana Use

Next we examine whether exposure to e-cigarette MLSA laws has an effect on other substance use behaviors among underage youth. In Table 5, DD estimates are presented separately for current drinking and current binge drinking, showing little evidence of any meaningful or consistent effect on alcohol use, though these average effects may mask heterogeneity in their timing. Hence, Table 6 presents models for these drinking outcomes based on the event study design. When separating out the lead and lags, the results are more sensitive to the addition of state-specific linear trends. When considering any current alcohol participation two or more years post-policy adoption, estimates that do not control for state trends suggest nil to minor negative effects. The lagged decrease in drinking becomes stronger by 1-3 percentage points (representing 4-9% relative to the sample mean) when state trends are added. For binge drinking, the variance in the estimates is greater from models with and without state trends. Lead effects are generally close to 0 and insignificant in all models, as are the contemporaneous effects. However, there appears to be a suggestively stronger response in binge drinking over time, similar to the patterns observed for smoking participation. Estimates conditional on state trends indicate about a 1.1 to 1.7 percentage point decrease in binge drinking two or more years post policy adoption. However, estimates that do not control for state trends generally show a nil (to weakly positive but insignificant) effect on binge drinking. While there is weak evidence that binge drinking may be negatively affected with some lag, standard errors are large and we cannot reject the null in most cases. Overall, the results in Tables 5 and 6 suggest no effects of e-cigarette MLSA laws on any youth drinking.

Table 7 presents estimates of the effect of e-cigarette MLSA laws on youth current marijuana use. Only one specification, model 8, which is limited to a narrow time window spanning 2009-2015 and which controls for state linear trends, suggests a significant decline in participation. This model indicates there is on average a 0.9 percentage point decline in marijuana use post e-cigarette MLSA laws. This relationship showed a stronger response over time with a 1.4 percentage point decline within 2 years post-enactment, and a 1.8 percentage
point decline two or more years post-enactment. However, these results are not robust enough to change in the sample frame or the omission of state trends.

We note that effects on substances other than tobacco are third-order effects, and so it is not surprising that they are quite weak. Various estimates in Tables 6 and 7 are suggestive of declines in binge drinking and marijuana use in association with e-cigarette MLSA laws, though the weight of the evidence confirms that the effects are expectedly quite small or nil. Hence, while our results suggest that restricting the purchase of e-cigarettes among underage youth may have spilled over into higher smoking participation, we find little evidence of additional substitution into drinking or marijuana use.

D. Placebo Checks and Heterogeneous Effects

Given that e-cigarette MLSA laws are by definition binding only for underage youth, this suggests a natural falsification test. The policy should have no causal effect on any addictive behaviors among youth who have aged out and who were not exposed to the policy while underage. That is, even if a state enacted an e-cigarette MLSA law of 18 in 2010, youth aged 18 or older in 2010 (19 years of age or older in 2011; etc.) should not be affected since they were never exposed to the restriction even when they were underage. Table 8 carries out this falsification, defining the sample as youth that have aged out of e-cigarette MLSA laws and were never exposed while underage, for each specification and substance use outcome. All of these estimates, most notably for current smoking participation, which earlier models suggested a significant effect among affected underage youth, are generally statistically insignificant and close to zero in magnitude.\(^{28}\)

In Tables 9-12, we assess whether the response in smoking behaviors is different across gender and race. Panel A of Table 9 shows the baseline DD estimate of the effects of an e-cigarette MLSA on current smoking among underage youth, separately for males and females. Panel B shows corresponding estimates from the event study. While the DD effects tend to suggest that males may be more responsive in terms of increasing their smoking participation

\(^{28}\) Only 2 out of the 32 are significant at the 10% level, to be expected within the probability of a Type I error.
when restricted from purchasing e-cigarettes, the event study suggests that these differences may reflect the timing of the effects. The short-term response (within two years of policy enactment) tends to be slightly higher for males relative to females. This may suggest that the average age of smoking initiation for female smokers is almost one year higher than for male smokers. Over an extended period of time (two or more years post-enactment) both genders appear to be equally responsive and we find significant lagged increases in smoking participation among both males and females.

When we stratify by race (white vs. non-white) in Table 10, the effects tend to be larger among non-whites, both in terms of the absolute magnitude as well as the relative increase since baseline smoking rates tend to be lower among non-white adolescents. In the event study results for white youth, an e-cigarette MLSA law is associated with at most a 1-2 percentage point increase in current smoking within 2 years of enactment and a 2-4 percentage point increase 2 or more years post-enactment. These findings can be compared to a 2-3 percentage point increase in the short-term and about a 3-5 percentage point increase over the longer term for non-white youth. Similar to females, some of this differential pattern may be related to a higher mean age of smoking initiation among non-white youth. The differential policy impact on youth smoking between white and non-white may seem puzzling since white youth tend to use e-cigarettes at a higher rate than non-white youth and one may expect the e-cigarette MLSA laws to be more binding on white youth. We therefore further decompose the non-white sample into African American, Hispanic, and Other races and see if the policy impact was clustered among Hispanic youth who are also likely to use e-cigarettes at a higher rate. Similar to females, some of this differential pattern may be related to a higher mean age of smoking initiation among non-white youth. The differential policy impact on youth smoking between white and non-white may seem puzzling since white youth tend to use e-cigarettes at a higher rate than non-white youth and one may expect the e-cigarette MLSA laws to be more binding on white youth. We therefore further decompose the non-white sample into African American, Hispanic, and Other races and see if the policy impact was clustered among Hispanic youth who are also likely to use e-cigarettes at a higher rate.29 Appendix Table 3 confirms that Hispanic youth and other race are much more likely to increase their smoking in response to e-cigarette MLSA laws than African Americans, confirming our hypothesis. In particular, an e-cigarette MLSA law is associated with a 1.7–3.0 percentage point increase in smoking among Hispanic youth, compared to a 1.4–2.7 percentage point increase in smoking among all non-white youth.

29 According to the 2015 national YRBSS, the prevalence of having ever used e-cigarettes among Hispanic, white, and black youth is 52%, 43%, and 42% respectively. The prevalence of current e-cigarette use among Hispanic, white, and black youth is 26%, 25%, and 18%
Tables 11-12 consider the heterogeneity across gender and race, respectively, for the inter-temporal effect of being exposed to an e-cigarette MLSA law. Using the models depicted in Table 11, we find no consistent differences across males and females, suggesting that exposure to an e-cigarette MLSA law when underage does not appear to have any persistent effects on smoking when the youth is no longer subject to the restrictions. However, with respect to race (Table 12), there appears to be some marked differences in these effects. Our findings show that the increase in current smoking persists even when youth are no longer subject to the age-based e-cigarette purchase restrictions for non-whites, suggesting a 2-3 percentage point increase in smoking participation. In contrast, white adolescents are less likely to smoke if exposed to an e-cigarette MLSA law when underage, once they have met the legal age. The racial difference in the inter-temporal effects mirrors that in the “contemporaneous” response while the youth is underage (Table 10). As non-white youth were significantly more likely to turn to smoking when constrained from purchasing e-cigarettes, we find that this increase persists even when the youth have aged out. However, the increase in smoking does diminish in magnitude compared to the underage effects in Table 10. For white youth, we found smaller increases in smoking when underage, and the results in Table 11 suggest that white youth reduce their smoking participation (presumably substituting to e-cigarettes) when they are no longer constrained from purchasing e-cigarettes.

7. Conclusion:

Economic theory suggests that e-cigarette MLSA laws may reduce e-cigarette use, and we find suggestive evidence of this using a single cross-section of data. Using MTF data, Abouk and Adams (2017) reached a similar conclusion. We also find strong evidence that e-cigarette MLSA laws increased the probability of youth smoking conventional cigarettes by approximately 1 to 1.4 percentage points (8-12% relative to the mean smoking rate). In particular, youth who have not smoked in the past but initiated their first cigarettes due to the e-cigarette MLSA laws may have contributed to about half of the increase in smoking participation. The other half of the smoking increase may have come from smokers continuing to smoke rather than using e-cigarettes to quit smoking due to the restrictions. The positive
effect of e-cigarette MLSA laws on youth smoking appear to fade once youth have aged out of the law, implying that these youth eliminated their smoking once they could legally buy e-cigarettes again. Our estimates of the effect of the laws on youth smoking are slightly larger than estimates from Friedman (2015) and Pesko et al. (2016), who both found that the laws increased smoking participation by roughly 0.9 percentage points. Our slightly larger estimate reflects two additional years of data in conjunction with the evidence we find that the lagged policy response tends to be stronger than the contemporaneous response. We find some heterogeneity in these average responses based on gender and race. However, our finding that e-cigarette MLSA laws increased cigarette use is different from findings by Abouk and Adams (2017). Given that both our study and Abouk and Adams (2017) use individual-level data, this alone does not appear to account for the differences in results. Given the disagreement in the literature on if e-cigarette MLSA laws increase or decrease smoking, further research exploring this relationship is warranted.

While federal regulations require all states to have a cigarette MLSA law of at least 18, some states have made the age limit for purchasing both cigarettes and e-cigarettes higher. As of the 4th quarter of 2016, four states had an MLSA of 19 and three states (California, D.C., and Hawaii) had MLSA laws of 21. Our results suggest some caution in raising MLSA laws for both cigarettes and e-cigarettes to 21. It may be preferable to raise cigarette MLSA laws to 21, but keep e-cigarette MLSA laws at 18 to encourage youth to quit smoking using e-cigarettes. Preventing them from legally buying e-cigarettes until age 21 may harden preferences for cigarettes and make quitting at that age more difficult. We find little evidence that e-cigarette MLSA laws impact alcohol or marijuana use. Given that alcohol or marijuana is less related to e-cigarettes than conventional cigarettes, the null results we found for youth use of these two substances are somewhat expected.

In sum, results from our study suggest that it is unclear if e-cigarette MLSA laws have a positive impact on public health. It appears that some portion of the decrease in e-cigarette use, about 30% based on crude TOT estimates, may come at the cost of higher conventional cigarette use, at least in the short-term until the youth has aged out of the restrictions. If e-cigarettes are only 5% as harmful as traditional cigarettes (Tobacco Advisory Group of the Royal
College of Physicians, 2016), then e-cigarette MLSA laws leading to increased smoking may cause greater harm than benefits. However, such net costs need to be balanced against other considerations such as the potential use of e-cigarettes for smoking cessation among older youth and among longer-term smokers.
References:


### Table 1 Summary Statistics

<table>
<thead>
<tr>
<th></th>
<th>Full Sample</th>
<th>Youth younger than 18</th>
<th>Youth 18 or above</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Youth substance use</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current smoker</td>
<td>0.19 [0.40]</td>
<td>0.18 [0.39]</td>
<td>0.28 [0.45]</td>
</tr>
<tr>
<td>Current drinker</td>
<td>0.39 [0.49]</td>
<td>0.38 [0.48]</td>
<td>0.50 [0.50]</td>
</tr>
<tr>
<td>Current binge drinker</td>
<td>0.23 [0.42]</td>
<td>0.22 [0.41]</td>
<td>0.33 [0.47]</td>
</tr>
<tr>
<td>Current marijuana user</td>
<td>0.20 [0.40]</td>
<td>0.19 [0.40]</td>
<td>0.25 [0.44]</td>
</tr>
<tr>
<td><strong>Youth demographic characteristics</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Females</td>
<td>0.51 [0.50]</td>
<td>0.52 [0.50]</td>
<td>0.45 [0.50]</td>
</tr>
<tr>
<td>White</td>
<td>0.58 [0.49]</td>
<td>0.58 [0.49]</td>
<td>0.57 [0.49]</td>
</tr>
<tr>
<td>Black</td>
<td>0.15 [0.36]</td>
<td>0.15 [0.36]</td>
<td>0.17 [0.38]</td>
</tr>
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<td>Hispanics</td>
<td>0.14 [0.35]</td>
<td>0.14 [0.35]</td>
<td>0.15 [0.35]</td>
</tr>
<tr>
<td>Other races</td>
<td>0.12 [0.33]</td>
<td>0.12 [0.33]</td>
<td>0.11 [0.31]</td>
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<tr>
<td>Grade = 9th</td>
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<td>0.32 [0.47]</td>
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<td>0.26 [0.44]</td>
<td>0.11 [0.31]</td>
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<tr>
<td>Grade = 12th</td>
<td>0.21 [0.41]</td>
<td>0.12 [0.32]</td>
<td>0.87 [0.33]</td>
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<tr>
<td><strong>Merged state-level policies</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-cigarette MLSA Laws</td>
<td>0.20 [0.40]</td>
<td>0.21 [0.41]</td>
<td>0.15 [0.36]</td>
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<tr>
<td>Cigarette taxes</td>
<td>1.75 [1.04]</td>
<td>1.78 [1.05]</td>
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<td>Beer taxes</td>
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<td>Medical Marijuana Law</td>
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<td>0.59 [1.04]</td>
<td>0.50 [1.00]</td>
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<tr>
<td>State unemployment rate</td>
<td>5.92 [1.92]</td>
<td>5.91 [1.91]</td>
<td>5.95 [1.98]</td>
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<tr>
<td>Natural log of per capita income</td>
<td>10.43 [0.19]</td>
<td>10.44 [0.19]</td>
<td>10.40 [0.18]</td>
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<td>Indoor cig restrictions in private workplaces</td>
<td>1.60 [1.32]</td>
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<tr>
<td>Indoor E-cig restrictions in private workplaces</td>
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<td>Zero-tolerance law</td>
<td>0.30 [0.46]</td>
<td>0.30 [0.46]</td>
<td>0.28 [0.45]</td>
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</table>

Notes: Means and standard deviation (in bracket) are reported. Youth substance use variables are defined in the text. E-cigarette MLSA Laws and cigarette taxes data come from CDC STATE System. Beer taxes come from NIAAA. State unemployment rate and per capita income data come from Bureau of Labor Statistics. Indoor cigarette use restrictions in private workplaces are created as a three-value index ("0"—no restriction; "1"—partial restriction; "2"—full restriction) Indoor e-cig restrictions in private workplaces and zero-tolerance laws are created as indicators. Both cigarette and beer taxes are inflation-adjusted using CPI-U.
Figure 1 Youth Substance Use Trends from 1991-2015
Table 2 – E-cigarette MLSA Laws and Youth Smoking
National and State YRBSS

### Panel A: Difference-in-Difference

<table>
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<tr>
<th>DV: Yth is a current smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
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</thead>
<tbody>
<tr>
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<td>0.013</td>
<td>0.013</td>
<td>0.010</td>
<td>0.014</td>
<td>0.010</td>
<td>0.011</td>
<td>0.011</td>
<td>0.007</td>
</tr>
<tr>
<td>(0.005)</td>
<td>(0.006)</td>
<td>(0.005)</td>
<td>(0.004)</td>
<td>(0.004)</td>
<td>(0.004)</td>
<td>(0.005)</td>
<td>(0.005)</td>
<td>(0.005)</td>
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</tbody>
</table>

### Panel B: Event Study Design

<table>
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<th>DV: Yth is a current smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
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<tr>
<td>E-cig MLSA Law 3yr Prior</td>
<td>-0.004</td>
<td>-0.012</td>
<td>-0.004</td>
<td>-0.008</td>
<td>-0.004</td>
<td>-0.006</td>
<td>-0.009</td>
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<tr>
<td>(0.005)</td>
<td>(0.005)</td>
<td>(0.004)</td>
<td>(0.004)</td>
<td>(0.005)</td>
<td>(0.005)</td>
<td>(0.005)</td>
<td>(0.005)</td>
<td>(0.006)</td>
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<td>(0.005)</td>
<td>(0.007)</td>
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<td>0.017</td>
<td>0.027</td>
<td>-0.006</td>
</tr>
<tr>
<td>(0.010)</td>
<td>(0.013)</td>
<td>(0.010)</td>
<td>(0.011)</td>
<td>(0.011)</td>
<td>(0.015)</td>
<td>(0.012)</td>
<td>(0.016)</td>
<td></td>
</tr>
</tbody>
</table>

| Full Controls               | Yes   | Yes   | Yes   | Yes   | Yes   | Yes   | Yes   | Yes   |
| State FEs                   | Yes   | Yes   | Yes   | Yes   | Yes   | Yes   | Yes   | Yes   |
| Year FEs                    | Yes   | Yes   | Yes   | Yes   | Yes   | Yes   | Yes   | Yes   |
| State-specific trend        | No    | Yes   | No    | Yes   | No    | Yes   | No    | Yes   |
| Mean of DV                  | 0.18  | 0.18  | 0.14  | 0.14  | 0.13  | 0.13  | 0.12  | 0.12  |
| Observations                | 1,075,651 | 1,075,651 | 724,413 | 724,413 | 634,364 | 634,364 | 543,510 | 543,510 |

Note: Standard errors, clustered at the state level, are in parentheses

* p < 0.10, † p < 0.05, ‡ p < 0.01, ‡‡ p < 0.001

All models include controls for gender, race, age, grade, cigarette and beer taxes, zero tolerance laws, smoke-free air laws, indicator for comprehensive restrictions on e-cigarette use in private work places, state unemployment rate, and natural log of state per capita income. Both cigarette and beer taxes are inflation-adjusted using CPI-U.

The sample has been restricted to youth younger than 18 years of age.

E-cig MLSA Law is set equal to one if the law was effective before February of that year and all the subsequent years.

---

Page 139
Table 3 — Inter-temporal Relationship Between E-cigarette MLSA Laws and Youth Smoking
National and State YRBSS

Panel A:  
**DV: Yth is a current smoker**

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLSA_Minor</td>
<td>0.005</td>
<td>0.009</td>
<td>0.005</td>
<td>0.006</td>
<td>0.004</td>
<td>0.000</td>
<td>0.007</td>
<td>0.004</td>
</tr>
<tr>
<td></td>
<td>(0.009)</td>
<td>(0.010)</td>
<td>(0.009)</td>
<td>(0.009)</td>
<td>(0.009)</td>
<td>(0.010)</td>
<td>(0.008)</td>
<td>(0.014)</td>
</tr>
</tbody>
</table>

Panel B:  
**DV: Yth is a current smoker**

<table>
<thead>
<tr>
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<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLSA Passed 1 Yr Ago</td>
<td>-0.004</td>
<td>-0.006</td>
<td>-0.004</td>
<td>-0.004</td>
<td>-0.003</td>
<td>-0.015</td>
<td>-0.004</td>
<td>-0.019</td>
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<tr>
<td></td>
<td>(0.010)</td>
<td>(0.014)</td>
<td>(0.010)</td>
<td>(0.015)</td>
<td>(0.011)</td>
<td>(0.016)</td>
<td>(0.011)</td>
<td>(0.015)</td>
</tr>
<tr>
<td>MLSA Passed 2 or more Yrs Ago</td>
<td>0.012</td>
<td>0.017†</td>
<td>0.013</td>
<td>-0.002</td>
<td>0.014</td>
<td>-0.012</td>
<td>0.013</td>
<td>-0.032**</td>
</tr>
<tr>
<td></td>
<td>(0.013)</td>
<td>(0.009)</td>
<td>(0.011)</td>
<td>(0.010)</td>
<td>(0.010)</td>
<td>(0.013)</td>
<td>(0.010)</td>
<td>(0.010)</td>
</tr>
</tbody>
</table>

Panel C:  
**DV: Yth is a current smoker**

<table>
<thead>
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<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLSA Passed 1 or more Yrs Ago</td>
<td>0.005</td>
<td>0.007</td>
<td>0.006</td>
<td>-0.003</td>
<td>0.007</td>
<td>-0.013</td>
<td>0.005</td>
<td>-0.026**</td>
</tr>
<tr>
<td></td>
<td>(0.010)</td>
<td>(0.010)</td>
<td>(0.009)</td>
<td>(0.010)</td>
<td>(0.009)</td>
<td>(0.011)</td>
<td>(0.009)</td>
<td>(0.011)</td>
</tr>
</tbody>
</table>

| Full Controls | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| State FEs    | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Year FEs     | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| State-specific trend | No | Yes | No | Yes | No | Yes | No | Yes |
| Mean of DV   | 0.28   | 0.28   | 0.23   | 0.23   | 0.22   | 0.22   | 0.22   | 0.22   |
| Observations | 148,593 | 148,593 | 89,728 | 89,728 | 77,566 | 77,566 | 64,854 | 64,854 |

Note: Standard errors, clustered at the state level, are in parentheses.

" p < 0.01, "" p < 0.001

All models include controls for gender, race, grade, cigarette and beer taxes, zero tolerance laws, smoke-free air laws, indicator for comprehensive restrictions on e-cigarette use in private work places, state unemployment rate, and natural log of state per capita income. Both cigarette and beer taxes are inflation-adjusted using CPI-U.

Youth is defined as a current smoker if he/she reported smoking at least one day in the past 30 days.

The sample has been restricted to youth aged 18 or above.

In Panel A, the policy variable "MLSA_Minor" is set equal to one if an e-cigarette MLSA law was effective when the youth was underage, but he/she has now aged out of the restriction.

In Panel B, the policy variable "MLSA Passed 1 Yr Ago" is set equal to one if e-cigarette MLSA laws have been in effect for one year.

In Panel C, the policy variable "MLSA Passed 1 or more Yrs Ago" is set equal to one if e-cigarette MLSA laws have been in effect for one or more years.
Table 4 – E-cigarette MLSA Laws and Youth Smoking Initiation
National and State YRBSS

Panel A: Difference-in-Difference

<table>
<thead>
<tr>
<th>DV: Yth is a first-time smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-cig MLSA Law</td>
<td>0.005</td>
<td>0.003</td>
<td>0.003</td>
<td>0.003</td>
<td>0.003</td>
<td>-0.000</td>
<td>0.004</td>
<td>-0.004</td>
</tr>
<tr>
<td></td>
<td>(0.005)</td>
<td>(0.003)</td>
<td>(0.004)</td>
<td>(0.003)</td>
<td>(0.004)</td>
<td>(0.003)</td>
<td>(0.004)</td>
<td>(0.003)</td>
</tr>
</tbody>
</table>

Panel B: Event Study Design

<table>
<thead>
<tr>
<th>DV: Yth is a first-time smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-cig MLSA Law 3yr Prior</td>
<td>-0.004</td>
<td>-0.006</td>
<td>-0.004</td>
<td>-0.007*</td>
<td>-0.005</td>
<td>-0.008†</td>
<td>-0.007</td>
<td>-0.005</td>
</tr>
<tr>
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<td>(0.003)</td>
<td>(0.004)</td>
<td>(0.003)</td>
<td>(0.004)</td>
<td>(0.004)</td>
<td>(0.004)</td>
<td>(0.005)</td>
<td>(0.005)</td>
</tr>
<tr>
<td>E-cig MLSA Law</td>
<td>0.004</td>
<td>0.002</td>
<td>0.003</td>
<td>0.008*</td>
<td>0.003</td>
<td>0.006</td>
<td>0.004</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>(0.004)</td>
<td>(0.004)</td>
<td>(0.004)</td>
<td>(0.004)</td>
<td>(0.005)</td>
<td>(0.004)</td>
<td>(0.005)</td>
<td>(0.004)</td>
</tr>
<tr>
<td>E-cig MLSA Law 1yr Post</td>
<td>0.002</td>
<td>0.002</td>
<td>-0.000</td>
<td>0.018*</td>
<td>0.001</td>
<td>0.019†</td>
<td>0.005</td>
<td>0.010</td>
</tr>
<tr>
<td></td>
<td>(0.006)</td>
<td>(0.007)</td>
<td>(0.006)</td>
<td>(0.008)</td>
<td>(0.007)</td>
<td>(0.008)</td>
<td>(0.009)</td>
<td>(0.008)</td>
</tr>
</tbody>
</table>

Full Controls
State FEs
Year FEs
State-specific trend
Time span
Mean of DV
Observations

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
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<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>0.10</td>
<td>0.10</td>
<td>0.08</td>
<td>0.08*</td>
<td>0.08</td>
<td>0.08</td>
<td>0.08</td>
<td>0.08</td>
</tr>
<tr>
<td></td>
<td>725,311</td>
<td>725,311</td>
<td>530,574</td>
<td>530,574</td>
<td>469,598</td>
<td>469,598</td>
<td>405,568</td>
<td>405,568</td>
</tr>
</tbody>
</table>

Note: Standard errors, clustered at the state level, are in parentheses.

† p < 0.10, * p < 0.05

All models include controls for gender, race, age, grade, cigarette and beer taxes, zero tolerance laws, smoke-free air laws, indicator for comprehensive restrictions on e-cigarette use in private work places, state unemployment rate, and natural log of state per capita income. Both cigarette and beer taxes are inflation-adjusted using CPI-U.

Youth is defined as a first time smoker if his/her age at the time of the survey matches his/her age of first-time smoking cigarettes; Youth never smoked a cigarette are coded zero and youth who initiated smoking when he/she was younger than the time of the survey were excluded. Ages12 and ≥18 are dropped due to perfect collinearity.
Table 5 – E-cigarette MLSA Laws and Youth Drinking (DD)
National and State YRBSS

<table>
<thead>
<tr>
<th>DV: Yth is a current drinker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-cig MLSA Law</td>
<td>0.014*</td>
<td>-0.003</td>
<td>0.004</td>
<td>0.002</td>
<td>0.002</td>
<td>0.002</td>
<td>0.002</td>
<td>-0.002</td>
</tr>
<tr>
<td></td>
<td>(0.006)</td>
<td>(0.008)</td>
<td>(0.007)</td>
<td>(0.008)</td>
<td>(0.007)</td>
<td>(0.007)</td>
<td>(0.007)</td>
<td>(0.007)</td>
</tr>
<tr>
<td>Mean of DV</td>
<td>0.38</td>
<td>0.38</td>
<td>0.34</td>
<td>0.34</td>
<td>0.33</td>
<td>0.33</td>
<td>0.31</td>
<td>0.31</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DV: Yth is a binge drinker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-cig MLSA Law</td>
<td>0.015**</td>
<td>-0.001</td>
<td>0.007</td>
<td>0.002</td>
<td>0.004</td>
<td>0.001</td>
<td>0.005</td>
<td>-0.002</td>
</tr>
<tr>
<td></td>
<td>(0.004)</td>
<td>(0.004)</td>
<td>(0.005)</td>
<td>(0.005)</td>
<td>(0.004)</td>
<td>(0.004)</td>
<td>(0.004)</td>
<td>(0.005)</td>
</tr>
<tr>
<td>Mean of DV</td>
<td>0.22</td>
<td>0.22</td>
<td>0.19</td>
<td>0.19</td>
<td>0.19</td>
<td>0.19</td>
<td>0.18</td>
<td>0.18</td>
</tr>
</tbody>
</table>

- Full Controls: Yes
- State FEs: Yes
- Year FEs: Yes
- State-specific trend: No
- Observations: 1,034,886

Note: Standard errors, clustered at the state level, are in parentheses
* p < 0.05, ** p < 0.01

All models include controls for gender, race, age, grade, cigarette and beer taxes, zero tolerance laws, smoke-free air laws, indicator for comprehensive restrictions on e-cigarette use in private work places, state unemployment rate, and natural log of state per capita income. Both cigarette and beer taxes are inflation-adjusted using CPI-U.

Youth is defined as a current drinker if he/she reported drinking at least on day in the past 30 days.
Youth is defined as a current binge drinker if he/she, in at least 1 day of the past 30 days, drank 5 or more drinks of alcohol in a row within a couple of hours.
The sample has been restricted to youth younger than 18 years of age.
Table 6 – E-cigarette MLSA Laws and Youth Drinking (Event Study Design)
National and State YRBSS

<table>
<thead>
<tr>
<th>DV: Yth is a current drinker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-cig MLSA Law 3yr Prior</td>
<td>-0.019&lt;sup&gt;**&lt;/sup&gt;</td>
<td>-0.009</td>
<td>-0.009</td>
<td>-0.009</td>
<td>-0.008</td>
<td>-0.005</td>
<td>-0.012</td>
<td>-0.019&lt;sup&gt;**&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>(0.006)</td>
<td>(0.006)</td>
<td>(0.006)</td>
<td>(0.006)</td>
<td>(0.007)</td>
<td>(0.009)</td>
<td>(0.009)</td>
<td>(0.010)</td>
</tr>
<tr>
<td>E-cig MLSA Law</td>
<td>0.012&lt;sup&gt;***&lt;/sup&gt;</td>
<td>-0.006</td>
<td>0.003</td>
<td>-0.001</td>
<td>0.001</td>
<td>-0.002</td>
<td>0.002</td>
<td>0.006</td>
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<tr>
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<td>(0.006)</td>
<td>(0.007)</td>
<td>(0.007)</td>
<td>(0.007)</td>
<td>(0.009)</td>
<td>(0.010)</td>
<td>(0.008)</td>
<td>(0.007)</td>
</tr>
<tr>
<td>E-cig MLSA Law 1yr Post</td>
<td>0.014</td>
<td>-0.025&lt;sup&gt;**&lt;/sup&gt;</td>
<td>-0.006</td>
<td>-0.014</td>
<td>-0.009</td>
<td>-0.014</td>
<td>-0.003</td>
<td>0.012</td>
</tr>
<tr>
<td></td>
<td>(0.008)</td>
<td>(0.012)</td>
<td>(0.011)</td>
<td>(0.020)</td>
<td>(0.012)</td>
<td>(0.021)</td>
<td>(0.014)</td>
<td>(0.016)</td>
</tr>
<tr>
<td>Mean of DV</td>
<td>0.38</td>
<td>0.38</td>
<td>0.34</td>
<td>0.34</td>
<td>0.33</td>
<td>0.33</td>
<td>0.31</td>
<td>0.31</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DV: Yth is a binge drinker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-cig MLSA Law 3yr Prior</td>
<td>-0.012&lt;sup&gt;***&lt;/sup&gt;</td>
<td>-0.006</td>
<td>-0.005</td>
<td>-0.003</td>
<td>-0.004</td>
<td>0.002</td>
<td>-0.006</td>
<td>-0.001</td>
</tr>
<tr>
<td></td>
<td>(0.005)</td>
<td>(0.004)</td>
<td>(0.005)</td>
<td>(0.006)</td>
<td>(0.006)</td>
<td>(0.007)</td>
<td>(0.007)</td>
<td>(0.007)</td>
</tr>
<tr>
<td>E-cig MLSA Law</td>
<td>0.014&lt;sup&gt;**&lt;/sup&gt;</td>
<td>-0.002</td>
<td>0.007</td>
<td>-0.001</td>
<td>0.005</td>
<td>-0.004</td>
<td>0.006</td>
<td>-0.006</td>
</tr>
<tr>
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<td>(0.004)</td>
<td>(0.004)</td>
<td>(0.005)</td>
<td>(0.006)</td>
<td>(0.006)</td>
<td>(0.005)</td>
<td>(0.005)</td>
<td>(0.006)</td>
</tr>
<tr>
<td>E-cig MLSA Law 1yr Post</td>
<td>0.024&lt;sup&gt;***&lt;/sup&gt;</td>
<td>-0.011</td>
<td>0.011</td>
<td>-0.012</td>
<td>0.007</td>
<td>-0.016</td>
<td>0.011</td>
<td>-0.017</td>
</tr>
<tr>
<td></td>
<td>(0.006)</td>
<td>(0.007)</td>
<td>(0.009)</td>
<td>(0.014)</td>
<td>(0.008)</td>
<td>(0.014)</td>
<td>(0.009)</td>
<td>(0.013)</td>
</tr>
<tr>
<td>Mean of DV</td>
<td>0.22</td>
<td>0.22</td>
<td>0.19</td>
<td>0.19</td>
<td>0.19</td>
<td>0.19</td>
<td>0.18</td>
<td>0.18</td>
</tr>
</tbody>
</table>

| Full Controls               | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| State FEs                  | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Year FEs                   | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| State-specific trend       | No  | Yes | No  | Yes | No  | Yes | No  | Yes |
| Observations               | 1,034,886 | 1,034,886 | 683,964 | 683,964 | 594,461 | 594,461 | 507,232 | 507,232 |

Note: Standard errors, clustered at the state level, are in parentheses

<sup>*</sup> p < 0.05, <sup>**</sup> p < 0.01, <sup>***</sup> p < 0.001

All models include controls for gender, race, age, grade, cigarette and beer taxes, zero tolerance laws, smoke-free air laws, indicator for comprehensive restrictions on e-cigarette use in private work places, state unemployment rate, and natural log of state per capita income. Both cigarette and beer taxes are inflation-adjusted using CPI-U.

Youth is defined as a current drinker if he/she reported drinking at least on day in the past 30 days.

Youth is defined as a current binge drinker if he/she, in at least 1 day of the past 30 days, drank 5 or more drinks of alcohol in a row within a couple of hours.

The sample has been restricted to youth younger than 18 years of age.
Table 7 – E-cigarette MLSA Laws and Youth Marijuana Use
National and State YRBSS

Panel A: Difference-in-Difference

<table>
<thead>
<tr>
<th>DV: Yth is a current MJ user</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-cig MLSA Law</td>
<td>-0.004</td>
<td>-0.001</td>
<td>-0.004</td>
<td>-0.006</td>
<td>-0.004</td>
<td>-0.004</td>
<td>-0.004</td>
<td>-0.009</td>
</tr>
<tr>
<td></td>
<td>(0.005)</td>
<td>(0.006)</td>
<td>(0.004)</td>
<td>(0.005)</td>
<td>(0.005)</td>
<td>(0.004)</td>
<td>(0.004)</td>
<td>(0.005)</td>
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</table>

Panel B: Event Study Design

<table>
<thead>
<tr>
<th>DV: Yth is a current MJ user</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-cig MLSA Law 3yr Prior</td>
<td>-0.009†</td>
<td>-0.011</td>
<td>-0.005</td>
<td>-0.002</td>
<td>-0.004</td>
<td>-0.006</td>
<td>-0.006</td>
<td>0.005</td>
</tr>
<tr>
<td></td>
<td>(0.004)</td>
<td>(0.006)</td>
<td>(0.003)</td>
<td>(0.006)</td>
<td>(0.004)</td>
<td>(0.006)</td>
<td>(0.005)</td>
<td>(0.005)</td>
</tr>
<tr>
<td>E-cig MLSA Law</td>
<td>-0.005</td>
<td>0.003</td>
<td>-0.004</td>
<td>-0.006</td>
<td>-0.003</td>
<td>0.002</td>
<td>-0.002</td>
<td>-0.014†</td>
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<tr>
<td></td>
<td>(0.004)</td>
<td>(0.007)</td>
<td>(0.004)</td>
<td>(0.008)</td>
<td>(0.004)</td>
<td>(0.007)</td>
<td>(0.005)</td>
<td>(0.008)</td>
</tr>
<tr>
<td>E-cig MLSA Law 1yr Post</td>
<td>0.007</td>
<td>0.018</td>
<td>0.006</td>
<td>-0.006</td>
<td>0.005</td>
<td>0.015</td>
<td>0.007</td>
<td>-0.018</td>
</tr>
<tr>
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<td>(0.007)</td>
<td>(0.014)</td>
<td>(0.007)</td>
<td>(0.018)</td>
<td>(0.008)</td>
<td>(0.015)</td>
<td>(0.008)</td>
<td>(0.016)</td>
</tr>
</tbody>
</table>

Full Controls
- Yes
- Yes
- Yes
- Yes
- Yes
- Yes
- Yes
- Yes

State FEs
- Yes
- Yes
- Yes
- Yes
- Yes
- Yes
- Yes
- Yes

Year FEs
- Yes
- Yes
- Yes
- Yes
- Yes
- Yes
- Yes
- Yes

State-specific trend
- No
- Yes
- No
- Yes
- No
- Yes
- No
- Yes

Time span
- 1991–2015
- 2005–2015
- 2007–2015
- 2009–2015
- 2009–2015

Mean of DV
- 0.19
- 0.19
- 0.19
- 0.19
- 0.19
- 0.19
- 0.19

Observations
- 1,096,105
- 1,096,105
- 731,805
- 731,805
- 639,619
- 639,619
- 547,068
- 547,068

Note: Standard errors, clustered at the state level, are in parentheses.

† p < 0.10, * p < 0.05

All models include controls for gender, race, age, grade, cigarette and beer taxes, zero tolerance laws, smoke-free air laws, indicator for comprehensive restrictions on e-cigarette use in private work places, state unemployment rate, and natural log of state per capita income. Both cigarette and beer taxes are inflation-adjusted using CPI-U.
Youth is defined as a current marijuana user if he/she reported using marijuana at least once in the past 30 days.
The sample has been restricted to youth younger than 18 years of age.
Table 8 – Falsification Tests
National and State YRBSS

<table>
<thead>
<tr>
<th>Panel A:</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>DV: Yth is a current smoker</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>E-cig MLSA Law</td>
<td>0.011</td>
<td>0.020(^\dagger)</td>
<td>0.011</td>
<td>0.011</td>
<td>0.010</td>
<td>0.005</td>
<td>0.011</td>
<td>0.007</td>
</tr>
<tr>
<td></td>
<td>(0.009)</td>
<td>(0.010)</td>
<td>(0.009)</td>
<td>(0.009)</td>
<td>(0.009)</td>
<td>(0.009)</td>
<td>(0.008)</td>
<td>(0.015)</td>
</tr>
<tr>
<td>Mean of DV</td>
<td>0.28</td>
<td>0.28</td>
<td>0.23</td>
<td>0.23</td>
<td>0.22</td>
<td>0.22</td>
<td>0.22</td>
<td>0.22</td>
</tr>
<tr>
<td>N</td>
<td>148,593</td>
<td>148,593</td>
<td>89,728</td>
<td>89,728</td>
<td>77,566</td>
<td>77,566</td>
<td>64,854</td>
<td>64,854</td>
</tr>
</tbody>
</table>

| Panel B: |  |  |  |  |  |  |  |  |
| DV: Yth is a current drinker | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| E-cig MLSA Law | 0.012 | -0.014 | -0.006 | -0.017 | -0.008 | -0.013 | -0.011 | -0.019 |
| | (0.012) | (0.013) | (0.013) | (0.016) | (0.013) | (0.016) | (0.014) | (0.016) |
| Mean of DV | 0.50 | 0.50 | 0.47 | 0.47 | 0.46 | 0.46 | 0.45 | 0.45 |
| N | 114,634 | 114,634 | 72,924 | 72,924 | 62,881 | 62,881 | 52,542 | 52,542 |

| Panel C: |  |  |  |  |  |  |  |  |
| DV: Yth is a binge drinker | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| E-cig MLSA Law | 0.018\(^\dagger\) | -0.008 | -0.001 | -0.011 | -0.004 | -0.010 | -0.005 | -0.014 |
| | (0.009) | (0.009) | (0.009) | (0.010) | (0.009) | (0.010) | (0.009) | (0.009) |
| Mean of DV | 0.34 | 0.34 | 0.31 | 0.31 | 0.30 | 0.30 | 0.29 | 0.29 |
| N | 114,634 | 114,634 | 72,924 | 72,924 | 62,881 | 62,881 | 52,542 | 52,542 |

| Panel D: |  |  |  |  |  |  |  |  |
| DV: Yth is a marijuana user | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| E-cig MLSA Law | -0.002 | -0.003 | -0.005 | -0.014 | -0.009 | -0.009 | -0.010 | -0.016 |
| | (0.010) | (0.011) | (0.010) | (0.012) | (0.010) | (0.012) | (0.009) | (0.011) |
| Mean of DV | 0.25 | 0.25 | 0.26 | 0.26 | 0.26 | 0.26 | 0.27 | 0.27 |
| N | 113,482 | 113,482 | 74,812 | 74,812 | 65,032 | 65,032 | 54,457 | 54,457 |

| Full Controls | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| State FEs | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Year FEs | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| State-specific trend | No | Yes | No | Yes | No | Yes | No | Yes |

Note: Standard errors, clustered at the state level, are in parentheses.
\(^\dagger\) p < 0.10

All models include controls for gender, race, grade, cigarette and beer taxes, zero tolerance laws, smoke-free air laws, indicator for comprehensive restrictions on e-cigarette use in private work places, state unemployment rate, and natural log of state per capita income. Both cigarette and beer taxes are inflation-adjusted using CPI-U.

The sample has been restricted to youth aged 18 or above.
Table 9 – E-cigarette MLSA Laws and Youth Smoking (stratified by gender)
National and State YRBSS

Panel A: Difference-in-Difference

<table>
<thead>
<tr>
<th>Male</th>
<th>DV: Yth is a current smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-cig MLSA Law</td>
<td>0.016**</td>
<td>(0.006)</td>
<td>0.018**</td>
<td>(0.005)</td>
<td>0.013†</td>
<td>(0.006)</td>
<td>0.018**</td>
<td>(0.005)</td>
<td>0.012†</td>
</tr>
<tr>
<td>Mean of DV</td>
<td>0.19</td>
<td>0.19</td>
<td>0.15</td>
<td>0.15</td>
<td>0.14</td>
<td>0.14</td>
<td>0.14</td>
<td>0.14</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Female</th>
<th>DV: Yth is a current smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-cig MLSA Law</td>
<td>0.009†</td>
<td>(0.006)</td>
<td>0.008</td>
<td>(0.006)</td>
<td>0.008</td>
<td>(0.005)</td>
<td>0.009†</td>
<td>(0.004)</td>
<td>0.007</td>
</tr>
<tr>
<td>Mean of DV</td>
<td>0.18</td>
<td>0.18</td>
<td>0.13</td>
<td>0.13</td>
<td>0.12</td>
<td>0.12</td>
<td>0.12</td>
<td>0.12</td>
<td></td>
</tr>
</tbody>
</table>

Panel B: Event Study Design

<table>
<thead>
<tr>
<th>Male</th>
<th>DV: Yth is a current smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-cig MLSA Law 3yr Prior</td>
<td>-0.002</td>
<td>(0.005)</td>
<td>-0.010†</td>
<td>(0.006)</td>
<td>-0.002</td>
<td>(0.004)</td>
<td>-0.004</td>
<td>(0.005)</td>
<td>-0.001</td>
</tr>
<tr>
<td>E-cig MLSA Law</td>
<td>0.016†</td>
<td>(0.006)</td>
<td>0.021**</td>
<td>(0.007)</td>
<td>0.014†</td>
<td>(0.007)</td>
<td>0.021**</td>
<td>(0.007)</td>
<td>0.014†</td>
</tr>
<tr>
<td>E-cig MLSA Law 1yr Post</td>
<td>0.026†</td>
<td>(0.010)</td>
<td>0.035**</td>
<td>(0.012)</td>
<td>0.024†</td>
<td>(0.012)</td>
<td>0.026†</td>
<td>(0.015)</td>
<td>0.022†</td>
</tr>
<tr>
<td>Mean of DV</td>
<td>0.19</td>
<td>0.19</td>
<td>0.15</td>
<td>0.15</td>
<td>0.14</td>
<td>0.14</td>
<td>0.14</td>
<td>0.14</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Female</th>
<th>DV: Yth is a current smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-cig MLSA Law 3yr Prior</td>
<td>-0.007</td>
<td>(0.005)</td>
<td>-0.014†</td>
<td>(0.005)</td>
<td>-0.006†</td>
<td>(0.004)</td>
<td>-0.012†</td>
<td>(0.005)</td>
<td>-0.007</td>
</tr>
<tr>
<td>E-cig MLSA Law</td>
<td>0.009</td>
<td>(0.005)</td>
<td>0.012</td>
<td>(0.008)</td>
<td>0.009</td>
<td>(0.006)</td>
<td>0.017**</td>
<td>(0.006)</td>
<td>0.009</td>
</tr>
<tr>
<td>E-cig MLSA Law 1yr Post</td>
<td>0.019†</td>
<td>(0.011)</td>
<td>0.029†</td>
<td>(0.014)</td>
<td>0.022†</td>
<td>(0.010)</td>
<td>0.033†</td>
<td>(0.013)</td>
<td>0.023†</td>
</tr>
<tr>
<td>Mean of DV</td>
<td>0.18</td>
<td>0.18</td>
<td>0.13</td>
<td>0.13</td>
<td>0.12</td>
<td>0.12</td>
<td>0.12</td>
<td>0.12</td>
<td></td>
</tr>
</tbody>
</table>

| Full Controls | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| State FEs | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Year FEs | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| State-specific trend | No | Yes | No | Yes | No | Yes | No | Yes | Yes |
Table 10 – E-cigarette MLSA Laws and Youth Smoking (stratified by race)
National and State YRBSS

Panel A: Difference-in-Difference

White

<table>
<thead>
<tr>
<th>DV: Yth is a current smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-cig MLSA Law</td>
<td>0.004</td>
<td>0.003</td>
<td>-0.000</td>
<td>0.009*</td>
<td>-0.001</td>
<td>0.007</td>
<td>0.001</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>(0.007)</td>
<td>(0.006)</td>
<td>(0.006)</td>
<td>(0.005)</td>
<td>(0.006)</td>
<td>(0.006)</td>
<td>(0.005)</td>
<td>(0.006)</td>
</tr>
<tr>
<td>Mean of DV</td>
<td>0.21</td>
<td>0.21</td>
<td>0.16</td>
<td>0.16</td>
<td>0.15</td>
<td>0.15</td>
<td>0.14</td>
<td>0.14</td>
</tr>
</tbody>
</table>

Non-white

<table>
<thead>
<tr>
<th>DV: Yth is a current smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-cig MLSA Law</td>
<td>0.027*</td>
<td>0.020***</td>
<td>0.024***</td>
<td>0.018***</td>
<td>0.023***</td>
<td>0.016**</td>
<td>0.024***</td>
<td>0.014**</td>
</tr>
<tr>
<td></td>
<td>(0.008)</td>
<td>(0.005)</td>
<td>(0.006)</td>
<td>(0.005)</td>
<td>(0.006)</td>
<td>(0.005)</td>
<td>(0.006)</td>
<td>(0.005)</td>
</tr>
<tr>
<td>Mean of DV</td>
<td>0.15</td>
<td>0.15</td>
<td>0.12</td>
<td>0.12</td>
<td>0.11</td>
<td>0.11</td>
<td>0.11</td>
<td>0.11</td>
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</tbody>
</table>

Panel B: Event Study Design

White

<table>
<thead>
<tr>
<th>DV: Yth is a current smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-cig MLSA Law 3yr Prior</td>
<td>-0.006</td>
<td>-0.010*</td>
<td>-0.006</td>
<td>-0.012*</td>
<td>-0.007</td>
<td>-0.013*</td>
<td>-0.006</td>
<td>-0.007</td>
</tr>
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<td>(0.005)</td>
<td>(0.004)</td>
<td>(0.005)</td>
<td>(0.004)</td>
<td>(0.006)</td>
<td>(0.004)</td>
<td>(0.006)</td>
</tr>
<tr>
<td>E-cig MLSA Law</td>
<td>0.003</td>
<td>0.006</td>
<td>0.001</td>
<td>0.018**</td>
<td>0.001</td>
<td>0.015*</td>
<td>0.002</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>(0.007)</td>
<td>(0.007)</td>
<td>(0.006)</td>
<td>(0.006)</td>
<td>(0.006)</td>
<td>(0.007)</td>
<td>(0.006)</td>
<td>(0.010)</td>
</tr>
<tr>
<td>E-cig MLSA Law 1yr Post</td>
<td>0.010</td>
<td>0.020</td>
<td>0.008</td>
<td>0.037***</td>
<td>0.009</td>
<td>0.029*</td>
<td>0.007</td>
<td>-0.004</td>
</tr>
<tr>
<td></td>
<td>(0.011)</td>
<td>(0.013)</td>
<td>(0.009)</td>
<td>(0.012)</td>
<td>(0.010)</td>
<td>(0.016)</td>
<td>(0.011)</td>
<td>(0.020)</td>
</tr>
<tr>
<td>Mean of DV</td>
<td>0.21</td>
<td>0.21</td>
<td>0.16</td>
<td>0.16</td>
<td>0.15</td>
<td>0.15</td>
<td>0.14</td>
<td>0.14</td>
</tr>
</tbody>
</table>

Non-white

<table>
<thead>
<tr>
<th>DV: Yth is a current smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-cig MLSA Law 3yr Prior</td>
<td>-0.003</td>
<td>-0.010*</td>
<td>-0.003</td>
<td>-0.003</td>
<td>-0.002</td>
<td>0.001</td>
<td>-0.010</td>
<td>-0.003</td>
</tr>
<tr>
<td></td>
<td>(0.007)</td>
<td>(0.006)</td>
<td>(0.006)</td>
<td>(0.006)</td>
<td>(0.006)</td>
<td>(0.006)</td>
<td>(0.007)</td>
<td>(0.007)</td>
</tr>
<tr>
<td>E-cig MLSA Law</td>
<td>0.027**</td>
<td>0.025***</td>
<td>0.026***</td>
<td>0.020*</td>
<td>0.025***</td>
<td>0.013*</td>
<td>0.029***</td>
<td>0.012*</td>
</tr>
<tr>
<td></td>
<td>(0.008)</td>
<td>(0.005)</td>
<td>(0.007)</td>
<td>(0.008)</td>
<td>(0.007)</td>
<td>(0.008)</td>
<td>(0.006)</td>
<td>(0.007)</td>
</tr>
<tr>
<td>E-cig MLSA Law 1yr Post</td>
<td>0.040**</td>
<td>0.044***</td>
<td>0.042**</td>
<td>0.024</td>
<td>0.040**</td>
<td>0.008</td>
<td>0.049***</td>
<td>0.004</td>
</tr>
<tr>
<td></td>
<td>(0.017)</td>
<td>(0.010)</td>
<td>(0.013)</td>
<td>(0.017)</td>
<td>(0.013)</td>
<td>(0.017)</td>
<td>(0.013)</td>
<td>(0.017)</td>
</tr>
<tr>
<td>Mean of DV</td>
<td>0.15</td>
<td>0.15</td>
<td>0.12</td>
<td>0.12</td>
<td>0.11</td>
<td>0.11</td>
<td>0.11</td>
<td>0.11</td>
</tr>
</tbody>
</table>

Full Controls

Yes Yes Yes Yes Yes Yes Yes Yes

State FE

Yes Yes Yes Yes Yes Yes Yes Yes

Year FE

Yes Yes Yes Yes Yes Yes Yes Yes

State-specific trend

No Yes No Yes No Yes No Yes

Time span


Note: Standard errors, clustered at the state level, are in parentheses

*p < 0.10, *p < 0.05, **p < 0.01, ***p < 0.001

All models include controls for gender, race, age, grade, cigarette and beer taxes, zero tolerance laws, smoke-free air laws, indicator for comprehensive restrictions on e-cigarette use in private work places, state unemployment rate, and natural log of state per capita income. Both cigarette and beer taxes are inflation-adjusted using CPI-U.

Youth is defined as a current smoker if he/she reported smoking at least one day in the past 30 days.

The sample has been restricted to youth younger than 18 years of age.
Table 11 — Inter-temporal Relationship Between E-cigarette MLSA Laws and Youth Smoking (stratified by gender)

National and State YRBSS

Panel A:

**Male**

<table>
<thead>
<tr>
<th>DV: Yth is a current smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLSA_Minor</td>
<td>0.003</td>
<td>0.009</td>
<td>0.002</td>
<td>0.008</td>
<td>0.004</td>
<td>-0.005</td>
<td>0.008</td>
<td>-0.002</td>
</tr>
<tr>
<td></td>
<td>(0.010)</td>
<td>(0.012)</td>
<td>(0.011)</td>
<td>(0.013)</td>
<td>(0.011)</td>
<td>(0.014)</td>
<td>(0.010)</td>
<td>(0.019)</td>
</tr>
</tbody>
</table>

**Female**

<table>
<thead>
<tr>
<th>DV: Yth is a current smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLSA_Minor</td>
<td>0.008</td>
<td>0.009</td>
<td>0.009</td>
<td>0.004</td>
<td>0.005</td>
<td>0.007</td>
<td>0.006</td>
<td>0.011</td>
</tr>
<tr>
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<td>(0.012)</td>
<td>(0.012)</td>
<td>(0.011)</td>
<td>(0.011)</td>
<td>(0.011)</td>
<td>(0.012)</td>
<td>(0.010)</td>
<td>(0.013)</td>
</tr>
</tbody>
</table>

Panel B:

**Male**

<table>
<thead>
<tr>
<th>DV: Yth is a current smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLSA Passed 1 Yr Ago</td>
<td>-0.006</td>
<td>-0.017</td>
<td>-0.010</td>
<td>-0.013</td>
<td>-0.007</td>
<td>-0.033</td>
<td>-0.009</td>
<td>-0.044</td>
</tr>
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<td>(0.019)</td>
<td>(0.015)</td>
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<td>(0.016)</td>
<td>(0.023)</td>
<td>(0.017)</td>
<td>(0.026)</td>
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</table>

**Female**

<table>
<thead>
<tr>
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<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLSA Passed 1 Yr Ago</td>
<td>-0.000</td>
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<td>0.003</td>
<td>0.007</td>
<td>0.001</td>
<td>0.014</td>
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<td>(0.014)</td>
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<td>(0.019)</td>
<td>(0.012)</td>
<td>(0.022)</td>
<td>(0.013)</td>
<td>(0.018)</td>
</tr>
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</table>

Panel C:

**Male**

<table>
<thead>
<tr>
<th>DV: Yth is a current smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLSA Passed 1 or more Yrs Ago</td>
<td>0.001</td>
<td>0.000</td>
<td>-0.001</td>
<td>-0.007</td>
<td>0.002</td>
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<td>0.003</td>
<td>-0.039</td>
</tr>
<tr>
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<td>(0.011)</td>
<td>(0.015)</td>
<td>(0.011)</td>
<td>(0.017)</td>
<td>(0.011)</td>
<td>(0.017)</td>
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</table>

**Female**

<table>
<thead>
<tr>
<th>DV: Yth is a current smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLSA Passed 1 or more Yrs Ago</td>
<td>0.010</td>
<td>0.014</td>
<td>0.015</td>
<td>0.004</td>
<td>0.013</td>
<td>0.001</td>
<td>0.010</td>
<td>-0.010</td>
</tr>
<tr>
<td></td>
<td>(0.013)</td>
<td>(0.011)</td>
<td>(0.011)</td>
<td>(0.013)</td>
<td>(0.011)</td>
<td>(0.014)</td>
<td>(0.011)</td>
<td>(0.014)</td>
</tr>
</tbody>
</table>

| Full Controls | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| State FEs | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Year FEs | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| State-specific trend | No | Yes | No | Yes | No | Yes | No | Yes |

Note: Standard errors, clustered at the state level, are in parentheses.

* p < 0.10, † p < 0.05
All models include controls for gender, race, grade, cigarette and beer taxes, zero tolerance laws, smoke-free air laws, indicator for comprehensive restrictions on e-cigarette use in private work places, state unemployment rate, and natural log of state per capita income. Both cigarette and beer taxes are inflation-adjusted using CPI-U.
Youth is defined as a current smoker if he/she reported smoking at least one day in the past 30 days.
The sample has been restricted to youth aged 18 or above.
### Table 12 — Inter-temporal Relationship Between E-cigarette MLSA Laws and Youth Smoking (stratified by race)

**National and State YRBSS**

#### Panel A:

**White**

<table>
<thead>
<tr>
<th>DV: Yth is a current smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLSA_Minor</td>
<td>-0.004</td>
<td>0.001</td>
<td>-0.007</td>
<td>-0.005</td>
<td>-0.008</td>
<td>-0.010</td>
<td>-0.007</td>
<td>-0.018</td>
</tr>
<tr>
<td></td>
<td>(0.013)</td>
<td>(0.014)</td>
<td>(0.013)</td>
<td>(0.012)</td>
<td>(0.013)</td>
<td>(0.012)</td>
<td>(0.012)</td>
<td>(0.016)</td>
</tr>
</tbody>
</table>

**Non-white**

<table>
<thead>
<tr>
<th>DV: Yth is a current smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLSA_Minor</td>
<td>0.019*</td>
<td>0.025*</td>
<td>0.022*</td>
<td>0.018</td>
<td>0.020*</td>
<td>0.018</td>
<td>0.022*</td>
<td>0.028*</td>
</tr>
<tr>
<td></td>
<td>(0.011)</td>
<td>(0.013)</td>
<td>(0.011)</td>
<td>(0.011)</td>
<td>(0.011)</td>
<td>(0.012)</td>
<td>(0.011)</td>
<td>(0.014)</td>
</tr>
</tbody>
</table>

#### Panel B:

**White**

<table>
<thead>
<tr>
<th>DV: Yth is a current smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLSA Passed 1 Yr Ago</td>
<td>-0.013</td>
<td>-0.026</td>
<td>-0.018</td>
<td>-0.029</td>
<td>-0.017</td>
<td>-0.037*</td>
<td>-0.017</td>
<td>-0.060**</td>
</tr>
<tr>
<td></td>
<td>(0.018)</td>
<td>(0.023)</td>
<td>(0.019)</td>
<td>(0.020)</td>
<td>(0.019)</td>
<td>(0.021)</td>
<td>(0.019)</td>
<td>(0.019)</td>
</tr>
</tbody>
</table>

**Non-white**

<table>
<thead>
<tr>
<th>DV: Yth is a current smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLSA Passed 1 Yr Ago</td>
<td>0.016</td>
<td>0.022</td>
<td>0.018</td>
<td>0.019</td>
<td>0.019</td>
<td>0.007</td>
<td>0.014</td>
<td>0.027</td>
</tr>
<tr>
<td></td>
<td>(0.014)</td>
<td>(0.015)</td>
<td>(0.013)</td>
<td>(0.017)</td>
<td>(0.013)</td>
<td>(0.017)</td>
<td>(0.012)</td>
<td>(0.021)</td>
</tr>
</tbody>
</table>

#### Panel C:

**White**

<table>
<thead>
<tr>
<th>DV: Yth is a current smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLSA Passed 1 or more Yrs Ago</td>
<td>-0.006</td>
<td>-0.007</td>
<td>-0.007</td>
<td>-0.016</td>
<td>-0.005</td>
<td>-0.030*</td>
<td>-0.005</td>
<td>-0.051***</td>
</tr>
<tr>
<td></td>
<td>(0.013)</td>
<td>(0.013)</td>
<td>(0.012)</td>
<td>(0.012)</td>
<td>(0.012)</td>
<td>(0.014)</td>
<td>(0.012)</td>
<td>(0.014)</td>
</tr>
</tbody>
</table>

**Non-white**

<table>
<thead>
<tr>
<th>DV: Yth is a current smoker</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLSA Passed 1 or more Yrs Ago</td>
<td>0.021*</td>
<td>0.026*</td>
<td>0.023*</td>
<td>0.002</td>
<td>0.022*</td>
<td>0.001</td>
<td>0.017</td>
<td>0.003</td>
</tr>
<tr>
<td></td>
<td>(0.011)</td>
<td>(0.013)</td>
<td>(0.010)</td>
<td>(0.015)</td>
<td>(0.011)</td>
<td>(0.015)</td>
<td>(0.011)</td>
<td>(0.018)</td>
</tr>
</tbody>
</table>

**Full Controls**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
</tr>
</thead>
</table>

**State FEs**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
<th>Yes</th>
</tr>
</thead>
</table>

| Year FEs | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| State-specific trend | No | Yes | No | Yes | No | Yes | No | Yes |

**Time span**

|---|------|---------|---------|---------|

**Note:** Standard errors, clustered at the state level, are in parentheses.

* p < 0.10, † p < 0.05, ‡ p < 0.01, ‡‡ p < 0.001

All models include controls for gender, race, grade, cigarette and beer taxes, zero tolerance laws, smoke-free air laws, indicator for comprehensive restrictions on e-cigarette use in private work places, state unemployment rate, and natural log of state per capita income. Both cigarette and beer taxes are inflation-adjusted using CPI-U.

Youth is defined as a current smoker if he/she reported smoking at least one day in the past 30 days.

The sample has been restricted to youth aged 18 or above.
Appendix Table 1 National and State YRBSS Observation Counts
State

1991

1993

1995

1997

1999

2001

2003

2005

2007

2009

2011

2013

2015

Total

Alabama
Alaska
Arizona
Arkansas
California
Colorado
Connecticut
Delaware
D.C
Florida
Geogia
Hawaii
Idaho
Illinois
Indiana
Iowa
Kansas
Kentucky
Louisiana
Maine
Maryland
Massachusetts
Michigan
Minnesota
Mississippi
Missouri
Montana
Nebraska
Nevada
New Hampshire
New Jersey
New Mexico
New York
North Carolina
North Dakota
Ohio
Oklahoma
Oregon
Pennsylvania
Rhode Island
South Carolina
South Dakota
Tennessee
Texas
Utah
Vermont
Virginia
Washington
West Virginia
Wisconsin
Wyoming
Total

2,444

5,120

3,917
1,596

4,421

2,099

1,862

1,026

1,742
141

435
395
1,974
259

1,107
2,336
1,985
268
1,887

131
1,435
2,479

408
1,670
2,198
658

1,721
1,439
3,714
281
1,730

3,502
1,503
1,553

483
1,268
3,545
1,979
2,110

2,131

2,863

3,333

2,442
2,633

1,997
2,357

2,528
1,218
2,846
1,927
2,802
193
2,319
2,257

1,845
1,183
1,744
1,802
2,463
304
2,377
2,590

1,810
1,343
2,698
2,746
5,779
270
2,429
2,638

863
811
1,531

5,130
486

5,461
2,469
1,702
315
2,061

6,840
2,278
4,467
2,090
3,793
824

340
1,563
691
1,830
261
213
3,772

5,098
2,744
1,148
1,384
2,956
2,653
1,666
1,692
3,842
1,299
1,267
1,486
718
3,723

6,854
402

1,843
440
178

4,982
3,579
1,627
1,667
492
1,682
1,588
1,909
3,766
158
1,325
1,398
257
3,479
95

1,654
1,279
3,876
1,327
1,877
297
2,000
2,421
316
7,409
2,033
4,172
1,921
4,500
3,062
1,513
2,133
1,973
1,115
9,079
2,793
289
4,711

30,930
9,326
24,006
19,937
29,894
2,491
15,693
23,437
824
50,627
23,956
18,800
22,836
29,171
14,259
7,293
10,734
19,401
13,194
44,961
114,835
4,272
42,230
1,642
21,299
22,615
37,385
19,782
19,964
27,823
12,712
37,647
92,409
36,523
17,572
3,519
12,683
887
5,493
22,435
36,420
20,377
22,482
46,426
26,528
69,509
16,317
1,854
21,423
25,627
24,599
1,277,059

1,177
2,728
4,107
416
269

2,491
1,550
3,970
4,272

2,536
1,202
101
242
214
508
547
445
1,231
3,303
242

766
479
247
2,426
252
454
3,259
373

249
145
370
144
322
1,749
183
2,489
3,560
2,005
2,662
661
491
2,712

135

524

488

188
362

6,020
1,638
2,517
4,513
141
687
422

38,055

4,619
1,336
3,735
1,358
4,338

376
3,107
3,272
61,594

230

624
198

1,525

274
1,110

2,284
204
1,455
6,039
2,060
823
1,632
4,385

3,134

255
3,864

1,746
5,386
2,493

1,827
1,459
2,402

2,178
2,175
2,820

2,133
2,095
2,810

1,507
2,072

1,453

1,652

1,676

737
280
4,043
339

235

2,324
155
309
3,191
1,580
224
397
184

171

214

675
344
1,382

354
768
1,528

273
1,873
1,509
553

671
5,434
1,177
1,198
3,144
64
83
2,071
1,674
53,046

556
223
272
1,494
6,003
1,589
578
949
1,349

108
1,808
1,603
2,033
64,392

3,995
509
1,789
564

487
75
5,313
1,643
265
2,715
1,479
6,868
746
1,308
1,855
1,590
55,927

1,361
1,596
611
9,022
1,042
6,967
54
261
2,327
2,684
66,383

1,471
1,798
2,678
2,913
1,947
1,298
305
104
9,987
2,522
1,649
299
1,366
316
1,775
887
2,100
1,919
2,628
1,537
6,184
245
1,719
2,278
1,507
84,328

45

1,963
2,987
3,706
1,529
1,249
1,800
5,417
9,939
4,466
1,710
279
1,923
268
423
2,316
1,567
1,567
1,924
5,821
1,710
6,997
349
101
1,549
2,593
2,455
107,271

5,591
3,146
1,692
2,102
4,432
1,473
2,196
1,726
1,437
8,445
1,590

1,923
1,865
3,846

3,636
188
1,763
1,681
1,785

1,729
1,581
689
2,780
13,688
3,975
1,722

2,403
1,450
2,203
5,495
15,335
5,550
1,767

2,842

1,397
247
1,067
3,106
1,070
2,122
2,176
4,766
1,544
8,190
98
246
2,071
3,074
2,802
127,152

210
2,133
1,206
1,577
2,182
4,906
2,097
5,744
439
1,598
2,234
2,174
108,555

1,846
344
4,022
3,719
207
1,359
1,730
5,685
13,161
3,324
1,863
1,136
450
3,814
1,437
1,502
2,874
5,841
1,657
8,267
1,603
167
2,375
3,615
2,439
136,187

2,089
2,257
1,063
8,343
51,769
4,627
292
2,144
1,825
4,745
1,824
2,069
1,590
2,027
5,325
10,409
2,171
1,919
158
1,465
264
2,357
1,553
1,273
1,847
3,479
2,118
7,776
195
1,753
2,776
2,924
171,026

2,050
4,022
2,057

2,465
9,112
54,356
264
4,879
745
2,040
1,594
4,308
1,634
1,787
14,310
208
8,486
10,406
5,891
2,064
227
1,934
483
4,004
1,311
1,257
4,371
1,226
20,151
4,310
102
1,803
2,317
203,143

Page 150


Appendix Table 2 – Cross-sectional Relationship Between E-cigarette MLSA Laws and Youth Use of E-cigarettes

National and State YRBSS

<table>
<thead>
<tr>
<th></th>
<th>Ever used e-cigarettes</th>
<th>Current vapor</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-cig MLSA Law</td>
<td>-0.044**</td>
<td>-0.012</td>
</tr>
<tr>
<td></td>
<td>(0.016)</td>
<td>(0.015)</td>
</tr>
<tr>
<td>Mean of DV</td>
<td>0.40</td>
<td>0.21</td>
</tr>
<tr>
<td>Full controls</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Census Region FEs</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Year</td>
<td>2015</td>
<td>2015</td>
</tr>
<tr>
<td>N</td>
<td>145,950</td>
<td>178,444</td>
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Note: Standard errors, clustered at the state level, are in parentheses

** p < 0.01

All models include controls for gender, race, age, grade, cigarette and beer taxes, zero tolerance laws, smoke-free air laws, indicator for comprehensive restrictions on e-cigarette use in private work places, state unemployment rate, and natural log of state per capita income. Both cigarette and beer taxes are inflation-adjusted using CPI-U.

Youth is defined as a current vapor if he/she reported using e-cigarettes at least one day in the past 30 days

The sample has been restricted to youth younger than 18

E-cig MLSA Law is set equal to one if the law was effective before February 2015.
Appendix Table 3 – E-cigarette MLSA Laws and Youth Smoking
(Stratified non-white sample)
National and State YRBSS

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<td>E-cig MLSA Law</td>
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<td>0.007</td>
<td>0.009</td>
<td>0.013*</td>
<td>0.009</td>
<td>0.014*</td>
<td>0.010</td>
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<td>0.029***</td>
<td>0.028***</td>
<td>0.020**</td>
<td>0.027**</td>
<td>0.018**</td>
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<td>(0.006)</td>
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</table>

|                      | 1       | Yes     | Yes     | Yes     | Yes     | Yes     | Yes     |
| Full Controls        | Yes     | Yes     | Yes     | Yes     | Yes     | Yes     |
|                      | Yes     | Yes     | Yes     | Yes     | Yes     | Yes     |
| State FEs            | Yes     | Yes     | Yes     | Yes     | Yes     | Yes     | Yes     |
|                      | Yes     | Yes     | Yes     | Yes     | Yes     | Yes     |
| State-specific trend | No      | Yes     | No      | Yes     | No      | Yes     | Yes     |

Note: Standard errors, clustered at the state level, are in parentheses.

* p < 0.10, ** p < 0.05, *** p < 0.01, **** p < 0.001
All models include controls for gender, race, age, grade, cigarette and beer taxes, zero tolerance laws, smoke-free air laws, indicator for comprehensive restrictions on e-cigarette use in private work places, state unemployment rate, and natural log of state per capita income. Both cigarette and beer taxes are inflation-adjusted using CPI-U.
Youth is defined as a current smoker if he/she reported smoking at least one day in the past 30 days.
The sample has been restricted to youth younger than 18 years of age.
Liberating Nicotine from Smoke to Save Lives Now:

Facing and Answering 7 Core Questions* to Guide Regulation, Policy, and Communications.


* The 7 core questions were originally put forth by Mitch Zeller, Director, Center for Tobacco Products, U.S. Food and Drug Administration.
Background

E-cigarettes and vaping are a contentious and complicated issue, and they also raise critical questions about society’s acceptance of the use of nicotine in any form. Seven core issues are raised by the emergence of a class of innovative products (like e-cigarettes) as alternative modes of nicotine delivery without combustion of tobacco. Emerging products are fundamentally changing the way nicotine is delivered and may disrupt the 120+ year reign of the cigarette as the dominant mode of delivering a deadly inhaled mix of toxic smoke along with nicotine.

The 50th Anniversary Surgeon General’s Report bluntly concluded: “The burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products; rapid elimination of their use will dramatically reduce this burden” p.7 and “The current rate of progress in tobacco control is not fast enough. More needs to be done.” p. 875.

Going forward, to minimize preventable premature death and suffering as quickly as possible, we present these responses to the seven issues, integrating both current science and values-based policy analysis to the critical questions that underpin regulations and communications on nicotine. Our focus is on the core issues raised by nicotine; at times, we mention vaping as a topical and clearly popular example, but vaping is merely an example, not the central issue. The central focus is more generally about reframing nicotine use to complement and enrich existing tobacco control strategies in the context of the very different modes of nicotine delivery when decoupled from the toxins in the inhaled smoke from combusted tobacco.

Can longer-term use of nicotine for those who need it be accepted?

As an alternative to the high probability of premature death from smoking, long-term use of nicotine delivered by relatively less harmful, non-combusted means is acceptable. The smoke inhaled from burning tobacco (combustibles like cigarettes) is deadly from the carbon monoxide and cancer-causing chemicals in the tar and not from the nicotine itself. For every two people who continue a lifetime of smoking, one life will be lost prematurely. People smoke for the nicotine but they die from the tar. Providing smokers with acceptable less harmful nicotine alternatives can yield massive health benefits. As an example, e-cigarette use (called vaping) is dramatically less harmful than combustibles. The United Kingdom Royal College of Physicians says: “Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure” (p. 87). Expert reviews of toxicological, clinical, and epidemiological evidence indicate that nicotine does not cause cancer and that the chemicals released during vaping are far fewer and well below the harm from inhaled smoke. New data should always be considered and added to the available evidence, but the public deserves our best judgment based on what we now know.

The dramatic difference in risk and in product characteristics between non-combusted modes of nicotine delivery and the toxic inhaled smoke from combustion should drive both personal decisions and the policy discourse about nicotine. The alternative classes of emerging products are vastly different from cigarettes. Thus, harms from nicotine also vary dramatically by different modes of delivery, including FDA-approved nicotine replacement medicinal products, non-combusted products like e-cigarettes and low-nitrosamine Swedish snus, all of which likely (or almost certainly) can be used long-term by most smokers with little evidence of harm from the long-term use of nicotine itself.

What about recreational nicotine use for adults who may want it?

Users of noncombustible nicotine should know there may be some risks, although dramatically smaller than the risk of cigarettes and other combustibles and should be able to choose based on accurate

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1 The 7 core questions were originally put forth by Mitch Zeller, Director, Center for Tobacco Products, U.S. Food and Drug Administration
relative risk information. In terms of impacts on health, recreational use of noncombustible nicotine by adults is vastly different from combustible smoking; the two should not be equated and such misperceptions should be corrected. Consumers must have full accurate and up-to-date information about relative harms of the different classes of nicotine products to make informed decisions.\(^{13}\)

**Can a short transitional period of dual use be ok? Or a longer period?**

Using both noncombustible nicotine products and cigarettes (dual use) is common among those attempting to quit smoking.\(^{14-16}\) Most smokers quitting with FDA-approved nicotine replacement therapy (NRT) still smoke and such use is permitted by labeling.\(^{17}\) Basically, dual use is a transition where a smoker tries out alternative products and methods until they find one that helps them stop smoking. This process can take time and should not be discouraged as a pathway towards eventual quitting or exclusive use of less harmful products. The goal must remain stopping use of combustibles completely and as soon as possible, but some smokers may need longer transition periods to achieve this goal. There is increasing scientific evidence that those who persist in finding an alternative nicotine product that is appealing and satisfying to them and then use it daily over an extended period (e.g. a month or more, rather than only a few times) are much more likely to quit smoking cigarettes or become exclusive e-cigarette users during the year following cessation of cigarettes.\(^8,16,18-22\)

**How much youth initiation can we tolerate?**

We should strive to prevent all youth initiation of nicotine. We should prohibit the sale of all nicotine-containing products to those under legal purchase age, something we are now doing in all 50 states. But this goal must be tempered by the realities of adolescent behavior despite our best prevention efforts.

Even with sales prohibitions, some youth will at least experiment with novel products, via “leakage” of products sold to adults into the underage market as youth do with many products, especially those predisposed to risk taking. On the one hand, if the leakage is to teenagers who otherwise would never have used nicotine in any form it is a potential concern from a health perspective if use persists beyond experimentation. A more substantial concern would accrue if some of those who would otherwise have been non-users of nicotine subsequently transition to becoming lifetime cigarette smokers. But the extent, or even the existence, of that behavior pattern remains unknown. On the other hand, use of e-cigarettes by those who otherwise would have started smoking anyway – or those who are already smoking and trying to quit – likely might represent a net health gain if e-cigarette use indeed displaced or prevented further progression to cigarette use.

Kozlowski and Warner (2017) carefully reviewed the evidence to date concerning the actual patterns of e-cigarette and tobacco use as well as the concerns of excessive harms to youth of having alternative less harmful forms of nicotine delivery on the marketplace.\(^{23}\) After a steep rise from 2011-2014, e-cigarette use among youth dropped significantly in 2016 and use remains largely experimental and among those already using tobacco.\(^{24-27}\) Kozlowski and Warner (2017) concluded that while society must be vigilant in tracking trends, the fears of harms seem to be exaggerated and are unlikely to undermine the larger potential benefits of alternative nicotine delivery systems being on the market (see also: Levy et al, 2016; Villanti et al 2016; Warner, 2015; 2016; Glasser et al, 2017).\(^8,25-28\) Such modes of delivery ideally should eventually make the use of smoked tobacco obsolete, protecting youth and adults alike from the most deadly form of nicotine delivery via combustion.\(^{29}\) Moreover, for adults and society in general, misleading youth or keeping from them truthful information to get them to do what we want is always a failed strategy.\(^{13}\)

**How much weight should diminished interest in quitting play?**

There is no evidence to suggest that meaningful numbers of people who have tried e-cigarettes or initiated dual use will stop there and lose all interest in achieving full cessation of combustibles. In fact, in the
years when e-cigarette use has increased most sharply, we have seen a faster drop in cigarette use among both adolescents and adults, leading to record low rates - and we also have seen a greater number of quit attempts in adults over that same time period.\textsuperscript{16,23,26,27,30,31} Until and unless evidence emerges that vaping substitutes for quitting, the possibility that it might deserves little weight in decision-making. What’s more, increasing evidence from recent and more scientifically robust studies indicates that alternative nicotine delivery systems, such as e-cigarettes, have surpassed nicotine replacement therapies as the leading method smokers are using to quit smoking.\textsuperscript{16} E-cigarette use is also associated with greater numbers of quit attempts and cessation success when used on a regular basis and with the availability of newer devices that deliver nicotine more effectively.\textsuperscript{8}

Can we revise labeling and indications for medical nicotine to increase quitting?

Quitting smoking is hard. Information that improves quit rates is therefore valuable. Many smokers wrongly believe any use of nicotine is as harmful as the use of combustibles,\textsuperscript{32-34} to some extent, that belief stems from misguided public health efforts. Smokers should know that nicotine without smoke is much less damaging to their health than nicotine in combustibles. Non-combustible nicotine products can be useful for smoking cessation.\textsuperscript{8,16,19,22,35,36} Alternative nicotine delivery can help smokers cut down and eventually quit by reducing the urge to smoke or preventing relapse.\textsuperscript{17} Sound public education must fully communicate the relative safety of different modes of nicotine delivery and especially when nicotine is decoupled from combusted tobacco smoke.\textsuperscript{13}

Where does the principle of harm reduction come in?

Harm reduction, like in many other areas of public health, should be embraced in tobacco control. It is a pragmatic approach that complements and enriches our proven current tobacco control efforts. Harm reduction is often misunderstood in the tobacco control community. Contrary to some skeptics’ characterizations, harm reduction acknowledges that no use of nicotine is preferred to any use of nicotine; thus, both prevention of any use of nicotine by underage youth and cessation of smoking by adults is desirable. However, for those who continue to smoke, it is pragmatic to recommend using lower-harm alternatives to combustibles to save many more lives that would otherwise be lost prematurely. This harm reduction strategy is consistent with the 50\textsuperscript{th} anniversary Surgeon General’s admonition that more must be done now to eliminate the preventable deaths overwhelmingly caused by cigarettes and other smoked tobacco use.\textsuperscript{1}
References


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Tobacco 21 laws are *bad* for public health

Separating Fact from Speculation

A presentation by:

thr4LIFE

Tobacco Harm Reduction 4 Life

Leading the way toward a Smoke-free America

Minnesota Smoke-free

THR4LIFE is a non-profit 501(c)(3)
**Background:** Tobacco 21 is an initiative to raise the minimum legal sales age (MLSA) for tobacco and vapor products. Proponents of this measure are admittedly crusading the state of Minnesota in an effort to convince municipalities to participate in the agenda, in hopes they can eventually convince lawmakers to pass the policy at a state level.

While on the surface ‘raising the smoking age’ may seem like a noble idea, upon further investigation, we find any potential benefit of the policy to be outweighed by the potential harm.

**Objective:** In this presentation, we aim to separate fact from speculation and misinformation by outlining popular claims made by Tobacco 21 proponents, followed by the results of our research and analysis.

**Our Mission:** Tobacco Harm Reduction 4 Life (THR4Life) was established to help smokers regain control over their lives by providing balanced and accurate information about tobacco harm reduction. We believe that honesty and transparency in public health is imperative to the long term well being of our communities. We assert that the best way to protect future generations from the harms of tobacco, is to begin with the adults in their lives. We advocate for the technological innovation of tobacco harm reduction as paving the way toward a smoke-free future, a healthier population, and a cleaner environment.
CLAIM: *Raising the minimum legal age to purchase tobacco products will reduce the amount of tobacco use by high school students.*

ANALYSIS: There is currently no conclusive evidence to indicate that Tobacco 21 laws are effective in preventing youth from tobacco use and access. There are ‘tobacco control’ commissioned, methodologically lacking surveys that speculate hopeful statistics, however, hopeful speculation does not qualify as conclusive evidence. *Psychological reactance may cause the target objective to backfire, increasing smoking*

We need to stop and think about the sociological and psychological repercussions of violating the Age of Majority rights, and arguably the Constitutional rights, of young adults. We need to consider the impact of removing freedoms from the same demographic of people that we are concurrently encouraging to risk their lives in service to our country, in the name of protecting our freedom. When rules are perceived as arbitrary, it adds to an overall diffidence toward the law. As young adults realize their freedom to chose has been removed, they may enter into reactance motivational state and act to regain control by not complying. The term for this is psychological reactance - an aversive affective reaction in response to regulations or impositions that impinge on freedom and autonomy. This is a very ‘human’ and common reaction to loss of free will, and has the potential to increase smoking.

Young people are particularly susceptible to unintended reverse psychology effects as they develop an appetite for independence. When making their own choices is at such a high level of importance to them, creating a new forbidden fruit to tempt them with is imprudent. By ‘raising the smoking age’, we are drawing unnecessary attention to smoking during a time when smoking among youth is already declining at an unprecedented rate.

Instead of creating an environment of ‘control’ for youth to rebel against, we need to foster a more positive environment that encourages youth to make good decisions because they want to. The appropriate response to our unprecedented decline in youth smoking and vaping, is to applaud our youth for making good choices and focus on positive reinforcement for a continued positive outcome. Tobacco 21 is essentially a punishment for doing well. Removing the simple freedom of choice from legal adults, is an inappropriate response to our declining youth [and adult] smoking rates.
Tobacco 21 sets the stage for black market, increasing tobacco access among youth

Under Tobacco 21 laws, cities lose revenue to neighboring cities and states while simultaneously **setting the stage for a bolstered black market for cigarettes in our schools**. Nothing is stopping a motivated 18-year-old from simply driving to neighboring cities or states, picking up cigarettes, and driving back to capitalize on the new business opportunity. This idea is nothing new. Many Minnesota smokers make the trek to North Dakota and Wisconsin for tax-free smokes since Minnesota raised the sin tax on cigarettes. Furthermore, cigarettes can easily be purchased online, duty-free. Keep in mind, these young “entrepreneurs” will **not be requiring age verification for sales**.

Prohibition is a failed strategy

History repeats itself; this is indisputable. Looking at our history can provide us with clarity and wisdom in making future decisions. When considering whether or not to enact a new prohibition, it is critical that we take a look at the results of similar prohibitive measures.

Alcohol prohibition was a failed strategy

The United States has a complex history regarding the legalization of dangerous drugs. In 1920, the 18th Amendment banned the sale of alcohol. The amendment aimed to stem what was seen as a growing moral decay of society and eventually led to the passage of the 19th Amendment, which gave women the right to vote.

But the 18th Amendment had some other major consequences as well. It helped create an epidemic of organized crime, giving rise to the era of Al Capone and others. It also cut down on tax revenues that could have helped the United States during the start of the Great Depression. In 1933, the 21st Amendment was approved, repealing the disastrous attempt at prohibition authorized by the 18th Amendment.

Raising the drinking age increased college binge drinking, does not prevent youth access

Since raising the drinking age to 21, there's been an **increase in college binge drinking** (ages 18-24). According to the CDC, "people aged 12 to 20 years drink 11 percent of all alcohol consumed in the United States. More than 90 percent of this alcohol is consumed in the form of binge drinks. On average, underage drinkers consume more drinks per drinking occasion than adult drinkers."

Alcohol is responsible for the deaths over 1,000 people in the U.S. between the age of 18-24 every year. The National Institute on Alcohol Abuse and Alcoholism says that even though the "21 year-old
drinking age has been in place for over 25 years, we are still facing an environment where drinking by people under 21 is the norm."

Statistically, more teens use alcohol, than cigarettes and marijuana combined - despite the legal drinking age being 21.

Prohibition on drugs remains ineffective

Similarly, the war on drugs has done nothing to decrease drug use. All it’s done is create a violent black market, the highest incarceration rate on the planet, and has cost the U.S. over $1 trillion since Nixon initiated it in the 1980’s.

“Torches of Freedom”, when discriminatory tobacco prohibitions backfire

Before the twentieth century, smoking was seen as a habit that was corrupt and inappropriate for women, and some states tried to prevent women from smoking by enforcing laws. In 1908 the New York City Board of Aldermen unanimously passed an ordinance that prohibited smoking by women in public. Following in 1921, a bill was proposed to prohibit women from smoking in the District of Columbia. Cigarettes became a way for women to challenge social norms and fight for equal rights as men. Eventually for women the cigarette came to symbolize ‘rebellious independence’. Women who otherwise wouldn’t have smoked, began smoking as a statement of social and political activism. This is a prime example of psychological reactance in regard to a tobacco prohibition, specifically one that unequally discriminated against a particular demographic of U.S. adults. This prohibitive attempt was rendered
ineffective at accomplishing the desired outcome, and resulted in an increase in smoking among the targeted demographic.

All of this proves that prohibition and restriction do not work. Every time the United States has opted to ban some kind of drug in some shape or form, a thriving drug trade has been born. Is that the kind of future we want to create for our children and our society? This kind of solution is not the kind that the state of Minnesota should pursue. Raising the age for tobacco consumption and purchase will not stem usage.

**Tobacco 21 laws push youth toward traditional cigarettes**

Tobacco 21 does nothing to prevent youth from obtaining cigarettes through other common means such as stealing them from a store or a parent, obtaining them consensually from a friend or family member over the age of 21, or even scavenging ash trays outside of grocery stores and gas stations.

Tobacco 21 prevents adults age 18-20 from access to smoke-free vapor products, which the Royal College of Physicians has concluded to be at least 95 percent less harmful than smoking. This measure is poised to keep the 90 percent of people who start smoking before the age of 18, bound to cigarettes for three additional years, hardening an addiction to smoking.

In a recently published National Bureau of Economic Research Working Paper titled "The Effects of E-cigarette Minimum Legal Sale Age Laws on Youth Substance Use", research supported by the National Institutes of Health concluded that laws banning sales of e-cigarettes to young adults actually pushes youth toward traditional cigarettes. Strict enforcement of these laws is linked to an increase in youth smoking participation of 0.7 to 1.4 percentage points. The study concludes that the unintended consequences of these laws is concerning and may have a negative impact on public health.

Tobacco 21 laws do not prevent 18 - 20 year olds from smoking. Under this policy, adults (age 18 - 20) are still legally allowed to possess and use tobacco products. Tobacco 21 simply creates an easily surmountable hurdle for those that smoke to obtain cigarettes, while discouraging access to and education in tobacco harm reduction products.

**CLAIM:** Needham Mass. saw a 48% decrease in youth smoking rates after implementing Tobacco 21.

**ANALYSIS:** Tobacco 21 proponents often cite Needham, Mass. as their golden example of the policy's success. Unfortunately, their claims are misleading, as they fall short of telling the whole story. The Boston suburb did see an impressive 48% reduction in teen smoking rates from 2006 to 2012 after implementing the policy, however, as Needham's director of public health points out, the city had enacted multiple other tobacco control efforts at the same time. "I wouldn't say it's all because of this [Tobacco 21]," she told WNYC. Additionally, 'the study analyzed data starting in 2006, a year after the
purchasing age hike. Kessel Schneider, study co-author, acknowledged this as a possible limitation to
the research as it's unclear exactly how teen smoking was trending in Needham during the years
leading up to the policy change.

The entire nation's smoking rates have been steadily declining for decades, reaching historic lows;
Needham is hardly an exception. For example, from 2011 to 2016, Minnesota's youth smoking rates
decreed by 56% despite having no Tobacco 21 laws in place.

Out of the 2 states and 200 plus communities that have passed this policy, this out of context and
inconclusive example of Needham, Mass. remains the only statistical claim of Tobacco 21 success.

**CLAIM:** Nicotine is highly addictive and dangerous.

**ANALYSIS:** The popular perception has long been that it is the nicotine that ‘addicts’ people to
smoking, but according to a number of recent studies, including one by the Royal College of Physicians
(RCP), this is not the case. The RCP is one of the most respected medical research groups in the world,
and was the the first to tell us smoking is dangerous. In their 2016 report “Nicotine without smoke:
Tobacco harm reduction”, RCP reports that nicotine, when isolated from the other chemicals in
tobacco cigarettes, is relatively benign in its harm, benefit, and addictiveness (compare to
caffeine), and that the most harmful and addictive property of tobacco cigarettes is not the nicotine,
rather it is the chemical laced smoke of combustible tobacco that is to blame for tobacco related cancers,
diseases, and addiction. This is why tobacco companies add thousands of additional chemicals to
tobacco - to create an addiction above and beyond simple nicotine.

This is echoed by the FDA which claims, “although any nicotine-containing product is potentially
addictive, decades of research and use have shown that NRT (Nicotine Replacement Therapy) products
sold OTC do not appear to have significant potential for abuse or dependence.” To date, there are
no documented cases of nicotine patches, gums, or lozenges creating addiction in users. Nicotine may
be the most well known chemical in cigarettes, but is not the culprit when it comes to cancer and other
tobacco related disease. Smoking causes cancer, nicotine does not.

The notion that nicotine is addictive dates back to the introduction of Nicorette in the 1980s, when for the
first time in history smokers were labelled as “addicts” - as people with no willpower - unable to give up
cigarettes without pharmaceutical nicotine products. Claims that ‘nicotine is more addictive than heroin’
were touted from the official “Surgeon General” report, “Nicotine Addiction”, published in 1988. These
findings were that of prominent anti-tobacco ‘experts’, who were later found in a 2014 Washington DC
court case to have significant financial ties to the pharmaceutical industry, particularity in the nicotine
replacement therapy market, during the time they were designated by the US government as scientific
editors of the official “Surgeon General” reports on tobacco. A judgment ordered the FDA to remove
these experts from Tobacco Products Scientific Advisory Committee (TPSAC) because of their extensive
conflicts of interest with pharmaceutical companies. According to the presiding judge over the case, their
recommendations must be considered “suspect” and “at worst unreliable” because of their long-standing
financial ties to the pharmaceutical companies. However, this has not stopped groups with special interests from cherry-picking “facts” from these reports.

The alarmist claims that ‘nicotine is the addictive and harmful aspect of smoking’ are rooted in corrupt financial interests of pharmaceutical corporations trying to gain a monopoly on the nicotine market through NRT cessation products.

The e-cigarette has been a threat to the pharmaceutical nicotine profits, since it succeeded in taking half of the Nicorette market in 2012. Survey results in the American Journal of Preventative Medicine revealed respondents using e-cigarettes more than 20 times per day had a quit rate of 70.0%. Of those who had stayed off the smokes for 6 months; 34.3% were not using e-cigarettes or any nicotine-containing products by that point.

These results are astounding compared to endorsed nicotine replacement therapies that are far more expensive. For example, a study on the effectiveness of nicotine patches found just 8.2% had abstained from smoking after 24 weeks. In a study of those using nicotine chewing gum, only 7.7% of the prescribed gum group and 8.4% in the over the counter gum group were not smoking at six months.

Smokers who switch to vaping are using a harm reduction method to abstain from cigarettes, and are able to detox the chemicals that are [intentionally] added to tobacco cigarettes to create an addiction above and beyond nicotine, while still satisfying cravings and oral fixation through a clean delivery system for nicotine suspended in vegetable glycerin and propylene glycol (both of which have been FDA approved for medical use for years.)

**CLAIM:** Vaping is a gateway to smoking, re-normalizes smoking.

**ANALYSIS:** Though repeated by many anti-tobacco groups, this speculation has no factual or statistical supporting basis. After a decade on the market, there is still no evidence that vaping is a gateway to smoking. Rather, there is evidence of the contrary. The CDC’s most recent data should put to rest the contention that electronic cigarettes are a gateway to smoking among youth. This new data shows that the prevalence of smoking among high school students was cut in half in just five years - from 2011 to 2016 - at the same time as the use of e-cigarettes among these very same students increased dramatically from 1.5% to a peak of 16.0% in 2015.

Not only has youth smoking declined at an unprecedented pace in the last five years, but for the first time, the prevalence of youth use of e-cigarettes has also declined, dropping from 16.0% in 2015 to 11.3% in 2016 (among high school students). Use of cigarettes among
high school students continued to fall between 2015 and 2016, dropping from 9.3% to 8.0%.

This is great news because it reveals that smoking is truly becoming unpopular among youth. The rate of decline in youth smoking is unprecedented. This despite the rapid rise in e-cigarette experimentation. These data are simply not consistent with the hypothesis that vaping is going to re-normalize smoking and that e-cigarettes are a gateway to youth smoking.

The drop in e-cigarette use is also reassuring because it suggests that vaping is largely a social phenomenon that involves experimentation and that the addictive potential of these products is quite low. It also suggests that the popularity of youth vaping has peaked and that concerns about vaping taking over and leading to nicotine addiction among a huge proportion of youth are not warranted.

Landmark studies from The Royal College of Physicians, Public Health England, among others have determined vaping does not act as a route into smoking for children or non-smokers.

CLAIM: Smoking causes 480,000 death per year in the U.S., and is responsible for approx $3 billion in annual excess medical expenditures in Minnesota.

ANALYSIS: According to the Royal College of Physicians’ report ‘Nicotine without smoke: tobacco harm reduction’, vaping has the potential to eliminate virtually all tobacco related harm. Researchers have concluded that e-cigarettes are beneficial to public health; that ‘smokers can therefore be reassured and encouraged to use them, and the public can be reassured that e-cigarettes are much safer than smoking.’ 11 million smokers have already successfully quit smoking by switching to vaping. Vaping has the potential to eradicate smoking in the U.S., alleviating the death toll and cost burden associated with smoking. Public Health England has already taken steps to promote vaping as a safer alternative to smoking. Bristol city council and public health officials have even offered carbon monoxide testing outside of local vape shops as an effort to persuade smokers to switch to vaping.

CLAIM: Adolescents who smoke are 3x more likely to use alcohol, 8x more likely to use Marijuana, and 22x more likely to use cocaine.

ANALYSIS: This claim illustrates that the legal status of a substance is not a barrier to youth who want to use it, and that ‘raising the smoking age’ is an ineffective way to combat youth smoking.

The age to purchase alcohol is 21 and has been for around 30 years. Marijuana and cocaine are illegal to purchase regardless of age. Though youth who experiment these substances may also smoke cigarettes, they do not use these substances because of cigarettes. Youth who have a proclivity toward using illicit and restricted substances, clearly do so regardless of age limit and legal status. There is no clear evidence that nicotine drives adolescents to use illicit substances. Rather, compromised psychological and emotional well being, and lack of awareness of the dangers and consequences, are to
blame for poor choices. Chaotic or abusive home life, depression, anxiety, anger, lack of self worth and confidence, rebellion and psychological reactance are all examples of root causes that lead an adolescent to make the choice to use a restricted substance.

More teens use alcohol than marijuana and tobacco combined. Clearly, the restrictive age of 21 hasn’t impeded them from acquiring it. Additionally, meth and heroin have both become a problem in many U.S. schools despite being illegal. If teens are acquiring illegal substances like this, what makes us think they will not find a way to acquire cigarettes? Diffidence toward the law will not decrease by creating more perceivably arbitrary laws; if anything, it will only increase through psychological reactance by insulting the autonomy of those entering Age of Majority.

CLAIM: During the years from ages 18-21, youthful experimentation often accelerates into daily use. It’s a time when the adolescent brain is highly vulnerable, not developed enough to make potentially life altering choices. Humans do not reach a fully developed state until about 25 years of age, and until then lack the maturity, judgment and the ability to access risk in an appropriate form.

ANALYSIS: At age 18, Minnesota adults can make their own medical decisions, get married, buy guns, own credit cards, vote, and join the military. If an 18-year-old commits a crime in Minnesota, they’ll be charged as an adult and could even face the death penalty. Restricting an 18-year-old adult from buying tobacco products conflicts with the Age of Majority rule as defined in Minnesota Statute 645.451. If these young adults are considered too young to chose whether or not to use tobacco or vapor products, then they are also certainly too young to make decisions such as to risk their life serving in the military, to get gender reassignment surgery, or to accrue debt that will follow them the rest of their lives.

Our focus should be on cultivating whole and healthy adults through positive reinforcement and encouragement. According to a new report from the Minnesota Department of Human Services, ‘rather than focusing on what youth are doing wrong, we should be emphasizing what the teens are doing right’. The CDC claims to have also found the approach to be effective in creating meaningful change on a range of issues.

Jill Ambuehl, a grant coordinator for Positive Community Norms in Hawley, MN describes the approach saying, "We are choosing to believe in our youth, so they can believe in themselves."

Meanwhile, tobacco control groups are taking the exact opposite approach. Not only are they overwhelming youth with negative statistics about the smoking rates of their peers, they are going as far as to negatively single out specific demographical groups, such as the LGBTQ the community.

For example: “If you identify as LGBTQ and are 18-24, you're nearly 2x as likely to smoke as your straight peers.” - Truth Initiative
This message directly segregates a group of young adults based on their sexual identity, and targets them by using what is known as the 'nocebo effect' to instill negative programming and subsequently, negative outcome.

On a broader scale, tobacco control groups use this same nocebo effect through Tobacco 21, by negatively portraying the competency of young adults to make their own choices regarding tobacco use, as well as the ability of underage teens to, “just say no”, by suggesting the government go as far as to step in and take rights away from legal adults to ‘protect the youth’. The underlying message here is that “we don’t believe in the youth to make good choices”. This sends the message to teens and young adults that they are so incapable of making good choices that they require government intervention.

This also reinforces the notion that smoking is of such prevalence, that drastic measures are being taken by municipalities to stop it. To an adolescent brain that is so “vulnerable” to suggestion, this is a dangerous misconception.

Tobacco control groups should take the advice from the MDOH, and focus more attention on celebrating our unprecedented and continued decline in youth and adult smoking. A quick look at the latest CDC data on youth smoking shows that our youth have already proven themselves responsible and worthy of our respect when it comes to making choices regarding tobacco use.

Contrary to popular belief, young adults are very informed about the dangers of smoking and using tobacco. If we are expecting young men and women to live and die for this country, we should give them all possible and reasonable freedoms. The decision of an adult to use tobacco or vapor products should not be decided by the government. That decision should come from each individual.

**CLAIM:** 70% of Minnesota adults are in favor of enacting Tobacco 21 laws.

**ANALYSIS:** An average taken of 2017 Minnesota public polls show 71% of respondents oppose ‘raising the smoking age’ to 21.

**CLAIM:** 65% of young people are in favor of raising the smoking age.

**ANALYSIS:** Anti-smoking groups often coach high school students into speaking in support of Tobacco 21, while concurrently claiming that youth under the age of 21 are not developed enough to comprehend the ramifications of decisions such as whether or not to use nicotine. This is contradicting if youth are not capable of making sound decisions until after they are 21, how then are they capable of comprehending
the consequences of enacting laws that remove the rights of legal adults to make decisions for themselves, and add to the erosion of autonomy of U.S. citizens?

Moreover, if this number is accurate, then this is great news because it indicates that this percentage of people is not interested in smoking. This is not the demographic that we need to worry about, as they are already inclined to be non-smokers. Rather, it is the alleged 35% of those who are not in favor of such a policy, that need our focus, as they are more likely to become smokers, and even more likely to do so out of psychological reactance after their right to choose as adults, is stripped.

**THR4Life Recommendation**

When considering the harm reduction benefits of vaping and the dangers of smoking, it may seem logical to raise the legal age to purchase tobacco products to 21, while keeping the age to purchase vapor products at 18. While this could encourage adults over the age of 18 to choose vaping over smoking, we still need to consider the potential psychological backlash of removing freedom from legal adults. **The last thing we want is to do is risk hardening a young person’s preference toward smoking, by turning smoking into a form of political activism or rebellion.**

Given the fact that our youth smoking and vaping rates are already steadily declining, we find tampering with this continued progress by adopting Tobacco 21 policies, to be hazardous to public health. We strongly advise legislators to consider the ‘big picture’ and the potential harm this legislation carries with it. Smoking and vaping are both losing popularity among youth, and community leaders should strive to **protect this progress by opposing Tobacco 21.**

**Tobacco 21 is a poor method of addressing tobacco use and the ordinance should not be adopted into law.**

“I support the goal of reducing smoking by young Minnesotans,” he said. “However, people who are 18, 19 and 20 years old are legally adults and should generally be allowed to make the same personal decisions as older adults.”

~ Mark Dayton, Governor of Minnesota ~
Nicotine without smoke: Tobacco harm reduction  
https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0

Promote e-cigarettes widely as substitute for smoking says new RCP report:  

E-cigarettes around 95% less harmful than tobacco estimates landmark review:  

Tobacco Use Among Middle and High School Students — United States, 2011–2016:  
https://www.cdc.gov/mmwr/volumes/66/wr/mm6623a1.htm?s_cid=mm6623a1_w

E-Cigarettes Do Not Promote Cancer Growth in Lab Tests:  

British city council to advocate vaping on No Smoking Day:  
http://ecigintelligence.com/british-city-council-advocates-for-e-cigs-on-no-smoking-day/

The Effects of E-Cigarette Minimum Legal Sale Age Laws on Youth Substance Use:  
http://www.nber.org/papers/w23313

Comparison of select analytes in aerosol from e-cigarettes with smoke from conventional cigarettes and with ambient air:  
http://www.sciencedirect.com/science/article/pii/S0273230014002505
Nicotine without smoke
Tobacco harm reduction

A report by the Tobacco Advisory Group of the Royal College of Physicians

April 2016
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The Royal College of Physicians
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The Royal College of Physicians (RCP) exists to improve the care of individual patients, and the health of the population. As tobacco smoking generates more illness and premature death than any other avoidable cause, preventing smoking has been a high priority for the RCP since the health harm of smoking was first recognised over 60 years ago. In the more than 50 years since our first report, Smoking and health, in 1962, we have argued consistently for more and better policies and services to prevent people from taking up smoking, and help existing smokers to quit.

Smoking is far less prevalent today than it was in 1962, but remains common, particularly among more disadvantaged individuals in our society. There are still almost nine million smokers in the UK, half of whom will die prematurely unless they quit. The evidence in this report demonstrates sustained progress over recent decades in preventing young people from becoming smokers, but also shows that much more must be done to increase the number of existing smokers who succeed in stopping smoking.

In 2007 the RCP published a report, Harm reduction in nicotine addiction, which argued for the application of harm-reduction strategies to tobacco dependence. We suggested that making effective, affordable, socially acceptable, low-hazard nicotine products available to smokers as a market alternative to tobacco could generate significant health gains, by allowing smokers to stop smoking tobacco, without having to stop using the nicotine to which they are addicted. Our report was published just as the prototypes of a new consumer alternative to tobacco, the electronic cigarette (e-cigarette), were first appearing on the UK market.

The rapid growth in use of e-cigarettes by smokers since 2007 demonstrates that many smokers want reduced-harm products, and it is also clear that many smokers have succeeded in quitting simply by substituting electronic for tobacco cigarettes. However, e-cigarettes have also proved to be highly controversial, attracting much criticism as well as support within medicine and public health, and indeed in wider society.
This report therefore aims to provide a fresh update on the use of harm reduction in tobacco smoking, in relation to all non-tobacco nicotine products but particularly e-cigarettes. It concludes that, for all the potential risks involved, harm reduction has huge potential to prevent death and disability from tobacco use, and to hasten our progress to a tobacco-free society. With careful management and proportionate regulation, harm reduction provides an opportunity to improve the lives of millions of people. It is an opportunity that, with care, we should take.

Professor Jane Dacre
President, Royal College of Physicians
Abbreviations

ASA  Advertising Standards Authority
ASH  Action on Smoking and Health
BAT  British American Tobacco
BSI  British Standards Institute
CO   carbon monoxide
COP  FCTC Conference of the Parties
COPD chronic obstructive pulmonary disease
CTADS Canadian Tobacco, Alcohol and Drugs Survey
CYP2A6 cytochrome P450 2A6 enzyme
e-cigarette electronic cigarette
ECITA Electronic Cigarette Industry Trade Association
EFTA European Free Trade Association
ENDS electronic nicotine delivery system
EU European Union
FCA Framework Convention Alliance
FCTC Framework Convention on Tobacco Control
FDA US Food and Drug Administration
FM03 flavin-containing monooxygenase 3
GABA γ-aminobutyric acid
GRPs gross rating points
HAZ Health Action Zones
HMRC HM Revenue and Customs
IGTC Institute for Global Tobacco Control
ITC International Tobacco Control policy evaluation project
MAO monoamine oxidase
MCA Medicines Control Agency
MHRA UK Medicines and Healthcare products Regulatory Agency
MMC mass media campaign
MPower Monitor, Protect, Offer, Warn, Enforce, Raise
nAChR nicotinic acetylcholine receptor
NICE National Institute for Health and Care Excellence
NMR nicotine metabolite ratio
NNN N′-nitrosonornicotine
## Tobacco harm reduction

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>NNS</td>
<td>nicotine nasal spray</td>
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<tr>
<td>NO</td>
<td>nitric oxide</td>
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<tr>
<td>NRT</td>
<td>nicotine replacement therapy</td>
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<tr>
<td>ONS</td>
<td>Office for National Statistics</td>
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<tr>
<td>PET</td>
<td>positron emission tomography</td>
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<tr>
<td>PHE</td>
<td>Public Health England</td>
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<tr>
<td>PMI</td>
<td>Philip Morris International</td>
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<tr>
<td>RCP</td>
<td>Royal College of Physicians</td>
</tr>
<tr>
<td>SALSUS</td>
<td>Schools Adolescent and Lifestyle and Substance Use Survey</td>
</tr>
<tr>
<td>SES</td>
<td>socio-economic status</td>
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<tr>
<td>SHARE</td>
<td>Smoking Harm Reduction Education Programme</td>
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<tr>
<td>SHS</td>
<td>second-hand smoke</td>
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<tr>
<td>SPECT</td>
<td>single-photon emission computed tomography</td>
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<tr>
<td>SSS</td>
<td>Stop Smoking Service</td>
</tr>
<tr>
<td>STS</td>
<td>Smoking Toolkit Study</td>
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<tr>
<td>TAPA</td>
<td>UK Tobacco Advertising and Promotion Act 2002</td>
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<tr>
<td>TPD</td>
<td>EU Tobacco Products Directive</td>
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<tr>
<td>TSNAs</td>
<td>tobacco-specific nitrosamines</td>
</tr>
<tr>
<td>UGT</td>
<td>uridine diphosphate (UDP) glucuronosyltransferase</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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Harm reduction is a strategy used in medicine and social policy to minimise harm to individuals and/or wider society from hazardous behaviours or practices that cannot be completely avoided or prevented. Examples include providing clean needles and syringes to intravenous drug users to reduce the risk of infection, promoting condom use by sex workers, drink-driving laws, protective clothing in sport, and motor vehicle safety measures and emission controls. Sometimes by appearing to condone or perpetuate hazardous behaviours that could in theory be prevented, harm-reduction approaches can be controversial, particularly in medicine. To their proponents, however, they represent pragmatic solutions to a range of otherwise intractable causes of avoidable death and disability.

Tobacco smoking is addictive and lethal. Half of all lifelong smokers in the UK die as a direct consequence of their smoking, and smokers lose an average of about 3 months of life expectancy for every year smoked after the age of 35; in sustained smokers this amounts to a total loss of around 10 years of life. Tobacco smoking harms others, through passive exposure of both adults and children to exhaled and sidestream smoke, while smoking in pregnancy impairs fetal growth and development, in some cases to the point of fetal death. Smoking causes fires and litter, reduces economic productivity and social engagement, and exacerbates poverty. Together these effects make smoking responsible for more loss of quality and quantity of life in the UK than any other avoidable cause. As smoking is strongly related to social disadvantage, the burden of ill health caused by smoking falls particularly on the most disadvantaged individuals, making smoking the largest cause of social inequalities in health in the UK.

Smoking is completely preventable, yet, more than half a century after the health harm of smoking first became widely known, almost 1 billion people worldwide still smoke. They do so primarily because they are addicted to the nicotine in tobacco smoke and, as this addiction can be extremely difficult to overcome, many will continue to smoke until they die. Conventional tobacco control policies, embodied in the World Health Organization’s (WHO’s) Framework Convention on Tobacco Control (FCTC) and MPOWER policy framework...
(Monitor tobacco use and prevention policies, Protect people from tobacco smoke, Offer help to quit tobacco use, Warn about the dangers of tobacco, Enforce bans on tobacco advertising, promotion and sponsorship, and Raise taxes on tobacco)\textsuperscript{12} aim to prevent the uptake of smoking and to help as many existing smokers to quit as possible. These approaches have contributed to a 50% reduction in UK smoking prevalence in the past 35 years,\textsuperscript{13} as well as increasing global success in smoking prevention.\textsuperscript{9,14} However, although smoking prevalence in the UK is now down to 18%,\textsuperscript{15} this figure translates into around 8.7 million current smokers\textsuperscript{16,17} sustaining significant harm from smoking. Harm reduction provides an additional strategy to protect this group, and their counterparts in other countries, from the burden of disability and early death that will continue to accumulate until and unless they stop smoking.

In 2007 the RCP published a report promoting the principle of harm reduction in nicotine addiction,\textsuperscript{18} arguing that, as most of the harm caused by smoking arises not from nicotine but from other components of tobacco smoke, the health and life expectancy of today’s smokers could be radically improved by encouraging as many as possible to switch to a smoke-free source of nicotine. While recognising the primacy of complete cessation of all tobacco and nicotine use as the ultimate goal to prevent harm from smoking, the report argued that promoting widespread substitution of cigarettes and other tobacco combustion products would, for smokers who made the change, achieve much the same thing.\textsuperscript{18} Harm reduction, as a complement to conventional tobacco control policies, could therefore offer a means to prevent millions of deaths among tobacco smokers in the UK alone.\textsuperscript{18} This argument was accepted and integrated into national tobacco control strategies published by the then Labour and subsequent coalition governments in 2010 and 2011,\textsuperscript{19,20} through the extension of the licence for nicotine replacement therapy (NRT) to include harm reduction by the Medicines and Healthcare products Regulatory Agency in 2010,\textsuperscript{21} and in guidance issued by the National Institute for Health and Care Excellence in 2013.\textsuperscript{22}

At the time of the 2007 report, the product categories available as potential smoking substitutes comprised smokeless tobacco, the least hazardous forms of which were then and still are illegal in the UK,\textsuperscript{18} and conventional NRT, which, although effective as a smoking cessation therapy, has proved to have limited appeal to many smokers.\textsuperscript{18} E-cigarettes, which appeared in the UK at around the time the 2007 report was published, have transformed this market, becoming the most popular choice of product for smokers hoping to quit or cut down on their smoking\textsuperscript{23,24} (see Chapter 5). In the UK and many other countries, however, e-cigarettes have proved highly controversial, attracting both widespread concern and disapproval, and strong support, from individuals and organisations both within and outside medicine. Policies on e-cigarettes vary widely between countries with some, such as the UK, currently allowing their sale as consumer products whereas others, eg Australia, prohibit the product\textsuperscript{25} (see Chapter 10).
Harm reduction, and in particular the role of e-cigarettes, has probably split global and, to some extent, national opinion on tobacco control more than any other issue. This report therefore aims to provide an update on harm reduction in the UK, particularly but not exclusively in relation to the role of e-cigarettes.

### 1.1 The harm of smoking

The harm that smoking causes to individuals and society is extensive and has been reviewed comprehensively in reports published by the RCP over the past 15 years,\(^3,4,10,26\) by the US surgeon general\(^27–30\) and by many other authorities. The main effects of smoking on health and wellbeing, particularly in the context of the UK population, are as follows.

#### 1.1.1 Mortality

The most recent detailed analysis of mortality caused by smoking in the UK uses data from 2010, when tobacco smoking caused an estimated 122,000 deaths in adults, equivalent to more than one in six of all deaths, in the UK.\(^31\) Although due to a wide range of diseases, 70% of these deaths were from three causes: lung cancer, chronic obstructive pulmonary disease (COPD) and vascular disease (Fig 1.1).

![Fig 1.1 Deaths attributable to smoking by disease in men and women, UK, 2009.\(^{31}\) (Data for figure from Peto et al.\(^{31}\))]
Deaths caused by passive smoking are more difficult to estimate with precision, but in 2003 over 10,000 adults in the UK were estimated to have died from lung cancer, cardiovascular disease or COPD caused by passive smoking. The figure today is likely to be lower, as a result of declining smoking prevalence and legislation making UK public places and workplaces smoke-free. Among children, around 40 cases of sudden infant death syndrome are caused by smoking in the UK each year, whereas passive exposure of the fetus arising from maternal smoking during pregnancy causes over 5,000 fetal or perinatal deaths each year.

1.1.2 Morbidity

Smoking during pregnancy accounts for around 2,000 premature births and 19,000 cases of low birth weight each year, and increases the risk of fetal anomalies. Among children, passive smoking has been estimated to cause around 165,000 new cases of disease, predominantly middle-ear disease and respiratory infections in 2008, generating over 300,000 primary care consultations and 9,500 hospital admissions in the UK each year. In adults, combined morbidity and mortality from smoking accounted for the loss of around 2 million disability-adjusted life years in the UK in 2010. In 2014 smoking caused over 450,000, or about 4% of all, admissions to hospitals in England. Most of these admissions were for cancer, or respiratory or vascular disease.

1.1.3 NHS and wider societal costs

Smoking costs the NHS more than £2 billion in direct costs, or more than 2% of the total NHS budget, every year. Costs of inpatient and primary care caused by passive smoking in children in 2007 exceeded £20 million. The total cost of smoking to society, including healthcare, social care, lost productivity, litter and fires, was conservatively estimated in 2015 to be around £14 billion per year.

1.1.4 Smoking and deprivation

Smoking prevalence is strongly and directly related to all measures of deprivation. Smoking prevalence among those in higher managerial and professional occupations in the UK is now close to 12%, whereas among those in routine and manual occupations the figure is over 28%. Among unemployed people, almost 40% smoke, as do around 40% of people with longstanding mental health problems and more than 70% of people who are homeless or imprisoned.
1.1.5 Normalisation effects

Smoking harms the health of others through behavioural effects, independent of tobacco exposure. It was estimated that, in the UK in 2011, over 200,000 11- to 15-year-olds started smoking\textsuperscript{34} and, although smoking rates have since fallen, it is still the case that, every day, hundreds of children become smokers. These new smokers are more likely to come from households that include a smoker\textsuperscript{35} or to have been exposed to smoking behaviour in the media\textsuperscript{36} or in their wider social environment.\textsuperscript{36} These effects tend to perpetuate addiction to smoking among successive generations of families and social groups, and hence also the consequent inequality in quantity and quality of life in disadvantaged groups.

1.2 Principles of tobacco harm reduction

Tobacco smoke contains thousands of constituents that determine the flavour and other characteristics of the smoke; but, crucially, they also combine to deliver nicotine to the lung in an aerosol, with physical properties that allow rapid absorption into the pulmonary circulation. Although other components of tobacco smoke may enhance the addictiveness of tobacco smoke, the main driver of tobacco smoking is addiction to nicotine.\textsuperscript{10,18} The mechanisms of nicotine addiction are complex, but it is evident that smokers experience an initial sensation of reward from exposure to nicotine; after sustained use and consequent desensitisation to nicotine’s effects, smokers seek nicotine primarily to relieve the symptoms of nicotine withdrawal.\textsuperscript{10,18} Regular nicotine use also confers rewards in some of the stimuli and behaviours associated with nicotine delivery, such as the sense of smoke in the throat, and the physical acts that are integral to smoking, such as unwrapping, sharing or handling cigarettes.

Nicotine is not, however, in itself, a highly hazardous drug (see Chapters 4 and 5). It increases heart rate and blood pressure, and has a range of local irritant effects, but is not a carcinogen.\textsuperscript{37} Of the three main causes of mortality from smoking, lung cancer arises primarily from direct exposure of the lungs to carcinogens in tobacco smoke, COPD from the irritant and proinflammatory effects of smoke, and cardiovascular disease from the effects of smoke on vascular coagulation and blood vessel walls. None is caused primarily by nicotine. For practical purposes, as argued by Mike Russell in the 1970s, ‘smokers smoke for nicotine but are killed by tar.’\textsuperscript{38} Although the nature and extent of any long-term health hazard from inhaling nicotine remain uncertain, because there is no experience of such use other than from cigarettes, it is inherently unlikely that nicotine inhalation itself contributes significantly to the mortality or morbidity caused by smoking. The main culprit is smoke and, if nicotine could be delivered effectively and acceptably to smokers without smoke, most if not all of the harm of smoking could probably be avoided.
It is also clear that many smokers would prefer not to have to smoke to get nicotine, provided that they can access the drug in doses and formulations that they find satisfying and acceptable. The availability and use of an oral tobacco product known as snus in Sweden, documented in more detail in our 2007 report (and revisited in Chapter 7), demonstrates proof of the concept that a substantial proportion of smokers will, given the availability of a socially acceptable and affordable consumer alternative offering a lower hazard to health, switch from smoked tobacco to the alternative product. Particularly among men, the availability of snus as a substitute for smoking has helped to reduce the prevalence of smoking in Sweden, which is now by far the lowest in Europe. The magnitude of the contribution made by the availability of snus over and above conventional tobacco control measures is difficult to quantify, but a recent study of the effect of withdrawal of snus from the market in Finland in 1995, when both Finland and Sweden joined the EU, but only Sweden was allowed to continue its use, estimates that over the following 10 years the availability of snus reduced smoking prevalence in Sweden by an additional 3.7 percentage points. Trends in snus use in Norway are similar to, and perhaps stronger than, those in Sweden, and there the use of snus is strongly associated with quitting smoking.

1.3 Role of harm reduction in tobacco control policy

In 1962, the RCP’s Smoking and health report promoted a range of smoking prevention measures, including a list of policies that, under the heading ‘Possible action by the government’, probably represented the first published comprehensive tobacco control strategy. The core components – preventing tobacco advertising, increasing prices, making public places smoke free, providing treatment for smokers, educating the public and restricting young people’s access to cigarettes – remain at the centre of modern tobacco control strategy as promoted by the WHO and the FCTC.

These policies are effective and, when countries and states adopt them comprehensively, the prevalence of smoking falls, slowly. Australia, Canada and the UK have implemented increasingly extensive ranges of tobacco control policies over recent decades and, in these countries, over the past 10 years or so, prevalence has fallen respectively by around 0.6, 0.75 and 0.7 percentage points per year. Adult smoking prevalence is now below 20% in all of these countries, but, even if these rates of decline can be sustained, it will take more than two decades before rates start to approach zero. Meanwhile, substantial numbers of people in these countries continue to smoke: nearly 9 million in the UK, 4.6 million in Canada and 3 million in Australia remain exposed to the harm of smoking. Tobacco control policies may have a greater effect when introduced together for the first time in a high-prevalence setting: in Uruguay,
for example, a comprehensive package of tobacco control measures was introduced in 2005, when adult smoking prevalence was around 34%, and led to a reduction in smoking prevalence of around 1.1 percentage points per year for the next 6 years. However, even if this rate of decline can be sustained, it will take three decades to eradicate smoking, during which most current smokers will continue to be harmed or killed by their addiction. It is therefore important to complement this approach with strategies to reduce or prevent harm in those who will otherwise continue to smoke.

To date, harm-reduction strategies have tended to focus on reducing emissions and absorption of toxins from conventional cigarettes, eg through the use of filters and attempts to limit tar yields, although the latter proved to be more of a marketing device for the tobacco industry than a genuine reduction in harm potential. More radical strategies, such as promoting alternative sources of nicotine as a sustained substitute for smoking, have until recently been pursued only in the context of therapies for individual smokers attempting to quit. The potential for more widespread nicotine product substitution at a population level, with the primary objective of changing the source of nicotine used by smokers rather than ending all nicotine use, has not to date been widely adopted as a public health policy. The evidence from Sweden suggests that the harm reduction could add a further 0.4 percentage points per year to the rate of decline in smoking prevalence, and hence make a substantial contribution to public health.

1.4 Developments since the publication of the 2007 RCP report and the need for this update

When the RCP published its last report on harm reduction in 2007, options for alternative nicotine products for use in a population-level harm-reduction strategy were limited to smokeless tobacco, the supply of which in the UK is subject to severe constraints under the terms of legislation passed in 1992, and medicinal NRT products, which many smokers find unsatisfactory as a long-term substitute for smoking. However, the nicotine harm-reduction landscape has since been transformed by the emergence of e-cigarettes which, as documented later in this report, have demonstrated a popularity among smokers akin to that of snus in Sweden. The emergence of e-cigarettes has also provoked substantial controversy among those involved in tobacco control, wider public health policy and practice, and the general population, and a spectrum of regulatory responses in different countries that range from free market access to outright prohibition. This report has been produced to review developments relevant to tobacco harm reduction since the publication of the 2007 RCP report Harm reduction in nicotine addiction, to look in particular at the effect that this new product category has had on smoking and nicotine use in the UK, and to make further
recommendations as to how the potential for this approach to prevent death and disability from tobacco use might be realised, within an appropriate and proportionate regulatory framework.

1.5 Summary

> Tobacco smoking is addictive, and causes an extensive range of harm to health and wellbeing in individuals and wider society.
> Tobacco smoking contributes more to social inequalities in health, and to overall death and disability, than any other avoidable cause.
> Smoking is preventable, and smoking prevalence falls progressively when countries implement a comprehensive range of tobacco control policies.
> The rate of decline is slow, however, with millions of smokers in the UK alone continuing to be exposed to the immediate and long-term hazards of smoking.
> Harm reduction aims to reduce or prevent harm in those smokers who do not respond to conventional tobacco control approaches by quitting smoking.
> Harm reduction works by providing smokers with the nicotine to which they are addicted without the tobacco smoke that is responsible for almost all of the harm caused by smoking.
> E-cigarettes are a new product class that has proved popular with smokers and offers a viable harm-reduction option.
> E-cigarettes have proved highly controversial and have provoked widely different regulatory responses in different countries.
> It is therefore important to look carefully at the role that these and other novel nicotine products might play in helping to prevent death and disability caused by smoking, and to consider how regulation should be applied proportionately to maximise this benefit.

References

4 Royal College of Physicians. Going smoke-free: the medical case for clean air in the home, at work and in public places. A report on passive smoking by the Tobacco Advisory Group of


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41 Maki J. The incentives created by a harm reduction approach to smoking cessation: Snus and smoking in Sweden and Finland. *Int J Drug Policy* 2014;26:569–74.


2.1 Recent trends and current prevalence of smoking in the UK

Reliable national data on the prevalence of smoking among adults in Britain were collected from 1972 to 2011 in the General Household Survey,\textsuperscript{1} and since that date in the Opinions and Lifestyle Survey\textsuperscript{1} and the Integrated Household Survey.\textsuperscript{2} Data from these sources demonstrate that, over the more than four decades for which survey data are available, smoking prevalence fell from 51% of men and 41% of women in 1972,\textsuperscript{1} to 21% of men and 16% of women in 2014\textsuperscript{2} (Fig 2.1). Applying age- and gender-specific smoking rates to the 2013 population estimates of the Office for National Statistics (ONS),\textsuperscript{3} there are approximately 8.7 million adult smokers in the UK, of whom 4.8 million are men and 3.9 million women.

![Fig 2.1 Smoking prevalence in men and women in Britain, 1972–2013\textsuperscript{1} and 2014\textsuperscript{2} (Adapted with permission from the Office for National Statistics\textsuperscript{1,2} under Open Government Licence.)]
Smoking has always been more common among men than women, and is also related to age and socio-economic status. Especially over the past two decades, smoking tends to be most common among young adults, and least so among older people, but is following a predominantly downward trend in all age groups (Fig 2.2).

Fig 2.2 Smoking among men and women in Britain, by age 1974–2013.1
(Adapted with permission from the Office for National Statistics1 under Open Government Licence.)
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Cross-sectional prevalence data by age demonstrate that smoking is currently most common among young adults, and particularly among men aged 25–34 (Fig 2.3). Age-group data also demonstrate marked falls in smoking prevalence.

Fig 2.3 Prevalence of smoking by age group and gender in Britain, 2014.² (Adapted with permission from the Office for National Statistics² under Open Government Licence.)

Fig 2.4 Smoking in Britain by age group, 2004¹ and 2014.² (Adapted with permission from the Office for National Statistics¹,² under Open Government Licence.)

Cross-sectional prevalence data by age demonstrate that smoking is currently most common among young adults, and particularly among men aged 25–34 (Fig 2.3). Age-group data also demonstrate marked falls in smoking prevalence.
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over the decade from 2004 to 2014 in all age groups, but particularly in younger adults (Fig 2.4).

Smoking among children is also falling, even more markedly than among young adults. Figure 2.5 shows that the proportion of children aged 11–15 in England who report that they currently smoke at least one cigarette a week has fallen by around two-thirds since the 1990s, to figures of 4% and 3%, respectively, in girls and boys. Over the past 10 years the prevalence of smoking in all people aged 11–15 has fallen from 9% to 3%, with smoking among the youngest participants (those aged 11 and 12) falling to almost zero (Fig 2.6). Similarly substantial declines in smoking prevalence among young people have also occurred in Scotland.

2.2 Smoking and disadvantage

Smoking is strongly associated with socio-economic disadvantage, however defined or measured. Figure 2.7 shows prevalence trends over time in Britain according to occupational socio-economic status, and demonstrates a falling prevalence in all groups since 2001, but also prevalence that is twice as high, and falling more slowly, among those in routine and manual occupations relative to the managerial and professional group.
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Fig 2.6 Smoking by age: children aged 11–15 in England, 2004 and 2014.4
(Adapted with permission from the Health and Social Care Information Centre4 under Open Government Licence.)

Fig 2.7 Prevalence of smoking by occupational socio-economic status, Britain 2001–131 and 2014.2 (Adapted with permission from the Office for National Statistics1,2 under Open Government Licence.)

A more detailed breakdown of smoking by occupation, from the Integrated Household Survey, demonstrates a clear and direct relationship between smoking
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prevalence and occupational social group, being highest in the least skilled occupations (Fig 2.8).

In 2013, smoking in Britain was almost twice as prevalent among unemployed people (35%) as among those in employment (19%), and in those with incomes below £20,000 per year (23%) than those with incomes greater than £40,000 (11%). Smoking is about twice as prevalent among those with a long-standing mental health condition than in those without (Fig 2.9), and similar among those with schizophrenia or other psychosis in 2010 to those in the general population in the 1970s. Among other severely deprived groups, such as those who are homeless, imprisoned, or dependent on other drugs or other substances, most smoke. The strong relationship between smoking and deprivation means that passive exposure to tobacco smoke, particularly in children, tends to be much higher among children living in relatively deprived households.

Socio-economically disadvantaged people not only are more likely to be smokers, but also tend to be more heavily dependent on smoking. Levels of cotinine, a metabolite of nicotine (see Chapter 4) and a marker of nicotine dependence, are consistently higher among relatively disadvantaged smokers across all age groups (Fig 2.10).

Fig 2.8 Smoking by occupation in Britain 2014. (Adapted with permission from the Office for National Statistics under Open Government Licence.)
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Fig 2.9 Smoking prevalence among people with a long-standing mental health problem, and in the general population, UK 1993–2013. (Updated for this report from the RCP.6)

Fig 2.10 Saliva cotinine levels in smokers in relation to age and deprivation (data from 1998 to 2003).8 (Adapted with permission from Action on Smoking and Health.8)
2.3 Trends in the uptake and progression of smoking in the UK

2.3.1 Smoking uptake

Most smokers in the UK start smoking during their teenage or early adult years. In Britain in 2011, the most recent year for which data are accessible, 68% of male and 65% of female current smokers, respectively, reported that they started smoking before age 18, and 95% and 93%, respectively, before age 25.9 Children in lower socio-economic status households tend to start smoking at an earlier age: 43% of smokers in 2011 who grew up in households in which the main wage earner was employed in a manual or routine occupation took up smoking before age 16, compared with 31% of those from professional and managerial households.9 Uptake after age 25 is rare in men and women, and in all socio-economic groups.9

Smoking status in young people tends to be less dichotomous than in adults, because much early use is occasional and experimental, with a relatively low likelihood of leading to sustained smoking. Comparison of smoking behaviour between children and adults is also complicated by the different survey questions used to define smoking in national surveys in these groups. Thus, by the age of 15 in 2014, 35% of children in England had tried smoking at least once, 5% had smoked occasionally but less than once per week and 8% were smoking regularly, which in this survey is defined as smoking at least once a week.4 From age 16, the question used to define regular smoking changes to ‘Do you smoke cigarettes at all nowadays?’,10 and by this definition 17% of those aged 16–19 in 2014 were regular smokers.2 Among those aged 20–24, smoking prevalence was 25% (see Fig 2.4).

However, these are cross-sectional data, so the prevalence of smoking in those aged 20–24 in 2014 will not necessarily apply to younger cohorts when they reach that age. As Figs 2.6 and 2.7 demonstrate, uptake of smoking among children and young people is falling rapidly, indicating that children born since the early 1990s may be substantially less likely than their predecessors to take up smoking, at least in their teens; and, unless these cohorts take up smoking in their 20s to a much greater degree than has typically been the case in the past, it appears that today’s children and young people in the UK are much less likely than their predecessors to become smokers. The marked decline in smoking prevalence among 11- to 15-year-olds began in 2006 (see Fig 2.6) and is likely to be attributable primarily to the major tobacco control interventions of the decade: the phased removal of tobacco advertising in the UK from 2002 and smoke-free legislation, which was in place across the UK by the end of 2007.

2.3.2 Quitting

The proportion of people who have smoked regularly in the past but do not smoke now increases progressively with age. Taking data for 2011,9 around 2% of
men and 4% of women aged 16–19 describe themselves as ex-smokers, whereas, of those aged 60 and over, the respective proportions are 45% and 30%. Although the latter figures are likely to be biased upwards by the higher mortality in continuing smokers, this bias will be less marked among those aged 50–59. In this age group in 2011, 27% of men and 24% of women were ex-smokers, whereas 20% and 18%, respectively, were still smoking.9 These data therefore indicate that over half of those who had ever been regular smokers quit before they reached the age of 60, but that over 40% continue to smoke beyond that age.

2.3.3 Uptake and quitting within birth cohorts

Cross-sectional data on current smoking prevalence and past quitting are not representative of trends within cohorts of UK individuals born at different times. Figure 2.11 shows General Household/General Lifestyle Survey data from 1972 to 2011, provided by the UK Data Service, analysed to estimate smoking prevalence within 5-year birth cohorts over the duration for which data are available. Figure 2.11 demonstrates that, in more recent birth cohorts, smoking prevalence tends to be highest at around 25 years of age, but also that the peak within-cohort
prevalence has fallen progressively in successive cohorts from almost 50% in those born between 1951 and 1955, to under 30% in those born since 1986. Peak prevalence levels in earlier cohorts are not known, but the steady downward trend in prevalence in all of them indicates that they were probably substantially higher. After age 24 the prevalence of smoking declines in all cohorts, and this decline is likely to be attributable primarily to quitting smoking during mid-adult life, and also to earlier mortality among smokers in older age groups. The rate of this decline in smoking prevalence within recent cohorts is of the order of 1 percentage point per year, which, if sustained, indicates that, by the time today’s 20- to 24-year-olds reach the age of 50, their smoking prevalence is likely to have fallen from around 30% (see Fig 2.4) to about 5%.

2.4 Current and expected future mortality and morbidity from smoking

Mortality from smoking tends to lag behind smoking prevalence by several decades, and reached a peak of around 151,000 deaths per year in the UK in the mid-1980s (Fig 2.12).\(^\text{11}\) This total has since declined progressively to 103,000 in 2009.\(^\text{11}\) Data for England since 2009 suggest that this trend has continued, with an estimated 78,200 people,\(^\text{12}\) equivalent to about 93,000 in the UK, killed by smoking in 2014.\(^\text{12}\) The decline has to date been due predominantly to a relatively marked fall in cardiovascular mortality (Fig 2.13), although modest...
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Fig 2.13 Deaths from smoking in England, by cause, 2003–13.12 (Adapted with permission from the Health and Social Care Information Centre12 under Open Government Licence.)

declines in all causes of premature mortality among smokers are expected over the coming decades.

Generating estimates of morbidity from smoking is a more complex process and direct data are not available. However, figures on hospital admissions attributable to smoking provide a proxy for morbidity, and demonstrate a sustained rise over the past decade, from 1.38 million in 2003–4 to 1.63 million in 2013–14.12

2.5 Summary

- Smoking prevalence has been falling for several decades in the UK, in all age groups, in both men and women.
- Smoking prevalence has fallen particularly markedly since 2007 among children and young people.
- Smoking remains much more prevalent among socio-economically disadvantaged individuals and those with mental health problems.
- Uptake of smoking appears to be falling progressively, whereas quit rates appear to be remaining relatively constant across successive cohorts.
- Smoking remains most prevalent among disadvantaged individuals, and addiction to nicotine tends to be higher in more disadvantaged smokers.
This means that the approximately 8.7 million smokers in the UK today include a high proportion of the most disadvantaged individuals in society, who as a result of higher levels of addiction are likely to find it particularly difficult to quit smoking.

Smoking is likely to be rare among today’s young people as they approach older age, but continuing efforts to reduce child uptake of smoking are vital.

However, smoking continues to cause significant mortality and morbidity, in part as a consequence of higher smoking rates in past decades.

Helping disadvantaged smokers to quit or else reduce the harm caused by smoking is therefore a key priority to prevent current and future death and disability.

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3 Effectiveness of current and future tobacco control policy

3.1 Background

In 1962, when most men and almost half of all women in the UK were regular smokers, the RCP’s report, *Smoking and health*, identified tobacco smoking as the primary cause of the twentieth-century global epidemic of lung cancer and proposed a range of policies to reduce smoking prevalence.¹ Progress with implementation of these policies remained slow, however, until the first comprehensive UK tobacco control policy document, *Smoking kills*, was published in 1998.² *Smoking kills* recognised the devastating effect of tobacco smoking on UK public health, and committed to reduce smoking in children and young people, help adults to stop smoking, prioritise reducing the prevalence of smoking in manual occupational groups as a means of decreasing health inequalities, and offer particular help to pregnant smokers. Drawing heavily on the policy recommendations of *Smoking and health*, *Smoking kills* defined a package of tobacco control policies including the following:

- a ban on tobacco advertising and sponsorship
- tobacco tax rises
- enforcement of underage sales laws
- reducing point-of-sale tobacco advertising
- introducing smoking cessation services
- facilitating access to smoking cessation medication
- voluntary measures to reduce passive smoke exposure in public places and workplaces.

Shortly after *Smoking kills* was published, powers for key policy areas, including health, were devolved to the newly established Scottish Parliament, Welsh Assembly and Northern Ireland Assembly, although some powers relevant to tobacco, such as fiscal policy (via the Treasury), remained within the remit of the Westminster government. However, *Smoking kills* had set the scene for tobacco policy changes throughout the UK and, in the years that followed, the main policies it recommended were implemented throughout England and the devolved nations. These new measures included comprehensive smoke-free
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legislation, which was implemented in Scotland in 2006 and throughout the rest of the UK by the end of 2007. Each of the UK nations has since produced their own tobacco control strategies, with some variation in emphasis and the timing of how policies were introduced. The core strategies are, however, broadly similar and articulated in the most recent tobacco control plan for England, which was published in March 2011. This plan committed to:

- implementing legislation to end tobacco displays in shops
- considering and consulting on plain packaging of tobacco products
- continuing to defend tobacco legislation against legal challenges by the tobacco industry
- continuing to follow a policy of using tax to maintain the high price of tobacco products
- promoting effective local enforcement of tobacco legislation
- encouraging more smokers to quit by using the most effective forms of support, through local stop smoking services
- publish a 3-year marketing strategy for tobacco control.

Progress has been made on all these objectives, particularly in ending point-of-sale tobacco displays and passing legislation mandating standardised packaging for tobacco products. The plan also proposed adopting a harm-reduction strategy based on helping tobacco users who cannot or are unwilling to quit smoking to substitute alternative safer sources of nicotine for tobacco, to be supported by guidance from the National Institute for Health and Care Excellence (NICE), which was in development at the time but published in due course in 2013, and undertook to encourage the development of new, affordable and acceptable nicotine products. The UK government elected in 2015 has committed to a new tobacco strategy, although a publication date has not been set.

In addition to national and devolved government actions, tobacco control policy in the UK is significantly influenced by international treaties and initiatives. UK tobacco policy is shaped by the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC), a global health treaty ratified by most of the world’s countries, including the UK, that defines a comprehensive range of tobacco control policies and practices that all political parties undertake to implement. At the European level, European Union (EU) single market rules have also been a driver of significant policy initiatives across all EU member states in recent years, including legislation banning tobacco advertising (2003/33/EC) and mandating health warnings on tobacco packs (2001/37/EC, known as the Tobacco Products Directive, or TPD). A revision of the TPD (2014/40/EU), which comes into force in 2016, will impose a minimum pack size of 20 cigarettes (and 50 g hand-rolling tobacco), require combined pictorial and text health warnings to cover 65% of the front and back of the pack, and end...
cigarette flavouring. The new TPD will also set out product standards and regulations on the sale of e-cigarettes (see Chapter 9). UK tobacco control policy thus continues to be shaped by both national initiatives and international agreements and legislation. The combination of these processes has led to the UK becoming the European leader in tobacco control policy implementation.

3.2 Tobacco control policy effectiveness and implementation in the UK

3.2.1 Increasing the price of tobacco products

Fiscal measures, including tobacco taxation, are a key element of tobacco control. In the UK, tobacco tax increased in the mid- to late 1990s, through an escalator of 3% above inflation from 1993 to 1997 and 5% above inflation from 1997 to 2000. From 2001 to 2008 taxes rose in line with inflation, until, in 2009, a tax escalator was reintroduced, which is currently set at 2% above inflation, a commitment that runs until the end of the current parliament in 2020. Overall, between 1980 and 2012 the affordability of tobacco declined by 28%, although, relative to the 1960s’ prices, tobacco was approximately 50% more affordable in 2006 than when Smoking and health was published in 1962, and remains more affordable today. The price of the most popular price category cigarettes, a metric that initially reflected the price of the most popular brand or brands on the market, but now typically represents the prices of the more expensive (premium-brand) cigarettes, has increased consistently over the last three decades (Fig 3.1), with the result that the UK now has some of the highest premium-brand prices in Europe. However, the price of cigarettes in the ultra-low price category favoured by younger and more disadvantaged smokers has remained virtually static in recent years, thus undermining the effects of tobacco tax rises.

The World Bank suggests that price increases through higher taxation are the single most effective and cost-effective tobacco control measure. Its estimates from the late 1990s suggested that a price increase of 10% typically decreases adult consumption by around 4% in developed countries. A 1996 study in the UK produced an estimate consistent with the World Bank figure, with a price increase of 10% reducing consumption by 5% and with evidence that lower socio-economic groups were more responsive than those in higher socio-economic groups to changes in the price of cigarettes. These figures were disputed in a recent paper by HM Revenue and Customs (HMRC), which estimated that the price elasticity of demand for cigarettes increased in the period from 1982 to 2009, suggesting that a 10% increase in price now reduces consumption by 10%. However, this study included duty-paid manufactured cigarettes only, and did not take into account other types of tobacco, such as...
hand-rolling tobacco, to which many smokers downtrade when prices for manufactured cigarettes rise.\textsuperscript{18}

Evidence from a wide range of settings consistently demonstrates the effectiveness of price increases as a tobacco control measure. From 1990 to 2005, France tripled inflation-adjusted cigarette prices by raising taxes 5\% or more every year in excess of inflation and, during the same period, cigarette consumption halved and smoking prevalence fell by a quarter.\textsuperscript{19} Comparable price increases in South Africa achieved similar reductions in consumption.\textsuperscript{19} However, the available evidence relates predominantly to the effects of relatively small, incremental price rises over time; the effects of sudden large price rises are less well defined.\textsuperscript{20} Data from France indicate that a single large increase in tobacco taxation in 2003, which caused the price of a packet of premium-brand cigarettes to rise in real terms by almost 20\%, resulted in a 13.5\% decline in sales.\textsuperscript{21} This implies that sudden large price increases may be more effective than repeated smaller rises.

There is also consistent international evidence that raising taxes to increase the price of tobacco reduces smoking among young people, who as a group are more responsive than adults to price increases.\textsuperscript{22–24} The US surgeon general’s report on preventing youth smoking concluded that increases in cigarette prices reduce
initiation, prevalence and intensity of smoking among both children and young adults. Evidence from developed countries indicates that a 10% increase in price reduces youth consumption by between 5 and 12%. There is also evidence from high-income countries that low socio-economic status (SES) groups are more responsive to price increases, indicating that tobacco price increases have a key role to play in reducing inequalities in health caused by tobacco use. Two systematic reviews have recently assessed the equity impact of tobacco control in high-income countries, in terms of differential impact on SES groups, in both young people and adults. The reviews found that the clearest and most consistent evidence of a positive equity impact (ie reduced inequalities in smoking) for all types of tobacco control in adults, and to a lesser extent in young people (as there are fewer studies on this), related to price increases.

Although UK tobacco prices increased throughout the 1990s, the effects of increasing taxation during this period were undermined by, among other things, a rapid increase in the market share for illicit cigarettes, which rose from 3% in 1996–7 to 21% by 2000–1. This meant that smokers were switching to cheap, illicit cigarettes rather than quitting in response to price rises. This and a relative absence of other tobacco control measures during this period resulted in little change in UK smoking prevalence, despite year-on-year price rises. From 2000, however, a comprehensive anti-smuggling strategy reduced the supply of illicit cigarettes from 21% in 2000–1 to 9% in 2012–13. This included, from 2006, legislation imposing substantial fines on manufacturers who failed to prevent their products from being smuggled into the UK. Since then, however, tax increases have been undermined by new developments in tobacco industry pricing strategy, with the creation of a range of ultra-low-price cigarettes and the practice of ‘overshifting’ tax on to more profitable premium brands, leaving ultra-low brand prices relatively unchanged. The consequence of this strategy is that many smokers who might otherwise quit smoking or else reduce their consumption in response to price rises now ‘downtrade’ to lower-price brands, or indeed switch to hand-rolling tobacco.

3.2.2 Restrictions on smoking in public places, workplaces and cars

The health effects of passive smoke exposure are well documented and, to protect workers and the public from these effects, bans or restrictions on smoking in public places and workplaces are a key component of tobacco control policy. In the UK, smoke-free legislation was introduced first in Scotland in March 2006, in Wales and Northern Ireland in April 2007, and in England in July 2007.

There is now extensive international and UK evidence that smoke-free laws are effective in reducing passive exposure to smoke. Before the 2007 smoke-free legislation, the highest levels of occupational passive exposure to smoke in the
UK occurred in serving staff in bars and pubs. A study of bar workers in England, Scotland and Wales showed that their exposure was reduced on average by between 84% and 93% after introduction of the legislation. Children are particularly vulnerable to the effects of tobacco smoke, and research in Scotland, Wales and Northern Ireland found that passive exposure of children to smoke declined after the introduction of the legislation in these countries. Between 1998 and 2012 in England, passive smoke exposure among children declined by 79%, and the most rapid decline occurred in the period immediately before smoke-free legislation came into force, thus coinciding with national mass media campaigns highlighting the dangers of passive smoke exposure. Smoke-free legislation in the UK has also had positive effects on child and adult health, with substantial reductions in preterm deaths, childhood admissions to hospital with asthma and adult admissions for myocardial infarction.

Smoke-free legislation also acts as an incentive to smokers to quit smoking. The Smoking Toolkit Study found that, at the time of the legislation in England, the number of smokers trying to quit smoking increased significantly, with approximately 300,000 additional quit attempts made. Scottish data suggest that quit attempts increased in the 3 months leading up to Scotland’s smoke-free legislation, after which there was a temporary fall in prevalence in addition to the secular reducing trend. A further study has suggested that, although smoke-free legislation was not associated with additional reductions in smoking prevalence, existing decreasing trends continued in the 18 months following implementation of the ban.

Two systematic reviews have recently assessed the equity impact of smoke-free policy in high-income countries on young people and adults. A youth review found that, of the six studies that had looked at the equity impact of comprehensive smoke-free legislation, two had a neutral effect and four were negative in terms of second-hand smoke (SHS) exposure. Declines in SHS exposure occurred predominantly among children who had low SHS exposure before smoke-free legislation, and who were from more affluent families. Thus, the substantial SES gradients in children’s SHS exposure levels remained unchanged. Welsh data showed that, although there was a significant decline among high-SES children perceiving adult smoking as the norm, there was no change among children from low-SES households. Thus, SES disparities in children’s perceptions of adult smoking as normative increased, which is of concern because social norms are important influences on smoking uptake. An adult equity systematic review found that comprehensive national smoke-free legislation was much more likely to have a neutral or positive equity impact than voluntary partial policies.

Following the success of smoke-free legislation in the UK, there are continuing efforts to extend smoke-free policies to other settings. Some cities are considering
extending smoke-free laws to outdoor public places including parks or other open spaces. Since October 2015 it has been illegal for drivers in England and Wales to smoke in private cars in the presence of children, and Scotland and Northern Ireland are in the process of introducing similar legislation. Recent UK research suggests that around one-fifth to one-third of 11- to 15-year-olds are exposed to SHS in cars sometimes or often, and that this is concentrated among those from more deprived backgrounds. Around three-quarters of adolescents reported disliking being exposed to SHS in cars. Around one-third of 8- to 15-year-olds who reported ever being exposed to SHS in cars felt too embarrassed or frightened to ask someone smoking in a car when they were present to stop. Most children, adults and adult smokers in the UK support a ban on smoking in cars where children are present.

3.2.3 Mass media campaigns

Tobacco control mass media campaigns (MMCs) use television, radio, newspapers and other media channels to reach large numbers of smokers and encourage them to quit smoking, reduce harm to self or others from tobacco use, and prevent young people from taking up smoking. Large-scale MMCs have been a key component of UK tobacco control strategy since the early 2000s, and there is strong evidence that tobacco control MMCs can increase adult smoking cessation and reduce youth uptake. Campaigns in England have varied in informational content; approximately half of the adverts between 2004 and 2010 warned of the negative consequences of smoking, whereas half contained information on how to quit smoking. In April 2010, the government ceased spending on national public health MMCs in England. A tobacco control MMC was reintroduced in England in September 2011, but at a much lower rate of funding. Mass media are also used to promote the ‘Stoptober’ campaign, which has run every year since 2012 and encourages smokers to quit for the month of October. Examples are shown in Fig 3.2.

The magnitude of the independent effect of MMCs on smoking behaviour is difficult to establish when, as is usually the case, they are used together with other tobacco control policies. However, several recent studies have assessed the impact of MMCs on a range of measures of quitting behaviour in England (and, to a lesser extent, Wales), including quit-line calls, hits on the national Smokefree website, and measures of cigarette consumption and smoking prevalence. Over the period from 2002 to 2009, when adult smoking prevalence in Britain fell from 26% to 21%, an estimated 13.5% of this decline was attributable to the effect of MMCs. A further study showed that positive emotive campaigns – predominantly those promoting the use of NHS Stop Smoking Services – and negative emotive campaigns – generally those containing negative health effects messages – played a statistically indistinguishable role in
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triggering this effect. More recently, the annual English Stoptober campaign, which aims to create a positive quitting trigger around a specific call to action – stopping for 28 days – and which uses a combination of traditional and new...
media, was estimated to have generated an additional 350,000 quit attempts and 9,000 permanent quitters in October 2012.63

Research from Australia has suggested that the level of exposure to MMCs required to obtain a detectable reduction in smoking prevalence is the equivalent of four exposures per person per month (390 gross rating points, known as GRPs).47 Between 2004 and the spring of 2010, campaign exposure in England exceeded this threshold in around 40% of months; in other months, exposure was lower, with no campaign at all during 1 in every 5 months.54 A recent study found that, below 400 GRPs per month, there was little impact of campaigns on quit-line calls in England, and that the effect increased significantly above the 400 GRP threshold,59 suggesting that efforts should be made to maintain exposure above this level.

The US surgeon general’s report on prevention of smoking in youth concluded that MMCs can be one of the most effective strategies in changing social norms and preventing youth smoking.23 The surgeon general concluded that the characteristics of effective campaigns included evoking strong negative emotions (eg health effects, deceptiveness of the tobacco industry), an appealing format, clear messages, intensity and adequate repetition (at least four advertising exposures per month over a 4-month period). There was strong evidence that MMCs aimed at adults also decreased smoking among young people.

Two recent systematic reviews have looked at the equity impact of MMCs on youth and adults. The youth equity review found only one study that had assessed the equity impact of MMCs on young people by SES.26 This was an evaluation of the US Truth campaign, which had mixed equity effects depending on the outcome measure used.65 The adult review found 30 studies that had looked at the equity impact of MMCs.27 These studies included a diverse range of approaches and messages, including some aimed at increasing quit motivations and/or attempts, and some aimed at increasing calls to quit-lines or uptake of free nicotine replacement therapy (NRT). The equity impact of these campaigns was inconsistent. This is perhaps not surprising given the diversity of messages, media formats and levels of exposure. There was some evidence that certain types of message, such as those with a higher emotional narrative, are more effective with low-SES smokers. A previous review also found that the impact of campaigns can vary by SES depending on the type of message, media format and mechanisms of engagement.66,67

### 3.2.4 Health warnings

Health warnings on tobacco packages are a means of communicating the risks of tobacco use to smokers. Text warnings became a legal requirement in the UK in
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Fig 3.3 Examples of UK text and graphic health warnings.68 (Adapted from Department of Health68 under Open Government Licence; Crown copyright.)

1971, and since 2008 graphic pictorial warnings covering 40% of the back of the pack, and text warnings covering 30% of the front of the pack, have been required (Fig 3.3). The new EU TPD will see a further increase in the prominence of health warnings, with picture and text warnings covering at least 65% of the front and back of tobacco packaging by May 2016.

Studies from a wide range of countries indicate high levels of awareness of pack health warnings among both smokers and non-smokers.69,70 Large text warnings have been shown to be linked to increased knowledge about the health risks of smoking71 and increased motivation to quit.72–77 In the UK, a study of text-only warnings found that they were noticed by over half of smokers,78,79 and that those noticing warning labels were more likely to know about the health risks of smoking.78 Pictorial warnings are likely to be most effective because they are more likely to be noticed, improve memory for the health message, and are associated with stronger beliefs about the risks of smoking and increased motivation to quit.69

Determining whether exposure to health warnings is causally related to changes in smoking behaviour has been difficult, owing to the challenges of disentangling their effect from those of other interventions.69–80 Research has suggested that pictorial health warnings increase the likelihood of a quit attempt.81 Further studies, in which UK data were analysed together with data from Australia, the USA and Canada, concluded that forgoing cigarettes as a result of noticing warnings and cognitive reactions to warnings is a predictor of quit attempts,82 and that health warnings can help to prevent relapse.83 Some studies have investigated the effect of health warnings on smoking prevalence,81–84 with some suggesting positive effects,81 although other factors may also have contributed.69 The US surgeon general’s report on prevention of smoking in youth concluded that small text-only health warning labels have limited impact on youth and
young adults, but that larger text or pictorial warnings that elicit strong emotional reactions are significantly more effective at discouraging tobacco use.23

Systematic reviews of the equity impact of tobacco control policies found no studies that had assessed the equity impact of health warnings in young people,26 and five studies of the effect of health warning labels in adults.27 EU text-only health warnings and the addition of a quit-line number to new pictorial health warnings were found to have had a greater impact on low-SES groups, and the rest were equity neutral.

3.2.5 Comprehensive bans on the advertising and promotion of all tobacco products, logos and brand names

Prohibiting advertising and promotion of tobacco products is a key element of tobacco control. Television advertising for tobacco products was banned in the UK in 1965 under the Television Act 1964, almost 25 years earlier than an EU directive that prohibited television advertising across the EU in 1989 (Television without Frontiers Directive (89/552/EEC)).85 This directive was replaced by the Audiovisual Media Services Directive (2007/65/EC) adopted in December 2007.86 Subsequently, the UK Tobacco Advertising and Promotion Act 2002 (TAPA) banned print media and billboard advertising from February 2003, tobacco direct marketing from May 2003 and sponsorship within the UK in July 2003.

Advertising bans have been shown to reduce smoking uptake in children by lessening its social desirability, and also to reduce tobacco consumption in adults. The introduction of comprehensive advertising bans in Norway, Finland and France resulted in significant reductions in tobacco sales in the period following the introduction of the legislation.87 The US surgeon general’s report on prevention of smoking among youth concluded that there is a causal relationship between tobacco advertising and promotion, and the initiation and progression of smoking in young people.23 It also concluded that comprehensive cigarette advertising bans reduce youth smoking. The World Bank has estimated that comprehensive advertising bans can reduce consumption by around 7%.88

A recent systematic review found four studies that had assessed the equity impact of restrictions and bans on advertising and promotion, all of which had a neutral equity effect.27 A similar review on the equity impact on young people found four US studies indicating that, when there is no enforced control of advertising, promotion or marketing of tobacco, there is the potential for increased inequality in youth smoking.26

The main exclusions from TAPA, and hence the key remaining forms of promotion, were displays of tobacco packs at the point of sale in shops, and the
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Fig 3.4 Examples of tobacco point-of-sale displays in small retailers in England, before and after prohibition.

pack itself. Legislation ending both of these exclusions has now been passed in
the UK. Point-of-sale displays were removed from large retailers such as
supermarkets in England, Northern Ireland and Wales from April, October and
December 2012, respectively, and April 2013 in Scotland. Point-of-sale displays in
smaller shops were prohibited across the UK from April 2015 (Fig 3.4). Studies of
the removal of point-of-sale displays in Iceland and Ireland suggest that the
policy is supported by the public and that there are signs that prohibition helps
to denormalise smoking.\textsuperscript{89} A recent systematic review of the impact of point-of-
sale promotion on youth smoking found that there was a positive association
between exposure and smoking-related outcomes, including smoking and
smoking susceptibility.\textsuperscript{90} The review also found that point-of-sale bans may
contribute to a shift in youth perceptions about peer smoking prevalence, but
found no evidence of short-term population-level impacts on smoking.
Legislation to introduce standardised tobacco packaging in the UK was approved in March 2015, and from May 2016 imposes a standard plain dark-green/brown design and a large graphic health warning on all tobacco packaging, and limits branding to a name and descriptor in a specified and standard plain font (Fig 3.5). A systematic review published in 2012 found that plain packs were rated as less attractive than branded equivalent packs, or unattractive, by young people.91 An independent review into standardised packaging published in 2014 concluded that the measure is likely to lead to a modest but important reduction in smoking, including among children.92 Public support for the measure is also reported to be high: in January 2015, a YouGov survey conducted for Cancer Research UK found that 72% of those polled supported standardised packaging.93

In 2012, Australia became the first country to introduce standardised packaging, and early evaluations suggest that the removal of branding from packaging has reduced the ability of the tobacco industry to use the pack to communicate to
young people and adults, and made products less appealing. There is also evidence that standardised packaging has increased both thoughts about quitting and quit attempts in adult smokers, and reduced smoking prevalence. Concerns that standardised packaging would lead to reductions in the price of cigarettes and increases in illicit tobacco consumption appear not to have been borne out.

With point-of-sale and standardised packaging legislation complementing TAPA, there are few remaining means by which smoking can be promoted in the UK. However, tobacco and related imagery remains prevalent in the media, including films, television programmes, magazines and social media. Although paid-for product placement is illegal under the terms of TAPA, smoking imagery remains common in popular films, computer games and on prime-time UK television. Evidence suggests that there is a clear association between exposure to such imagery in the media and young people starting smoking. Smoking in the media thus remains a major driver of smoking uptake among children and young people, and needs to be addressed.

3.2.6 Restricting young people’s access to tobacco products

Measures to reduce young people’s access to tobacco have been recommended as a means of reducing uptake of smoking. Evidence arising mostly from the USA indicates that reducing youth access to tobacco by implementation of the minimum age-of-sale laws reduces smoking prevalence among young people, although this is highly dependent on levels of enforcement and access to alternative non-retail sources of cigarettes. European evidence indicates that access to cigarette-vending machines was significantly associated with regular smoking by young people.

Across the UK, the minimum age at which young people are permitted to purchase tobacco was raised from 16 to 18 in 2007, and legislation prohibiting vending machines was implemented between 2011 and 2013. The increase in minimum purchase age in England was associated with a significant reduction in regular smoking among 11- to 15-year-olds and a decline in smoking prevalence among 16- to 17-year-olds. The percentage difference in current smoking pre- and post-legislation was significantly greater among those under 18 than in older age groups. However, the effect of the legislation is undermined by substitution of other means of access, particularly proxy purchasing by adults. Scotland banned such sales in 2010 and England from 2015, although the Scottish legislation appears not to have been successful in reducing proxy sales.

A recent systematic review of the equity impact of tobacco control policies found only five studies that have assessed the equity impact of such measures on
Two were equity positive (greater impact on low-SES youth), two neutral (no difference by SES) and one negative (greater impact on high-SES youth). Thus, no overall conclusion can be drawn about their equity impact. However, stronger (ie comprehensive and enforced) US state-level, age-of-sale laws were associated with lower smoking initiation and a reduction in low-SES adolescent girls moving on to regular smoking. In England, raising the age of sale from 16 to 18 was associated with a significant reduction in regular smoking among those aged 11–15 years, with no difference by SES (measured by eligibility for free school meals). However, although the percentage of high-SES pupils who found it difficult to buy cigarettes from a shop increased, this was not the case for low-SES pupils.

3.2.7 Treatments to help dependent smokers stop, including increasing access to medications

Evidence-based smoking cessation treatments typically comprise behavioural interventions, delivered as brief advice from healthcare professionals, telephone quit-lines, more intensive one-to-one or group counselling, and pharmacotherapies, including NRT, bupropion and varenicline. The UK was one of the first countries to make these services easily available to all smokers as a tobacco control policy. In England and Wales, NHS Stop Smoking Services (NHS SSSs), free at the point of use, were launched in areas of high deprivation defined as Health Action Zones (HAZs) in 1998–9, and extended to the rest of England and Wales in 2000–1. The number of people using NHS SSSs grew year on year, rising to over 800,000 in 2011–12, although they have fallen each year since then to a total of 450,582 in 2014–15.

These services, which use evidence-based guidelines and strongly recommend the use of pharmacotherapy, have been shown to be effective over a number of years. A national evaluation conducted in the early years after their establishment found that 53% of attendees confirmed abstinence at 4 weeks, with 15% still abstinent at 1 year. This study has recently been updated, and 1-year abstinence rates are now lower, at 8%; however, some of this change may be attributable to the growth of less intensive and hence less effective forms of support, such as one-to-one interventions in pharmacies rather than individual or group behavioural support delivered by smoking cessation specialists. In the UK, cessation support is also available to smokers through stop smoking helplines and websites where smokers can speak to or converse online with a trained expert adviser. In a recent trial using the NHS Stop Smoking helpline, approximately 20% of smokers who agreed to set a quit date were abstinent at 6 months. The number of calls to the NHS quit-line is small, however, averaging 20,000 per month between 2005 and 2010.
Pharmacological therapies such as NRT, bupropion and varenicline are highly effective when delivered with behavioural support (see Chapter 5), and initiatives to increase access to these treatments by smokers should improve the success of quit attempts. Making cessation therapies available on reimbursable prescriptions and NRT products available on general sale, which occurred in the UK between 1999 and 2002, resulted in a rapid increase in the proportion of quit attempts supported by medication from 28% to 61%.\(^{119}\) However, a great deal more could be done to extend delivery of stop smoking interventions, particularly by making intervention a component of all NHS care delivery, including secondary care.\(^{120}\)

Smoking cessation services tend to be more effective in adults than in young smokers. The US surgeon general’s report on prevention of smoking in youth concluded that several cessation programmes for youth are efficacious in the short term but that, in contrast to adults, there is little evidence of the efficacy of pharmacotherapies in youth cessation.\(^{23}\) Data from the NHS SSSs indicate that relatively few under-18-year-olds access these services, and that those who do have lower quit rates than other age groups.\(^{121}\) A recent systematic review found only two studies that had assessed the equity impact on youth of cessation services.\(^{26}\) Participants in both studies were mobile phone owners in their late teens / early 20s, who were motivated to quit and received text messaging support. Only one study demonstrated a long-term effect on quitting and this was significant only in low-SES intervention participants.

The contribution of NHS SSSs to the reduction in smoking prevalence over recent years has been estimated at between 0.1 and 0.3% above the background quit rate per year.\(^{122,123}\) Although the impact on prevalence of policies and initiatives to improve access to treatment is modest, these interventions have been successful in reaching smokers in the most disadvantaged areas,\(^{123}\) who tend to be more addicted and have the most difficulty stopping.\(^{124}\) A recent systematic review of cessation studies concluded that untargeted smoking cessation interventions across Europe are, on balance, likely to have increased inequalities in smoking. However, the same review found that the comprehensive UK stop smoking services, which are targeted at low-SES smokers, have reduced inequalities in the harm caused by smoking, because higher reach among low-SES smokers compensates for lower quit rates.\(^{27}\)

### 3.3 Cumulative impact of conventional tobacco control policies and future challenges

Although evidence of the impact of individual interventions on smoking prevalence is limited by the difficulty of separating out the independent effects of individual components from a wider package of measures, the multi-component approach adopted in the UK appears to be...
effective, for both adults and young people. The effectiveness of comprehensive packages of tobacco control policies has been further demonstrated in a recent study of the association between MPOWER policies – a list of measures developed by the WHO that are intended to assist in the implementation of interventions required by the FCTC (Monitor tobacco use and prevention policies, Protect people from tobacco smoke, Offer help to quit tobacco use, Warn about the dangers of tobacco, Enforce bans on tobacco advertising, promotion and sponsorship, and Raise taxes on tobacco) – and changes in prevalence, by scoring countries according to their implementation of MPOWER measures. The study showed that countries with higher MPOWER composite scores experienced greater decreases in current tobacco smoking between the years 2006 and 2009, and therefore underlines the need to implement the widest possible range of policies.\textsuperscript{125} The study also assessed the effect of changes in each MPOWER measure on changes in current tobacco smoking, and confirmed existing evidence that price increases are the most effective tobacco control measure.

Figure 3.6 demonstrates the declines that have occurred in smoking prevalence among adults and young people in Britain since \textit{Smoking kills} was published in 1998, in relation to the timeline of policies introduced. The reduction of adult
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smoking by around one-third, and by almost twice that proportion among young people, represents a substantial success for tobacco control policy. However, these figures also demonstrate that, despite this progress, smoking remains a significant public health problem in the UK, with around one in five adults still smoking regularly. These smokers, who are increasingly predominantly from the more deprived SES groups in UK society, have by definition proved resistant to policies applied to date, and also by definition are in desperate need of measures to help them stop smoking.

The Scottish Government has recently set a target for Scotland to become ‘tobacco free’, defined as a smoking prevalence below 5%, by 2034. Figure 3.7 demonstrates how challenging it will be to meet this objective given current trends in smoking prevalence, particularly among low-SES groups, and it will be equally challenging in the rest of the UK. If such an ambition is to be realised, new tobacco control approaches that can bring about substantial declines in smoking among the most deprived individuals in society are urgently needed.

3.4 Developing a more effective tobacco control policy approach

There are many ways in which existing UK tobacco control policies could be improved and complemented to achieve faster declines in smoking
prevalence. In addition to policy measures already in place, greater investment in innovative MMCs, reversing declines in the uptake of SSSs and wider integration of smoking cessation interventions into NHS service delivery, extending smoke-free policies to a wider range of public places, preventing smoking promotion through media imagery and other loopholes in advertising and promotion legislation, and tighter measures to prevent youth access would all make contributions to this end.

However, the most effective policy measure is price. Repeated substantial increases in tobacco price, and removal of the price differentials for premium cigarettes, budget cigarettes and hand-rolling tobacco, would have a substantial impact, particularly among low-SES groups. The effect of taxes can be further enhanced if some of the revenue generated is used to support comprehensive tobacco control strategies. However, the negative effect of price rises on the incomes of those who continue to smoke, as well as the need to do more in general to provide smokers with alternative means to stop smoking, demands additional alternative approaches. Making non-tobacco nicotine products available to smokers, as envisaged in the Tobacco Control Plan for England and advocated in this report, could not only reduce the prevalence of smoking but also offset the negative effect of increased tax on continuing smokers by providing a more affordable and acceptable alternative product.

3.5 Summary

- Increasing the price of cigarettes reduces smoking prevalence, particularly among young and relatively disadvantaged smokers.
- Price increases may be more effective if introduced in single large rather than multiple small increments.
- The effect of price increases is undermined by the availability of illicit tobacco, and the option for smokers to downtrade to ultra-low-price cigarettes and hand-rolling tobacco.
- Smoke-free legislation has reduced passive exposure of children and adults to smoke, and may also have generated some further reduction in smoking prevalence.
- MMCs reduce smoking in all age groups and are an important factor in enhancing the effectiveness of other interventions, but are effective only if sufficiently well funded.
- Graphic health warnings on packs discourage smoking uptake, and encourage and sustain quit attempts.
- Removal of tobacco advertising is particularly effective in reducing smoking uptake, and both point-of-sale display prohibition and standardised packaging of tobacco products further reduce exposure to tobacco branding.
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- Smoking imagery in the media, both branded and unbranded, remains a strong promotional driver of smoking, particularly among young people.
- Raising the minimum age of sale, and prohibiting vending machine sales, reduces smoking among young people.
- Providing cessation support to smokers helps them to quit smoking and, if widely available, increases the rate at which smoking prevalence declines.
- Smokers from low-SES groups are particularly likely to respond to price increases and graphic health warnings.
- Existing tobacco control policy could be enhanced by: further reducing the affordability of tobacco, particularly of budget cigarettes and hand-rolling tobacco; investing in MMCs; preventing smoking imagery in the media, including social media; and extending smoke-free policies to outdoor areas.
- NHS SSSs need to be expanded, and appropriately funded to be integrated and actively promoted in clinical care pathways.
- However, even with all such measures in place, millions of people in the UK will continue to smoke for the foreseeable future. Alternative approaches, particularly for young and disadvantaged smokers, are urgently needed.
- Promoting the use of alternative, acceptable and more affordable nicotine products as a harm-reduction strategy has the potential to complement existing tobacco control policy, and in particular to offset the potentially regressive nature of tobacco tax rises.

References


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44 Laverty A, Millett C. Smoking ban in cars will benefit disadvantaged children most. *BMJ* 2014;348:g1720.


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provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities. www.wipo.int/wipolex/en/details.jsp?id=7882 [Accessed 22 February 2016].


94 Miller C, Ettridge K, Wakefield M. Research paper: ‘You’re made to feel like a dirty filthy smoker when you’re not, cigar smoking is another thing all together.’ Responses of Australian cigar and cigarillo smokers to plain packaging. Tob Control 2015;24:i58–65.


96 White V, Williams T, Wakefield M. Has the introduction of plain packaging with larger graphic health warnings changed adolescents’ perceptions of cigarette packs and brands? Tob Control 2015;24:i42–9.

97 Durkin S, Brennan E, Coomber K et al. Short-term changes in quitting-related cognitions and behaviours after the implementation of plain packaging with larger health warnings: findings from a national cohort study with Australian adult smokers. Tob Control 2015;24:26–32.


99 Scollo M, Bayly M, Wakefield M. Did the recommended retail price of tobacco products fall in Australia following the implementation of plain packaging? Tob Control 2015;24:90–3.

100 Scollo M, Zacher M, Durkin S et al. Use of illicit tobacco following introduction of standardised packaging of tobacco products in Australia: results from a national cross-sectional survey. Tob Control 2015;24:i76–81.


Tobacco harm reduction


118 Ferguson J, Docherty G, Bauld L *et al.* Effect of offering different levels of support and free nicotine replacement therapy via an English national telephone quitline: randomised controlled trial. *BMJ* 2012;344:e1696.


127 Duffy, S. Creating a generation free from tobacco: how far have we come and where to next? Powerpoint presentation to University of Aberdeen Global Health Seminar, March 27 2015. Edinburgh: ASH Scotland.


4.1 Nicotine chemistry and absorption

Nicotine is a naturally occurring alkaloid present in the leaves of the tobacco plant, and is the major psychoactive compound and mediator of addiction to tobacco use.1 Nicotine absorption across cell membranes is highly pH dependent, because only non-ionised nicotine can cross biological membranes and be absorbed into the bloodstream.2 Nicotine is a weak base with a $pK_a$ of approximately 8,2 so, in the relatively acidic medium of cigarette smoke with a pH typically ranging from 6.0 to 7.8, more than half of the nicotine in tobacco smoke is protonated3 and cannot be absorbed. Manipulating the pH of tobacco smoke to make it more alkaline thus increases nicotine absorption.4

The average nicotine content of commercially available manufactured cigarettes is around 10 mg, but, as a result of loss in sidestream smoke, retention in the cigarette stub and delivery of nicotine in ionised form, only about 1 mg is absorbed from each cigarette smoked.5 When tobacco smoke is inhaled, nicotine passes through the alveolar membranes of the lung into the pulmonary venous circulation. It is then carried into the heart, and then directly into the arterial system, reaching the brain within 10–20 s. The rate of increase in arterial nicotine concentration achieved by inhaling nicotine is thus faster even than that achieved by intravenous administration, with peak arterial concentrations occurring at around 20 and 30 s, respectively.6 After smoking a single cigarette, arterial nicotine concentrations differ according to the type of cigarette and the way in which it is smoked. Thus, one study reported arterial levels of only about 20 ng/mL,6 but some smokers can achieve arterial nicotine concentrations of about 60 ng/mL with just a few puffs7 and arterial concentrations of 100 ng/mL have been reported after smoking a single cigarette.8 The arterial blood nicotine levels achieved by inhaling nicotine are much higher than in the venous circulation8 (Fig 4.1). As the rate at which an addictive drug reaches the brain influences its addictive potential,9 the fast absorption and delivery of nicotine after inhaling tobacco smoke underpin the rapid behavioural reinforcement of smoking.10
In contrast, when nicotine is swallowed, it is absorbed from the gastrointestinal tract into blood that flows into the portal veins and hence to the liver, where it undergoes substantial first-pass metabolism. Oral nicotine therefore generates very low and similar systemic venous and arterial blood levels. Conventional nicotine replacement therapy (NRT) products avoid this first-pass metabolism by delivering nicotine via the skin, mouth or nose, blood from which drains directly into the systemic venous system. NRT thus generates higher arterial nicotine levels than those achieved by gastrointestinal absorption, but levels in arterial blood are similar to those in venous blood and much lower than those achieved by inhalation. There are also marked differences in venous plasma concentrations of nicotine achieved, depending on the form and dose of NRT used (Fig 4.2). The variation in time to reach maximal nicotine plasma concentration is due, in part, to differences in administration duration as well as absorption time that occur with each route of delivery.

The relatively slow delivery of nicotine to the brain achieved by NRT is much less reinforcing, and hence much less likely to generate dependence, than cigarette smoking. However, forms of NRT that deliver nicotine relatively quickly, such as the nasal spray, are thought to be more likely to generate dependence than others. Overall, however, the addictive potential of cigarettes is much higher than that of NRT or other non-inhaled nicotine products. Clinically, very few users of NRT become dependent on it.
4.2 Nicotine metabolism

Around 70–80% of absorbed nicotine is metabolised to cotinine, and around 90% of this metabolism is via the hepatic cytochrome P450 (CYP) 2A6 enzyme. The majority of cotinine is then further metabolised to 3′-hydroxycotinine in a reaction mediated exclusively by CYP2A6. Both nicotine and its metabolites are excreted in urine. As most nicotine clearance occurs via metabolic (ie non-renal) means, variability in nicotine metabolism is likely to cause substantial variation in the rate of nicotine clearance between individuals. The ratio 3′-hydroxycotinine: cotinine is known as the nicotine metabolite ratio (NMR), which serves as a phenotypic indicator of CYP2A6 enzymatic activity. As CYP2A6 represents the major route of nicotine clearance, the NMR is also strongly correlated with the rate of nicotine clearance.
Variation in the CYP2A6 gene, which has an impact on the functionality of the CYP2A6 enzyme, is common and associated with alterations in the rate of nicotine clearance, together with a variety of smoking behaviours. Slower nicotine metabolism, as inferred from CYP2A6 genotypes or as measured directly by the NMR, is associated with lower cigarette consumption, lower nicotine dependence, lower smoking-related reward and lower risk of being a current smoker. Slower nicotine metabolism is also associated with an increased likelihood of unaided cessation (ie cessation without behavioural or pharmacological support) and cessation in clinical trials, in which slow metabolisers are typically more likely to achieve abstinence on both placebo and NRT. A separate study that used an alternative CYP2A6 phenotype measure also found associations between slow nicotine metabolism and higher abstinence rates. The prevalence of slower nicotine metabolism differs according to ethnicity, predominantly owing to interethnic variability in patterns of CYP2A6 allele expression. The frequency of CYP2A6 alleles conferring reduced or loss of CYP2A6 activity is generally higher in African and East Asian populations than in European populations, as reflected by a higher prevalence of reduced nicotine metabolism in populations of African and East Asian descent (approximately 40–50%) versus European descent (approximately 10–25%). In addition to CYP2A6-mediated nicotine inactivation, nicotine can be inactivated through N-glucuronidation and N'-oxidation, through metabolism by uridine diphosphate (UDP) glucuronosyltransferase (UGT) 2B10 and flavin-containing monooxygenase (FMO) 3, respectively. The resulting minor nicotine metabolites, nicotine N-glucuronide and nicotine N'-oxide, account for up to 5% and 7% of a nicotine dose that can be recovered from urine, respectively. In individuals with no functional CYP2A6 activity, FMO3- and UGT-mediated nicotine metabolism may be more important for nicotine clearance, however, reduced FMO3 function did not substantially affect nicotine metabolism in individuals with reduced CYP2A6 activity. UGT2B10 can also metabolise cotinine to cotinine N-glucuronide, comprising 12–17% of a nicotine dose recovered from urine. A second UGT enzyme, UGT2B17, metabolises 3'-hydroxycotinine to 3'-hydroxycotinine O-glucuronide, and accounts for about 9% of a nicotine dose recovered from urine. Several of these minor enzymes involved in the nicotine and cotinine metabolic pathway (FMO3, UGT2B10 and UGT2B17) are highly polymorphic, with some genetic variants leading to altered activity of these enzymes. Variation in FMO3 is associated with minor alterations in nicotine metabolism, but appears to be of insufficient magnitude to alter cigarette consumption or total tobacco dose in light smokers of African-American ancestry. In heavy smokers of European ancestry, variation in FMO3 has little effect on consumption, unless restricted to those with faster CYP2A6 activity (a difference of about three cigarettes a day). The influence of UGT genetic variation, tested to date on variation in nicotine
metabolism, is also relatively modest and does not appear to alter smoking
behaviours substantially.\textsuperscript{35,36} Although UGT2B17 genetic variation is associated
with altered 3'-hydroxycotinine metabolism,\textsuperscript{36} variation in genes for UGTs that
alters cotinine and 3'-hydroxycotinine metabolism is unlikely to affect smoking
behaviours because cotinine and 3'-hydroxycotinine are essentially inactive
metabolites of nicotine.

4.3 Systemic and central nervous system effects

4.3.1 Nicotinic acetylcholine receptors

Nicotine exerts its pharmacological effects through binding to nicotinic
acetylcholine receptors (nAChRs). These receptors are universally expressed in cells
throughout the body,\textsuperscript{37} including the central and peripheral nervous systems,
where they play a key role in mediating nicotine dependence and addiction. The
nAChRs are ligand-gated ion channels composed of five transmembrane subunit
proteins arranged around a central pore. Neuronal nAChRs consist of $\alpha$ ($\alpha_2$–$\alpha_{10}$) and $\beta$ ($\beta_2$–$\beta_4$) subunits,\textsuperscript{38} each of which is encoded by a single gene (denoted with
a 'CHRN' prefix), and may be homomeric or heteromeric in terms of subunit
composition. Different combinations of subunits result in receptors differing in
pharmacological and physiological profiles.\textsuperscript{39,40} Individual subtypes differ, e.g. in
their affinity for nicotine, and sensitivity to upregulation and desensitisation after
nicotine exposure.\textsuperscript{40}

Each nAChR subtype has a distinct distribution profile within the brain, which can
be determined through assessment of subunit mRNA using techniques such as \textit{in situ}
hybridisation, and through imaging techniques such as positron emission
tomography (PET) and single-photon emission computed tomography (SPECT),
using subtype-selective radioligands.\textsuperscript{40} The differential expression of specific
subunits, with distinct biological functions in brain regions mediating specific
behaviours, allows nicotine to exert a broad range of effects.\textsuperscript{41} The $\alpha_4\beta_2$ receptor
is the most commonly expressed subtype in the human brain, and historically
has been implicated through animal models as critical to the experience of
nicotine's reinforcing effects (e.g Picciotto \textit{et al.}\textsuperscript{42}). In recent years, however, the
importance of the less studied $\alpha_3$- and $\alpha_5$-receptor subunits in mediating
nicotine dependence has been recognised. The $\alpha_5$-receptor subunit appears to
play a key role in determining aversive responses to high doses of nicotine.\textsuperscript{43}

4.3.2 Systemic and central nervous system effects

Nicotine, at relatively low doses, is a stimulant. It increases heart rate, and has
been reported to have beneficial effects on cognition and performance,
improving attention, memory and fine motor skills. Tolerance to nicotine can develop rapidly (within a few days of use), and cessation of use then results in the experience of withdrawal symptoms, both somatic and affective, such as anxiety, restlessness, inability to concentrate, irritability and change in appetite. Chronic exposure to nicotine results in a number of neuroadaptions, including desensitisation of nAChRs and upregulation in their expression, both of which are linked to nicotine tolerance and withdrawal.

4.3.3 Mechanisms of effect

Nicotine exerts its complex effects (including arousal, mood modulation and pleasure) via several neurotransmitter pathways. Once bound to neuronal nAChRs, nicotine facilitates the release of dopamine, serotonin and a host of other neurotransmitters including γ-aminobutyric acid (GABA), glutamate, noradrenaline, acetylcholine and endorphins. The mesolimbic dopamine pathway has, perhaps, been the most widely studied in relation to nicotine dependence. Dopamine release in the nucleus accumbens, resulting from nicotinic stimulation of dopaminergic neurons in the ventral tegmental area, is crucial to the processing of rewarding and reinforcing the effects of nicotine. Indeed, dopamine release in the nucleus accumbens appears to be critical in the experience of the rewarding effects of many drugs of abuse. Continued pairing of the rewarding/reinforcing effects of nicotine with specific sensory and environmental stimuli (which could include, for example, the smell of tobacco smoke or the sight of a pack of cigarettes – smoking-related behaviours) results in these stimuli also acquiring reinforcing properties. These cues (conditioned reinforcers) have been linked to the maintenance of smoking, smoking-related cravings and relapse.

4.4 Toxicity and potential hazards

4.4.1 Toxicity of nicotine

Although nicotine is a toxic compound, overdosing on nicotine products used as directed is almost impossible, given the individual ability to titrate dose and the short half-life of nicotine (see Development of addiction below – Section 4.5). However, ingestion of high doses (purposeful or accidental) can be fatal. Historically, the lethal dose of nicotine for a human adult has consistently been stated to be about 60 mg, corresponding to an oral median lethal dose (LD₅₀) of approximately 0.8 mg/kg. However, this figure has recently been disputed in the light of reports of non-fatal suicide attempts or accidents involving nicotine ingestion, leading to an estimate that the lower dose limit for fatal outcomes is likely to be 500–1,000 mg ingested nicotine, equivalent to an oral LD₅₀ of 6.5–13 mg/kg.
4.4.2 Potential hazards of short- and long-term nicotine use

At commonly used dose levels, short-term nicotine use does not result in clinically significant harm. The safety of NRT products, which have typically been used for days or weeks in the context of an attempt to quit smoking, is well established\(^49\) (see Chapter 5 for further detail), with no evidence of any increase in the risk of heart attack, stroke or death.\(^50,51\)

Evidence about long-term nicotine or NRT use is relatively scarce, and concerns have been raised that long-term NRT use may increase cancer risk, in part owing to endogenous formation of carcinogens such as N\(^\prime\)-nitrosonornicotine (NNN).\(^52\) However, studies carried out in experimental animals largely indicate that nicotine alone is not carcinogenic.\(^53\) *In vitro* and *in vivo* studies in animals do, however, suggest that nicotine can have tumour-promoting effects through activation of intracellular signalling pathways. Such effects include cell proliferation, enhanced angiogenesis and decreased apoptosis.\(^37,49\) However, it is important to note that many studies in this area have used nicotine at higher doses than those achieved in heavy smokers.\(^54\) *In vitro* research suggests that nicotine can have a negative impact on the function of some cells within the cardiovascular system,\(^55\) and adverse effects on glucose metabolism.\(^56\) However, robust evidence on the safety of long-term nicotine use in humans from the 5-year Lung Health Study, in which participants were actively encouraged to use NRT for several months and many continued to consume NRT for a much longer period, demonstrates no association between sustained NRT use and the occurrence of cancer (lung, gastrointestinal or any cancer) or cardiovascular disease.\(^57,58\) In addition, a recent clinical trial comparing 8, 24 and 52 weeks of NRT treatment found that treatment duration was not associated with any adverse effects, further supporting the safety of long-term NRT use.\(^59\)

Although there is little evidence on the safety of using nicotine for periods longer than 5 years, and no data on the safety of long-term use of nicotine by inhalation other than when delivered by tobacco smoke, it is widely accepted that any long-term hazards of nicotine are likely to be of minimal consequence in relation to those associated with continued tobacco use. Notably, and in recognition of this fact, the UK Medicines and Healthcare products Regulatory Agency (MHRA) recently approved an extension to the indication of NRT to include ‘harm reduction’,\(^60\) defined as ‘for use as a substitute or partial substitute for smoking tobacco, both for those making an attempt to quit and those not currently intending to make a quit attempt, without any restriction on its duration of use’.\(^61\) Guidelines on harm-reduction approaches to smoking from the National Institute for Health and Care Excellence (NICE) further state that ‘it is safer to use licensed nicotine-containing products than to smoke’ and ‘there is reason to believe that lifetime use of licensed nicotine-containing products will be considerably less harmful than smoking’.\(^62\)
Research from animal studies suggests that fetal exposure to nicotine may lead to adverse postnatal health consequences and that cognitive function and development are adversely affected by nicotine exposure during both the fetal and the adolescent periods. The relevance of these findings to human brain development remains uncertain, however. There is evidence that smoking in adolescence is associated with cognitive and attentional impairments in later life, and possibly an increased risk of mental health problems, but it is difficult to exclude the effects of confounders of this association in the observational studies available.

### 4.5 Development of addiction

Nicotine is the primary addictive component in cigarettes and other tobacco products. It establishes and maintains addiction, thereby sustaining use, through a range of complex actions on brain neurochemistry, which have been reviewed in detail elsewhere. However, the addictiveness of any nicotine-containing product depends on several factors beyond merely the presence of nicotine. These factors primarily include the rate at which nicotine is absorbed and delivered to the brain, and the dose of nicotine delivered. Other factors, such as the speed at which the drug is metabolised and how soon withdrawal symptoms occur, play a role. This is particularly relevant to nicotine, given its short half-life (about 2 hours), but this is a feature of the drug more than the product delivering the drug. A nicotine-containing product will therefore be more or less addictive depending on the dose and rate at which the nicotine is delivered. Essentially, a product that delivers a high dose rapidly will have a greater liability for addiction than one that delivers a low dose slowly. In this section, we describe the importance of these factors.

#### 4.5.1 Dose effects on addiction potential

Dose is an important factor in the development of nicotine dependence. Animal models clearly demonstrate an inverted-U relationship between nicotine dose and self-administration, although there is interindividual variability in the shape of this curve, some of which is under a genetic influence. Therefore, increasing the dose is associated with increased self-administration up to a point, after which higher doses become increasingly aversive and ultimately toxic. One advantage of the short half-life of nicotine is, however, that it enables consumers to self-titrate their achieved dose. The dose (ie plasma concentration) of nicotine achieved via use of different nicotine-containing products varies considerably (see Fig 4.1 – the total dose achieved is reflected by the area under the curve for each product). Figure 4.1 also illustrates the considerable variability in speed of delivery across these products which, as discussed above, also contributes to addiction liability.
4.5.2 Rate of nicotine clearance

Nicotine is metabolised principally in the liver, with a half-life for elimination of approximately 2 h (although, as discussed above, this varies considerably between individuals). As a result of this short half-life, plasma nicotine concentrations drop rapidly after nicotine administration, leading to withdrawal symptoms, prompting further nicotine administration in regular users, eg in a typical heavy, dependent smoker, nicotine levels increase rapidly after smoking a cigarette (by about 5–30 ng/mL), then drop before increasing again after smoking the next cigarette. Over the course of a day, plasma nicotine concentrations rise gradually to a steady state of between about 10 and 50 ng/mL.\(^8\) The combination of a short half-life and regular administration via frequent smoking (eg hourly) results in a distinctive pattern of nicotine concentrations, as represented in Fig 4.3. Critically, overnight abstinence leads to the almost-complete elimination of nicotine from the body, leading to marked withdrawal on waking, and the need to consume nicotine in order to reverse these symptoms.

Fig 4.3 Simulated plasma nicotine concentrations obtained after smoking a cigarette every hour for 16 h. (Adapted and reprinted from Le Houezec\(^8\) with the permission of the International Union Against Tuberculosis and Lung Disease. Copyright © The Union.)
4.6 Smoke constituents influencing the addictive potential of cigarette smoke

The addictive potency of cigarettes (and indeed other tobacco products) is influenced by not only their nicotine content but also other aspects of product design, including substances added to the cigarette to enhance nicotine delivery and absorption. Monoamine oxidase (MAO) inhibitors in tobacco smoke increase the levels of amines in the brain, such as dopamine and serotonin, and may subsequently potentiate the reinforcing effects of nicotine.\(^6^9\) Indeed, animal studies have demonstrated that MAO inhibitors facilitate nicotine self-administration and enhance its motivational properties.\(^7^0,7^1\) These findings may also contribute to the strong reinforcing properties of nicotine from cigarettes.

Sugars and polysaccharides are commonly added to tobacco products\(^7^2\) to increase the formation of aldehydes, including formaldehyde and acetaldehyde, in tobacco smoke. Acetaldehyde itself has addictive potential,\(^7^3\) as demonstrated through self-administration experiments in animals,\(^7^4\) but it also enhances the addictive potential of nicotine. The interaction between these compounds also generates a rewarding effect that exceeds the additive effects of either component in rodent studies.

Menthol and other flavourings (including cloves and liquorice) increase the palatability of cigarette smoke and, in the case of menthol and cloves, facilitate deeper inhalation and therefore a higher nicotine dose (owing to their cooling/local anaesthetic effects). These are widely added at levels below those used in what are conventionally considered to be ‘flavoured’ cigarettes. Flavours may also become conditioned reinforcers in themselves, as a consequence of their repeated pairing with nicotine.\(^7^5\) In addition, menthol inhibits metabolism of nicotine to cotinine, purportedly through inhibition of CYP2A6 enzyme activity,\(^7^6\) thus increasing the effect of nicotine. Cocoa and chocolate, which contain theobromine, are also common additives in tobacco. Theobromine is a bronchodilator, and thus has been proposed to enhance nicotine absorption in the lungs. However, the theobromine content of cigarettes was deemed too low to exert bronchodilatation in a recent review.\(^7^7\) Levulinic acid is an additive with a sweet caramel taste, but it also alters the pH and so reduces the ‘harshness’ of inhaled smoke.\(^7^8\) This, similarly to menthol, facilitates a higher nicotine dose.

Alkaline additives such as ammonia compounds are among the most common additives used in cigarette manufacture.\(^7^9\) These substances are added to cigarettes (and other tobacco products) to manipulate the pH. As discussed above, increasing the pH increases the proportion of non-ionised, or freebase, nicotine, which is more physiologically active than the ionised form, crossing biological membranes more readily. Tobacco industry scientists have extensively investigated the potential of pH manipulation to optimise nicotine delivery (see
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Hurt and Robinson. Curing methods used in the production of tobacco can also influence the pH of tobacco smoke. In particular, air-cured tobacco, as used in cigars, generates nicotine at a relatively high pH, facilitating absorption from oral and upper airway mucosa. Cigarette tobacco is largely flue cured, resulting in nicotine at a lower pH and lower upper airway absorption, hence requiring inhalation into the much larger surface area of the lung alveoli to achieve significant absorption.

4.7 Impact of cigarette design characteristics on nicotine delivery

A number of physical characteristics of cigarettes have been engineered to influence nicotine delivery, including cigarette dimensions, filtration, ventilation, paper porosity and tobacco shred size. Ventilation, for example, serves to manipulate nicotine, tar and carbon monoxide levels through dilution of tobacco smoke, and is achieved through the introduction of holes in both the filter and the paper wrap. Ventilation technology was used in the production of ‘light’ or ‘low-tar’ cigarettes, which were promoted by the tobacco industry as healthier alternatives to full-strength cigarettes. However, these descriptions have been shown to be misleading and for this reason have been banned in the UK. Although smoking machine assessments give readings indicating that these cigarettes yield lower doses of nicotine, studies in humans have shown that smokers compensate by altering their smoking topography (ie the way in which people smoke their cigarettes). Thus, smokers use deeper inhalation, increased number of puffs per cigarette, etc when smoking these cigarettes, in order to achieve the same dose of nicotine attained when smoking stronger brands. This results in equivalent levels of exposure to the harmful constituents of tobacco smoke.

Smoking topography also affects nicotine delivery. Smokers can make changes to their blood nicotine levels by altering depth and frequency of inhalation and volume of smoke inhaled. A 20-a-day smoker can halve the number of cigarettes that they smoke, but sustain the same plasma nicotine levels by taking larger and deeper puffs. It is this compensatory behaviour that leads to a lack of association between machine-determined nicotine levels in cigarettes and the nicotine dose and quantity of toxic smoke inhaled by a smoker (see below). This may be why reductions in the amount individuals smoke, although making it easier for them to go on to quit, have a relatively limited impact on health outcomes compared with quitting altogether. There are also sex differences in smoking topography (women typically take smaller puffs than men) and ethnicity (African-American individuals typically smoke more of their cigarette than people of European descent).

Mood may also affect the way in which people smoke, with positive effect being associated with a greater increase in blood nicotine levels.
4.8 Lessons from cigarette design for harm-reduction product development

Nicotine is the primary addictive component sustaining tobacco use, but is not the cause of the vast majority of harm associated with tobacco use. Therefore, a product that delivers nicotine in the absence of other constituents of tobacco will be associated with dramatically less harm. The safety of NRT demonstrates this and, although long-term use is relatively uncommon, there is sufficient evidence to conclude that any harm from long-term nicotine use will still be negligible compared with the harm of tobacco use. However, nicotine-containing products such as NRT, although very low in harm, are also substantially less satisfying to smokers than, for example, cigarettes, as evidenced by their modest efficacy as smoking cessation products. As discussed above, this is due to the favourable nicotine delivery characteristics and unique range of behavioural reinforcers associated with cigarette smoking. The ideal harm-reduction device should therefore deliver nicotine in a manner as similar as possible to cigarettes, while at the same time maximising palatability and nicotine delivery to approximate the experience of cigarette smoking more closely.

4.8.1 Targeting the determinants of addictiveness

The principal determinants of the addictiveness of a nicotine-containing product are the dose that it delivers, and the speed with which the dose is delivered. Given that most cigarette smokers are dependent (at least to some degree) on nicotine, targeting these determinants is a critical requirement of any harm-reduction product. The use of additives in tobacco products and the design of the cigarette are both engineered to enhance nicotine delivery from the cigarette, by modifying both the palatability of the cigarette smoke (and therefore the ease with which it can be inhaled, facilitating rapid delivery and self-titration) and the bioavailability of the nicotine contained within it. Other factors, such as the taste and smell of cigarette smoke, and the behavioural action of smoking, can themselves become conditioned reinforcers over time and, although secondary to the effects of nicotine, are important drivers of continued smoking.

4.8.2 E-cigarettes and harm reduction

E-cigarettes meet many of the criteria for an ideal tobacco harm-reduction product. Although nicotine delivery from e-cigarettes depends on a number of factors, including level of user experience and device characteristics, they can in principle deliver a high dose of nicotine, in the absence of the vast majority of the harmful constituents of tobacco smoke (or at least at negligible levels), in a way that enables accurate self-titration (see Chapter 5). They also provide some of the
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cues associated with cigarette smoking, such as taste and throat rasp, as well as behavioural actions such as hand-to-mouth movement. At present therefore, although little is known of the kinetics of nicotine uptake from e-cigarettes into arterial blood, e-cigarettes offer a substitute to smoking that is more likely, on theoretical grounds, to prove satisfying and acceptable to smokers than NRT.

4.9 Summary

> Nicotine is the primary addictive component of tobacco smoke.
> When inhaled into the lungs, nicotine from tobacco smoke is absorbed and delivered to the brain much more quickly, and in higher doses, than can be achieved by other routes of absorption.
> This rapid delivery of repeated high doses of nicotine to the brain is thought to underpin the addictive nature of cigarettes.
> Nicotine is metabolised quickly, causing blood levels to fall rapidly after dosing. People who metabolise nicotine more slowly, and therefore maintain more constant blood levels, tend to be less heavily addicted.
> Nicotine is a stimulant that improves concentration and fine motor skills. However, once tolerance is acquired, unpleasant withdrawal symptoms occur when nicotine blood levels fall.
> Sustained use of nicotine is reinforced by some of the co-stimuli of smoking, such as the taste and sensation of tobacco in the throat, and the smells and behaviours associated with smoking.
> The tobacco industry has manipulated other constituents and additives in tobacco to enhance the addictiveness of nicotine in smoke.
> NRT products may not be effective in some smokers because they replicate few of the delivery, sensory or behavioural characteristics of cigarettes.
> E-cigarettes have the capacity to replace more of the characteristics of tobacco cigarettes than conventional NRT, and therefore have potential as effective smoking substitutes.

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5 Non-tobacco nicotine products

5.1 Introduction

For many years, the range of non-tobacco nicotine products available in the UK has been dominated by nicotine replacement therapy (NRT) products, developed and licensed as medicines to aid smoking cessation. The range of NRT products available has grown to include transdermal patches, chewing gum, lozenges, nasal spray, oral pouch, oral spray, oral strips and the ‘inhalator’, a device that provides a nicotine vapour for oral absorption. In recent years the licences for these products have been extended in several countries, including the UK, to include use to assist smoking reduction and temporary abstinence.

There is strong evidence from randomised controlled clinical trials that NRT can be an effective smoking cessation therapy. A Cochrane review carried out in late 2012 identified 150 such trials, and concluded that all commercially available forms of NRT increase the likelihood of successful cessation among smokers making a quit attempt.¹ NRT products also have a very good safety record.² The products differ in the speed of nicotine delivery and the degree of behavioural replacement for smoking that they provide, but are fairly similar in the amount of nicotine that their strongest formulation delivers. Some require specific techniques for correct use (eg chewing gum and nasal spray), whereas others (eg the transdermal patch) are very simple to use. None, however, reproduces the rapid delivery of high doses of nicotine achieved by inhaling tobacco smoke, and few smokers find them enjoyable or satisfying.

NRT products have traditionally been produced and marketed by the pharmaceutical industry, but in recent years tobacco companies have also begun to acquire or develop products manufactured to standards similar to those of NRT products. Examples of these ‘clean’, non-tobacco nicotine products include Zonnic nicotine gum, marketed by Niconovum, part of Reynolds American Inc, and Verve nicotine-containing discs marketed by NuMark, part of Philip Morris. In the past 5 years, however, the non-tobacco nicotine market has been transformed by the emergence of e-cigarettes, which are now the most widely used form of non-tobacco nicotine. Unlike NRT, they have been marketed as

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consumer products rather than therapeutic goods, and also, unlike most forms of NRT, they retain several important features of smoking other than nicotine delivery, including similar hand-to-mouth movements, behavioural rituals, an inhaled sensory stimulus and a range of flavours. These characteristics make e-cigarettes attractive to a wide range of smokers, including many who do not or would not use NRT; hence, they provide a potentially viable, lower-hazard market competitor to tobacco cigarettes. As consumer products, they are subject to varying degrees of regulation in different countries, and are evolving quickly as the technology improves. Most e-cigarettes are marketed by independent companies importing products from China, but some production is now based in the UK. Several leading brands have now been bought by tobacco companies (see Chapter 8).

The non-tobacco nicotine market in the UK and many other countries is thus in a state of rapid change, with use of e-cigarettes already eclipsing that of pharmaceutical NRT (see Chapter 7), and an increasingly wide range of new products that deliver nicotine at or close to medicinal standards, some of them marketed by the tobacco industry, becoming available. Indeed the status quo of the nicotine market, whereby medicines have to date been made exclusively by pharmaceutical companies, has recently been challenged by the award of medicines licences to two new products: a nicotine-metered dose inhaler (Voke), and an e-cigarette (E-Voke), both of which are being brought to market by Nicoventures, a subsidiary of British American Tobacco.

This chapter provides a summary of currently available non-tobacco nicotine products, their pharmacokinetic profile, safety, addiction potential and trends in their use. Where blood or plasma nicotine levels are given, they relate to those in venous blood (see Chapter 4) unless stated otherwise.

5.2 NRT products

5.2.1 Transdermal nicotine

5.2.1.1 Doses and pharmacokinetics

Commercially available transdermal nicotine patches provide nicotine at a controlled rate for absorption through the skin into the systemic venous circulation. Products vary in dose from around 7 to 25 mg per patch, and deliver nicotine for either 16 or 24 h. High-dose examples include patches that deliver 25 mg over 16 h, or 21 mg over 24 h; lower doses, which are intended for weaning some weeks after smoking cessation, deliver (for example) 15 or 10 mg over 16 h, or 14 or 7 mg over 24 h. The rationale behind the 24-h patch is that it delivers nicotine during sleep and thus provides some protection against urges to smoke immediately after waking. The occasional drawback of 24-h delivery,
which is avoided by 16-h formulations, is that nicotine can cause vivid dreams or otherwise disturbed sleep.

The rate of absorption of nicotine from transdermal patches is slow, although there are some differences in pharmacokinetic profile between available products. In general, after application of the patch there is a delay of up to 2 h before plasma nicotine levels start to rise. High-dose products can generate maximum venous plasma concentrations of 16–18 ng/mL at around 6–12 h.3,4 Plasma nicotine levels at 24 h are about 11 ng/mL with the 24-h patch, and 3 ng/mL with the 16-h patch.3 During use a small reservoir of nicotine accumulates in the skin under the patch, which means that nicotine continues to be absorbed into the blood for an hour or so after the patch has been removed.

5.2.1.2 Safety profile

The nicotine patch has a good safety profile, even when more than one high-dose patch is applied simultaneously.5 In addition to the generic nicotine effects outlined briefly in Chapter 4, which apply to all the products described in this section, the most common side effects of the nicotine patch are insomnia, abnormal dreams, and skin irritation at the application site. There were early case reports of cardiovascular adverse effects, but more robust reviews suggest that these were not caused by NRT.6

5.2.1.3 Addiction potential

The addiction potential of nicotine products is generally related to the speed of nicotine delivery, with faster delivery systems more likely to be used long term.7,8 As transdermal patches deliver nicotine very slowly, long-term dependence is not expected to be a problem, and empirical evidence confirms that this is indeed the case.7,9

5.2.2 Oral and nasal nicotine

5.2.2.1 Doses and pharmacokinetics

Oral and nasal NRT products deliver nicotine more rapidly than nicotine patches, typically achieving peak plasma nicotine concentrations within 30–60 min. However, this kinetic profile is due in part to the sustained-release formulations used in many oral products, and faster absorption is possible. Formulations that spray nicotine solutions directly on to the mouth or nasal linings are among the most quickly absorbed NRT products, achieving peak levels within about 10 min of dosing. Nicotine absorption is influenced by the pH of the oral lining, being faster in relatively alkaline conditions. As with all oral or nasal products, nicotine that is swallowed undergoes extensive first-pass
metabolism (see Chapter 4) and makes no appreciable contribution to levels of nicotine in the blood.

**Nicotine gum**

Nicotine gum is available in two strengths, 2 mg and 4 mg, with the higher dose recommended for more dependent smokers. The nicotine contained within the gum is released on chewing and absorbed through the tissues lining the mouth. After chewing a single 2-mg piece of gum, peak plasma concentrations of 3–5 ng/mL are observed within 30–60 min, and chewing a 2-mg piece of gum every hour results in plasma nicotine concentrations of between 12 and 16 ng/mL. The maximum concentration ($C_{\text{max}}$) for a single dose of 4-mg gum is around 10 ng/mL, and regular dosing can generate plasma nicotine concentrations of between 27 and 32 ng/mL.

**Nicotine oral disc**

A recently developed nicotine oral disc has similar characteristics to the gum. It is a non-dissolving polymer disc containing 1.5 mg tobacco-derived nicotine, which is released when it is chewed. Chewing for 15 min results in an increase in plasma nicotine concentration of around 2 ng/mL.

**Nicotine oral pouch**

The nicotine in this product is in a powder, contained in a small pouch designed to be held in the mouth. A single 4-mg pouch, if held against the inner lining of the cheek for 30 min, produces a peak plasma concentration of approximately 10 ng/mL.

**Nicotine lozenges and sublingual tablets**

Products in this NRT category differ in how quickly they dissolve in the mouth, and in their dose and pharmacokinetic profile. A single 1-mg lozenge creates a peak plasma concentration of around 2 ng/mL, a 2-mg lozenge between 4 and 5 ng/mL and a 4-mg lozenge about 10 ng/mL, all within about 60 min. A study of a 2.5-mg nicotine lozenge showed that single use resulted in a maximum plasma concentration of 10.8 ng/mL in 30 min. Regular use of lozenges (eg one every 1–1.5 h) results in plasma nicotine concentrations of between 10 and 15 ng/mL for the 1- and 2-mg lozenges and 20 and 26 ng/mL for the 4-mg lozenge. The pharmacokinetic profile of the 2-mg sublingual tablet is similar to that of the 2-mg lozenge.

**Nicotine oral film**

This product contains 2.5 mg nicotine in a thin film, designed to be applied to the roof of the mouth, where it dissolves in less than 5 min. Use of a single strip
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produces a peak plasma nicotine concentration, similar to the 2-mg lozenge and gum, of between 4 and 5 ng/mL.

**Nicotine inhalator**

The nicotine inhalator consists of a plastic tube holding a replaceable cartridge containing either 10 or 15 mg nicotine. When the user inhales through the device, nicotine vapour is generated, which deposits on and is absorbed through the lining of the mouth. Although used by inhalation, this product does not achieve appreciable pulmonary delivery or absorption, and the pharmacokinetic profile is similar to that of other oral NRT products. After 20 min intensive use, around 2 mg nicotine is released from the device, resulting in peak plasma concentrations of up to 8 ng/mL and, if this use is repeated hourly for 10 h, levels of around 20–25 ng/mL are achieved. Most users do not, however, use the device with this level of intensity, so lower plasma levels, similar to those achieved by 2-mg gum, are more typical. Nicotine release from this device decreases with ambient temperature so, in cold conditions (<15°C), users should be advised to keep the inhalator warm.

**Nicotine nasal and mouth sprays**

The nasal spray delivers nicotine solution to the nasal mucosa and, after a single 1-mg dose (two sprays containing 0.5 mg nicotine), a peak plasma nicotine concentration of about 5–6 ng/mL is observed within 10–15 min. Taking an hourly dose results in a steady-state plasma concentration of about 10 ng/mL. Although one of the fastest-acting NRT products, the nasal spray is also one of the most aversive to use initially.

The nicotine mouth spray also delivers nicotine quickly. Each spray delivers 1 mg nicotine and results in a peak plasma concentration of around 3–4 ng/mL within 10 min. A 2-mg dose gives a plasma concentration of around 5–6 ng/mL. Another mouth spray formulation has shown higher maximum plasma concentration (10 ng/mL) with a 2-mg dose, but with a slightly longer time (15 min) to reach this.

**5.2.2.2 Safety profile**

Similar to the nicotine patch, oral and nasal nicotine products have a good safety profile. The most commonly reported adverse effects are related to mouth and throat irritation, and hiccups. The nasal spray is a local irritant to the nasal lining.
5.2.2.3 Addiction potential

Some 5% of smokers who use oral nicotine products to stop smoking will continue to use them for a year or longer.\textsuperscript{9} With the nicotine nasal spray, this figure is closer to 10%,\textsuperscript{9} which probably reflects the faster nicotine delivery of this product. Long-term users are usually people who were highly dependent on nicotine from their cigarettes and who would be relatively unlikely to maintain long-term abstinence from smoking without such help.\textsuperscript{21} There are no documented cases of non-smokers becoming dependent on NRT.

5.2.3 Dual use of NRT and smoked tobacco products

NRT appears to be safe and well tolerated when used together with smoking.\textsuperscript{22,23} Randomised placebo-controlled trials of dual use indicate that the occurrence of expected symptoms of nicotine overdose, such as nausea and palpitations, is uncommon.\textsuperscript{24,25} A meta-analysis of NRT use before quitting found no increase in adverse events in patch users compared with those on placebo.\textsuperscript{26} No reported concerns over the use of NRT while smoking have arisen from post-marketing surveillance. Smokers who also use NRT (known as ‘dual users’) are approximately twice as likely in the following months to make a quit attempt, and to quit smoking, than those who do not.\textsuperscript{27,28}

5.3 E-cigarettes

E-cigarettes provide nicotine for inhalation in a vapour generated by heating a solution containing water, nicotine, propylene glycol, vegetable glycerine and typically also some flavouring. E-cigarettes were developed and first marketed in China in around 2003, and appeared on the market in the UK about 4 years later. The quality of early devices was variable, as was the consistency of the nicotine solutions (e-liquid) that they contained\textsuperscript{29} and their ability to deliver nicotine, which, in some cases at least, was poor.\textsuperscript{30} Newer studies have demonstrated some improvements in quality, at least in relation to declared nicotine content.\textsuperscript{31,32}

The many brands and models of e-cigarettes available can be grouped into three broad categories of different appearance (Fig 5.1). The original or first-generation e-cigarettes were designed to be of similar size and appearance to a conventional cigarette, and hence are sometimes known as ‘cigalikes’. These devices typically comprise two components: a battery and a ‘cartomiser’, a section of the device that contains nicotine solution and a vaporiser. Although some cartomisers are refillable, most are disposable, ie designed for single use and replacement when empty. Second-generation e-cigarettes are larger,
Fig 5.1 The three generations of e-cigarettes: (a) first generation; (b) second generation; and (c) third generation. (Images provided by Anna Phillips.)
typically the size of a large fountain pen, and incorporate a more powerful battery linked to a permanent vaporiser, and a tank system that users can refill with nicotine solution. Third-generation devices are typically larger still, with a still more powerful battery, usually with two heating elements (coils), and allow users to vary power and sometimes also the draw resistance of the device. Third-generation devices are also designed to allow modifications and substitution of individual components according to preference. Second- and third-generation devices generally deliver nicotine more effectively than first-generation devices (see below). The nicotine, propylene glycol, glycerine and flavouring contents of e-liquids also vary substantially, particularly in relation to nicotine content (with some being nicotine free), and in the ratio propylene glycol:glycerine.

5.3.1 Pharmacokinetics

Nicotine delivery from e-cigarettes is influenced by the concentration of nicotine and other constituents of the e-liquid, and the puffing (‘vaping’) technique used, and has generally increased with successive generations of the technology. The earliest first-generation devices delivered little or no nicotine, e.g. two early products containing a 16 mg/mL nicotine solution; when tested in smokers who had not previously used e-cigarettes, it was found that the devices delivered either very little nicotine, achieving a maximum blood level of 1.3 ng/mL at 20 min, or none at all. However, with improved technology and more experienced users, nicotine delivery is improved, e.g. whereas one study found that, among naive users, 5 min free use of an e-cigarette containing 24 mg/mL nicotine produced a peak plasma concentration of 4.6 ng/mL within 5 min, after 4 weeks’ practice the same users were achieving levels of 5.7 ng/mL. A study of a more advanced first-generation e-cigarette containing 18 mg/mL nicotine, and using a longer puffing (vaping) regimen (10 puffs 30 s apart on six occasions every 30 min), resulted in a maximum plasma nicotine concentration of 7.4 ng/mL at 2.5 h after the first puffing bout. In experienced users, using the same 10 puffs in a 5-min regimen, plasma nicotine levels can rise by around 8–16 ng/mL within 5 min of the first puff.

Use of higher nicotine concentrations in the e-liquid increases nicotine delivery, as does the inclusion of propylene glycol. In a study that examined nicotine delivery from a first-generation e-cigarette containing either 16 or 24 mg/mL nicotine, in either 75% glycerine or a 50% glycerine:20% propylene glycol e-liquid, peak plasma nicotine concentrations after 30 min of controlled puffing were highest (18 ng/mL) with the 24 mg/mL nicotine in the mixed glycerine:propylene glycol formulation, and lowest (10 ng/mL) with the 16 mg/mL nicotine in 75% glycerine solution. The propylene glycol:glycerine mix formulation delivered more nicotine at either dose than the...
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75% glycerine solution. This higher delivery is thought to result from the lower boiling point of propylene glycol (187.6°C) than of glycerine (290°C).

Nicotine delivery is generally better from second- and third-generation devices, eg in a direct comparison with first-generation devices using a prescribed 5-min puffing regimen, second-generation e-cigarettes produced significantly higher rises in plasma nicotine concentration (by 4 ng/mL vs 2 ng/mL) at 5 min⁴¹ (Fig 5.3), and with repeated use these devices can sustain venous blood levels comparable with those expected in smokers.⁴² In a study examining the nicotine delivered by a third-generation device, experienced vapers were able to achieve a greater rise in blood nicotine levels than naive users under the same prescribed 5-min puffing regimen (5.8 ng/mL vs 2.7 ng/mL at 5 min),⁴³ although the speed of nicotine delivery remains much slower than from cigarettes.

Levels of the nicotine metabolite cotinine, which reflect nicotine intake over the past 3–4 days,⁴⁴ are similar in experienced e-cigarette users to those observed in smokers,⁴⁵–⁴⁷ indicating that e-cigarettes are capable of delivering...
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5.3.2 Safety profile

E-cigarettes are generally well tolerated. Similar to oral NRT products, reported short-term adverse effects relate predominantly to mouth and throat irritation, and tend to be self-limiting.\(^{29,48,49}\) As with all new products, however, long-term or rare adverse effects will remain uncertain until e-cigarettes have been in widespread use for several decades. Discussion of the potential long-term adverse effects of e-cigarette use is therefore limited to consideration of the likely effects of sustained inhalation of the known constituents of e-cigarette vapour.

Analysis of vapour generated by e-cigarettes has identified a number of potentially harmful constituents delivered alongside the nicotine and other
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E-liquid components. These include volatile organic compounds, carbonyls, aldehydes, tobacco-specific nitrosamines (TSNAs) and metal particles, but all at much lower levels than in cigarette smoke.\textsuperscript{50–64} Levels of formaldehyde and other aldehydes can be relatively high when vaporisation occurs at high temperatures,\textsuperscript{65,66} although in practice this overheating generates an aversive taste known as a ‘dry puff’, which vapers avoid.\textsuperscript{66,67} Recent reviews of the health effects of toxins inhaled during normal use of e-cigarettes have expressed concerns over potential adverse effects based on the presence of these contaminants,\textsuperscript{68–70} but not their levels, which are generally the more important determinant of toxicity. In normal conditions of use, toxin levels in inhaled e-cigarette vapour are probably well below prescribed threshold limit values for occupational exposure,\textsuperscript{71} in which case significant long-term harm is unlikely. Some harm from sustained exposure to low levels of toxins over many years may yet emerge, but the magnitude of these risks relative to those of sustained tobacco smoking is likely to be small. However, consideration of the potential harm of long-term e-cigarette use should serve as a guide to evidence-based product development, regulation and monitoring.

5.3.3 Areas of potential concern over hazards arising from vapour exposure

Areas of potential concern over the long-term effects of e-cigarette use include the effects of vapour constituents depositing in the mouth, upper airway and lungs, and systemic effects of vapour components absorbed as a result of swallowing or inhalation. The vapour constituents to be considered consist of those that should be present in e-liquids, and hence also the vapour, including: nicotine, propylene glycol, glycerine and flavours; those arising from impurities and contaminants in the e-liquid, which vary between batches and suppliers;\textsuperscript{72} and toxins, particles and other components created by the vaporisation process. The long-term adverse effects of nicotine are likely to be minimal\textsuperscript{73} (see also Chapters 4 and 7), although it is acknowledged that the effects of sustained inhalation of nicotine, in isolation from tobacco smoke and as opposed to absorption by another route, have not been studied. There are, however, no grounds to suspect that inhaled nicotine will have an appreciably different risk profile from nicotine delivered via other routes of absorption. The following discussion therefore relates to the effects of other constituents of e-cigarette vapour.

Inhaled vapours deposit first, and often substantially, in the mouth and upper airway. Much of this deposition is then swallowed, absorbed from the gastrointestinal tract and excreted, mostly in urine, either unchanged or after metabolism. This process of deposition, absorption and excretion of TSNAs and other carcinogens in tobacco smoke probably accounts for the increased risks of
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cancer of the oropharynx, stomach, bladder and other organs involved in the absorption and excretion process in smokers. The presence of carcinogens in e-cigarette vapour therefore increases the risk of similar outcomes but, in view of the very low levels of exposure generated by e-cigarette vapour, the magnitude of any increase in risk, in either relative or absolute terms, is likely to be low.

After passing through the mouth and upper airway into the lungs, larger particles and droplets in inhaled vapours deposit substantially throughout the intrapulmonary airways, to be either absorbed and excreted as above, or expectorated. Vapour components <5 µm in diameter reach the alveoli, where they either deposit and are then absorbed or cleared through phagocytosis or other processes, or are exhaled. In tobacco smoking, the deposition of carcinogens carried in tobacco smoke results in an increased risk of lung cancer, whereas oxidants and other toxins and irritants in smoke cause direct and inflammation-induced damage to lung tissues, which leads to chronic bronchitis and emphysema (chronic obstructive pulmonary disease (COPD)) and to pulmonary fibrosis. Smoke components absorbed from the lung, including particles and carbon monoxide, contribute to the increased risk of cardiovascular disease in smokers and, together with local effects, to an increased risk of infection. Although e-cigarette vapour contains a far less extensive range of toxins, and those present are typically at much lower levels, than in tobacco smoke, it is appropriate to consider potential hazards of e-cigarettes in relation to this spectrum of harm.

5.3.3.1 Generic effects of vapour

Data on the effects of e-cigarette vapour on the airways are limited to studies of short-term exposure. Use of an e-cigarette in healthy individuals for 5 min has been shown to reduce exhaled nitric oxide (NO) and increase airway resistance, consistent with an irritant effect on the airways resulting in mucosal oedema, smooth muscle contraction or increased production of lung secretions in response to the vapour. Another study reported a reduction in exhaled NO after inhaling vapour from an e-cigarette, with or without nicotine, of an order of magnitude similar to that provoked by conventional cigarette smoke. However, short-term e-cigarette use has been found to have no effect on spirometric markers of lung function and another study found no difference in reported adverse events over 12 weeks’ use of an e-cigarette with or without nicotine, or conventional NRT. It is therefore far from clear whether these short-term airway effects will translate into long-term airway damage. Furthermore, as smoking cessation is associated with a reduction in respiratory symptoms in people with respiratory disease, many smokers who switch to an e-cigarette are likely to experience improvements in respiratory symptoms. This is illustrated in a study that followed a small cohort of patients with asthma, in whom improvements in symptoms and respiratory function were observed after
switching from smoking to vaping. These observations therefore provide reassurance about short-term use of e-cigarettes in relation to adverse respiratory effects. One survey from Hong Kong has reported a higher prevalence of respiratory symptoms among Chinese adolescents who were ex- or never-smokers, and reported any use of an e-cigarette in the preceding month. However, e-cigarettes were used by only 1.1% of the total sample and 0.1% of never-smokers and, as use of e-cigarettes was not quantified, there is no evidence that those reporting symptoms were using the product regularly.

E-cigarette vapour has been reported to influence resistance to infection, and to delay recovery from influenza infection, in an animal model, although the validity of these findings and relevance to the effects in humans are far from clear. At the time of writing we are not aware of any published evidence on cardiovascular effects of e-cigarette use other than those attributable to nicotine. It is known, however, that the vapour does not deliver appreciable amounts of carbon monoxide, which represents a significant advantage relative to tobacco smoke. A study of carcinogen excretion in participants’ urine after use of e-cigarettes or tobacco cigarettes found significantly lower levels of TSNAs, benzene and polyaromatic hydrocarbons with e-cigarettes, demonstrating systemic absorption of these carcinogens and hence some degree of potential cancer risk, although clearly much less than that associated with smoking.

5.3.3.2 Propylene glycol and glycerine

Propylene glycol is an active ingredient of the solutions used to generate the synthetic smoke widely used in the performing arts and nightclubs, and in this context is generally considered to be safe. In animal studies, a month of exposure to propylene glycol vapour produced no apparent tissue toxicity of the lung, liver or kidney in beagles or rats, although 90 days’ nasal inhalation in rats was associated with an increase in the number of goblet cells and mucin production in the nasal mucosa at levels of exposure >1.0 mg/L. An early study examined long-term exposure to propylene glycol vapour over 12–18 months in rats and monkeys, and identified no lung or other adverse effects. However, acute exposure to propylene glycol has been shown to induce airway irritation and cough in humans, together with minor airflow obstruction. One study also found an association between levels of propylene glycol exposure in the home, and asthma and rhinitis in children.

Evidence on the adverse effects of inhaled glycerine is limited to a single case report of lipoid pneumonia with onset of symptoms associated with commencing e-cigarette use. The pneumonia was attributed to glycerine-based oils in the e-liquid, although commentators pointed out that glycerine is an alcohol and not a lipid. There have been no further reported cases of this
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outcome. Studies of repeated inhalation in rats found no evidence of damage to the lungs.97,98

5.3.3.3 Flavours

Although the flavours used in the e-cigarette liquid are generally those considered safe when ingested orally, some are irritant to the airways and the safety of most flavours after heating and inhalation is unknown.99 Diacetyl is an example of a flavour used in popcorn, and some other foods, that is safe for oral consumption but which, when heated and inhaled in large doses over long periods of time, can cause irreversible bronchiolitis.100 Vapour produced from e-liquids containing flavours has been demonstrated to be more cytotoxic than unflavoured vapour101 and, although both are far less so than tobacco smoke, this exposure may increase airway inflammation.102 In vitro experimental studies have also reported increased susceptibility of airway cells to viral infection after direct contact with e-liquid103 and evidence of cytotoxicity from cinnamon flavours, although the relevance of direct effects of contact with e-liquid, as opposed to vapour, is unclear.50 Although no study so far shows any clear hazards of flavours in e-cigarette vapour, those derived from flavours seem the most likely to pose appreciable health risks from long-term use.

5.3.3.4 Components generated by vaporisation

Heating propylene glycol or glycerine can cause decomposition to low-molecular-mass carbonyl compounds including formaldehyde and acetaldehyde, which can be carcinogenic in large doses.104 A study investigating the effect of varying the heating element voltage in e-cigarettes found that, at low voltage, levels of these compounds were up to 800-fold lower than in tobacco smoke, but that, at higher voltage (4.8 V), the levels were similar.56 In a study involving a third-generation – or variable-voltage – e-cigarette, negligible levels of formaldehyde were generated at lower (normal) power settings, but, when used at maximum power with 3- or 4-s puffs, levels 5–15 times higher than those found in cigarette smoke were observed.65 However, in a study simulating this ‘dry puff’ use, generating high levels of formaldehyde (up to 355 µg), acetaldehyde (up to 206 µg) and acrolein (up to 210 µg), experienced vapers were easily able to detect dry puffs and none could tolerate them.66 Under normal conditions of use, the levels were negligible.66

Two studies have examined urinary levels of aldehydes in vapers. One was a cross-sectional study that demonstrated considerably lower levels of urinary acrolein and crotonaldehyde in vapers than in smokers.89 The other was a cohort study that examined the change in urinary acrolein level when smokers switched to vaping. Significant decreases in acrolein concentrations were observed in smokers who switched completely to e-cigarettes as well as in those who were
both smoking and vaping, showing that 'dual use' of tobacco cigarettes and e-cigarettes leads to a reduction in smoke intake.88

In addition to the vaporised liquid, e-cigarette devices include metals, ceramics and rubber, all of which may become aerosolised in the process of vapour generation,62,105,106 eg copper particles of respirable size (0.450–2.02 µm) have been demonstrated in e-cigarette vapour at a level six times that seen in conventional cigarette smoke;57 levels of nickel and silver that are also higher than those in tobacco smoke have been noted.60 Whether these exposures comprise a significant health hazard remains uncertain. Potential toxicity of metal and other fine particles include carcinogenicity, cardiovascular disease and diseases such as COPD and interstitial lung disease, which are characterised by sensitisation, chronic inflammation or tissue remodelling.107 Inhalation of small particles, over both the short and the long term, also increases the risk of cardiovascular events.108 However, this is probably not a major concern because levels of exposure are well below recognised safety thresholds,109 and could be reduced still further by improving manufacturing processes and standards.

5.3.3.5 Hypersensitivity reactions

Hypersensitivity pneumonitis has been described in response to a range of inhaled organic materials. Allergy to nickel, which can be present in very small amounts in e-cigarette vapour, is a relatively common problem in clinical practice,110 although there has been no reported case of this problem in e-cigarette users. A case of eosinophilic pneumonia has been reported in a smoker who tried an e-cigarette,111 but again this has not been replicated and hence is of uncertain relevance.

5.3.3.6 Relevance to potential long-term harms

The above observations indicate that e-cigarettes deliver a much smaller range of toxins at much lower concentrations than cigarettes, and therefore indicate that harm from e-cigarette use is likely to be far less than that from smoking. They also demonstrate a possibility that some harm from long-term e-cigarette use cannot be dismissed. From first principles, we would expect repeated and sustained inhalation of the generally low concentrations of particulates, oxidants, carcinogens and other constituents to pose some risks to health, particularly in relation to COPD and lung cancer. However, the absolute magnitude of any risk attributable to e-cigarette use is likely to be very small in absolute terms, and hence substantially smaller than that arising from tobacco smoking. A recent evidence review concluded that e-cigarette vapour can contain some of the toxins present in tobacco smoke, but at much lower levels, and that the long-term health effects of e-cigarette use, although unknown, are likely to be much less, if
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at all, harmful to users or bystanders than cigarette smoke. An analysis based on expert opinion quantified the likely harm to health and society of e-cigarettes at about 5% of the burden caused by tobacco smoking, and a recent report by Public Health England supported this conclusion.

With appropriate product standards to minimise toxin and contaminant exposure in e-cigarette vapour, it should be possible to reduce risks of physical health still further. It is also possible, although unlikely, that other, unexpected harm from inhaling e-cigarette vapour over the longer term might yet emerge. Although it is not possible to quantify the long-term health risks associated with e-cigarettes precisely, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure.

5.3.3.7 Effects of passive exposure to e-cigarette vapour

Users of e-cigarettes exhale the vapour, which may therefore be inhaled by others, leading to passive exposure to nicotine. There is, so far, no direct evidence that such passive exposure is likely to cause significant harm, although one study has reported levels of polycyclic aromatic hydrocarbons that were outside defined safe-exposure limits. It is clear that passive exposure will vary according to fluid, device and the manner in which it is used. Nicotine from exhaled vapour can be deposited on surfaces, but at such low levels that there is no plausible mechanism by which such deposits could enter the body at doses that would cause physical harm.

5.3.4 Addiction potential

Speed of nicotine delivery seems to be important for smokers’ satisfaction and addiction potential. As outlined in Chapter 4, as a consequence of pulmonary absorption, cigarettes deliver nicotine to the brain very quickly. Although there are no available data on arterial nicotine levels after e-cigarette use, its venous delivery kinetics appear similar to those of products delivering to the mouth or upper airway, suggesting that pulmonary absorption from currently available e-cigarettes is low. In addition to this, the addictiveness of cigarettes is probably also related to other chemicals in tobacco smoke that enhance nicotine’s effects. These observations tally with other evidence, eg e-cigarette users report that they feel less dependent on them than on tobacco cigarettes, and empirical evidence from adolescent use suggests that, although adolescents experiment with e-cigarettes, few – if any – never-smokers who do so become regular e-cigarette users. The addiction potential of currently available e-cigarettes is therefore likely to be low. NRT and e-cigarettes may satisfy smokers who are already using nicotine, but they have little appeal for never-smokers. This may
change in the future, however, if e-cigarette and other nicotine inhalation technology improves sufficiently to achieve significant pulmonary absorption.

5.3.5 Dual use of e-cigarettes and tobacco cigarettes

Observational population-level evidence indicates that dual users of both tobacco and e-cigarettes are more likely to make an attempt to stop smoking than smokers who do not also use e-cigarettes, but it is not yet clear whether they are more likely to succeed\(^{119,120}\) (see Chapter 6). Some researchers have found a lower subsequent cessation rate among smokers who tried e-cigarettes but continued to smoke than among smokers who did not try e-cigarettes, but this could be explained by self-selection and exclusion of smokers who switched completely to e-cigarettes. One study found that daily users of the more advanced models had a higher cessation rate.\(^{120}\) Experience with NRT suggests that e-cigarette use is likely to increase the proportion of smokers making a quit attempt, but appropriate evidence on this effect is not yet available. A recent study has shown that dual users maintain their intake of nicotine, but reduce their intake of smoke and related toxins significantly.\(^{88}\) Obtaining nicotine from an alternative source leads to a reduction in smoking.\(^{22}\)

5.3.6 Use to inhale other drugs

Refillable e-cigarettes can be used to inhale other materials including cannabis oil or narcotics. Although such use is outside the scope of this report, use of e-cigarettes to deliver cannabis is likely, as is the case for nicotine, to be substantially less hazardous than conventional inhalation of cannabis smoke either alone or mixed with tobacco.

5.4 Products in development

At the time of writing there is a range of non-tobacco nicotine products in development, most of which are variations on the formulations outlined above, but some of which represent genuinely novel approaches, with the potential to deliver nicotine by inhalation with significant pulmonary absorption. As this is the route of absorption that generates the fastest increases in arterial blood levels, this range of products may prove to be the most effective, and also possibly the most addictive, smoking substitutes.

A metered-dose inhaler using propellants to deliver small droplets of nicotine to the respiratory tract has been developed.\(^{121}\) Ten puffs of a 50-µg nicotine/puff inhaler, inhaled via a spacer, resulted in peak plasma nicotine concentrations of...
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12.5 ng/mL within 6 min of finishing the 10 puffs. A 100-µg dose was also tested and resulted in slightly lower peak nicotine concentrations (9.4 ng/mL), most probably owing to the greater adverse effect of coughing at the higher dose. Voke is an inhaler device that is similar in shape and size to a conventional cigarette; it is charged and recharged with an aerosol containing nicotine, propylene glycol and a propellant from a small pressurised canister (similar to those used in asthma inhalers), housed in a pack about the size of a pack of 20 cigarettes. Inhalation of the entire contents of the device provides 0.45 mg of nicotine to the user, with nicotine measurable in arterial blood (mean 2.06 ng/mL) within 2 min of the first inhalation, suggesting at least some pulmonary absorption. A \(C_{\text{max}}\) of 3.7 ng/mL in arterial blood was reached in 7 min. A \(C_{\text{max}}\) in venous blood of approximately 3 ng/mL was reached within 15–20 min. Hourly use results in steady-state plasma nicotine levels of between 8 and 10 ng/mL.\(^{122}\) The product has now been awarded a medicines licence, and hence is likely to be brought to market, although at the time of writing no date has been set.

Nicotine pyruvate is formed from the combination of nicotine and pyruvic acid. Its salts are small (similar in size to the particulate matter in cigarette smoke) and so can be carried deeper into the respiratory tract in the process of inhalation, and are less harsh than pure nicotine to inhale. An inhaler has been developed that contains pyruvic acid and nicotine, which are combined when the user draws air through the device. In participants taking 10 controlled inhalations over 5 min, plasma nicotine levels rose to 5 ng/mL within 5 min when using a dose of 20 µg nicotine pyruvate per puff, and to 8.3 ng/mL with a 30-µg dose.\(^{123}\) This technology was purchased by Philip Morris International Inc in 2011,\(^{124}\) but has not yet been brought to market.

The Aradigm AERx system, which was developed for inhalation of insulin, has also been tested for nicotine delivery.\(^{125}\) There are limited published data about nicotine delivery, but those that are available on the company website\(^{126}\) suggest that nicotine delivery is rapid. The product has not, however, yet been commercialised.

5.5 Summary

- The market in non-tobacco nicotine products in the UK has been dominated for several decades by NRT.
- NRT is licensed as a medicine to help smokers quit smoking, and there is strong clinical trial evidence of effectiveness in this role.
- NRT is also licensed for use to help smokers cut down on smoking, and for temporary abstinence.
- NRT products have an excellent safety profile and present negligible risks to users.
- However, NRT products do not reproduce the rapid, high-dose delivery of
tobacco smoke, and reproduce few if any of the behavioural components of tobacco smoking.

- The dominance of NRT has been challenged in recent years by a growing range of consumer nicotine products, some of which are made to high standards of purity but not necessarily licensed as medicines, and by e-cigarettes, which are now more widely used than NRT.
- Unlicensed nicotine products made to high standards of purity are also likely to have very little risk for users.
- Currently available e-cigarettes are manufactured to variable standards, and many are therefore likely to be more hazardous than NRT.
- Nicotine delivery from e-cigarettes is variable and, with some first-generation devices, very low.
- However, e-cigarette design is evolving quickly, with newer models delivering higher doses of nicotine than their predecessors, and hence being more satisfying for smokers.
- Some of the carcinogens, oxidants and other toxins present in tobacco smoke have also been detected in e-cigarette vapour, raising the possibility that long-term use of e-cigarettes may increase the risks of lung cancer, COPD, cardiovascular and other smoking-related diseases.
- However, the magnitude of such risks is likely to be substantially lower than those of smoking, and extremely low in absolute terms.
- These potential health risks arise primarily from contaminants and components generated by the vaporisation process, which should be amenable to reduction through technological and purity improvements.
- New nicotine products in development are likely to extend the range of choices available to smokers further, increasing purity and safety, and, in those achieving greater pulmonary absorption, addictiveness.
- Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure.

References

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93 Robertson OH, Loosli CG. Tests for the chronic toxicity of propylene glycol and triethylene glycol on monkeys and rats by vapor inhalation and oral administration. *J Pharmacol Exp Ther* 1947;91:52–76.


Fabbro SK, Zirwas MJ. Systemic contact dermatitis to foods: nickel, BOP, and more. *Curr Allergy Asthma Rep* 2014;14:463.


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6 Quitting smoking

6.1 Introduction

Quitting smoking is the most effective means by which smokers can avoid the premature death and disability caused by smoking. This chapter describes current patterns of smoking cessation in the UK, to provide context in which to consider the position and role of harm-reduction policies. As in Chapter 5, data are again drawn from the Smoking Toolkit Study (STS: www.smokinginengland.info), the only national survey within the UK that provides detailed data on smoking cessation behaviour in a representative general population sample. Although limited to smokers in England, STS data are likely to be broadly representative of trends across the UK. This chapter uses STS and other data to explore recent trends in quitting behaviour, and the association between e-cigarette use and smoking prevalence, and to consider approaches to increasing the number of quit attempts made. It also describes patterns of use of e-cigarettes among young people.

6.2 Quit attempts and quit success

STS data indicate that the proportion of smokers making at least one quit attempt each year has fallen over the past 8 years, from 43% in 2007 to 32% in the first 9 months of 2015 (Fig 6.1). This overall trend was reversed in 2012 and 2013, when 34% and 39% made quit attempts, but has since fallen again. These attempts were slightly more likely to occur in women and younger adults and, in 2014 and 2015, among those in non-manual occupations (Fig 6.2).

The proportion of these attempts that are successful in the short term, which can be identified as survey responses from individuals reporting that they have made a quit attempt in the past year and are now not smoking, is around 16%, a slight increase since 2011 (Fig 6.3). There were no marked differences in the proportion of successful attempts in relation to age or gender, but success was more likely among those in higher occupational groups (Fig 6.4).
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Fig 6.1 Proportion of people who have smoked in the past year who made at least one serious quit attempt in that year\(^1\) (data from 42,386 people who smoked in the past 12 months; 2015 figures based on January to September data). (Adapted from the Smoking Toolkit Study\(^1\) with permission.)
Fig 6.2 Proportions of people who have smoked in the past year making at least one serious quit attempt in that year, by gender, age and occupational group (data details as per Fig 6.1). (Adapted from the Smoking Toolkit Study with permission.)
Fig 6.3 Proportion of people who have tried to stop in the past year and are currently not smoking\(^1\) (data from 15,720 people who tried to stop smoking in the past 12 months; 2015 figures based on January to September data). (Adapted from the Smoking Toolkit Study\(^1\) with permission.)

Fig 6.4 Proportion of people who have tried to stop in the past year and are currently not smoking by occupational social group (data details as per Fig 6.3).\(^1\) (Adapted from the Smoking Toolkit Study\(^1\) with permission.)
6.3 Methods used to quit

The methods chosen by smokers in England to help them to quit, reported in the STS study between 2007 and 2015, are represented in Fig 6.5. Until 2013, the most commonly used aid to cessation was nicotine replacement therapy (NRT) bought over the counter, but NRT has been displaced as the most popular choice by a rapid increase in the use of e-cigarettes in England since 2012 (see also Chapter 5). The proportion of smokers who use no aid to cessation has fallen progressively over recent years, but remains above 40%.

![Percentage of smokers using different aids to cessation in at least one quit attempt in the past year](image)

**Fig 6.5** Percentage of smokers using different aids to cessation in at least one quit attempt in the past year \(^1\) (data from 15,720 people who tried to stop smoking in the past year; 2015 figures based on January to September data; respondents may use more than one method per quit attempt). NRT OTC = nicotine replacement therapy bought from a shop; NRT Rx = nicotine replacement therapy obtained on prescription; Varen = varenicline (Champix) prescribed therapy; Bupr = bupropion (Zyban) prescribed therapy; E-cig = e-cigarette; Behav’l support = one-to-one sessions with an adviser or group support; None = none of the aforementioned. Use of other methods such as telephone quit-lines is very low. (Adapted from the Smoking Toolkit Study\(^1\) with permission.)

Evidence from randomised trials\(^2\) and English population data\(^3-6\) indicate that there are three main categories of quit attempt in terms of aids used; these are grouped below in relation to their relative likelihood of success.

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6.3.1 Lowest likelihood of success

The approaches to quitting associated with the lowest likelihood of success are those that are unaided, including use of over-the-counter NRT and use of NRT without professional support. STS data suggest that there is little or no difference in the likelihood of quitting using either of these methods.\textsuperscript{5,6} This observation contrasts with randomised trial evidence that NRT can increase the likelihood of cessation,\textsuperscript{7} and suggests that trial procedures, and perhaps in particular an element of professional instruction and follow-up, may be crucial to NRT effectiveness. This, in turn, indicates that providing even minimal behavioural support to purchasers of NRT could improve the likelihood of successful quitting. As one in five smokers who tried to quit smoking in 2015 did so using NRT purchased from a shop or pharmacy, the low effectiveness of this approach represents a considerable lost opportunity to promote cessation.

6.3.2 Intermediate likelihood of success

Quit attempts among STS participants are around 50% more likely to succeed if they involve NRT, varenicline or bupropion obtained on prescription (and hence involving at least some contact with a health professional), or an e-cigarette bought from a shop.\textsuperscript{3–6} These methods are typically used by more heavily addicted smokers who would otherwise be expected to have a lower chance of success than those using the methods of lowest effectiveness.\textsuperscript{8} The fact that NRT obtained on prescription yields higher success rates than over-the-counter NRT suggests that, again, with this product, some form of clinical supervision or involvement is required for NRT to have an effect. This may be because without supervision smokers use NRT incorrectly, eg by using too little, or use the therapy for too short a time. However, this in turn raises the question of why use of e-cigarettes, which in the limited clinical trials available to date appear to be of similar efficacy to NRT,\textsuperscript{9} appears to be effective even without this supervision. There are, however, a number of possible explanations, as follows.

6.3.2.1 Nicotine delivery kinetics

Although early-generation e-cigarettes delivered relatively little nicotine, experienced e-cigarette users, particularly when using a later-generation product, can achieve venous blood levels similar to those obtained from smoking\textsuperscript{10} (see Chapter 5). Although this is also possible with NRT, it generally requires very frequent dosing with a short-acting product used in combination with a nicotine transdermal patch,\textsuperscript{11} and few consumers of NRT are likely to be aware of the need to follow this kind of dosing regimen. It is therefore possible that users
adopting e-cigarettes without direction on optimal use are more likely to achieve satisfactory nicotine substitution than those choosing NRT.

6.3.2.2 Duration of use

There is a tendency for e-cigarettes to be used for longer than NRT. Although some smokers who use NRT to stop smoking continue to use NRT for months or even years after quitting, they are in a minority; most discontinue the product within a few weeks. In contrast, many users of e-cigarettes continue using the product both before and after quitting smoking, and for a longer period after quitting than most NRT users.12–15

6.3.2.3 Sensory replacement

Unlike NRT, e-cigarettes replicate many of the sensory characteristics of smoking. As outlined in Chapter 4, nicotine addiction is sustained not only by the rewarding characteristics of nicotine itself, but also by reward given to the stimuli and behaviours associated with nicotine delivery.16 As sensory replacement can reduce tobacco withdrawal symptoms,17 the sensation of vapour in the back of the throat, the plume of exhaled vapour, the hand-to-mouth action, and various other sensory and behavioural similarities with cigarettes may help to make e-cigarettes a closer sensory substitute for tobacco smoking than NRT products.

6.3.2.4 Cultural acceptability

Particularly among smokers, e-cigarettes are a socially and culturally accepted direct substitute for smoking. E-cigarette users can still share smoking breaks with and be accepted by other smokers, thus sustaining a social identity as a smoker, but can also tap into the enthusiasm, knowledge sharing and social support for e-cigarette use generated via online user groups and vaping websites. Also, unlike NRT, e-cigarettes are not medicalised, and use does not imply rejection of smoking or a commitment to quitting.

6.3.2.5 Confounding

People who choose to purchase e-cigarettes may differ from those who choose NRT in relation to factors that also influence the likelihood of successful quitting. Although STS analysis suggests that differences in characteristics known to predict smoking cessation outcome, including nicotine dependence, age, social grade and recent history of quit attempts, do not account for the difference in quit rates between those using e-cigarettes and those using NRT,3–6 it is still possible that unmeasured confounding variables could account for the apparent advantage of e-cigarettes.
Clarifying whether and why over-the-counter e-cigarettes appear to be more effective than NRT purchased in the same way clearly requires further research, comparing e-cigarettes and other cessation pharmacotherapy in head-to-head pragmatic trials, and exploring the importance of sensory replacement and other characteristics of the products involved.

6.3.3 Highest likelihood of success

STS data indicate that the greatest improvement in quit rates comes from use of NRT, varenicline or bupropion together with multi-session, face-to-face specialist behavioural support from a qualified stop smoking adviser. This method tends to be used by the most heavily addicted smokers, who would therefore be expected to have the lowest success rates of the three categories but, after adjustment for characteristics associated with likelihood of cessation, this approach appears to increase success rates by between two- and threefold. As NHS Stop Smoking Services (SSSs) have only recently started to support quit attempts using e-cigarettes, the available data on success rates are limited, but early experience estimates quit rates to be at least as high as among those using other medication. In the year to March 2015 in England, only 2,221 SSS users made a quit attempt using an unlicensed nicotine product (ie an e-cigarette), from a total of 445,979 setting a quit date. The average quit rate in all smokers using SSSs was around 51%, and among e-cigarette users it was 66%; although factors other than the product itself are likely to be involved in this difference, the finding is certainly consistent with high efficacy as a cessation therapy.

6.3.4 Trends in uptake of different quitting methods over time

Figure 6.6 shows the proportions of quit attempts using these three groups of quitting methods among smokers in England from 2009 to 2015. It demonstrates that use of specialist services is rare among smokers and that, although most of those making a quit attempt still use the least effective methods to do so, the proportion using methods of intermediate effectiveness is increasing, largely as a consequence of increased use of e-cigarettes.

Through use of estimates of relative effectiveness based on Cochrane reviews of trials of medication and behavioural support, supplemented by the data from smokers in England described above, the growth in use of intermediate effectiveness methods between 2012 and 2015 from 18% to 40% is likely to have generated many thousands of additional successful quit attempts by 2015; the figure for 2014 is likely to be around 19,000. However, these trends also demonstrate that much more needs to be done to increase the number of smokers attempting to quit, and to increase the proportions...
Quitting smoking

6.4 What motivates smokers to try to quit and what are the obstacles?

Smokers make a quit attempt when the desire to quit and confidence in success reach an action threshold. Environmental factors can trigger a quit attempt by either momentarily raising motivation above this threshold or reducing the level of the threshold. In this context, the environment includes social norms about the desirability of smoking, as well as triggers such as health campaigns or advice on smoking from health professionals.

Survey data suggest that, in Britain, motivation to quit is driven primarily by health concerns and the financial cost of smoking, whereas factors such as...
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concern about the effect of smoking on one’s family, not liking being addicted to smoking and feeling stigmatised are present but less frequently cited.26,27 The most important environmental trigger identified from smokers’ reports is health professional advice.26 Mass media campaigns can also play an important role,28 although this does not appear to be explicitly recognised by smokers.26 The introduction of a comprehensive ban on smoking in indoor public areas appears to have had a short-term, but not a sustained long-term, effect on quitting.29

The main personal barriers to making an attempt to quit smoking appear to be enjoyment of smoking, having a positive smoker identity and low confidence in success.27,30 Motivation may also be reduced by smoking among other people who are important to the smoker, such as a partner or friends, colleagues and wider family, although evidence for this influence is less strong.27

6.5 Why do more smokers not try to quit and how could the numbers be increased?

The figures outlined in this chapter thus far relate to the approximately one in three smokers who make a quit attempt each year. Although it is essential to ensure that as many of those as possible succeed in quitting, it is at least as important to increase quit attempts among the remaining majority of smokers who do not make a quit attempt in any given year. Measures are therefore required to increase the proportion of smokers making any attempt to quit smoking, as well as to increase the likelihood of success among those who try.

Chapter 3 outlined the population measures that can influence both quitting and uptake of smoking, and identified price rises and media campaigns as among the most effective. As studies of smokers also identify that the main drivers of motivation to quit are concerns about the health consequences of smoking and the cost of smoking,26,27 the evidence is consistent in indicating that the most effective approaches to increase quit attempt numbers in the UK are likely to comprise price rises and media campaigns using health messages. However, advice from a health professional is also identified by smokers as a key trigger for quit attempts,26 and it would appear that a great deal more could be done to increase the delivery of such advice. Figure 6.7 shows the proportion of smokers in England who report having received advice to stop smoking from their GP in the past year during 2010–15, and reveals that fewer than 40% of smokers recall having received advice to quit; of these, only two-thirds recall having received an offer of help with quitting. Equivalent data from people accessing NHS secondary care services are not available, but anecdotal evidence suggests that delivery of smoking cessation advice and support is also low. As over 1 million
smokers are admitted to hospitals in the UK each year, this also represents a substantial missed opportunity to initiate and support quit attempts.

These findings indicate that guidance from the National Institute for Health and Care Excellence (NICE), which recommends that health professionals should offer help to quit at every opportunity, and support of harm-reduction initiatives among those unwilling to quit, is not being implemented sufficiently widely. Clinical trial evidence also suggests that, although simple advice from a physician to quit is effective, offers of support are more effective, generating quit attempts in around 40% of those receiving the offer. Therefore, there is substantial scope for healthcare professionals to increase the rate of quit attempts by integrating advice and support to quit smoking in all healthcare consultations.

Since 2004, GPs in the UK have received financial incentives to record smoking status and provide advice on smoking, which, although unspecified, is generally interpreted as advice to quit. This scheme applied initially only to smokers with smoking-related conditions and people with serious mental health disorders, but in 2012 was extended to cover everyone who smokes. Moreover, in 2012, the contracted requirement was changed from an offer of advice to an offer of pharmacotherapy and referral for smoking cessation support. Early evidence on the scheme demonstrated that it led to marked increases in the recording of both...
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smoking status and delivery of advice, but no increase in the prescription of pharmacotherapy\textsuperscript{36} over the background trend.\textsuperscript{37} A later evaluation of the 2012 change showed a similar result for all smokers, with increased recording by GPs of smoking status, delivery of advice to quit and referral to smoking cessation services, but no actual increase in prescription of pharmacotherapy.\textsuperscript{38} A similar scheme that rewarded hospitals for ensuring that opportunistic advice on smoking was given to patients was introduced in 2012, and there is also no evidence that this initiative has had any effect.\textsuperscript{39} Reform of these schemes would therefore appear appropriate.

6.6 How could changes in the availability of nicotine products influence quitting behaviour?

Evidence from time-series analyses indicates that increasing the availability of NRT, and introducing new smoking cessation medications to the market, increases the use of these products by smokers trying to stop smoking, but does not increase the proportion of smokers attempting to quit.\textsuperscript{40}

Evidence from placebo-controlled trials indicates that use of an NRT product while continuing to smoke can increase the likelihood of a quit attempt (see Chapter 5), and that this effect is due to the nicotine in the products rather than being a placebo response.\textsuperscript{41} Population-level data confirm that smokers who use an NRT product while smoking are more likely to try to stop, and eventually to succeed in quitting.\textsuperscript{42–45} Although the mechanism for this effect does not appear to involve increased confidence in quitting,\textsuperscript{43} it is possible that nicotine from the NRT product interferes with the maintenance of the association between smoking and nicotine reward, and hence reduces the motivation to smoke. It is also possible that encouraging smokers to experiment with nicotine products, including e-cigarettes, would generate more quit attempts and hence increase smoking cessation. The limited available evidence on this indicates that quit attempts are indeed more common among daily e-cigarette users who continue to smoke, but that successful quitting using the early-generation ‘cigalike’ devices is less common.\textsuperscript{46,47} Research into methods of increasing quit rates among people experimenting with alternative nicotine sources, perhaps by finding ways to deliver quitting advice and behavioural support, is therefore needed.

6.7 Summary

> Approximately one in three smokers in the UK currently attempts to quit each year, but only about one in six of those who try to quit remains abstinent for more than a few weeks or months.
Most smokers who try to quit do so without accessing professional help, preferring either to use no help or support, or else to use NRT or e-cigarettes bought over the counter.

Those who use over-the-counter NRT appear to be no more likely to quit than those getting no help.

Smokers who use over-the-counter e-cigarettes or prescribed medications are more likely to succeed.

The greatest increase in the chances of stopping successfully occurs with prescribed medications used together with specialist behavioural support.

The effectiveness of e-cigarettes used with behavioural support is uncertain, but early data demonstrate a relatively high quit rate.

Smokers are motivated to make a quit attempt in particular by cost and health concerns.

Price rises, media campaigns and brief advice from health professionals are therefore likely to increase the numbers of smokers trying to quit.

Health professional advice and support to quit smoking should be offered as a routine component of healthcare consultations.

Smokers who use nicotine products as a means of cutting down on smoking are more likely to make quit attempts. Promoting wider use of consumer nicotine products, such as e-cigarettes, could therefore substantially increase the number of smokers who quit.

New research is needed to improve the effectiveness of over-the-counter NRT, and to find ways of providing behavioural support to smokers who choose e-cigarettes.

References


7.1 Sources of data

Although detailed data on the prevalence of smoking in Britain have been collected for some decades (see Chapter 2), sources of survey data on the use of nicotine replacement therapy (NRT) or unlicensed nicotine products are relatively limited. The most detailed source is the Smoking Toolkit Study (STS: www.smokinginengland.info), a monthly, household, face-to-face survey of representative samples of the population of England aged 16 and over, in operation since 2007. Data on all smoking and non-tobacco nicotine-containing products, including e-cigarettes, have been collected since 2007 for smokers, since 2011 for recent ex-smokers (<1 year), and since 2013 for never-smokers and long-term (>1 year) ex-smokers. Other large national surveys have added questions on e-cigarettes much more recently, eg in 2014 in the Opinions and Lifestyle Survey and Scottish Health Survey. Data on use of e-cigarettes by children have also begun to be collected only relatively recently in national surveys in England, Scotland and Wales. Action on Smoking and Health (ASH) UK has commissioned annual surveys of e-cigarette use among adults since 2010 and children since 2013, and these extend beyond simple measures of prevalence to include reasons for use, and a range of other factors. The STS is the only source of data on NRT use. This chapter draws on all these sources to review trends in use of NRT and e-cigarettes in Britain over recent years. Most of the data presented are drawn from samples of smokers and recent ex-smokers participating in the STS.

7.2 Trends in the use of non-tobacco nicotine products among adults

Before the widespread uptake of e-cigarette use began in around 2011, NRT was being used by between 15% and 20% of smokers in England (Fig 7.1). However, use of non-tobacco nicotine products has risen sharply since 2011, primarily as a result of a marked increase in e-cigarette use, which has more than offset a more sustained decline in use of licensed NRT. In 2015 about 28% of smokers were
using at least one non-tobacco nicotine product, and more than 20% an e-cigarette (Fig 7.1).

Among recent (<1 year) ex-smokers, use of non-tobacco nicotine products also rose between 2012 and 2015, despite a fall in the use of NRT (Fig 7.2). In 2015 more than half of all recent ex-smokers were using a non-tobacco nicotine product, with more than 40% of these being e-cigarette users.

Fig 7.1 Prevalence of use of NRT, e-cigarettes or any non-tobacco nicotine products among current cigarette smokers in England 2007–151 (data from 36,896 cigarette smokers; 2015 figures based on January to September data). (Adapted from the Smoking Toolkit Study9 with permission.)

Fig 7.2 Prevalence of use of NRT, e-cigarettes or any non-tobacco nicotine products among recent ex-smokers in England 2011–141 (data from 2,318 people who stopped smoking in the past year; 2015 figures based on January to September data). (Adapted from the Smoking Toolkit Study9 with permission.)
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Data for longer-term (>1 year) ex-smokers, which are available since 2013, show a slightly different pattern, with generally lower levels of prevalence of use and stable NRT prevalence, whereas e-cigarette use has increased (Fig 7.3).

The explanation for these trends is not certain, but is likely to be mainly due to continued e-cigarette use among people who have used them to quit smoking, because the proportion of smokers in England who have stopped smoking but then take up an e-cigarette within a year of stopping is only about 10%. The ASH survey in 2015 found that the principal reasons given by ex-smokers who are currently vaping are ‘to help me stop smoking entirely’ (61%) and ‘to help me keep off tobacco’ (53%). The principal reasons given by current vapers who still smoke are ‘to help me reduce the amount of tobacco I smoke, but not stop completely’ (43%) and ‘to help me stop smoking entirely’ (41%). Whether some of these individuals would otherwise have relapsed back to cigarette smoking, had e-cigarettes not been available, is not clear. Exploration of the explanations for these trends is an important area for future research.

Among never-smokers, non-tobacco nicotine use is extremely uncommon. In 2015, 0.1% of never-smokers were using NRT and 0.3% an e-cigarette, and these figures have remained virtually unchanged since 2013 (Fig 7.4).
Among current smokers and recent ex-smokers, e-cigarettes tend to be used by a slightly higher proportion of younger than older smokers (Fig 7.5), but this use does not differ by socio-economic status (Fig 7.6) or gender.

Fig 7.4 Prevalence of use of NRT, e-cigarettes or any non-tobacco nicotine products among never-smokers in England, 2013–15 (data from 24,041 never-smokers; 2015 figures based on January to September data). (Adapted from the Smoking Toolkit Study with permission.)

Fig 7.5 Age distribution of e-cigarette or NRT users in 2013–15 (data from 11,186 smokers and <1 year ex-smokers; 2015 figures based on January to September data). (Adapted from the Smoking Toolkit Study with permission.)
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Fig 7.6 Social grade distribution of e-cigarette and NRT users in 2013–15 (from 11,186 smokers and <1 year ex-smokers; 2015 figures based on January to September data). AB, professional managerial; C1, clerical; C2, skilled manual; D, semi-skilled manual; E, unskilled manual/unemployed. (Adapted from the Smoking Toolkit Study with permission.)

Fig 7.7 Proportion of adults in Scotland in 2014 who had ever used an e-cigarette, by age and sex. (Adapted from the Scottish Government with permission under Open Government Licence.)
The Opinions and Lifestyle Survey estimated that, in the first quarter of 2014, e-cigarettes were being used by 11.8% of smokers, 4.8% of ex-smokers and 0.14% of never-smokers. Data from Scotland indicate that, in 2014, around 15% of men and women reported ever having used an e-cigarette, and about 5% reported current use. This current use was entirely restricted to current smokers (of whom 15% were current e-cigarette users) and ex-smokers (7%). Of never-smokers, 1% reported ever using an e-cigarette, and none were current users. ‘Ever use’ was much more prevalent among younger people (Fig 7.7).

Annual surveys by ASH demonstrate data consistent with STS findings, with almost 60% of smokers in Britain ever having tried an e-cigarette, and just under 18% reporting current use in 2015. Similar to the STS findings, current use had remained unchanged between 2014 and 2015 after rapid growth since 2010 (Fig 7.8).

As in the Scottish data, however, this use of e-cigarettes has occurred almost entirely among current and ex-smokers; in 2015, the prevalence of current use of e-cigarettes among never-smokers was 0.2%. The most frequently reported reasons for using e-cigarettes were to quit smoking, to help maintain abstinence having already quit and, among dual users, to cut down on smoking. The ASH survey in 2015 also explored the type of e-cigarettes that respondents were using, and demonstrated that most had started use with first-generation disposable or ‘cigalike’ devices, but then migrated to second- and third-generation refillable or tank designs (Fig 7.9).
Over 80% of e-cigarette users surveyed by ASH in 2015 were using flavoured e-liquids. Tobacco was the most popular flavour (35% of users), but fruit (25%) and menthol (19%) were also popular.7

7.3 Trends in the use of non-tobacco nicotine products among children

Data on the use of non-tobacco nicotine among children are limited to e-cigarette use. Annual surveys by ASH of young people in the UK since 2013 demonstrate that awareness of e-cigarettes has grown substantially, such that, in 2015, only 7% of young people reported no knowledge of these products, and the proportion of young people who had tried e-cigarettes increased over these three surveys from 5% to 13% (Fig 7.10).8

However, of the 13% of young people who reported in 2015 ever having tried an e-cigarette, most (80%) had done so only once or twice.8 Only 2.4% of all participants in the survey had used e-cigarettes once or more a month, and 0.5% once or more a week. The Scottish SALSUS (Schools Adolescent and Lifestyle and Substance Use Survey) study5 reported similar findings among 13- and 15-
year-olds in 2013, with 7% and 17%, respectively, reporting ever having tried to use or used an e-cigarette, and only 1% in each age group using the product more than ‘once or a few times’. In 2014, the Welsh Health Behaviour in School-aged Children survey of 11- to 16-year-olds in Wales reported that 12.3% of participants had ever used an e-cigarette, and 1.5% were using e-cigarettes at least once a month. The 2014 Smoking, Drinking and Drug Use survey of children aged 11–15 in England found that 22% of participating children had ever used an e-cigarette, but only 1% reported regular use. Regular use of e-cigarettes among young people in the UK thus appears to be very rare. As in adults, it appears that it occurs predominantly among those who are using, or have used, tobacco cigarettes. In 2013 in the Scottish study, all of those who reported having used e-cigarettes more than a few times had been, or were still, smokers (Fig 7.11).

The 2014 Welsh survey reports very similar findings, with young people aged 11–15 who had ever used an e-cigarette being over 20 times more likely than never-users to have ever smoked; those using e-cigarettes more than once a month were more than 100 times more likely to be smoking cigarettes at least once a week. The 2015 ASH survey also reports a strong association between use of e-cigarettes and tobacco cigarettes (Fig 7.12), with almost all e-cigarette users either being current smokers, or having tried or been regular smokers in the past. Regular e-cigarette use in the 2014 English Smoking, Drinking and Drug Use survey was exclusive to children who had at least tried smoking.
Of those using e-cigarettes in the ASH survey, most used a tank or other refillable device, and most used e-liquids with fruit (42%), tobacco (23%) or menthol (13%) flavours.8

Fig 7.11 Use of e-cigarettes, by smoking status, among 13- and 15-year-olds in Scotland in 2013.5 (Adapted from NHS National Services Scotland5 with permission under Open Government Licence.)

Fig 7.12 Young people aged 11–18 who have ever tried an e-cigarette, by smoking status, UK, 2015.8 (Adapted from ASH8 with permission under Open Government Licence.)
7.4 Summary

- Use of e-cigarettes among adults in the UK was rare before 2010, but has since increased to the point that up to one in five smokers now uses an e-cigarette, more than twice as many as use NRT.
- The proportion of smokers using NRT has fallen by about half over this period, but the proportion using any non-tobacco nicotine product has increased to just under 30%.
- These trends are similar but more marked among recent ex-smokers, 40% of whom use an e-cigarette.
- Use of e-cigarettes among adults who have never been regular smokers is very rare.
- There is a slightly greater likelihood that younger adult smokers will use e-cigarettes than NRT; in Scotland, younger men are more likely to use them.
- Adult regular e-cigarette users tend to use tank or other refillable devices, rather than first-generation ‘cigalikes’, and tobacco-, fruit- or menthol-flavoured nicotine.
- The proportion of young people in Britain aged <18 who have ever used an e-cigarette is increasing, but remains low.
- Most use among young people appears to be single or very occasional experimentation. Use more than once a month is relatively rare and more than once a week extremely rare.
- Regular use is almost exclusively limited to young people who are already either regular or occasional smokers, or have experimented with smoking in the past.
- Young regular users of e-cigarettes also favour later-generation devices, and fruit, tobacco or menthol flavours.
- In adults and young people in the UK, therefore, use of e-cigarettes is limited almost entirely to those who are already using, or have used, tobacco.

References

Tobacco harm reduction


8.1 The need for harm reduction

Prevention of smoking is vital to public health, and much progress has been made in reducing the prevalence of smoking in the UK over recent decades (see Chapter 2). However, the data presented in Chapter 2 also demonstrate that this success has been achieved primarily by reducing uptake of smoking among younger people, more than improvements in the rate at which established smokers quit smoking. It is, however, these established smokers in middle and older age who will generate most of the population burden of morbidity and premature mortality caused by smoking over the next two decades. As established smokers today are more likely to be socio-economically disadvantaged or to have mental health problems (see Chapter 2), this burden of disease will fall disproportionately on these groups who, as a result of higher levels of addiction to nicotine, also find it particularly difficult to quit smoking.

Increasingly powerful incentives for existing smokers to try to quit smoking, and strong support to help them succeed, are therefore urgently required. Further application and extension of the conventional policy options summarised in Chapter 3 might be expected, at best, to sustain the decline in smoking prevalence of close to 0.7 percentage point per year achieved over the past decade in the UK (see Fig 2.1, Chapter 2), the consequence of which will be that most of the current smokers in the UK, and particularly the most heavily addicted smokers, will continue to smoke for several decades. The public health imperative in relation to smoking is, however, to reduce prevalence as much and as quickly as possible, for example, to achieve the widely agreed objective of a ‘tobacco-free’ society (comprising smoking rates of 5% or less in all socio-economic groups) by 2035, and this requires the addition of new strategies. Harm reduction offers the potential to add significantly to the current rate of decline in smoking prevalence among all population groups. The availability of alternatives to tobacco, as a source of nicotine for the most heavily addicted smokers, also allows the application of much higher levels of taxation on tobacco without necessarily exacerbating poverty in those smokers who find themselves unable to quit in response to increases in tobacco prices. In Sweden,
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the availability of snus has been estimated to have added around 0.4 percentage point per year to the rate of decline in smoking prevalence.\textsuperscript{4} E-cigarettes, and other non-tobacco nicotine products, surely have the potential to achieve at least the same in the UK.

Harm-reduction approaches, by promoting substitution of tobacco with less hazardous sources of nicotine, thus represent a potentially powerful complement to existing prevention policy, particularly among the relatively highly addicted and typically disadvantaged smokers who are likely to find it most difficult to quit.\textsuperscript{5,6} However, pursuing a harm-reduction strategy also carries risks of unwanted effects in society. This chapter explores some of the harms caused by tobacco smoking in different periods of life, and the probable balance of risks and benefits of harm-reduction approaches based on substitution with NRT or other non-tobacco nicotine products, particularly e-cigarettes.

8.2 Potential hazards of harm reduction

Although harm-reduction approaches have the potential to reduce the hazard of nicotine use among the current smoking population, they also bring potential hazards to wider public health. For example, a product that is half as damaging to health as tobacco smoking has the potential to halve the harm caused by smoking in society, if used exclusively and completely as a substitute for tobacco by current smokers, and young people who would otherwise have become smokers. That benefit would be reduced or even reversed, however, if the new product came to be sufficiently widely used among non-smokers that the benefits to smokers were eclipsed by harm sustained by non-smokers. The benefit of harm reduction to smokers would also be offset at population level if use of harm-reduction products increased the risk of smoking uptake (known as gateway progression, see below), undermined existing tobacco control measures by making the act of smoking socially acceptable again (renormalisation) or discouraged quitting by being used as a partial substitute for tobacco smoking (‘dual use’), without progression to complete substitution among smokers who would otherwise have quit. These processes are discussed in more detail below.

8.2.1 Renormalisation

In relation to tobacco smoking, renormalisation refers to processes that undermine or reverse a progressively increasing perception in society that smoking is not a normal or desirable behaviour.\textsuperscript{5} For much of the 20th century smoking was part of the fabric of British life, and children grew up perceiving...
smoking to be something that many, if not most, adults did. In recent years, however, the acceptability of smoking has changed, particularly as a consequence of prohibition of tobacco advertising, smoking in enclosed public places and point-of-sale displays, and other measures. Although smoking remains relatively common, and hence relatively normal, in some communities or social groups, this is no longer the case in general. Examples of renormalisation might include: the use of e-cigarettes in areas where smoking is prohibited, thus creating an impression that smoking is acceptable; advertising or other imagery that evokes tobacco smoking through e-cigarette use; behavioural modelling from use of e-cigarettes by parents, siblings, peers, friends, celebrities or others; or other processes that in some way make smoking more appealing.6,7

8.2.2 Gateway progression

Gateway progression is a process by which, in relation to tobacco smoking, use of non-tobacco nicotine is proposed to cause uptake of smoking that would not otherwise have occurred. Gateway theory has its origins as a descriptive model for progression from use of soft drugs to use of hard drugs, and a recent review of evidence from animal models concluded that nicotine exposure may indeed increase susceptibility to other drug use, independent of other determinants of common liability.8 In nicotine use, however, the gateway theory has also been applied as a predictive model proposing that use of non-tobacco nicotine is likely to cause progression to use of nicotine through tobacco smoking,9 and therefore that use of e-cigarettes by non-smokers, and particularly by children, could cause smoking uptake independent of other determinants of smoking initiation. Similar concerns have in the past been expressed in relation to nicotine replacement therapy (NRT) and smokeless tobacco.9

8.2.3 Dual use

Dual use refers to the concomitant use of non-tobacco nicotine by smokers who continue to smoke tobacco. As outlined in Chapter 5, reasons for dual use include relief of nicotine withdrawal symptoms at times when smoking is not allowed, or a desire to cut down on smoking without necessarily a commitment to quit. However, concerns have been expressed that dual use may inadvertently sustain smoking by making it easier to abstain when smoking is prohibited and the smoker might otherwise have quit, and that smokers who could otherwise have quit elect for dual use instead, in the mistaken belief that this generates significant health gains. There are particular concerns that the tobacco industry will promote dual use of e-cigarettes as a means of sustaining, rather than cutting down or quitting, tobacco smoking in their customers10 (see Chapter 9).
8.3 Harm to health and wellbeing of self and others from smoking at different stages of life

Smoking directly damages the health of all who smoke (see Chapter 1), increasing the risk of a wide range of fatal and non-fatal illnesses\(^1\) and causing over 120,000 deaths in the UK in 2010.\(^2\) However, the adverse effects of smoking extend well beyond this direct harm to the individual smoker, and are not limited to the later period of life when the increased mortality in smokers becomes more acute. Through the life course of any individual from the point of conception, maternal smoking (and hence fetal exposure in utero) impairs fetal growth and development, and increases rates of fetal and neonatal death, low birth weight, preterm birth and developmental anomalies.\(^3\) Passive maternal smoking during pregnancy increases the risk of stillbirth and developmental anomalies\(^3,\)\(^4\) and reduces birth weight.\(^5\) In childhood, passive exposure to tobacco smoke causes sudden infant death, respiratory infections, middle-ear disease and exacerbation of asthma.\(^8\) Passive exposure to others’ smoke during adulthood causes transient symptoms such as eye and throat irritation at all ages, and in later life contributes to higher mortality from lung cancer, cardiovascular disease and chronic obstructive pulmonary disease (COPD).\(^9\)

Harm from smoking is not limited to that arising from inhaling tobacco smoke. Probably through behavioural modelling and opportunities for experimentation, children whose parents or other household members smoke are more likely to take up smoking themselves,\(^1\) thus perpetuating smoking and its consequent harm in successive generations. Smoking rates in the wider communities and environments that children grow up in also influence smoking uptake, because children whose peers smoke, and those exposed to smoking imagery in the media, are more likely to become regular smokers.\(^1\) Smoking is a significant drain on family budgets, exacerbating poverty,\(^2\) and a drain on wider society, which suffers the opportunity cost of funding over £3.3 billion in direct healthcare and social care costs in the UK, and over £10 billion in lost productivity and other societal costs.\(^2\) Thus, although smoking has little direct effect on the personal health of individual smokers during early adult life,\(^2,\)\(^3\) the risks to others, especially children, are substantial.

As outlined above, all or almost all of these harms could be prevented or else much reduced by substitution of smoked tobacco with a less hazardous source of nicotine. The potential benefits and risks to individual and societal health of doing so are now considered in relation to the two main options currently available in the UK: conventional NRT products and unlicensed non-tobacco nicotine products, including e-cigarettes.
8.4 Harm reduction with conventional NRT products

8.4.1 Health harms

As use of nicotine alone in the doses used by smokers represents little if any hazard to the user, complete substitution of smoking with conventional NRT products is, for practical purposes, the equivalent of complete cessation in almost all areas of harm to the user. NRT products do not emit vapour and so are not a source of passive exposure for adults or children. Packaging and dose restrictions render accidental poisoning in children highly unlikely. Questions remain about the safety of nicotine in pregnancy and potential effects on fetal development and mortality, although one recent study has reported a lower occurrence of developmental abnormality among children whose mothers used NRT in pregnancy than in those whose mothers did not.

8.4.2 Renormalisation of and gateway to smoking

Only the Nicorette inhalator bears any resemblance to a cigarette, so users of most NRT products provide no behavioural modelling that could encourage primary uptake of, or sustain, tobacco smoking by others. Use of NRT among never-smokers is rare at all ages and, despite early concerns to the contrary, there is no reported evidence that use of the inhalator or any other NRT product in young people has ever acted as a gateway to smoking.

8.4.3 Dual use and gateway from smoking

NRT was developed as a smoking cessation therapy for use after an abrupt and complete cessation of tobacco smoking. The efficacy of NRT used in this way is well established. More recently, however, NRT has been licensed in the UK for use together with continued smoking, to relieve withdrawal symptoms during temporary abstinence from smoking, or to cut down on smoking, ie for dual use. Before the advent of e-cigarettes, up to 15% of current smokers in England used NRT in this way, although the proportion is now closer to 5% (Fig 8.1). Although cutting down on smoking achieves relatively little in terms of health benefits, use of NRT together with tobacco smoking does appear to reduce compensatory smoking to a modest extent and, among smokers with no intention to quit, to increase, by as much as twofold, the likelihood of a subsequent quit attempt. It also protects those around the smoker from the harmful effects of passive smoking. For this and other reasons, dual use of NRT and tobacco smoking is licensed by the Medicines and Healthcare products Regulatory Agency (MHRA) and recommended by the National Institute for Health and Care Excellence.
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(NICE) as a tobacco harm-reduction strategy. As use of NRT in this way increases the likelihood of quitting, in these circumstances NRT acts as a gateway from smoking.

8.4.4 Population health effects of substitution of smoking by NRT

With the possible exception of use during pregnancy, complete substitution of smoking by NRT achieves much the same in health terms as quitting both smoking and all nicotine completely. Widespread uptake of NRT by non-smokers would therefore result in little harm to public health, but is in any case rare. Gateway progression from NRT to smoking among those who have never smoked does not, for practical purposes, occur. Dual use results in a modest reduction in tobacco smoking of little or no significance to health, but promotes quitting. Promotion of NRT as a reduced harm substitute for smoking is therefore unequivocally good for health. Economic analysis of the use of NRT in a harm-reduction strategy, including a range of scenarios in which opting to cut down rather than quit detracted to different degrees for those who would otherwise have quit, found that all options were cost-effective in relation to preventing major disease costs to the NHS, and hence were acting in favour of population health.

Fig 8.1 Self-reported use of NRT or e-cigarettes to aid cutting down on smoking, England, 2009–15. (Adapted from the Smoking Toolkit Study with permission.)

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8.5 Substitution with e-cigarettes

8.5.1 Health harm

As e-cigarettes have been in widespread use in the UK and most other countries for less than a decade, the health effects of long-term use are as yet unknown. As outlined in Chapter 5, there is very little evidence that short-term use of e-cigarettes causes any appreciable harm to users or to others, but information on long-term health effects of repeated and sustained inhalation of e-cigarette vapour is of necessity limited to inference, based on knowledge of the vapour's constituents. The oxidant, particulate, carcinogen and other toxin contents summarised in Chapter 5 would be expected, from first principles, to increase the risk of lung cancer, COPD, cardiovascular disease and other diseases caused by smoking, but at much lower levels of risk. For the less common health sequelae of smoking, levels of increased risk are likely to be negligible. The risks attributable to long-term inhalation of nicotine in isolation from tobacco smoke, and of the propylene glycol, glycerine and other components unique to e-cigarettes, are also uncertain but likely to be low. The health harm to long-term users of e-cigarettes is therefore likely to be marginally greater than for those who use conventional NRT.

Harm to others from vapour exposure is negligible (see Chapter 5). The effects of maternal use on the fetus are unknown but, on the grounds of the very low levels of toxins in vapour, are probably close to those of NRT. Accidental poisoning in children from ingestion of e-cigarette solutions, which has been reported and typically results in nausea and vomiting, are preventable through the use of childproof fasteners.

8.5.2 Renormalisation and gateway to smoking

First-generation e-cigarettes were designed to resemble tobacco cigarettes in approximate shape and size, and hence their use provides a behavioural model similar to smoking, which could appeal to young people or smokers trying to quit smoking, appear to undermine smoke-free policy, and be used by the tobacco industry to cross-promote smoking imagery and hence tobacco products through e-cigarette advertising (see Chapter 9). However, even first-generation products are visually distinct from cigarettes, and exhaled vapour easily distinguishable from tobacco smoke in terms of appearance, smell and irritancy, making confusion unlikely between e-cigarettes and tobacco cigarettes in areas covered by smoke-free legislation. Later-generation e-cigarettes have less or no physical resemblance to tobacco cigarettes. Use of e-cigarettes to generate smoking imagery in advertisements is prevented under UK advertising codes of practice.
Data from Wales indicate that children whose parents or peers use e-cigarettes are more likely to experiment with e-cigarettes themselves, and to intend to smoke in the future, than children without this exposure. However, as parental e-cigarette use occurs almost exclusively among current or former smokers, children in these households would be expected to have higher smoking intentions, and it is unclear whether this risk is either increased or decreased by the availability of e-cigarettes as opposed to tobacco cigarettes.

The prevalence data on the use of e-cigarettes by both adults and children presented in Chapter 7 demonstrate that e-cigarette use in Britain is, to date, almost entirely restricted to current, past or experimental smokers. As with NRT, there is no evidence thus far that e-cigarette use has resulted, to any appreciable extent, in the initiation of smoking in either adults or children; the extremely low prevalence of use of e-cigarettes among never-smoking adults and children indicates that, even if such gateway progression does occur, it is likely to be inconsequential in population terms. Although it remains important to monitor the use of e-cigarettes in young people, to ensure the quick identification of evidence of any increase in uptake of smoking arising from e-cigarette use, it appears that, to date, concerns over gateway progression into smoking are unfounded. The association between e-cigarette and tobacco cigarette use is therefore more likely to arise from common liability to use of these products, and to use of e-cigarettes as a gateway from, rather than to, smoking.

8.5.3 Dual use and gateway from smoking

Office for National Statistics data indicate that, in the first quarter of 2014, 11.8% of smokers, 4.8% of ex-smokers and 0.14% of never-smokers in Britain used e-cigarettes; smoking prevalence data from the same source indicate that these proportions represented approximately 2.2%, 2.6% and 0.08% of the total adult population, respectively. On these figures, therefore, about 45% of e-cigarette users in Britain are using them together with smoking, which is about twice as many as do so with NRT. As dual use of NRT is recommended as a means of increasing the likelihood that smokers will attempt to quit smoking, and early-generation e-cigarettes appear to be approximately as effective as NRT as a cessation aid, it follows that the same is likely to apply to e-cigarettes. Observational data from England confirm that smokers who use e-cigarettes at least daily are indeed twice as likely to make a quit attempt, or else to reduce their smoking, than those who do not, although in this study the likelihood of success among those attempting to quit was not increased by e-cigarette use. Independent clinical trials and observational data from the Smoking Toolkit Study indicate that e-cigarette use is associated with an increased chance of quitting successfully, but further longitudinal and trial data would be helpful to define any such effect more precisely.
These findings suggest, however, that, among smokers, e-cigarette use is likely to lead to quit attempts that would not otherwise have happened, and in a proportion of these to successful cessation. In this circumstance, e-cigarettes act as a gateway from smoking. However, it is not yet known whether, or by how much, e-cigarettes are being dually used by smokers who would otherwise have quit completely, and hence act as a barrier or delay to cessation. It is also not known whether or by how much a preference to try to quit using e-cigarettes is displacing uptake of the more effective conventional NHS Stop Smoking Services (SSSs) or other services combining pharmacotherapy with behavioural support, and hence reducing overall quit numbers, or whether this effect is counteracted by the much broader reach and uptake of e-cigarettes relative to NHS SSSs.

It seems likely that the chance of successful quitting with e-cigarettes would be increased if smokers who chose to use them, whether for cutting down or quitting, could also receive additional behavioural support, and perhaps, given the evidence that the combination of two nicotine products is more effective than one alone, were encouraged to combine e-cigarette use with a nicotine transdermal patch. Research and development of methods are clearly needed to engage and support smokers who start to use e-cigarettes, for whatever reason, to increase the likelihood of successfully quitting.

8.5.4 Population health effects of substitution of smoking with e-cigarettes

Thus far, the availability of e-cigarettes appears to have been positive for UK public health. Uptake has been rapid among adults and limited almost entirely to smokers, and has contributed to a continued downward trend in UK smoking prevalence. Use by children who would not otherwise smoke appears to be minimal. In many ways, therefore, their availability and adoption as a consumer alternative to smoking share many parallels with the use of snus as a consumer harm-reduction product in Sweden. Although long-term safety remains a concern, it appears likely that the combined influences of impending regulatory controls (see Chapter 10) and technological advances will lead to significant improvements in the probable long-term hazard profile of these products in the near future. These developments mean that unlicensed e-cigarettes are likely, in the near future, to approximate to NRT in terms of long-term hazard. The arrival on the market of licensed products, whether e-cigarettes or other novel designs, will make that prospect even more of a reality. In that case, e-cigarettes are likely to share the efficacy of NRT as a harm-reduction option under most circumstances.

However, the creation of models of these beneficial effects for products available today, and also those of potentially adverse influences such as widespread uptake...
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by non-smokers, gateway effects into smoking and sustaining dual use rather than quitting among established smokers, is difficult and inevitably dependent on assumptions about the probable magnitude of these influences. At the time of writing, we are aware of only two published attempts to do so. A proof-of-concept study applying Markov modelling to a cohort of adults aged 18–24 in the USA developed two models of smoking and e-cigarette use, the more conservative of which predicted that the prevalence of adult cigarette smoking within the cohort would increase from 15% at baseline to 21% after 10 years.52 These figures do not therefore appear applicable to the UK, where a 6 percentage point increase in smoking prevalence after the age of 25 has not happened in over 40 years (see Fig 2.11). A Monte Carlo analysis approach, modelling various scenarios of relative uptake by smokers and non-smokers, and at levels of harm relative to smoking ranging from 1% to 50%, predicted population benefits as long as use of e-cigarettes is concentrated among those who already smoke, or would otherwise have become smokers.53 As the true magnitude of e-cigarette harm is likely to lie at the low end of that modelled range, and experience to date indicates that use of e-cigarettes is almost entirely confined to smokers, these predictions support the notion that e-cigarettes, within the context of a regulatory environment designed to discourage use among youth and never-smokers, are likely to benefit public health.

8.6 Summary

> Uptake of smoking is falling in the UK, but most current smokers are likely to continue smoking for many years.
> Most of the morbidity and mortality caused by smoking in the short- and near-term future will occur in people who are smoking now.
> More effective measures to help existing smokers to quit smoking, as soon as possible, are therefore urgently needed.
> Harm reduction has the potential to complement conventional tobacco control policy by offering an alternative means for smokers to stop smoking tobacco.
> Substituting medicinal nicotine (NRT) for tobacco almost completely prevents any further damage to self or others from nicotine use.
> Although the long-term hazards of e-cigarette use are not yet clearly defined, e-cigarettes are probably close to NRT in the harm that their use confers on the user and others.
> The long-term hazard associated with e-cigarette use is likely to fall, as a result of regulatory and technological developments.
> There is no evidence that either NRT or e-cigarette use has resulted in renormalisation of smoking.
> None of these products has to date attracted significant use among adult never-smokers, or demonstrated evidence of significant gateway progression into smoking among young people.
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> NICE guidance recommends dual use of NRT for harm reduction, largely because dual users are more likely eventually to quit smoking.
> Evidence on the natural history of smoking among dual users of e-cigarettes is less well established, but a similar effect is likely.
> Promotion of the use of non-tobacco nicotine, including e-cigarettes, as widely as possible as a substitute for smoking, in the context of a regulatory framework designed to discourage use among youth and never-smokers, is therefore likely to generate significant health gains in the UK.

References

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31 Moore D, Aveyard P, Connock M et al. Effectiveness and safety of nicotine replacement
therapy assisted reduction to stop smoking: systematic review and meta-analysis. BMJ 2009;338:b1024.


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9.1 Introduction

In 2013, the investment bank Goldman Sachs identified e-cigarettes as one of eight emergent themes in the global economy capable of ‘creative destruction’, representing a new technology that could offer consumers a significantly superior proposition and potentially ‘forcing established companies and business models to either adapt or die’. In the same year, The Economist newspaper similarly asked whether the rise of e-cigarettes represented the tobacco industry’s ‘Kodak moment’ – ‘its version of the point at which the world’s leading maker of camera film realised that consumers had gone digital, and it was too late to chase them’. The continuing profitability of the tobacco industry, which arises overwhelmingly from sales of tobacco cigarettes, suggests that such reports of the industry’s demise are at best premature. However, these claims do highlight the substantial degree of uncertainty about the commercial implications of e-cigarettes for the future of the tobacco industry and therefore for the strategic development of tobacco control.

The disruptive effect of e-cigarettes is not confined to the tobacco industry. The chairman of the pharmaceutical giant GlaxoSmithKline, for example, has acknowledged that, in response to the declining performance of their nicotine replacement therapies (NRTs), the company considered manufacturing e-cigarettes before concluding that such a step would be ‘just too controversial’. Leading tobacco companies have, perhaps predictably, made a different decision, implementing a rapid programme of investment in and acquisition of vapour devices. The public health implications of such developments remain uncertain and contested, and reflect broader debates about the role of harm reduction in general. At one end of the spectrum, harm-reduction advocates and researchers see advantages in engaging an industry skilled in marketing nicotine in the promotion of products that could offer a potential exit strategy from selling cigarettes: identifying, for example, the ‘need to create a situation in which there are incentives for tobacco companies to gradually become nicotine companies … [such] that their long-term profits are going to be in other products than cigarettes’. At the other end of the spectrum are those who see no such prospect,
claiming, for example, that ‘only the most naive or captured advocates for vaping could fail to acknowledge that the tobacco industry wants people who vape to smoke and vape, not vape instead of smoking’. This chapter explores the motives for and potential consequences of the tobacco industry’s engagement in harm reduction and, in particular, the emerging e-cigarette market.

9.2 The tobacco industry and e-cigarettes

E-cigarettes have emerged as a significant component of the market in nicotine products with astonishing rapidity, both in the UK and globally. The market research company Nielsen identified e-cigarettes as the fastest-growing product in British supermarkets during 2014, with sales across large grocers increasing by almost 50%. A report on the UK market in nicotine vapour devices by the industry analysts Euromonitor suggested even greater growth, with a category that was worth only £25 million as recently as 2011 having reached overall sales of £459 million in 2014. This growth also reflected changing consumer preferences, with first-generation (‘cigalike’) devices (see Chapter 5) being displaced in the UK by the rapid expansion of tank systems and of e-liquids, which experienced value growth of 110% and 145% respectively in 2014. This shift is also strongly evident in other leading western European markets, although ‘cigalikes’ retain majority shares in both Russia and the USA. The UK e-cigarette market is now estimated to be the world’s second largest, being exceeded only by the USA, whereas global sales of an estimated $US6.5 billion now dramatically outstrip the declining international market for NRT (US$2.4 billion), and are equivalent in value to cigarette sales in the world’s 20th-largest cigarette market.

Having perhaps been taken by surprise by the rise of e-cigarettes, the transnational tobacco companies have all now committed to major initiatives in this emergent industry. A key moment was the April 2012 acquisition of the e-cigarette brand blu™ by the US-based cigarette manufacturer Lorillard for $US135 million, marking the tobacco industry’s first major foray into the e-cigarette market. In December 2012, British American Tobacco (BAT) became the first leading tobacco company to buy a British e-cigarette manufacturer through its purchase of CN Creative, the maker of Intellicig. This complemented BAT’s earlier formation of what was billed as a stand-alone start-up company, Nicoventures, to ‘focus exclusively on the development and commercialisation of innovative regulatory approved nicotine products’. All of the leading international cigarette manufacturers have now made substantial acquisitions or launched strategic initiatives in nicotine products, principally in e-cigarettes. Altria and Philip Morris International (PMI) manage vapour brands including Mark Ten, Nicolites and the heat-not-burn product iQOS; BAT brands include Vype, Intellicig and an inhaled nicotine device called Voke; Japan
Tobacco International have purchased E-Lites and launched Ploom; RJ Reynolds have developed Vuse and Revo, whereas Imperial Tobacco launched Puritane through its Fontem Ventures subsidiary and, in July 2014, obtained the blu™ brand that was sold as part of Reynolds’ takeover of Lorillard.11–12,17

These investments have, to date, been weighted heavily towards first-generation ‘cigalikes’, which mimic tobacco cigarettes more closely, but tend to deliver lower doses of nicotine than, later-generation devices (see Chapter 5), and it has been suggested that this is a deliberate strategy to avoid promoting products likely to be effective in aiding cessation.18 Recent developments suggest diversification, with tobacco companies looking beyond ‘cigalikes’: the Vivid Vapours e-liquid brand has become increasingly prominent in the UK after its acquisition by PMI, and the blu™ product range is expanding via its e-liquid portfolio.19 Investments in heat-not-burn technology (positioned as reducing risks associated with combustion by electronically heating tobacco rather than burning it6), as well as in non-tobacco nicotine products (see Chapter 5), further increase the diversity of tobacco company initiatives in reduced risk products, and PMI’s launch of its iQOS Heatsticks, under its flagship Marlboro brand in test markets in Japan and Italy, suggests that this development is of major strategic importance to PMI.20 It does appear that tobacco industry efforts to build a market for reduced-risk products are now centred on vapour devices, as epitomised in July 2015 by PMI announcing the dissolution of its snus joint venture with Swedish Match while extending its international strategic collaboration with Altria in vaping products.21

The engagement of the tobacco industry in the reduced-risk product sector is thus changing rapidly, and in relation to e-cigarette products is likely to continue to do so, given, among other things, the expected changes in regulatory context, new patterns of ownership and investment, the currently fragmented market, absence to date of dominant brands, and continuing technological innovation and shifting consumer preferences. Such uncertainties notwithstanding, however, rapid growth in the e-cigarette market is predicted to continue over the next few years, with Euromonitor suggesting that the global market for vaping products could reach US$50 billion by 2030. This is clearly a substantial and enticing prospect from a commercial perspective, although it needs to be interpreted alongside an expectation that it will remain a fraction of the market in tobacco products, with cigarettes remaining the dominant product category.22

9.3 E-cigarette marketing

The first television advertisement for an e-cigarette, promoting the then independently owned E-Lites brand, was broadcast in the UK in January 2013.11 This was followed a year later by advertisements for Vype, an e-cigarette
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marketed by BAT and representing the first overt paid-for television advertisement by a tobacco company in over two decades,\(^23\) and then, later in 2014, by advertisements showing the act of vaping for the VIP e-cigarette brand.\(^24\) Such developments occurred amid considerable ambiguity about how and whether existing regulatory frameworks applied to reduced-risk nicotine products. This led to a public consultation by the Committees of Advertising Practice,\(^25\) followed by the issuance of specific guidance\(^25,26\) intended to govern the period until the implementation of more stringent regulation of advertising, sponsorship and promotion under the 2014 revision of the EU Tobacco Products Directive 2014/40/EU.

The development of television advertising campaigns forms one strand of an extensive array of marketing, sponsorship and promotional efforts that have contributed to the rapid growth of the e-cigarette market. Sports sponsorship deals, for example, have included Nicolites partnering with Birmingham City Football Club, whereas E-Lites secured distribution deals and designated vaping areas in Celtic and Rangers football stadiums in Glasgow, and invoked the strong association between tobacco and motorsport in announcing its sponsorship of the British Superbike Championship.\(^27–29\) E-Lites secured the first product placement for e-cigarettes in a music video by the artist Lily Allen. Packaging innovations have included ‘smart packs’ produced by blu\(\textsuperscript{TM}\) e-cigarettes that vibrate and flash a blue light when within 50 feet of other users, and which can transmit to Facebook and Twitter profiles, whereas Vapestick has created a retro-style computer game named Electronic cigarette wars. PMI also offered retailers free retail display shutter cases heavily branded with its Vivid e-liquid and Nicolites e-cigarettes, in preparation for the second stage of UK point-of-sale display legislation, which prohibited point-of-sale display of any tobacco product from April 2015.\(^30\)

Such high-profile activity is indicative of the recent rise of e-cigarette promotions across multiple fields, driven by rapidly escalating expenditure. During 2013, around £8.4 million was spent in the UK promoting five leading brands (E-Lites, Vype, SkyCig, NJOY King and Gamucci) across press, television, radio, the internet and outdoor media, figures that were to be dwarfed in 2014\(^31\) with BAT’s television advertising for Vype as part of a £3.6 million marketing campaign and SkyCig announcing investment in a £20 million marketing campaign.\(^27\) A similar surge in marketing spending has occurred in the USA, where a study of advertising spending across television, print, radio and the internet found that expenditure in the second quarter of 2013 amounted to $US28 million, some eight times more than that for the equivalent period in 2012.\(^32\)

This escalation of marketing expenditure reflects the increased resources available following the wave of investments in e-cigarettes by the tobacco industry, with the latter’s engagement in marketing raising distinct concerns.
Looking at the future development of the market in vapour devices from a commercial perspective, this represents both opportunity and risk, because leading tobacco companies 'have the capital to turn e-liquid brands into household names but also the reputational impairment to attract draconian regulation to the category'. In this context, discussions about how to regulate the marketing of e-cigarettes are inevitably coloured by the tobacco industry’s long-standing global reliance on advertising and marketing to promote and maintain cigarette consumption, particularly by targeting young people. Health campaigners have raised concerns about the extent to which some e-cigarette advertising has sought to replicate imagery and themes that have long been central to marketing cigarettes. Magazine adverts for e-cigarettes in the USA have, for example, been seen as depicting equivalents to the rugged masculinity of the Marlboro Man or the glamorous independence of the Virginia Slims woman, sponsorship of sports and music events, and the development of sweet flavours are seen as enhancing appeal among youth, and blu™ e-cigarettes’ use of a cartoon ‘Mr Cool’ evoked the notorious Joe Camel cartoons. In the UK, rules on advertising limit such opportunities and the Advertising Standards Authority recently upheld complaints about an advert for VIP e-cigarettes that showed a woman vaping ‘in a sultry and glamorous way’, creating a strong association with traditional smoking and thereby ‘indirectly promoting the use of tobacco products’. Complaints about a UK advert for Vape Nation were upheld as encouraging use of e-cigarettes among ex-smokers.

Maintenance of extensive marketing freedom and potentially controversial promotional strategies for e-cigarettes has been defended as likely to appeal to smokers, and it has been argued that excessive regulation is likely to protect the market monopoly of tobacco cigarettes by inhibiting competition from e-cigarettes. Analyses from a social marketing perspective, however, have emphasised risks associated with e-cigarette marketing in general, and the role of tobacco companies within such activities in particular. In presenting the promotion of e-cigarettes as a reinvention of tobacco marketing, de Andrade et al highlight the active promotion of dual use, in which marketing activities are identified to have been ‘promoting long term use as a permanent alternative to tobacco, and a temporary one in public places where smoking is banned’. An analysis of the marketing strategy of tobacco company-owned e-cigarettes for Cancer Research UK was organised around a distinction between marketing targeted at potential consumers and those activities oriented towards ‘stakeholders’, such as policymakers and public health agencies (Table 9.1).

Although debate about the potential for such campaigns to renormalise or inadvertently promote smoking continues, attention is increasingly focused on the tobacco industry’s use of e-cigarettes and the wider harm-reduction agenda to rebuild its links with policymakers, and public health and other key stakeholders.
Table 9.1 Tobacco-owned e-cigarettes – the marketing strategy

<table>
<thead>
<tr>
<th>Marketing challenge</th>
<th>Marketing strategy</th>
<th>Stakeholders</th>
</tr>
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</table>
| Who
| Objective | Long-term sales of tobacco through ‘next-generation’ product (especially in developed countries), profit maximisation | Responsibility, legitimacy, credibility, access to policymakers/regulatory processes, public–private partnership, scientific proof |
| What | Reduced-harm product, safer alternative to cigarettes, used for pleasure, lifestyle products | Harm reduction |
| How
| Product: safe nicotine, used anywhere, flavoured lifestyle products | Product: harm reduction |
| Price: financial – affordable; psychological – safer and glamorous | Price: financial – priceless, saving lives; psychological – it would be negligent to ignore this offering |
| Promotion: where tobacco products cannot be advertised, lifestyle and celebrity | Promotion: health bodies/experts, charities, politicians, regulators |
| Place: everywhere tobacco is available, company websites, point-of-sale displays | Place: regulated space |
| Positioning: safer smoking alternative, necessity, capitalise on consumer’s preference | Positioning: differentiation from NRT products, reframe perceptions of nicotine use, alternative for those who cannot or will not quit |

9.4 Undermining tobacco control

The recognition of a fundamental conflict between public health objectives and tobacco industry interests has become a central tenet of tobacco control, epitomised by Article 5.3 of the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC), which requires countries to protect the setting and implementation of tobacco control policies from the industry’s commercial and other vested interests. The emergence of a distinctive model of
health governance, centred on minimising engagement with the industry, has led to tobacco companies experiencing increasing political marginalisation and difficulty obtaining access to policy elites. In this context, investments in harm reduction and e-cigarettes offer potential opportunities to claim legitimacy in re-engaging with policymakers, and even to rehabilitate what has become a pariah industry. If realised, these opportunities may therefore undermine tobacco control.

Tobacco companies have long sought to redress the challenge of a toxic reputation by seeking to establish partnerships or common ground with public health researchers and advocates. A key element of PMI’s ‘Project Sunrise’ in the mid-1990s, for example, was to ‘enhance our credibility’ by linking with ‘moderate’ tobacco control organisations on issues such as youth access legislation.

Tobacco companies’ interest in the concept of harm reduction increased markedly following a 2001 Institute of Medicine report, driven by recognition of a dual opportunity to both ‘(re-)establish dialogue with and access to policymakers, scientists and public health groups and to secure reputational benefits via an emerging corporate social responsibility agenda’. The emergence of pure nicotine alternatives to traditional forms of tobacco consumption has thus created increased opportunities for both interaction with policymakers and the depiction of common ground with public health. In the context of a public consultation on the future of the NHS, for example, Imperial Tobacco met with the then minister for public health, and subsequently made a submission in which the company invoked its interests in harm reduction to argue against exclusion from policymaking and to position itself as a potential partner for the government. Several tobacco industry submissions to a Department of Health consultation on the future of tobacco control similarly used interests in harm reduction as a basis for suggesting that it could positively contribute to the challenge of reducing health inequalities.

Exploiting such opportunities was a key part of the remit of Nicoventures following its establishment by BAT. In 2012, Nicoventures initiated a medical education plan named the Smoking Harm Reduction Education Programme (SHARE), holding a series of meetings with healthcare professionals, including a round table at the Royal Society of Medicine, and publishing proceedings in GP and Pharmacy Magazine. In June 2013, Nicoventures approached public health officials across various regions in the UK to discuss harm reduction and regulation, with a sales representative describing the company as complying with the regulatory standards required of a pharmaceutical company. BAT also appointed Dr Richard Tubb to their board of directors in January 2013, describing this former physician to the president of the USA and ex-director of the White House Medical Unit as ‘a prominent and well respected expert in the field of tobacco harm reduction’ whose appointment ‘further demonstrates our commitment to putting science at the heart of our business’. The company
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devoted its 2013 sustainability focus report to the issue of harm reduction, depicting BAT as a potential partner in a public health revolution; this included an endorsement of the group’s strategy by Dr Delon Human, a global health consultant and former head of the International Food and Beverage Alliance, as having the expertise and public commitment to harm reduction to suggest that ‘BAT’ could become part of the solution to addressing the epidemic of tobacco-related disease. The report claims that ‘(m)ore collaboration between the tobacco industry, academia and tobacco research centres is … key to establishing an evidence-based regulatory framework to assess new products.

Alongside such examples of formal endorsements, tobacco companies have also opportunistically cherry-picked statements from leading public health organisations and researchers so as to imply common ground and a shared perspective. The harm-reduction section of the PMI website cites a 2014 report from Public Health England (PHE) as recognising a need for ‘appropriate regulation, careful monitoring, and risk management’ for harm-reduction products; the citation is presented under a headline claim that the ‘public and private sectors are starting to embrace the public health opportunity new products provide’, but does so without noting that the PHE report highlights the involvement of the tobacco industry among ‘potential hazards, unintended consequences, (and) harms to public health’.

A key element of the strategic value of harm-reduction discourse to tobacco companies is its ability to polarise opinions held by those involved in tobacco control policy, fracturing the remarkable degree of political consensus that has characterised the tobacco control movement and been central to its success. PMI’s ‘Project Sunrise’ centred on the recognition of unity as a key strength of tobacco control, and promoting division was seen as critical to combating the movement’s success. The company’s strategy sought to exploit latent tensions between groups that it labelled ‘moderates’ and ‘prohibitionists’, and this finds strong contemporary echoes in the depiction of competing wings of tobacco control comprising ‘pragmatists’ who favour harm-reduction approaches being opposed by ‘idealists’ or ‘zealots’.

In this context, the very public dispute in 2014 between competing perspectives on harm reduction via ‘duelling letters’ from public health researchers and practitioners to the director-general of WHO, Dr Margaret Chan, appears very welcome from a tobacco industry perspective. The initial open letter of 24 May 2014 with 53 prominent signatories was prompted by a concern that harm reduction was being ‘overlooked or even purposefully marginalised’ in preparing for the forthcoming sixth Conference of Parties of the WHO FCTC. The letter began to receive significant media coverage on 29 May 2014 and on the same day BAT issued a press release calling ‘for tobacco harm reduction to be adopted as a progressive public health policy’.

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subsequent letter remains prominent on the harm-reduction pages of BAT’s website, emphasising ‘the importance of dispassionate presentation and interpretation of evidence’ and the challenge to find ‘an appropriate framework’ of regulation balancing opportunities and risks. These twin themes are also repeatedly invoked in the company’s subsequent 2014 harm-reduction report. Its introduction by chief executive Nicandro Durante suggests that ‘the challenge is that these are new products which many governments are still unsure how to regulate’ and cites ‘the growing weight of evidence and arguments in support of harm reduction’. The report highlights a call from a paper by three of the letter’s signatories for regulatory decisions to be ‘proportional, based on evidence, and incorporate a rational appraisal of likely risks and benefits’, presenting a variation on BAT’s long-standing claim to ‘support sensible regulation’.

Although neither the reputational management nor policy engagement opportunities afforded by harm reduction have yet been exploited with success that can be considered transformational, a number of strategically valuable ‘wins’ for the tobacco industry can be identified. Notable here is the success of BAT’s Nicoventures in securing marketing authority from the UK Medicines and Healthcare products Regulatory Agency (MHRA) for its nicotine inhaler Voke, a success has been described as ‘an important waypoint on the industry’s journey to self-rehabilitation’. Vype, also owned by BAT’s Nicoventures, is marketed as a ‘pharmaceutical-grade product’ and sold via Lloyds Pharmacy, whereas Puritane e-cigarettes, owned by the Imperial Tobacco subsidiary Fontem, are exclusively available in Boots. Such distribution deals are inconsistent with advice from the Royal Pharmaceutical Society, and both bring reputational benefits of association with prominent high-street chemists and create strategic opportunities. Puritane’s deal with Boots is seen as leaving it well placed to benefit from any reclassification of e-cigarettes to ‘directly rival smoking cessation aids’.

9.5 E-cigarettes and the future of the tobacco industry

Tobacco companies’ investments in e-cigarettes, as with earlier incarnations of the harm-reduction debate, have been characterised by considerable uncertainty, false starts and fluctuations, and there is nothing to suggest that the recent developments outlined above constitute a fixed and settled strategic direction, whether for specific companies or for the industry as a whole. There is, however, now a sufficient basis to draw some preliminary conclusions informed by marketing campaigns, investor presentations and stated strategic priorities. Such conclusions need to be informed by the historical experience of how and why tobacco companies viewed earlier reduced-risk products, with which striking similarities are becoming evident. One potential parallel has recently been drawn
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in light of the history of NRT, via tension between two competing conceptions of NRT as a therapeutic device to aid cessation and as a cigarette alternative capable of delivering nicotine in the ‘right way’. This analysis highlights the dangers of the potential of e-cigarettes being ‘easily compromised in the hands of tobacco companies, reflected by their tendency for imagining nicotine replacements … as creatively complementing rather than creatively destroying the market for combustible tobacco products.’

More broadly, the tobacco industry’s recent involvement with e-cigarettes carries echoes of its earlier rise to dominance of the Swedish snus market via acquisitions and joint ventures between 2001 and 2009, eg an analysis of BAT corporate documents from this period yielded no substantive evidence of the company encouraging smokers to switch permanently to smokeless tobacco, but indicated instead that these were essentially defensive investments that protected the status quo and the dominance of the cigarette by shifting ‘snus from a threat (a product that may have competed with cigarettes) to a major opportunity’ that presented common interests with public health and an alternative future amid long-term decline in cigarette sales.

One significant difference that emerges from comparison with the snus experience is the prominence afforded e-cigarettes and reduced-risk products in contemporary investor presentations. This contrasts with a near absence of snus from earlier BAT and PMI presentations, which suggest that snus was not central to business strategy. The reformulation of BAT’s vision statement to become ‘the world’s best at satisfying consumer moments in tobacco and beyond’ indicates newfound strategic centrality for nicotine projects, mirrored in PMI’s designation of reduced-risk products as ‘our greatest growth opportunity’. Although the reputational and stakeholder engagement advantages of e-cigarettes for tobacco companies are clearly considerable, this does seem also to represent a consumer market in which growth prospects are being taken seriously.

The extent to which this constitutes a transformation of the strategic landscape for tobacco companies should not, however, be overstated. To return to the image of creative destruction, the emphasis seems to be very much on e-cigarettes creatively complementing conventional products within an expanded portfolio, not on displacing the industry’s ongoing reliance on the conventional cigarette. Hence BAT has been unequivocal that their ‘ambition remains to lead the global tobacco industry’, retaining confidence in the growth of the global tobacco business and developing their portfolio of ‘beyond tobacco products’ within a single integrated view of the consumer. New products are therefore positioned alongside traditional cigarettes, combustible innovations and non-combustible offers in creating multiple satisfying ‘consumer moments’. Similarly, PMI chairman Louis Camilleri’s speech to the company’s 2015 annual meeting emphasised that ‘we expect our combustible products to be the core of our
profitability growth for many years to come’, notwithstanding the significance attached to investing in and developing reduced-risk products. The decision to launch the company’s heat-not-burn iQOS system under the Marlboro brand is also consistent with ongoing concerns that tobacco companies are using e-cigarette marketing to promote dual use, thereby complementing and sustaining rather than challenging the future dominance of the cigarette.

Any suggestion that tobacco companies are using investments in e-cigarettes as a vehicle to secure their long-term exit from the cigarette market therefore looks like misplaced optimism. Their engagement in harm reduction is likely to be better understood in terms of exploring an emerging opportunity that can buttress their core business, and promise the maintenance of both their licence to operate and the prospect of rehabilitation. Appraising the implications of this perspective for the broader role of harm reduction within the future of tobacco control remains contentious, but it does serve to highlight the ongoing importance of protecting health policy from tobacco industry interference and of maximising compliance with guidelines for the effective implementation of WHO FCTC Article 5.3.

Although the most optimistic interpretations of increased tobacco industry interests in reduced-risk products might suggest the prospect of some degree of shared interest with public health, the economic and political contexts within which such products are being promoted suggests that any such appraisal is dangerously naive and holds the potential significantly to undermine tobacco control policy and practice internationally. Interests in e-cigarettes and other reduced-risk products create important strategic opportunities for the tobacco industry, and therefore compound the complexities confronting public health in dealing with the harm-reduction agenda. The appropriate response is therefore to strengthen and broaden protections against conflicts of interest, protecting ‘tobacco control activities from all commercial and other vested interests related to [e-cigarettes], including interests of the tobacco industry’.

9.6 Summary

The e-cigarette market has demonstrated massive growth in value and, until relatively recently, has been driven by independent e-cigarette companies.

This success represents a potential challenge to the traditional business model of the tobacco industry, but also creates important commercial and political opportunities.

After some delay the tobacco industry is now engaging in the e-cigarette market, and the possible reasons for doing so include:
- promotion of low-efficacy products that are likely to fail and hence minimise the threat to tobacco sales
- use of intellectual property rights to bring legal challenges against competitors
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- ensuring a share in the emerging e-cigarette market to harness a new, disruptive technology
- using these products to sustain tobacco smoking by promoting them as a complement rather than an alternative to tobacco
- using the products also to promote smoking through advertising and promotion to adults and children
- attracting customers who currently use competitors’ tobacco products
- creating justification to re-engage with policymakers, hence undermining the WHO FCTC (Article 5.3)
- exploiting harm reduction to build credibility in corporate social responsibility initiatives
- using harm reduction as a pretext to engage with and disrupt the activities of scientists and advocates in tobacco control.

The engagement of the tobacco industry in the e-cigarette market thus represents a significant potential threat to UK national and global tobacco control.

References


10 Smithers R. Electronic cigarettes and sports nutrition products lead grocery sales boost.
E-cigarettes, harm reduction and the tobacco industry


18 Torjesen I. Tobacco industry is investing in electronic cigarette types least likely to help smokers quit. BMJ 2015;350:h2133


35 Campaign for Tobacco-free Kids. 7 ways electronic cigarette companies are copying big tobacco's playbook, 2 October 2013 (online). www.tobaccofreekids.org/tobacco_unfiltered/post/2013_10_02_ecigarettes [Accessed 15 August 2015].


46 Peeters S, Gilmore AB. Understanding the emergence of the tobacco industry’s use of the term tobacco harm reduction in order to inform public health policy. *Tob Control* 2015;24:182–9.


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10.1 What does nicotine product regulation need to achieve?

Products are regulated to ensure that they are safe and fit for purpose; the general product regulations that apply to all consumer products sold in the UK, and their equivalents in other countries, are intended to achieve this for general consumer goods. In the case of products for which safety is particularly important, these general product regulations are often supplemented or superseded by higher levels of specific safety regulation, with medicines, for example, being required to meet especially high standards of manufacturing, safety, product information and efficacy. The overall purpose of all of this regulation is, however, to ensure that consumers can access products that serve their purpose within reasonable bounds of safety, quality and efficacy.

The rationale for regulating nicotine products is the same as for any other, but is complicated by the fact that the market leader in nicotine products in the 20th and 21st centuries, the cigarette, is so intrinsically hazardous that it is beyond the scope of conventional general product regulations, and as an addictive product is too entrenched in society to be amenable to prohibition. It is therefore important that the approach to regulating non-tobacco nicotine products recognises the need not only to meet the general requirements of safety and fitness for purpose, but also to encourage the development and uptake of competitive alternatives to the fatally toxic product currently chosen by most habitual nicotine users. Therefore, although regulation of all products should be proportionate to their potential hazard, proportionality in nicotine regulation must also incorporate the consideration that regulation that discourages or delays the development and use of non-tobacco nicotine is likely, in effect, to sustain tobacco smoking and hence perpetuate harm to smokers and wider society.

This report has argued that nicotine use, of itself, presents relatively little risk to users or wider society, and that most of the harm that arises from nicotine use is attributable to the vehicle of delivery, with tobacco smoke being by far the most hazardous. It therefore follows that, although the ideal course of action for any smoker is to quit smoking and all nicotine use, quitting smoking by long-term
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substitution with a less hazardous nicotine source is the next best option. Nicotine regulation should therefore be designed to make non-tobacco nicotine a more attractive, available and affordable option for smokers than cigarettes, to prevent, as far as possible, uptake of nicotine use by never-smokers, particularly children, and to make smoked tobacco products as unappealing as possible.

When the RCP last reported on nicotine regulation in 2007, the range of available nicotine products fell into three classes: smoked tobacco, smokeless tobacco and nicotine replacement therapy (NRT). We argued then that the prevailing regulatory structure intrinsically favoured smoked tobacco over both NRT, which was regulated as a medicine, and smokeless tobacco, of which the lowest-hazard product, Swedish snus, is prohibited in the UK. The emergence of e-cigarettes has added a whole new product class to this range, and this spectrum of choice is likely to be increased still further by new technologies in development (see Chapter 5). The nicotine regulatory framework has also undergone substantial change since 2007.

This chapter describes recent developments and impending changes in UK nicotine regulation, identifies key areas of concern, and discusses alternative approaches that might increase the public health benefit accrued from the emergence of e-cigarettes and other non-tobacco nicotine. The discussion is based in the UK setting and pertains to the three broad types of nicotine product available on the UK market: tobacco, unlicensed nicotine products (predominantly e-cigarettes) and nicotine products that are licensed as medicines.

10.2 Current regulation of tobacco, and licensed and unlicensed nicotine products

10.2.1 Tobacco products

Since 1998, a comprehensive tobacco control strategy has been introduced in the UK, the component measures of which are discussed in more detail in Chapter 3. Regulatory approaches have included: reducing affordability by increasing taxation and reducing the size of the cheap and illicit market; imposing packaging and labelling requirements (including the implementation of standardised packaging legislation from May 2016); prohibiting all advertising, promotion and sponsorship; restrictions on where, how and to whom tobacco products can be sold; and smoke-free policies determining where tobacco can be used. After unsuccessful attempts to regulate the cigarette itself by restricting tar levels, regulation of product contents and emissions has not been extensively pursued, other than to prevent fires by reducing ignition propensity. The overall package of tobacco control policies in place in the UK is one of the most...
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advanced in the world, with the UK currently highest in the European tobacco control league table. The new EU Tobacco Products Directive (TPD) will, from May 2016, impose a range of new restrictions on tobacco products, which include a minimum pack size of 20 cigarettes (and 50 g hand-rolling tobacco), restrictions on the shape of packs, combined pictorial and text health warnings that cover 65% of the front and back of the pack, and prohibition of flavourings including, after a delay, menthol.

10.2.2 Unlicensed nicotine products

E-cigarettes (most of which contain nicotine) and other unlicensed nicotine products are currently regulated in the UK by the EU General Product Safety Directive. This has recently been supplemented by legislation in England imposing a minimum purchase age of 18 years, which is currently in the process of being introduced elsewhere in the UK. General product regulations do not require products to be tested before being put on the market, but do allow retrospective action to remove products found to be faulty or harmful. In July 2015, the British Standards Institute (BSI) published a fast-track voluntary standard for e-cigarettes (PAS 54115), which was sponsored by the Electronic Cigarette Industry Trade Association (ECITA (EU) Ltd) and facilitated by the BSI. This standard gives guidance on the manufacture, import, labelling, marketing and sale of vaping products, including e-cigarettes, e-shishas and e-liquid mixing kits. However, at the time of writing it is not clear how widely this standard is being adopted by manufacturers and importers.

E-cigarette marketing in the UK has to comply with compulsory advertising codes administered by the Advertising Standards Authority (ASA). Although those codes contain general rules that apply to all advertising, concerns about the promotion of e-cigarettes led the ASA to introduce sector-specific rules in November 2014. These require the following of e-cigarette advertising: to be socially responsible; not to promote any design, imagery or logo that might be associated with a tobacco brand or show the use of a tobacco product in a positive light; to make clear that the advertised product is an e-cigarette and not a tobacco product; not to undermine quit smoking messages; and not to contain health or medicinal claims unless the product holds a medicines licence. There is a commitment to review progress with these rules after 12 months.

Although not subject to the smoke-free legislation that prohibits tobacco smoking in enclosed public places and workplaces, some businesses and organisations prohibit e-cigarette use in places where this legislation already prohibits smoking. Given the lack of evidence on the harmfulness of e-cigarette vapour to others (see Chapter 5), it would be inappropriate for national legislation to prohibit their use in public places and workplaces. At the time of
going to press, an attempt by the Welsh government to legislate to ban the use of e-cigarettes in some enclosed places and workplaces had failed and was considered unlikely to be reintroduced in the next parliament after the elections in May.8

There are some circumstances, such as prisons and mental health settings, where tobacco smoking is particularly prevalent. The option to use e-cigarettes where tobacco smoking is banned could help to introduce and sustain fully smoke-free policies, eg the South London and Maudsley NHS Foundation Trust implemented a policy that allows some types of e-cigarette to be used, as part of a care treatment pathway, in private spaces or grounds where smoking is prohibited.9 Prisons in England and Wales have made single-use e-cigarettes available for sale to prisoners as a smoking substitute, in preparation for implementing fully smoke-free policies across the prison estate which started in late 2015.10

10.2.3 Licensed nicotine products

Nicotine products licensed as medicines, generally known as nicotine replacement therapy (NRT), have been available in the UK since 1980. They were initially licensed by the Medicines Control Agency (MCA) for use to relieve nicotine withdrawal symptoms during attempts to quit smoking, and were subject to an extensive range of cautions and contraindications that arose from the use of comparison of adverse effects with those of placebo, rather than continued smoking.

The MCA was replaced in 2003 by the UK Medicines and Healthcare products Regulatory Agency (MHRA), which was established with a wider remit, including a new objective to make ‘an effective contribution to public health’. In 2005 the MHRA made some substantial changes to their regulation of NRT products in response to a review and recommendations by the Committee on Safety of Medicines, an advisory committee to the MHRA.11 These included the adoption of smoking rather than placebo as the comparator for NRT, which allowed some contraindications (eg stable cardiovascular disease) that inhibited use of NRT by smokers to be removed, extending the licence for NRT to include pregnant smokers, and smokers aged 12 and over, and allowing some NRT products to be used for cutting down in order to quit, as well as for abrupt quitting. There has also been a progressive relaxation of restrictions on the availability of NRT over recent years, starting in 2001 when prescriptions of NRT products became reimbursable through the NHS, and subsequently through extensions to retail availability by allowing NRT products to be sold by general retailers as well as pharmacies. Direct advertising of NRT to the public is permitted subject to regulations12 requiring the following from promotions: they are not misleading and do not imply that products are ‘safe’; they are compliant with the details listed in the summary of product characteristics; they are presented objectively to encourage rational use of
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the product; and they are not directed exclusively or principally at people aged under 16. Provision of free samples of NRT for promotional purposes remains prohibited. Since 2007, NRT sold over the counter has been subject to VAT at a reduced rate of 5% to help make products more affordable.13

In 2010, the MHRA expanded the indication for NRT to allow long-term use as a harm-reduction alternative to smoking for those who were unwilling or unable to quit.14 The question of whether e-cigarettes should be regulated as medicines was considered by the MHRA at this time, which proposed that nicotine be deemed a medicine by function, thereby requiring that e-cigarettes should either be licensed as medicines or removed from the market. However, as immediate classification as medicines would have caused all e-cigarettes on the market at the time to be withdrawn, and hence potentially cause the many smokers who had already switched from using tobacco cigarettes to e-cigarettes to go back to tobacco smoking, the MHRA consulted on options15 that included implementing medicines regulation immediately, or after a delay allowing e-cigarette manufacturers and importers to comply, or else imposing no additional regulation. The proposed licensing option was described by the MHRA as ‘light touch’ and presented as a simplified, and hence quicker and less costly, route to medicines licensing. In particular, the proposed ‘light touch’ approach assumed that any product that delivered nicotine to a degree comparable with existing licensed nicotine products was clinically effective, thus removing the requirement for manufacturers or importers of e-cigarettes or other nicotine-containing products to carry out clinical trials to demonstrate efficacy.

The consultation received over 1,000 responses, most of which came from e-cigarette users opposed to any regulation, or else supporting regulation introduced in a way that allowed e-cigarettes to remain available to them. Responses from public health organisations, including the RCP, were generally supportive of ‘light touch’ regulation, but most recommended a delay to allow time for manufacturers to comply. Support for immediate regulation, with removal of unlicensed products from the market within 21 days, came from organisations including pharmaceutical companies, pharmacist and trading standards groups, and Imperial Tobacco.15 The MHRA responded by allowing e-cigarettes to remain on the market pending further consideration, and in 2013 announced that it would require all nicotine products to be licensed as medicines from the date of implementation of a revision of the TPD (see Section 10.3 below). The TPD version under consideration at that time required medicines regulation for all but very-low-dose products. The MHRA later rebadged the medicines licensing process for nicotine products as ‘right touch’ regulation.

In 2014, a revised version of the TPD, which superseded the MHRA proposal by providing an alternative route to market for e-cigarettes without a medicines licence, was negotiated and agreed.3,16 Medicines regulation remained an option
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for manufacturers and importers of e-cigarettes, and the MHRA continues to encourage companies to apply voluntarily for licences. However, licensing is no longer mandatory and, at the time of going to press in early 2016, only one e-cigarette, owned by British American Tobacco (BAT), had been awarded a medicines licence by the MHRA and was not yet commercially available. It is not known whether medicines licence applications have been made for other e-cigarette products. A medicines licence has, however, been awarded to a nicotine inhaler (not an e-cigarette) called Voke, developed by Kind Consumer and licensed to BAT, but at the time of going to press this product had not been marketed.

10.3 The 2014 EU TPD

The 2014 revision of the EU TPD, which comes into effect from May 2016, imposes significant new regulations on nicotine products, including e-cigarettes and refill containers that do not have a medicines licence. Although limited areas of flexibility in implementation for member states remain, the main provisions of the TPD in relation to e-cigarettes are as follows:

1 Manufacturers and importers of e-cigarettes must provide a detailed notification to the government-appointed ‘competent authority’ of a range of details relating to each product, and make this information publicly available. Non-compliant products can be manufactured until 20 November 2016 and sold until 20 May 2017. Products already on the market by 20 May 2016 must be notified by 20 November 2016. New products or substantial modifications introduced into the market between 20 May and 19 November 2016 must be notified at least 1 day in advance of going on sale. From 20 November 2016 all new products or substantial modifications must be notified 6 months in advance of going on sale.

2 Required details include: quantification and toxicological data for all ingredients and emissions, including when heated, and their potential health and addictive effects; nicotine delivery and uptake; a description of the product components and production process; and a declaration of responsibility for the quality and safety of the product when used under normal or reasonable foreseeable conditions.

3 There will be a limit on total nicotine content in e-cigarettes, which will be allowed to contain a maximum of 2 mL nicotine solution at a maximum nicotine concentration of 20 mg/mL. Refill containers will be subject to a maximum volume of 10 mL. Nicotine and all other ingredients used in manufacture must be of high purity and not pose a risk before or after heating, and substances other than those declared should be present only in trace quantities, which are unavoidable during manufacture. Products must be child and tamper proof, and protected against breakage and leakage.
4 Nicotine doses are required to be delivered at consistent levels under normal conditions of use.

5 Products should include a leaflet, which, among other things, contains instructions, warnings, and information on contraindications, possible adverse effects, addictiveness and toxicity. Outside packaging must list ingredients, nicotine content and delivery per dose, carry a batch number, and a health warning stating ‘This product contains nicotine which is a highly addictive substance’. Outside packaging must not include any promotional element or feature to suggest that the product is less harmful or has other health or lifestyle benefits.

6 Cross-border advertising, sponsorship and promotion in the press and broadcast and internet media are prohibited, as are cross-border sales unless subject to a registration scheme. Domestic advertising through billboards, at point of sale, on public transport or other local media is permitted unless prohibited by domestic legislation, as is under consideration in Scotland. Provision of information about products online is still legal.

7 Manufacturers and importers must deliver an annual submission on their products to governments, which should include comprehensive data on sales volumes, consumer preferences, mode of sale and market developments. These submissions should be made publicly available unless classified as trade secrets.

8 Manufacturers, importers and distributors of products are required to establish and maintain a system for collecting information about all the suspected adverse effects on human health. Corrective action is required if there are reasons to believe that products are not safe or of good quality, or not conforming to the directive.

9 Regulation of flavours, and age of sale, remains the responsibility of member states.

At the time of going to press, the UK government’s intention to transpose the TPD into UK law was still the subject of a legal challenge by an e-cigarette company, Totally Wicked. However, in December 2015 the advocate general dismissed this and other challenges to the TPD and, although a final court ruling is not due until 4 May, it now seems likely that the TPD will be implemented as originally proposed on 20 May 2016. The UK competent authority for e-cigarettes under the EU TPD will be the MHRA. From 20 May 2016, therefore, all e-cigarettes sold in the UK will be regulated by the MHRA either under the provisions of the TPD or as medicines, or both.
10.4 Advantages and disadvantages of medicines and TPD regulation of non-tobacco nicotine

The impending need for e-cigarettes and other non-tobacco nicotine products, either currently on the market or in development, to comply with one of the above regulatory options has significant implications for suppliers of these devices, and for wider public health. Both approaches have significant advantages and disadvantages, which suppliers will have to balance in their decision on which route or routes to pursue. These are as follows.

10.4.1 Medicines licensing

Key advantages to manufacturers who pursue medicines licensing include:

- higher consumer confidence in product quality and safety
- relief from TPD limits on nicotine solution concentration and volume
- freedom to advertise on TV, radio and in printed media, in line with MHRA rules
- freedom to make justified health claims in relation to quitting and harm reduction
- no obligation to carry health warnings informing consumers that nicotine is addictive
- eligibility for use in, and for subsidised prescription through, the NHS
- potentially subject to 5% rather than 20% VAT in the UK.

The main disadvantage of medicines licensing is the cost in time and money of the application process itself, and of the much higher manufacturing standards required of medicines. It is understood that the MHRA estimates first application costs at between £252,000 and £390,000, and annual recurring costs at between £65,000 and £249,000 for each product. In practice, however, it is likely that application costs incurred by companies inexperienced in negotiating this regulatory system may be significantly higher, whereas the additional cost of manufacturing to the medicines standard is estimated at several million pounds. These financial and related opportunity costs inevitably represent a significant barrier to innovation and market entry for new licensed nicotine products, and favour larger, better resourced entities such as pharmaceutical and transnational tobacco companies. Licensing and presentation of products as medicines may also undermine the perception of e-cigarettes as a consumer rather than a medical product, and hence inhibit experimentation and use.

That only one licence has been awarded to an e-cigarette product in the 5 years since the MHRA announced its 'light touch' licensing option, despite the rapid growth and hence evident value of the e-cigarette market and verbal reports from...
the MHRA that ‘several’ e-cigarette companies had enquired about licensing, indicates that mandatory medicines regulation, had it been imposed as originally intended by the MHRA, would indeed have resulted in a period of several years in which no e-cigarettes were available for sale in the UK. Mandatory medicines licensing, as originally proposed, would therefore have been counterproductive to public health. Given the high product quality and safety standards that medicines licensing guarantees, as well as the option of providing products on prescription to those on low incomes, it is clearly desirable that the range of e-cigarette products available to consumers and health professionals includes some that are licensed as medicines. As recommended elsewhere, a review of the MHRA licensing process for e-cigarettes, to minimise the extent to which licensing procedures and demands unnecessarily obstruct the progress of new medicinal products to market, is clearly needed.

10.4.2 TPD regulation

At the time of writing, the exact detail of how the proposed TPD regulation will operate has not been published. It appears likely, however, that regulation under the TPD will offer e-cigarettes and other non-tobacco nicotine products a route to market that is less onerous, and hence quicker and less expensive, than medicines regulation.

The principal benefits of TPD regulation to consumers are that they will ensure that products that claim to deliver nicotine actually do so, and therefore that consumers are likely to find them effective, and provide reassurance that toxins and other by-products in vapour are at known and pragmatically low levels, thus protecting consumers from easily avoidable harm. Although it is inevitable that these reporting and performance requirements will impose costs on manufacturers and importers, these TPD measures appear to be congruent with the basic regulatory objective of ensuring that products are fit for purpose, and reasonably safe.

Other measures imposed by the TPD on e-cigarettes are less overtly constructive, however. The cap on nicotine concentrations may limit the effectiveness of e-cigarettes as a smoking substitute, particularly for heavier smokers. The derogation to member states of limits on the use of flavours, which may be a significant source of oxidant activity in e-cigarette vapour (see Chapter 5), may result in marked differences in relative potential harm of e-cigarettes available in different member states. Restrictions may also result in non-compliance. The restrictions on e-cigarette marketing, in effect limiting these to the point of sale, billboards, bus stops and other advertising that does not cross borders, limits opportunities for inappropriate promotion of e-cigarettes to non-smokers, including children, but also inevitably inhibits promotion to smokers. However,
as most smokers are aware of e-cigarettes, and word of mouth and social media appear to have been the main drivers of use to date, it remains to be seen whether these advertising restrictions will reduce uptake by smokers. The Scottish Parliament is currently considering going further than the TPD to prohibit all advertising of e-cigarettes in Scotland other than at the point of sale.24

The requirement for nicotine products covered by the TPD to carry a health warning emphasising the risks of nicotine, when licensed nicotine products do not, appears illogical, as does the restriction on statements comparing the relative risks of e-cigarettes and tobacco cigarettes. The health warning required under the TPD provisions may also reinforce misperceptions about nicotine (see Section 10.7 below).

A further concern about TPD regulation is that, although a facility to recall products from the market is written into the legislation, there are no powers to relax regulations if usage and innovation are unnecessarily or inappropriately constrained by them. Despite requiring a review 3.5 years after implementation and at 2-yearly intervals thereafter, the previous EU TPD was not revised for 13 years, which is of great concern because much quicker mechanisms of feedback and revision will be required to maximise the benefits as well as minimise the risks of e-cigarettes. For these reasons, it is clearly important that TPD implementation be closely monitored to assess the extent of unintended, as well as intended, effects on the availability and use of non-tobacco nicotine products and, in particular, the consequences of these effects on tobacco smoking rates; it should also ensure that prompt action be taken if TPD regulation proves to work against, rather than for, the benefit of public health. We therefore recommend annual review in the UK.

10.5 The future of nicotine regulation

The UK is currently ahead of most countries in having an agreed set of principles on what nicotine regulation should be designed to achieve, which, as stated in our last report, is that ‘The current nicotine regulatory framework needs to be changed so that it encourages as many smokers as possible to quit smoking and all nicotine use completely, and encourages those who cannot quit to switch to a safer source of nicotine, while minimising use by people who would not otherwise have used nicotine products’. The UK government has reinforced the need for harm reduction alongside abrupt cessation and preventive approaches to tobacco control by introducing ‘new routes to quitting’,25,26 which involve encouraging smokers to reduce their cigarette consumption as a precursor to complete quitting, manage their nicotine addiction by using a safer alternative product when unable to smoke, and dramatically reduce harm to themselves and
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others by using a safer alternative to smoking whenever possible at other times. The UK government also encouraged innovation in the design and marketing of nicotine delivery medicines. The MHRA, by relaxing its regulation of nicotine-containing products, is following the same path. In 2013, the National Institute for Health and Care Excellence (NICE) produced public health guidance on harm-reduction approaches to smoking, recommending the integration of harm reduction into NHS and other care pathways. Public Health England has also recently endorsed the principles of the approach set out in the RCP’s 2007 report, as has civil society, through the more than 120 health-related organisations that endorsed the recent Smoking still kills policy document published by Action on Smoking and Health in 2015.

However, there is still some disagreement about the appropriate level of regulation to meet these principles. Some argue that medicines regulation is the best guarantee of safety, although experience to date suggests that it is too restrictive; some argue that the TPD regulatory framework about to be introduced is too stringent and will undermine the growing market for less harmful alternative nicotine products and restrict innovation; some believe that proposed TPD regulation does not sufficiently address the potential short- and long-term hazards of e-cigarette use which, although likely to be far less than those of smoking (see Chapter 5), could be minimised by medicinal quality and safety standards.

In 2007, the RCP argued for the creation of a regulatory authority specifically designed to cover all nicotine products, and to rationalise regulatory controls by making them proportionate to product hazards. However, experience elsewhere of giving powers to regulatory bodies to cover all nicotine products, eg in the USA and Canada, has not been encouraging (see Chapter 11), although in any case the current aversion to new regulation in the UK does not make a new regulatory body a feasible option at present. Some countries have regulated e-cigarettes in the same way as tobacco products, which we believe to be entirely inappropriate because e-cigarettes do not contain tobacco, and have a very different profile of risk. The political reality is therefore that, for the coming years, unless the legal challenge to the TPD is successful (see below), non-tobacco nicotine products in the UK will be regulated either by the TPD or as a medicine, whereas tobacco products will continue to be limited by the TPD and other national restrictions on use and presentation. It remains to be seen whether this approach will benefit public health by encouraging widespread substitution of smoked tobacco by non-tobacco nicotine in current and future smokers, or will in effect sustain smoked tobacco as the most widely used nicotine product. Much will depend on the approach taken by the MHRA in its role as the competent authority for TPD implementation. It is, however, crucial that the UK takes care to implement the revised TPD in such a way as to minimise, as far as is consistent with the regulations, the burden to manufacturers and importers in...
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meeting the TPD requirements. It is also important to look again at the medicinal licensing route to market, to try to make compliance more attractive to producers.

10.6 If e-cigarettes are removed from the TPD, what are the alternatives?

Following the December advocate general’s legal opinion, it seems likely that regulation under the TPD will go ahead. However, starting from the counterfactual allows options for a more appropriate regulatory structure to be set out within a European context. If the legal challenge to e-cigarette regulation under the revised TPD succeeds, then the previous status will prevail, unless and until the EU develops a new regulatory framework. This could be in the form of a new revision to the TPD, but past experience indicates that this would be likely to take years to materialise. An alternative is the earlier MHRA proposal to regulate all nicotine products as medicines, which to date has proved to operate against public health interest and has, in any case, been subject to successful legal challenges in other EU member states. Another option is to develop harmonised EU-wide standards under the General Products Safety Directive process, which could be less costly for manufacturers and importers to comply with than if each member state developed its own. Such standards could build on those being developed under the European CEN/TC 437 process, which is one of the three European standardisation organisations officially recognised by the EU and the European Free Trade Association (EFTA) as responsible for developing and defining voluntary standards at the European level.

A balance is needed to make products attractive, palatable, satisfying and effective substitutes for tobacco smoking, but also as safe as is reasonably possible, and avoiding use by adolescents and never-smokers. A pragmatic approach would retain the reporting requirements on nicotine delivery and toxins in e-cigarette vapour proposed under the TPD (see Section 10.3 above), adhere to industry and product standards, incorporate obvious safety measures such as childproof and tamper-proof seals and design, and simple advice on how to charge e-cigarettes safely. Advertising should be permitted as per current codes of practice administered by the ASA (with regular reviews to ensure that they remain fit for purpose), with the facility to promote claims of reduced risk in relation to tobacco smoking. Limits on nicotine dose and the requirement for health warnings are probably not appropriate. Any voluntary approach would have to build on the current BSI PAS 54115 standard for product regulation and the compulsory advertising codes, which are currently under review. Alternatives to the above approaches have been suggested, such as regulation as food or cosmetics, but neither regulatory structure seems appropriate to a product that is
inhaled. Whatever approach is taken, it will remain essential to monitor sales and uptake of non-tobacco nicotine products, so that early action can be taken to deal with any trends or patterns of use likely to be detrimental to public health interest.

10.7 Providing consistency in messages to smokers

Recent evidence indicates that smokers are confused about the relative risks of tobacco and e-cigarettes, with many coming to believe that the health hazards of e-cigarettes and tobacco cigarettes are similar. Health professionals are also uncertain about the role of unlicensed nicotine products in healthcare provision, with many feeling reluctant to recommend or endorse a product or product class that is relatively unregulated and has unknown long-term health effects. The introduction of a regulatory structure for unlicensed products, as, for example, proposed under the TPD, may help to overcome these reservations, but there is a need for clear guidance on the role of unlicensed nicotine products in clinical services. The National Centre for Smoking Cessation and Training has produced new guidance on integrating e-cigarette use into the provision of smoking cessation services*, but to date NICE, which has issued extensive guidance on smoking cessation and harm reduction to organisations responsible for public health and tackling tobacco use, health professionals and the general public, has not addressed this issue. Some stop smoking services are providing advice and behavioural support to smokers interested in using e-cigarettes with encouraging results (see Chapter 6), but health professionals have a wider role to play in providing support and reassurance to e-cigarette users in routine contacts. NICE guidance should, therefore, be updated to include pragmatic recommendations on the role of e-cigarettes in tobacco harm reduction.

10.8 Taxation and price

Price is a key driver of consumer behaviour and, if the potential for e-cigarettes and other non-tobacco nicotine products to act as a widespread substitute for smoked tobacco is to be fully realised, it is crucial that they are priced as advantageously as possible in relation to tobacco. It is for this reason that the VAT applied to NRT products in the UK was reduced from 20% to 5% in 2007. Adding to the tax burden of e-cigarettes by including them in the remit of the EU Tobacco Tax Directive, and hence requiring them to be taxed as tobacco products in addition to the current taxation through VAT, would therefore be counterproductive. A rational approach to nicotine taxation would be to apply

*www.ncsct.co.uk/usr/pub/Electronic_cigarettes_A_briefing_for_stop_smoking_services.pdf
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tax in proportion to their hazard, in which case the tax on e-cigarettes and other non-tobacco nicotine products should be held stable or even reduced. The availability of these products as a viable alternative for people addicted to nicotine does, however, provide justification for further tax increases on tobacco.

10.9 Summary

> The ideal regulatory framework for nicotine products is one that minimises harm to society arising from nicotine use.
> At present, nicotine is in widespread use in UK society and the most popular source of nicotine, the cigarette, is by far the most hazardous of those available.
> Nicotine regulatory approaches should therefore be designed to encourage as many smokers as possible to either quit all nicotine use, or switch completely from smoking to an alternative source of nicotine.
> Products are regulated to ensure that they are safe and fit for purpose. Regulation of e-cigarettes and other similar products should therefore aim to minimise potential exposure to harmful vapour constituents, ensure that those that deliver nicotine do so in doses that smokers find satisfying, and encourage substitution for smoked tobacco.
> Regulatory restrictions should therefore be designed to safeguard against unnecessary hazard but should also be proportionate, so as not unnecessarily to inhibit the development, availability and use of viable alternatives to smoking.
> Attempts by the MHRA over the past 5 years to adapt medicines licensing to the rapidly developing e-cigarette market has resulted in the award of only two medicines licences for alternative nicotine products, and no licensed e-cigarette has come to market.
> Regulations for e-cigarettes proposed in the new revision of the EU TPD include quality controls that are more permissive and, in our view, more proportionate than medicines regulation, but include some measures that may inappropriately constrain the e-cigarette market and hence inhibit e-cigarette use.
> At the time of going to press, the TPD regulations for e-cigarettes are still the subject of a legal challenge, but are expected to come into effect from 20 May 2016.
> In the event that the legal challenge succeeds, then a replacement regulatory approach should retain the requirements on reporting of nicotine delivery and toxins in e-cigarette vapour proposed under the TPD, and adhere to industry and product standards.
> To encourage smokers to switch from tobacco to less hazardous sources of nicotine, it is vital that non-tobacco nicotine products be excluded from tobacco taxes.
It is essential that NICE and other health organisations give clear guidance on the role of e-cigarettes, licensed or unlicensed, in smoking cessation and tobacco harm reduction.

Effective regular surveillance, which we recommend should be annual, will be required to monitor intended and unintended impacts of regulation, and a rapid feedback mechanism to allow changes to be made to ensure that the potential benefits of e-cigarettes are maximised, while minimising the risks.

References


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11 Harm reduction and e-cigarettes: an international perspective

11.1 Harm reduction and tobacco control policy implementation in the UK

Since the publication of the white paper *Smoking kills* in 1998, the UK has introduced an extensive and comprehensive range of tobacco control measures (see Chapter 3) and, having been at the forefront of the global smoking epidemic of the 20th century, is now a world leader in smoking prevention. As a result, UK smoking prevalence has declined substantially and at a rate similar to that observed in other countries that have also implemented comprehensive tobacco control programmes such as Australia, Canada, the USA (in California) and Uruguay. As discussed in Chapter 10, in addition to this comprehensive package of conventional tobacco control policies, England has also adopted a complementary harm-reduction policy strand that is embedded in national policy through government health and tobacco control strategies, guidance by the National Institute for Health and Care Excellence (NICE) and medicines regulation. To our knowledge the UK is the only country in the world to have developed, and to be in the process of implementing, a proactive tobacco harm-reduction approach to smoking prevention. This chapter describes the regulation of e-cigarettes and their use in other countries.

11.2 Approaches to regulation of e-cigarettes in other countries

There is a wide variation in approaches taken in different countries to the regulation of e-cigarettes and other unlicensed, non-tobacco nicotine products. The Institute for Global Tobacco Control (IGTC) summarises policy approaches in a total of 123 countries, including 90 from a World Health Organization (WHO) report on e-cigarette policies. Regulations are evolving rapidly, so the discussion here and in the following sections is based on data reported on the IGTC website unless otherwise stated, and was accurate at the time of going to press. A discussion of whether published regulations have actually been enforced is beyond the scope of this chapter.

*http://globaltobaccocontrol.org*
Also at the time of going to press, the use of e-cigarettes had been completely prohibited in three countries (Cambodia, Jordan and the United Arab Emirates), prohibited in enclosed public places in 15 countries and restricted in a further eight, prohibited on public transportation in 19 countries and restricted (or limited to non-nicotine-containing products) on certain public transportation vehicles in three. Restrictions on purchase or sale comprise: a minimum age for e-cigarette purchase which is usually the same as that for traditional cigarettes, and ranges from 18 to 21 years in 16 countries; prohibition (26 countries) or restrictions (21 countries) on the sale of all types of e-cigarette, including restriction or prohibition of sale or requirement for marketing authorisation for products that have nicotine. Of the 47 countries banning or restricting e-cigarettes in their policies. Twelve other countries had explicit promotion bans/restrictions. Two countries (Togo and the Republic of Korea) impose taxes on e-cigarettes in addition to general sales taxes. Similar to the UK, some countries, including the USA, allow e-cigarettes to be sold under general consumer product regulations.

The experience of regulating e-cigarettes along with other nicotine products in a single regulatory structure, as proposed by the RCP in 2007, has since proved less encouraging than hoped. The US Food and Drug Administration (FDA), already responsible for regulating medicinal nicotine, was given responsibility for regulating tobacco products in 2009 and, after a legal decision, announced in 2011 that e-cigarettes would be brought within the remit of tobacco product regulation. At the time of writing the FDA still has more stringent regulations on the sale of medicinal nicotine than the UK, and has not yet put a regulatory process for e-cigarettes in place. Similar to the US experience with FDA regulation, Health Canada’s jurisdiction over all tobacco and nicotine products, which regulates nicotine under the Food and Drug Act, requires a marketing authorisation for e-cigarettes containing nicotine, and none has yet been awarded. The effect of this is therefore an actual prohibition of sale. In practice, however, this is not being observed, because a recent Canadian House of Commons’ report concluded that e-cigarettes with nicotine were still available in Canada. The report put forward recommendations to develop a new legislative framework for e-cigarettes that would probably allow their sale with nicotine, but with strict controls on marketing in line with those for tobacco. In the absence of a clear regulatory approach by Health Canada at the federal level, a number of provinces have already moved to impose strict regulations on e-cigarettes, including prohibition of use in public places, and of advertising and display.*

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Thus, the experience of a single regulatory authority in both the USA and Canada is that, in both cases, the authority has been unable to use its powers effectively to regulate nicotine products in relation to their hazard. Indeed, in both cases, single-body regulation of all nicotine products has probably hindered, rather than enabled, access to reduced-hazard nicotine products.

11.3 Awareness and use of e-cigarettes in different countries

Although there is a rapidly growing body of research on the prevalence of e-cigarette use in adults and adolescents internationally, methodological differences in the definition and measurement of ever, past or current use, particularly in adolescent research, make direct comparisons between studies difficult. This section therefore describes trends internationally drawing predominantly on between-country surveys; Section 11.4 analyses the relationship between regulatory frameworks and use where the evidence enables such comparisons to be made.

11.3.1 Awareness and use of e-cigarettes in adults

Significant variability in the prevalence of use of e-cigarettes has been observed between countries over time, but international surveys demonstrate rapid global increases in e-cigarette use across high-, middle- and low-income countries. The earliest between-country study\textsuperscript{18} assessed e-cigarette awareness and use among nationally representative samples of smokers and recent ex-smokers based on 2010–11 data from the International Tobacco Control policy evaluation project (ITC) in the UK, the USA, Australia and Canada. In the UK and the USA, e-cigarettes are regulated as consumer products; in Canada, e-cigarettes containing nicotine require authorisation, but none has been authorised; in Australia there is a ban on the sale and importation of e-cigarettes with nicotine, although there is a mechanism for legal import as an unapproved medicine with a doctor’s prescription. Awareness and current use were higher in the two countries where there were fewer restrictions (the USA and the UK).

The Canadian Tobacco, Alcohol and Drugs Survey (CTADS) also found, in 2013, much lower levels of e-cigarette use among adults in Canada than in the UK.\textsuperscript{19} Another ITC study compared trends in awareness, trial and use of e-cigarettes among nationally representative samples of smokers and ex-smokers in the UK and Australia.\textsuperscript{20} Use (defined as less than monthly or more often) of e-cigarettes was 18.8% in the UK and 6.6% in Australia in 2013; however, use increased at the same rate in both countries between 2010 and 2013.\textsuperscript{20} It therefore appears that prohibition may have delayed the uptake of e-cigarettes in Australia, but has not prevented a subsequent rapid increase in use.
A further ITC study presented data from 10 countries (the USA, the UK, Australia, Canada, the Netherlands, South Korea, Malaysia, Brazil, Mexico and China) surveyed at different time points between 2009 and 2013. Again, there was considerable variation in e-cigarette awareness and use among them: awareness varied from 88% in the Netherlands (where e-cigarettes are regulated as a consumer product with some restrictions) to 31% in China (where sale and purchase are legal at the national level, although may be restricted in some regions); self-reported trials varied from 20% in Australia to 2% in China; and current use from 14% in Malaysia (where sale, distribution or importation of unlicensed nicotine-containing e-cigarettes is prohibited; nicotine-containing e-cigarettes can be sold only by licensed pharmacies or registered medical practitioners) to 0.05% in China. These differences are likely to be due in part to differences in survey dates, but also to differences in regulations, market forces and enforcement. However, Malaysia had the highest prevalence of e-cigarette use despite tight restrictions on their sale.

The Global Adult Tobacco Survey has also published data on e-cigarette use among smokers and non-smokers from four middle- and low-income countries: Indonesia (in 2011), Malaysia (2011), Qatar (2013) and Greece (2013). At the time of the surveys, all these countries prohibited the sale of e-cigarettes apart from Malaysia, where only nicotine-containing e-cigarettes were restricted. E-cigarette awareness was highest in Greece (88.5%), followed by Qatar (49%), Malaysia (21%) and Indonesia (10.9%). Current use (daily and non-daily) of e-cigarettes among smokers was again highest in Malaysia (in this survey prevalence of use was 10.4%), followed by Qatar (7.6%), Indonesia (4.2%) and Greece (3.4%). Use of e-cigarettes among non-smokers was highest in Greece (1.3%), followed by 0.4% in each of the other three countries. Again, these data demonstrate little evidence that more restrictive national policies on e-cigarettes result in lower levels of use.

The most recent Eurobarometer survey carried out in November and December 2014, enabled an assessment of use of both tobacco cigarettes and e-cigarettes (defined as e-cigarettes or other similar electronic device) among people aged 15 years and over in the 28 European Union (EU) member states. France, Cyprus and Estonia (where e-cigarettes are regulated as either consumer or medicinal products according to nicotine content) had the highest proportions of respondents stating that they had ever tried e-cigarettes (17% or higher); France and the UK had the highest prevalence of current e-cigarette use (both 4%) and the UK had the highest proportion of current smokers who also used e-cigarettes (11%). Fewer than 1% of never-smokers currently used e-cigarettes in every country surveyed. The most common reason given for using e-cigarettes was to stop or reduce smoking. Across the EU, 14% of smokers or ex-smokers who had tried e-cigarettes reported that they had helped them to stop smoking completely, 13% that they had helped them to stop for a while before...
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relapsing, 45% that they had not reduced their tobacco smoking and 21% that they helped them to reduce, but not stop, tobacco use. Ireland (24%) and the UK (21%) had the highest proportions of respondents who reported successfully stopping smoking with the help of e-cigarettes. The proportion of smokers using e-cigarettes in their quit attempts was highest in countries regulating them as consumer products: the UK and Ireland (19%), France (18%) and Cyprus (16%). The Eurobarometer noted that there were continuing declines in smoking across the EU at a time when e-cigarette use was increasing, as has been observed in UK surveys (see Chapters 2 and 7) and in the USA.26

11.3.2 Awareness and use of e-cigarettes by adolescents

We have been unable to find any survey using a consistent methodology to compare awareness and use of e-cigarettes among adolescents in different countries. Data on people aged 15 and over are included in the 2014 Eurobarometer study referred to above,24 which reported the prevalence of current use of e-cigarettes among people who had never smoked at 0%, suggesting that there were few such users among young or older people.

Survey data on the prevalence of e-cigarette use in young people at the country level are more extensive, but methodological differences, including the use of different definitions or terms to describe the different stages of e-cigarette use (ever, trial, current use), and differences in age ranges studied, limit the comparability of these findings. A recent review concluded that the common pattern emerging in countries where data were available was of very high awareness and increasing trial of e-cigarettes among young people, but very low levels (3% or less) of regular use.27 However, there were two countries where current use was substantially higher: Poland (where e-cigarettes are classified as consumer products, but with cartridges subject to regulations on chemical mixtures) at around 30%,28 and Hawaii (where e-cigarettes are classified as consumer products), where 29% of the sample of young people had tried e-cigarettes and 18% had used them in the past month.29

Serial surveys of young people in the USA have documented a rising prevalence of ever use of e-cigarettes30–32 and demonstrated that, as in the UK (see Chapter 7), those who use e-cigarettes are more likely also to smoke tobacco.31 A cohort study from California35 found that secondary school pupils who had not smoked, but reported having ever tried an e-cigarette, were more likely at 6- or 12-month follow-up to have ever tried a tobacco cigarette. A cohort study of a national US sample of 694 never-smokers who were classified as non-susceptible to tobacco smoking at baseline in 2013–14, and restudied in 2015,34 found that the 16 participants who reported ever
having used an e-cigarette at baseline were significantly more likely, after controlling for other covariates, to have become susceptible to cigarette smoking or have smoked at least one puff of a cigarette at follow-up. However, claims that these findings indicate that e-cigarette use may cause uptake of tobacco smoking have been challenged on the grounds of common liability (see Chapter 8), lack of measures of more regular use of either e-cigarettes or tobacco cigarettes, and that, during the time that these studies have been carried out, the prevalence of tobacco smoking among young people in the USA fell to a 22-year low.35–37 There is evidence from the USA that adolescent smokers using e-cigarettes are also more likely to use products such as tobacco hookahs or shisha and blunts (marijuana and tobacco).38

11.4 Patterns of use across countries with different regulatory regimes

Although standardised between-country data on e-cigarette use over time are generally lacking, it is clear from the evidence presented above that, whereas countries with more liberal policies (which typically involve regulating e-cigarettes as consumer products) have higher levels of adult e-cigarette use, prohibition and tight restrictions have not prevented increasing uptake of e-cigarette use among adults in other countries. For adolescents the data are less clear but, as an example, the 2013 CTADS of Canadians aged 15 years and older found that 9% had ever tried an e-cigarette, with trials being higher among young people aged 15–19 years at 20%.19 This latter percentage is not dissimilar from the percentage who had tried e-cigarettes in the UK in 2015 (12.7% of 11- to 18-year-olds). Again, therefore, it appears that prohibition of sale has had little effect on experimentation with e-cigarettes in Canada, at least not in the younger age groups in these studies. A recent US study assessed the impact of state bans on sales of e-cigarettes on smoking rates among 12- to 17-year-olds across the USA,39 and found that reducing access through age-of-sale laws increased smoking among 12- to 17-year-olds, suggesting that restrictive regulations on e-cigarettes may be counterproductive.

In the EU, as set out in Chapter 10, the introduction of the Tobacco Products Directive40 will lead to a common regulatory platform from May 2016, although individual member states will be able to go further in prohibiting all advertising (as is under consideration in Scotland), restricting or prohibiting their use in public places (recently under consideration in Wales), legislating for an age of sale (set at 18 in England), restricting or prohibiting flavours, and implementing additional taxation. Monitoring the impact of these regulatory changes, and of their variations across the EU, will provide a useful indicator of the impact of different regulatory approaches.
11.5 Harm reduction and the WHO Framework Convention on Tobacco Control

E-cigarettes were not available when the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) was first negotiated. However, the FCTC alludes to harm reduction in Article 1, where tobacco control is defined as including ‘harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke’. This is further considered in Article 5.2(b), which states that ‘each Party shall, in accordance with its capabilities … adopt and implement effective legislative, executive, administrative and/or other measures and cooperate, as appropriate, with other Parties in developing appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke’. The FCTC does not have a remit for the regulation of medicinal nicotine, although it has produced guidelines on tobacco dependence and cessation (Article 14 of the FCTC).

The growing popularity of e-cigarettes led to discussions on their role at the biennial FCTC Conference of the Parties (COP), the governing body of the treaty, in 2010 and 2012. At the 2012 COP5, the WHO was asked to produce a report on ‘options for prevention and control’ of e-cigarettes (referred to as electronic nicotine delivery systems or ENDSs) for consideration at the next COP. The WHO report to COP6 focused on three areas of concern: health risks to users and non-users; efficacy in helping smokers to quit smoking and (ultimately) nicotine use; and interference with existing tobacco control efforts and implementation of the FCTC. The main focus of the report was on the latter issues, but, in terms of health risks, the report concluded that ‘well-regulated ENDS’ would be likely to be less toxic than tobacco cigarette smoking for established adult smokers. In relation to smoking and nicotine cessation, the report concluded that e-cigarettes might have a role in supporting attempts to quit for individuals who had failed treatment, or who were intolerant of or refused conventional treatments. The report discussed and recommended parties to regulate e-cigarettes as either medicines or tobacco products, in accordance with the FCTC.

In response, the Framework Convention Alliance (FCA, a coalition of over 350 non-governmental organisations from over 100 countries) developed a consensus position. The FCA concluded that, because of differences in regulatory systems and national circumstances, it would be difficult to reach consensus at COP6 on specific regulatory approaches to ENDSs. Instead, the FCA position paper set out the following principles as a starting point for reaching agreement on the role and regulation of e-cigarettes, for consideration by the COP:
1 The global burden of death and disease from tobacco is primarily caused by smoking.

2 Although quitting tobacco use is paramount, quitting nicotine use altogether is the best option.

3 For those unable to quit, switching to alternative sources of nicotine that are less harmful than tobacco can reduce, often very substantially, the harm that smoking causes to the individual.

4 The benefits of such an approach would be maximised if uptake were limited to existing smokers who are unable to quit.

5 The risks of such an approach would be minimised by limiting uptake by never-smokers, in particular among young people, and by taking measures to protect non-users and discourage long-term dual use.

6 There could be negative unintended consequences from over-regulation, just as there could be from under-regulation.

7 The involvement of tobacco companies in the production and marketing of e-cigarettes is a matter of particular concern, because there is an irreconcilable conflict of interest between those profiting from the sale of tobacco and public health.

After discussion by the COP, a decision was taken to ask parties to the FCTC to take note of the WHO report, and the WHO was asked to produce a further report with updated intelligence for consideration in time for COP7, which will be held in the last quarter of 2016. The decision also asked parties to the FCTC to consider ‘prohibiting or regulating’ e-cigarettes, suggesting that this could be as tobacco, or medicinal or consumer products, and to comprehensively monitor their use. E-cigarettes will therefore be discussed again at the next WHO FCTC COP in November 2016 in India.

In the case of tobacco, a range of comprehensive tobacco control measures has been found to be effective and been codified in the FCTC. E-cigarette regulation does not sit appropriately within the context of the FCTC, the explicit objective of which is control of the supply of and demand for a lethal product, tobacco, through the introduction of increasingly restrictive and prohibitive regulatory measures. Furthermore, there is as yet an insufficient evidence base or range of national experience that would enable the development of a detailed set of recommendations for the specific approaches to many of the complicated regulatory issues that these products raise at the global level.

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11.6 Summary

A variety of different approaches to tobacco harm reduction and regulation of e-cigarettes, including extension of regulations for alternative products to e-cigarettes and including complete prohibition, have been adopted in different countries around the world.

The prevalence of use of e-cigarettes is rising or already significant in some countries that have attempted to prohibit use, suggesting that prohibition is not an effective approach to regulation.

Surveillance data are limited in most countries, as are the use of consistent terminology and standardised measures of e-cigarette use, so between-country differences are difficult to assess.

There is general recognition that comprehensive monitoring and surveillance of the evidence and national regulatory experience of e-cigarettes are essential.

The WHO recognises a role for e-cigarettes as part of a harm-reduction strategy for smokers, but in the context of a recommendation by the FCTC COP that they be regulated to minimise any potential risks.

However, currently there is no consensus about what this regulatory framework should be, and as yet an insufficient evidence base, or range of national experience, that would justify the development of a regulatory structure at a global level.

References


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12.1 Moral and ethical considerations of harm-reduction strategies

This report has made the case for applying harm-reduction principles to tobacco smoking, principally to prevent avoidable harm to smokers. There is, however, a strong ethical dimension to the use of harm-reduction strategies in tobacco control that were discussed in some detail in our earlier report; these strategies include a duty to ensure that options to reduce harm are made available to smokers, and provision of a substitute for tobacco to smokers, particularly those on low incomes, to protect them from the hardship that might otherwise arise from applying tax increases to provide a stronger fiscal disincentive to smoke. There are, however, wider considerations arising from concerns over the broader effects of applying harm-reduction strategies in society.

The central ethical concern is with harm, and whether the harm-reduction strategies identified and adopted will, in practice, reduce it. However, there are also wider questions relating to the ethos of harm reduction itself, over and above any examination of the effectiveness of particular strategies. In some areas of public health (particularly in drug control, alcohol control and sex work control, for example), there is a societal concern that the behaviour being targeted is inherently wrong. Drug addiction, prostitution and drunkenness, it is sometimes thought, are inherently bad, and the proper focus of public health should not be on making the use of drugs, or sex work, or excess alcohol consumption safer; it should be on eradicating these behaviours. In tobacco control, however, this argument is rarely made: few people acknowledge smoking as a behaviour that is immoral. Its harms are real and serious, and inflicting these on unwilling third parties is wrong, but these concerns fit quite naturally within the harm-reduction model.

A second concern is with the distribution of harm. A harm-reduction strategy could be considered to have failed if the net harm were reduced, but the distribution of harm changed in a way that was unjust, eg if, as a result of the harm-reduction strategy, some socially or economically vulnerable group...
Ethics and conclusions

became more at risk of harm, or systematically less able to benefit from smoking cessation and prevention strategies. The benefit to existing smokers of switching to e-cigarettes is clear, but, if large numbers of never-smokers were to take up e-cigarette use, they would be exposing themselves to health risks that would otherwise be avoided, and financial costs, which are of particular detriment to poorer smokers, that they would not otherwise incur. At present this does not appear to be happening, but it could occur, for example, if the addictive potential of e-cigarettes and other non-tobacco nicotine products increases over time.

A third concern relates to social responsibility: if engaging in harm reduction involves working with corporate actors with a track record of deceit or other socially irresponsible business practices, and particularly of undermining public health, then there is a concern that doing so may have wider ramifications than the harm-reduction strategy itself. Such engagement might, for example, discredit other public health interventions or institutions that are focused on ending these bad practices. We can think of this as ‘reputational harm’. Conversely, it may be that such corporate actors acquire some perverse benefit from such engagement: by appearing to be responsible in one area (the provision of reduced-harm products) they might be able to reclaim a good reputation in other areas, however undeservedly. From a ‘harm-reduction’ point of view, these factors must be considered, but these harms may be inchoate and hard to measure, certainly compared with the real benefits accruing to harm-reduction products in terms of reductions in mortality and morbidity.

Setting aside these objections to harm reduction in principle, we turn instead to the objections that might be raised against particular harm-reduction strategies from within a focus on harm. Obviously, the most important consideration is whether the harm-reduction intervention actually does reduce harm, in terms of reduction of lives (and life years) lost, increase in numbers of smokers who successfully quit smoking tobacco, reductions in the numbers of new smokers, etc. However, as for any other medical or public health intervention, we need to consider any particular strategy in the light of available alternatives: in particular, if we focus on regulation of a tobacco harm-reduction product, we need to ask whether the regulatory mechanism is the most effective in reducing harm, or whether some other approach would be more effective. We need to ask whether adoption of a particular regulatory approach makes the production of some products more likely than others, and whether the products favoured by this approach are, in fact, better from a harm-reduction and public health point of view than those disfavoured. As within the harm-reduction model, the least harmful intervention is the most ethical intervention, we need always to keep in mind that choice of regulatory approach must be seen in ethical terms. The evidence summarised in this report goes some way towards addressing these questions.
12.2 Smoking and public health

Tobacco smoking is the biggest avoidable cause of death and disability in the UK. In 2014, 21% of men and 16% of women were smokers,² which in absolute terms represents almost 9 million people. Half these smokers, or 4.5 million people, alive in the UK today will have their lives cut short by smoking and, if their smoking continues unabated, their total loss of life will amount to nearly 90 million years.³,⁴ Their smoking will also cause thousands of fetal deaths and cases of childhood illness, and deaths in non-smoking adults, and cost our health services and wider society billions of pounds. This massive burden of death, disability and lost opportunity has been entirely avoidable, and much of it can still be prevented by measures that encourage as many smokers as possible, as soon as possible, to stop smoking. As the biggest beneficiaries of preventing smoking are individuals who are disadvantaged, marginalised or have mental health problems, prevention of smoking will make society both healthier and more equal. Smoking may be less prevalent today than when the RCP published its first report on smoking and health in 1962,⁵ but it is still our biggest health problem. All measures that can be deployed to prevent smoking should therefore be applied, as quickly as possible, and to their maximum effect.

12.3 The effect of conventional tobacco control approaches

The UK is a world leader in tobacco control policy. Since the late 1990s, a comprehensive package of policies, including an advertising ban, smoke-free legislation, high taxes, minimum purchase age, mass media campaigns, a point-of-sale display ban and clinical services to help smokers to quit, has been introduced, and will be enhanced in 2016 by standardised packaging legislation. The result in the UK has been the same as in other countries that have followed this approach: smoking prevalence has fallen steadily, but slowly. However, the decline in smoking prevalence that has occurred over recent decades appears to owe more to success in preventing the uptake of smoking: quit rates among established smokers have changed relatively little. However, it is the adults smoking today, particularly those in middle and older age, who will generate most of the burden of death and disability caused by smoking in the short- and near-term future, and it is these adults whom tobacco control policies need to target in particular if this burden of harm is to be reduced. All existing and new policies with the potential to promote smoking cessation, particularly among disadvantaged groups, should therefore be applied to their fullest extent.
12.4 Priorities for conventional tobacco control policy implementation

Of the range of policies available, the UK has already achieved a relatively high level of prohibition of tobacco advertising and smoke-free policy. Opportunities to promote tobacco brands will be further reduced by the introduction of mandatory standardised packaging in May 2016, although a great deal more could be done to reduce exposure of children and young people to the normalising effect of smoking imagery in the media, including films, television programmes, music videos and computer games. Children may also be less likely to grow up thinking that smoking is a normal or aspirational adult behaviour if they were exposed less to smoking behaviour among adults in their everyday lives, which could be achieved by extending smoke-free policies to outdoor areas, eg at school gates, play areas, town centres and other areas where smokers congregate in view of children. Making hospital premises completely smoke free generates an opportunity to initiate and support cessation among the many smokers, and their visitors, who use hospital services. Similarly, making prisons smoke free will provide an opportunity to reduce the very high prevalence of smoking among prisoners. More could also be done to reduce retail availability of tobacco to children, particularly in areas close to schools, and the requirement that tobacco retailers be licensed would be a useful step towards making enforcement of regulations easier. Mass media campaigns are effective in motivating smokers to try to quit, but require funding to achieve and sustain the necessary intensity and salience for success. Cessation services also need to be adequately funded, and in clinical settings integrated much more systematically into routine health service delivery. Large increases in tobacco prices, particularly in the lower cost range of products preferred by low-income smokers, have a particular potential to reduce smoking among disadvantaged groups. Proper funding of enforcement measures against illicit tobacco and measures to curtail the tobacco industries’ own involvement in this trade are crucial. All these measures would be likely to help to achieve further reductions in smoking prevalence. However, almost all would be complemented by promoting harm-reduction approaches that encourage smokers, who otherwise prove unwilling or unable to quit smoking, to switch to an alternative, low-hazard source of nicotine.

12.5 Nicotine addiction and its effects

Nicotine is the main addictive component of tobacco smoke. Although other tobacco smoke components probably contribute to the development of nicotine addiction, it is the capacity to achieve rapid increases in systemic arterial levels through pulmonary absorption that makes tobacco smoking particularly addictive, as well as lethal, although factors such as the taste and smell of
cigarette smoke, and the behavioural action of smoking, can reinforce nicotine use and hence themselves become important drivers of continued smoking. At low doses, nicotine is a stimulant, which in the short term increases heart rate and may improve attention, memory and fine motor skills. Although potentially lethal at very high doses, at the blood levels typically achieved by smoking nicotine does not result in clinically significant short- or long-term harms. Nicotine is not a carcinogen; there is no evidence that sustained human use of nicotine alone increases the risk of cancer. It is possible that nicotine exposure during the fetal and/or adolescent periods causes cognitive impairment, but in all other respects, and certainly in relation to tobacco smoke, the real and potential hazards of sustained nicotine use are negligible. The harm of smoking is therefore caused not by nicotine, but by other constituents of tobacco smoke. Non-tobacco nicotine products that reproduce the nicotine delivery and behavioural characteristics of smoking, without the many other toxins in tobacco smoke, therefore have the potential to allow smokers to continue to use nicotine and avoid the significant harm to themselves and others that smoking causes.

12.6 Non-tobacco nicotine products

A wide range of nicotine replacement therapy (NRT) products, licensed as medicines to reduce symptoms of nicotine withdrawal among people trying to quit smoking, is available. In clinical trials, NRT has been shown consistently to be effective in helping smokers to quit smoking. Although initially developed to help people give up all smoking and nicotine use, NRT licences have been extended to include short-term use to relieve withdrawal symptoms during temporary abstinence from smoking, and long-term use as a partial or complete substitute for smoking (harm reduction). These licensed applications of NRT, which are endorsed by the National Institute for Health and Care Excellence (NICE), promote dual use of NRT and tobacco on the grounds that smokers who learn to use NRT in this way are more likely to quit smoking completely. NRT products have to date been produced by pharmaceutical companies and offer high levels of purity and hence safety, such that a smoker who switches from tobacco to NRT use, but continues to use NRT in the long term, probably achieves much the same in health terms as a smoker who quits all tobacco and nicotine use.

The choice of non-tobacco nicotine products in the UK has been substantially extended by the emergence of e-cigarettes, which have to date been marketed as consumer alternatives to smoking. E-cigarettes offer a behavioural experience that is much closer to smoking than is the case with NRT products, and later-generation e-cigarettes appear able to achieve venous nicotine levels similar to those of tobacco smoking. The extent to which inhalation of e-cigarette vapour results in rapid pulmonary absorption remains uncertain, but it seems likely that,
as the technology improves, the degree of pulmonary absorption will increase, making the products more effective as smoking substitutes, but also increasing addictiveness, and hence posing the new ethical problems highlighted above. E-cigarettes generate vapour from a solution that typically contains nicotine, propylene glycol and glycerine, but, in addition to these constituents, e-cigarette vapour contains a variable range of compounds arising from impurities in the solutions or generated by the heating process that produces vapour. There appear to be few, if any, significant short-term adverse effects of e-cigarette use, but adverse health effects from long-term exposure to constituents of vapour cannot be ruled out. Although unknown, the hazard to health arising from long-term vapour inhalation is unlikely to exceed 5% of the harm from tobacco smoke. Switching from tobacco to e-cigarettes is therefore likely to be almost as effective in preventing harm as switching to NRT. However, the recent award of a medicines licence to an e-cigarette product raises the prospect of e-cigarettes with safety profiles similar to NRT becoming available in the near future.

12.7 How smokers in the UK try to quit, and their chances of success

Around one in three smokers in the UK tries to quit each year, but only around one in every six of those who try to quit is successful. Those who try are slightly more likely to be younger and female, and to be in non-manual occupations; those in non-manual occupations are also more likely to succeed. Most of those who try to quit do so without help, or until recently by using NRT bought over the counter. Over the past 3 years, however, e-cigarettes have become the most widely used aid to quitting.

The observational data on quitting used in this report suggest that those who use prescribed medication and behavioural support from a qualified stop smoking adviser (typically through NHS Stop Smoking Services (SSSs)) are two to three times more likely to succeed than those using no help. However, the use of NHS SSSs has declined significantly in recent years, such that they are now accessed by only a small minority of smokers. For reasons that are not clear, those who use over-the-counter NRT appear to be no more likely to succeed in quitting smoking than those using no help, whereas those who use e-cigarettes, or NRT or other pharmacotherapy provided by a healthcare professional, are around 50% more likely to succeed than those using no help at all.

The popularity of e-cigarettes has thus resulted in a substantial increase in the proportion of smokers using effective help to quit. It is probable that adding behavioural support would increase the likelihood of quitting with e-cigarettes still further, and this is an important area for new research. Possible explanations for the popularity of e-cigarettes, and their effectiveness relative to NRT, include...
Tobacco harm reduction

their ability to replace some of the behavioural components of smoking, their relatively high nicotine delivery, the fact that smokers tend to try them for longer and with more frequent dosing than NRT, and their cultural acceptability.

Smokers are motivated to make a quit attempt in particular by cost and health concerns. Price rises, media campaigns and health professional advice are therefore likely to increase the numbers of smokers trying to quit.

12.8 Use of e-cigarettes by smokers and non-smokers

E-cigarettes are used almost exclusively by smokers who are trying to cut down or quit smoking, or who have quit smoking. Among adults, use by non-smokers is extremely rare. A higher proportion of non-smoking children than adults have experimented with e-cigarettes, but most of those who do have smoked in the past, or are current smokers. More than experimental use among children who are not also experimenting with tobacco is rare. Among regular users, whether children or adults, second- and third-generation devices are now much more widely used than first-generation ‘cigalike’ devices. Fruit flavours are popular among e-cigarette users, whether adults or children.

12.9 Harm reduction and population health

The emergence and consumer success of e-cigarettes, as a partial or complete substitute for smoking, reflects significant potential to reduce the harm caused by smoking to society by encouraging as many smokers as possible to use e-cigarettes, or indeed other non-tobacco nicotine products, rather than tobacco cigarettes. There are many, however, who retain significant concerns over the potential risks and adverse effects of this approach, for both individuals and wider society.

Concerns that e-cigarettes are not hazard free are justified, but this hazard could be minimised by a combination of technological development and appropriate regulation. Concerns that e-cigarettes will be used dually by smokers are inconsistent with current guidance and licence indications for NRT, which encourage dual use as a step towards quitting smoking and of protecting those around the smoker from the harmful effects of second-hand smoke. All the UK evidence, and almost all the international evidence, on the use of e-cigarettes by children and young people to date indicates that concerns about e-cigarettes helping to recruit a new generation of tobacco smokers through a gateway effect are, at least to date, unfounded, although vigilant surveillance is required to ensure that the emergence of any such effect is detected and reversed promptly. Renormalisation concerns, based on the premise that e-cigarette use encourages
tobacco smoking among others, also have no basis in experience to date. Exploitation of e-cigarette advertising as a means of promoting tobacco smoking by tobacco companies is perhaps a more real concern, but will largely be prevented by impending controls on advertising in the EU Tobacco Products Directive (TPD). 8

12.10 Regulation and harm reduction

It is difficult to determine, and more difficult still to apply, the right level of regulation for reduced-harm products. The wide range of different regulatory approaches adopted in different countries in relation to e-cigarettes, which spans a spectrum from freedom to market as a consumer product to complete prohibition, reflects a desire, on the one hand, to encourage as many smokers as possible to switch from tobacco to e-cigarettes and, on the other, to prevent harm to users or others from e-cigarette use. A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, eg exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks. However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult.

In the UK, consumer product regulation supported by advertising codes of practice has worked well to date, but does not guarantee that products actually deliver nicotine to a degree that smokers will find satisfying or, more importantly, that vapour is as toxin free as is reasonably possible. Medicines regulation guarantees efficacy and safety, but imposes high manufacturing, compliance and opportunity costs. That even the streamlined Medicines and Healthcare products Regulatory Agency (MHRA) ‘right touch’ medicines regulation has to date awarded a licence to only one e-cigarette, and none that has come to market, indicates that mandatory medicines regulation of e-cigarettes, although valuable as a complement to other regulatory approaches, is not ideal as a single regulatory approach. EU TPD regulation, if implemented as planned, offers a compromise between these two approaches by requiring emission reporting that will enable consumers to identify the best and cleanest nicotine delivery systems, but includes much, such as health warnings and nicotine content limits (see Chapter 10), that is potentially counterproductive. None of these approaches is therefore ideal, and experience in other countries does not offer better alternatives. The UK needs a nicotine regulatory system that applies controls on products in proportion to their potential harm, to promote innovation and diversity, ensure reasonable levels of protection for consumers and, above all, discourage tobacco use.

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The use of reduced-harm products, and hence the health gains that they generate, is also influenced by other regulatory policies. Applying low levels of tax to non-tobacco nicotine products, as, for example, the 5% VAT rate levied on NRT, helps to make reduced-harm products attractive to smokers and offset the potentially regressive effect of tobacco tax increases. Allowing messages on harm relative to smoking in commercial and government media campaigns could help to reverse the growing misconception that e-cigarettes and tobacco cigarettes are similarly harmful (see Chapter 10). Prohibition of use of e-cigarettes where smoking is also prohibited may discourage smokers from trying e-cigarettes, and may also contribute to a false impression that they are similarly harmful. The inclusion of recommendations on use of unlicensed (and, in due course, licensed) e-cigarettes in NICE guidance is another example of an area where policies can change to encourage more smokers to switch from smoking to a non-tobacco nicotine product.

12.11 The tobacco industry and e-cigarettes

Tobacco companies make their money by selling tobacco, and the industry’s recent programme of investment and acquisitions in e-cigarettes perhaps indicates recognition that these products represent a disruptive technology that should be harnessed to protect the core business of selling tobacco, exploited to expand tobacco markets or developed as an opportunity to make nicotine products attractive to non-smokers. There is little likelihood that the industry sees e-cigarettes as a route out of the tobacco business, but it is highly likely that e-cigarettes will be exploited to enhance claims of corporate social responsibility, and to undermine implementation of Article 5.3 of the World Health Organization Framework Convention on Tobacco Control. There is no firewall between a ‘good’ tobacco industry that is marketing harm-reduction products in the UK and a ‘bad’ one that promotes smoking, or undermines tobacco control activities, in low- and middle-income countries.

12.12 Conclusions

Harm reduction was proposed by the RCP in 2007¹ as a means of reducing still further the vast burden of death and disability that tobacco smoking causes in our society. The evidence summarised in this report demonstrates that the emergence of e-cigarettes has generated a massive opportunity for a consumer-as well as a healthcare-led revolution in the way that nicotine is used in society. As the technology of these and other non-tobacco nicotine products improves, so the vision of a society that is free from tobacco smoking, and the harm that smoking causes, becomes more realistic. Experience to date suggests that, as predicted in principle in the 2007 report,¹ the availability of e-cigarettes has been beneficial to UK public health. There is, however, no room for complacency and
it is particularly important that patterns of use of tobacco and non-tobacco nicotine continue to be monitored closely, and prompt remedial measures applied to deal with changes that are counterproductive to health. The potential for the tobacco industry to exploit and appropriate harm reduction, to undermine public health and bolster sales of tobacco, is a real problem that is likely to become more acute as tobacco companies move into the licensed, as well as unlicensed, nicotine market, but that problem can be managed with vigilance and care. Large-scale substitution of e-cigarettes, or other non-tobacco nicotine products, for tobacco smoking has the potential to prevent almost all the harm from smoking in society. Promoting e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible, as a substitute for smoking, is therefore likely to generate significant health gains in the UK.

12.13 Summary

> Smoking is the biggest avoidable cause of death and disability, and social inequality in health, in the UK.
> Most of the harm to society and to individuals caused by smoking in the near-term future will occur in people who are smoking today.
> Vigorous pursuit of conventional tobacco control policies encourages more smokers to quit smoking.
> Quitting smoking is very difficult and most adults who smoke today will continue to smoke for many years.
> People smoke because they are addicted to nicotine, but are harmed by other constituents of tobacco smoke.
> Provision of the nicotine that smokers are addicted to without the harmful components of tobacco smoke can prevent most of the harm from smoking.
> Until recently, nicotine products have been marketed as medicines to help people to quit.
> NRT is most effective in helping people to stop smoking when used together with health professional input and support, but much less so when used on its own.
> E-cigarettes are marketed as consumer products and are proving much more popular than NRT as a substitute and competitor for tobacco cigarettes.
> E-cigarettes appear to be effective when used by smokers as an aid to quitting smoking.
> E-cigarettes are not currently made to medicines standards and are probably more hazardous than NRT.
> However, the hazard to health arising from long-term vapour inhalation from the e-cigarettes available today is unlikely to exceed 5% of the harm from smoking tobacco.
> Technological developments and improved production standards could reduce the long-term hazard of e-cigarettes.
There are concerns that e-cigarettes will increase tobacco smoking by renormalising the act of smoking, acting as a gateway to smoking in young people, and being used for temporary, not permanent, abstinence from smoking.

To date, there is no evidence that any of these processes is occurring to any significant degree in the UK.

Rather, the available evidence to date indicates that e-cigarettes are being used almost exclusively as safer alternatives to smoked tobacco, by confirmed smokers who are trying to reduce harm to themselves or others from smoking, or to quit smoking completely.

There is a need for regulation to reduce direct and indirect adverse effects of e-cigarette use, but this regulation should not be allowed significantly to inhibit the development and use of harm-reduction products by smokers.

A regulatory strategy should, therefore, take a balanced approach in seeking to ensure product safety, enable and encourage smokers to use the product instead of tobacco, and detect and prevent effects that counter the overall goals of tobacco control policy.

The tobacco industry has become involved in the e-cigarette market and can be expected to try to exploit these products to market tobacco cigarettes, and to undermine wider tobacco control work.

However, in the interests of public health it is important to promote the use of e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible as a substitute for smoking in the UK.

References


Nicotine without smoke
Tobacco harm reduction
A report by the Tobacco Advisory Group of the Royal College of Physicians
April 2016
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Regent's Park
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Community reductions in youth smoking after raising the minimum tobacco sales age to 21

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ABSTRACT

Objective Raising the tobacco sales age to 21 has gained support as a promising strategy to reduce youth cigarette access, but there is little direct evidence of its impact on adolescent smoking. Using regional youth survey data, we compared youth smoking trends in Needham, Massachusetts—which raised the minimum purchase age in 2005—with those of 16 surrounding communities.

Methods The MetroWest Adolescent Health Survey is a biennial census survey of high school youth in communities west of Boston; over 16 000 students participated at each of four time points from 2006 to 2012. Using these pooled cross-section data, we used generalised estimating equation models to compare trends in current cigarette smoking and cigarette purchases in Needham relative to 16 comparison communities without similar ordinances. To determine whether trends were specific to tobacco, we also examined trends in youth alcohol use over the same time period.

Results From 2006 to 2010, the decrease in 30-day smoking in Needham (from 13% to 7%) was significantly greater than in the comparison communities (from 15% to 12%; p < .001). This larger decline was consistent for both genders, Caucasian and non-Caucasian youth, and grades 10, 11 and 12. Cigarette purchases among current smokers also declined significantly more in Needham than in the comparison communities during this time. In contrast, there were no comparable differences for current alcohol use.

Conclusions Our results suggest that raising the minimum sales age to 21 for tobacco contributes to a greater decline in youth smoking relative to communities that did not pass this ordinance. These findings support local community-level action to raise the tobacco sales age to 21.

INTRODUCTION

Raising the legal age of tobacco sales to 21 to reduce youth smoking has gained increasing support among prevention advocates 1 who are working to reduce youth smoking initiation as a primary means of preventing addiction later in life. Nearly 1 in 10 high school youth experiment with cigarettes before age 13, and 4% have smoked regularly. 2 These youth who initiate smoking in adolescence are at greater risk of becoming addicted to tobacco as adults. 3 4 Conversely, research shows that the majority of adults who are addicted to cigarettes began smoking daily before age 18. 4

In addition, many people who purchase cigarettes for minors are under 21 themselves. 5 This suggests that prohibiting young adults under 21 from purchasing cigarettes would reduce the number of legal buyers in adolescents’ social circles, thereby disrupting the supply of cigarettes to adolescents. Given that youth attitudes towards smoking, such as perceived risk and disapproval of smoking, have levelled off or lessened since 2007, 6 reducing access to cigarettes is an important prevention strategy.

A recent report by the Institute of Medicine suggests that raising the minimum age of legal access to tobacco to 21 would result in a 12% decrease in the prevalence of tobacco use among today’s teenagers once they become adults. 7 Another simulation of the impact of raising the legal smoking age to 21 in the USA suggests that adolescent smoking would be reduced by more than half in 7 years. 8 There is broad public support for this effort, with 70% of adults in support of raising the minimum sales age to 21, including a majority of adults in all demographic and smoking status categories. 9 Despite these promising projections, there is little direct evidence that raising the minimum purchase age for tobacco would lead to a decline in youth smoking.

In April of 2005, Needham, Massachusetts became the first town in the USA to raise the minimum tobacco sales age to 21; it was not adopted elsewhere in the USA until 2012 (DJ Wilson, Director, Massachusetts Municipal Association Tobacco Control Technical Assistance Program, personal communication, 7 November 2014.). In this paper, we use data from the MetroWest Adolescent Health Survey (MW AHS) to compare youth smoking trends from 2006 to 2012 in Needham with 16 surrounding communities that did not pass this ordinance. To the best of our knowledge, this is the first study to examine trends in the actual prevalence of smoking associated with raising the minimum sales age. We examined: (1) whether smoking declined more in Needham than in the nearby communities; and (2) whether the effect was specific to tobacco or if similar patterns were also found for alcohol.

METHODS

The MW AHS is a school-based census of youth in 25 communities in the Boston metropolitan area served by the MetroWest Health Foundation, having the primary goal of informing local prevention efforts. It has been administered biennially since fall, 2006 to students in grades 9–12. Of the 26 public high schools in the region served by the foundation, 18 began the survey in 2006. Of these, 17 high schools participated in all four surveys (2006, 2008, 2010 and 2012) and are included in this analysis. Student participation rates ranged from 88.8% to 89.6% over the four surveys, and the number of participants ranged from 16 385 to...
17 089 each year. Student gender and grade distributions were similar across all years.

Measures

The MWAHS instrument is a classroom-administered anonymous survey that incorporates items from the Center for Disease Control and Prevention’s Youth Risk Behavior Survey. We examined two tobacco outcome measures: (1) current (30-day) cigarette smoking (any vs none) using the question “During the past 30 days, on how many days did you smoke cigarettes?”, and (2) current (30-day) purchase of cigarettes in a store (any vs none), using the question “During the past 30 days, how did you usually get your own cigarettes?” with seven response categories: did not try to get cigarettes/bought them in a store/gave someone else money to buy them for me/borrowed or bummed them/a person 18 or older gave them to me/took them from a store or family member/got them some other way. This latter measure of store purchases was restricted to current smokers under age 18 who gave a response other than that they did not try to get cigarettes in the past 30 days. We also examined current (30-day) alcohol use (any vs none) to determine if trends for smoking and drinking differed.

Analyses

To compare smoking outcomes in Needham with the 16 comparison communities, we conducted pooled cross-sectional analyses. First, we fit a series of Poisson regression models for each of the two smoking outcomes (current smoking and current purchase of cigarettes in a store) using generalised estimating equations (SAS Proc GENMOD). The models estimated three parameters: (1) differences in the proportion of youth reporting each outcome at baseline (2006), comparing Needham to the 16 surrounding communities ($\beta_1$); (2) change in these proportions across consecutive survey years (eg, 2006–2008, 2008–2010, and 2010–2012) across all study communities ($\beta_2$); and (3) whether the change over time differed between Needham and the comparison communities, the main parameter of interest ($\beta_3$). All models adjusted for two measures of school composition: per cent of students receiving free/reduced cost school lunch (an index of socioeconomic status) and per cent of Caucasian students (an index of racial/ethnic composition), both mean centred. For example, to compare the prevalence of current smoking between 2006 and 2008, we used data for these 2 years only and fit the following model:

$$\text{Smoking} = \beta_0 + \beta_1 \text{Needham} + \beta_2 2008 + \beta_3 2008 \times \text{Needham} + \beta_4 \% \text{free lunch} + \beta_5 \% \text{non - white}$$

Similar models were fit comparing 2008 with 2010 and 2010 with 2012, with separate models estimated for the prevalence of current cigarette use, current purchase of cigarettes in a store and current alcohol use.

Second, we modelled the prevalence of current smoking, current store purchases of cigarettes and current alcohol use for years 2006–2010 only, with a linear term for study year because, as shown below, models including these years produced a consistent pattern of results. This final model was:

$$\text{Smoking} = \beta_0 + \beta_1 \text{Needham} + \beta_2 \text{Study year} + \beta_3 \text{Study year} \times \text{Needham} + \beta_4 \% \text{free lunch} + \beta_5 \% \text{non - white}$$

where again $\beta_3$ is the coefficient of interest reflecting differences in change over time for Needham compared with the 16 comparison communities from 2006 to 2010. This model was fit for current smoking and current alcohol use for various subgroups (gender, race/ethnicity, grade) to examine whether the overall pattern of results was consistent across different student populations.

RESULTS

Smoking behavior

Thirty-day smoking prevalence is shown in figure 1A, along with the results of the Poisson regression models that summarise the findings for consecutive survey years. In 2006, current smoking did not differ significantly between Needham and the 16 comparison communities. From 2006 to 2008, current smoking decreased at a greater rate in Needham than in the comparison communities ($\beta_1 = -0.174$, $p<0.001$), and again from 2008 to 2010 ($\beta_1 = -0.278$, $p<0.001$). However, from 2010 to 2012, decreases in current smoking were significantly greater in the comparison communities than in Needham ($\beta_1 = 0.143$, $p<0.01$).

Results of additional analyses on current smoking restricting data to the time period 2006–2010 are presented in table 1. These analyses were restricted to the first three surveys because that was the period of time during which the decline in youth smoking was significantly greater in Needham relative to the comparison communities. In 2006, shortly after the minimum purchase age was raised in Needham, the estimated prevalence of 30-day smoking between Needham and the comparison communities did not differ ($\beta_1 = 0.062$; ns (non-significant)); the prevalence for all communities decreased significantly with time ($\beta_2 = -0.050$; $p<0.001$). Most notably, the overall decline in Needham’s 30-day smoking prevalence exceeded that of the comparison communities combined ($\beta_1 = -0.108$; $p<0.001$). This statistically greater decline in Needham was observed for all subgroups (females, males, Caucasian, non-Caucasian, and by student grade), with the exception of ninth grade youth, who reported low levels of smoking.

Cigarette purchases in stores

From 2006 to 2012, the percentage of youth under age 18 who purchased cigarettes in stores decreased significantly more in Needham (from 18.4% to 11.6%) than in the comparison communities (from 19.4% to 19.0%; $p<0.001$) (see figure 1B). The findings follow the same general pattern as current smoking: the rate of decline in purchasing cigarettes in Needham relative to the comparison communities was greatest for the period from 2006 to 2008 ($\beta_1 = -0.667$; $p<0.001$), lessened for the period from 2008 to 2010 ($\beta_1 = 0.200$; $p<0.05$), and did not show a significant change from 2010 to 2012 ($\beta_1 = 0.029$; ns). Since the pattern of findings was similar to that of current smoking, we also examined the overall change from 2006 to 2010; the decline in store purchases in Needham over this period was greater than in the comparison communities ($\beta_1 = -0.465$, $p<0.001$).

Comparison to alcohol use

Notably, the findings for current alcohol use were distinct from those for current cigarette smoking: from 2006 to 2012, there was a general decline in the 30-day prevalence of drinking, with no significant differences between Needham and the comparison communities over any of the consecutive survey waves (see figure 1C). Models for the combined years spanning 2006–2010 also show that there was no significant difference in the 30-day prevalence of drinking in Needham compared with the 16 comparison communities ($\beta_1 = -0.003$; ns (data not shown)).
DISCUSSION

As more communities are debating whether or not to raise the minimum sales age of tobacco, it is important to examine the effects this policy may have on youth smoking and access to cigarettes. Comparing data from Needham and 16 surrounding communities, we showed a significantly greater decline in current smoking in Needham soon after the minimum purchase age was raised, overall and for males, females, Caucasian and non-Caucasian smokers. Figure 1 shows the trends in current cigarette smoking, store purchases of cigarettes, and alcohol use in Needham vs 16 comparison communities, 2006–2012. *p<0.05, **p<0.01, ***p<0.001. † Among current smokers who tried to obtain cigarettes in the past 30 days.

Note: The minimum purchase age was raised to 21 in 2005. The numbers between time points represent the β coefficients from a series of Poisson regression models that estimated the change in use/purchase in Needham relative to the 16 comparison communities over consecutive time periods (2006–2008, 2008–2010, and 2010–2012) controlling for race/ethnicity and socioeconomic status at the school level.

Table 1 Stratified models predicting 30-day cigarette smoking, Needham versus 16 comparison communities, 2006–2010

<table>
<thead>
<tr>
<th>Cigarette smoking</th>
<th>Total</th>
<th>Gender</th>
<th>Race/ethnicity</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Females</td>
<td>Caucasian</td>
<td>9th</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>10th</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>11th</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>12th</td>
</tr>
<tr>
<td>Intercept</td>
<td>−1.922***</td>
<td>−2.032***</td>
<td>−1.831*</td>
<td>−1.947***</td>
</tr>
<tr>
<td>β1—target community (Needham)</td>
<td>0.062</td>
<td>0.258***</td>
<td>−0.101</td>
<td>0.089*</td>
</tr>
<tr>
<td>β2—time</td>
<td>−0.050***</td>
<td>−0.084***</td>
<td>−0.025</td>
<td>−0.058***</td>
</tr>
<tr>
<td>β3—time×target community</td>
<td>−0.108***</td>
<td>−0.214***</td>
<td>−0.038*</td>
<td>−0.129***</td>
</tr>
<tr>
<td>Percentage of free/reduced lunch</td>
<td>0.026***</td>
<td>0.032***</td>
<td>0.021***</td>
<td>0.030***</td>
</tr>
<tr>
<td>Percentage of Caucasian</td>
<td>0.020***</td>
<td>0.026***</td>
<td>0.016***</td>
<td>0.021***</td>
</tr>
</tbody>
</table>

The coefficient of time×target community represents the change in prevalence of 30-day use in Needham relative to the 16 comparison communities from 2006 to 2010. *p<0.05, **p<0.01, ***p<0.001.

β1, difference in log-odds of a 30-day prevalence of smoking between Needham and non-Needham communities at 2006; β2, change in log-odds of a 30-day prevalence of smoking per 2-year interval, from 2006 to 2010, in non-Needham communities; β3, difference in change of log-odds of a 30-day prevalence of smoking per 2-year interval, from 2006 to 2010, between Needham and non-Needham communities.
non-Caucasian youth, and for students in grades 10, 11 and 12. These trends were significant from 2006 to 2010, but not from 2010 to 2012, suggesting that raising the minimum purchase age may contribute to a greater decline in smoking in the years immediately following its adoption. As the smoking rate decreased in Needham, floor effects might have slowed the rate of decline in the period from 2010 to 2012; however, the smoking rate still declined by 18% in that final period.

In addition to lower levels of smoking, Needham youth also reported a significantly greater decline in purchasing cigarettes from stores in the years immediately following the legislation. This was true despite the fact that the youth population in Needham is very mobile, and closely neighbouring suburban communities maintained a minimum sales age of 18 throughout the study period. The decline in smoking in Needham may have been even more pronounced if surrounding communities had also increased the tobacco sales age to 21, as this would have further limited access. Youth who purchase cigarettes are more likely to supply cigarettes to other youth,12 13 and these social opportunities during any portion of the study period. This indicates that the observed pattern of change appears to be specific to cigarette smoking and not due to a broader decline in substance use or reporting patterns.

Enforcement may partially explain the apparent success of raising the minimum tobacco sales age in Needham. Effective enforcement is important in the success of laws designed to prevent tobacco sales to minors.14 In 2008, more than 18 000 compliance checks for cigarette sales to adolescents under the age of 18 were conducted in Massachusetts towns with state-funded tobacco control programmes, with an illegal sales rate of 8.3%. In Needham, 57 compliance checks were conducted, with zero illegal sales to those under the age of 18 occurring.15 Increasing the tobacco sales age to 21 may have made it less likely that adolescents under the age of 18 would have been sold tobacco.

Several limitations are worth noting. First, this study was not initially designed to evaluate the minimum sales age legislation; the 2006 survey was administered more than 1 year after the legislation was adopted in April of 2005; therefore, there is no baseline measure of youth smoking. It also does not take into account the fact that the minimum sales age in Needham was increased in phases: it was first raised from 18 to 19 in April of 2003, then to 20 in April of 2004, and finally to 21 in April of 2005. Data reported from the Youth Risk Behavior Survey conducted in Needham (Needham Youth Risk Behavior Survey, unpublished raw data, 2001–2005) and the state of Massachusetts16 in 2001, 2003 and 2005 provide some information on trends prior to the current study. In Needham, current smoking was similar in 2001 (21%) and 2003 (20%), and then dropped to 13% in 2005, corresponding with the first two increases in the minimum sales age. During the same time period, smoking decreased in Massachusetts from 26% to 21% during 2001–2003, and then was stable at 21% in 2005. This suggests that the greater decline in smoking in Needham in this study may be a continuation of a trend that began earlier, possibly around the time when the minimum sales age was initially raised. Second, Needham also passed a law in 2009 prohibiting tobacco sales in pharmacies, which may have contributed to the smoking decline after the 2008 survey. With the exception of one other study community that banned pharmacy sales in 2011, neither Needham nor any of the comparison communities adopted any of the Massachusetts Tobacco Control Program’s five priority prevention policies during the study period (banning pharmacy sales, capping tobacco licenses, regulating single cigarette purchases, banning flavoured tobacco sales and regulating electronic cigarette purchases) (M Paskowky, Director of Surveillance and Evaluation, Massachusetts Tobacco Cessation and Prevention Program, Massachusetts Department of Public Health, personal communication, 6 November 2014).

This study did not account for non-policy-related programmes in Needham or the other communities. Finally, this study analysed the use of cigarettes only and did not examine the use of other tobacco products.

Despite these limitations, this study shows promising results on the potential impact of raising the minimum sales age of tobacco. Further, raising the minimum age is relatively simple to implement given the existing mechanisms to restrict tobacco purchases and conduct compliance checks.17 As this approach is considered in more and more localities, our findings provide strong evidence of its potential to save lives by preventing youth access, initiation and ultimately addiction.

What this paper adds

- An increasing number of communities are implementing policies to raise the minimum sales age of tobacco to 21, but there is little direct evidence regarding whether this strategy is effective in reducing youth smoking.
- We have demonstrated that, after raising the minimum sales age in Needham, Massachusetts, smoking and cigarette purchases declined significantly more in Needham relative to 16 comparison communities.
- These findings are valuable to localities that are considering raising the minimum age, in showing that this approach has the potential to reduce youth access and initiation, with potentially life-saving benefits.

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Contributors All authors participated in the study conceptualisation. SKS originated the study, oversaw data collection and drafted portions of the manuscript. SLB and KD oversaw the analysis and contributed substantially to the manuscript writing. JPW contributed to the conceptualisation and manuscript editing. LO contributed substantially to the study design and manuscript writing.

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Competing interests None declared.

Ethics approval The study was approved in all years by the Institutional Review Board at Education Development Center, Inc, Waltham, Massachusetts, USA.
REFERENCES


14. DiFranza JR. Which interventions against the sale of tobacco to minors can be expected to reduce smoking? Tob Control 2012;21:436–42.


Community reductions in youth smoking after raising the minimum tobacco sales age to 21

Shari Kessel Schneider, Stephen L Buka, Kim Dash, Jonathan P Winicoff and Lydia O'Donnell

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September 12, 2017

Members of the City Council
City of Plymouth
3400 Plymouth Boulevard
Plymouth, MN 55447

Dear Members of the Plymouth City Council,

I am writing on behalf of the Twin Cities Medical Society in support of raising the legal age for tobacco sales in Plymouth from 18 to 21. The Twin Cities Medical Society is an organization that represents approximately 4,500 physicians and medical students living and working in the seven-county Twin Cities metropolitan area. One of our key missions is advocating for policies that promote public health.

Our physician members share all too often that tobacco is still a problem for their patients. E-cigarette use is also on the rise among Minnesota youth. We know that exposure to nicotine while the adolescent brain is still developing increases the risk of mood disorders, permanent lowering of impulse control and other addictions later in life. A Tobacco 21 ordinance would be a bold step toward protecting another generation from a lifetime of tobacco addiction, and ultimately disease and premature death.

Restricting the sale of tobacco to those 21 and older is the next step in reducing Minnesota youth smoking initiation rates. Almost 95% of adult smokers pick up the habit before age 21, and increasing the gap between those who can legally purchase tobacco will limit high schooler’s access to these products. By increasing the purchasing age for tobacco, Plymouth will reduce the number of youth and young adults that are exposed to these highly addictive products.

We stand behind this effort, and you. Thank you for protecting the public health of Plymouth residents.

Sincerely,

Matt Hunt, MD
President of the Twin Cities Medical Society
From: "Cap O'Rourke" <cap@orourkesc.com>
To: "Luke Fischer" <lfischer@plymouthmn.gov>
Subject: Plymouth Tobacco and Vapor Ordinance

Council Members
and Mayor

~

I am writing this morning regarding the work session you are holding,

to discuss raising the age to purchase tobacco and vapor products to 21

I work with a coalition of small businesses in Minnesota

that manufacture and sell vapor products and we feel strongly - that by including vapor in this new ordinance -
you are actually hurting public health

by not only making it more difficult for those who started smoking at a young age
to access this alternative when they reach age 18

but also by sending a message to all adults

that smoking and vaping have the same health effects,

which is simply not supported by scientific data.

I have attached some recent studies and reports (all done by independent organizations)

that show the benefits of vaping and how vapor products can be part of the solution to eliminating the effects of smoking.

If you have any questions please feel free to contact me.

I will attend tonight's work session as well.
1. The most recent study, just published this month by researchers in Georgetown, Michigan, and Yale shows that by switching smokers to vaping we could reduce the number of premature deaths by 1.6-6.6 million over the next 10 years. Tobacco Control

2. Here are two more comprehensive reports about vapor products from the Royal College of Physicians and Public Health UK. RCP is an internationally recognized health organization that first warned of the dangers of smoking in 1962. They state that vapor products are at least 95% safer than smoking and should be encouraged as an alternative to smoking. Public Health England also supported vapor products as a smoking alternative. BOTH organizations found no data supporting the notion that youth vaping will lead to smoking. (reports attached)

3. A report issued this spring by over 25 tobacco researchers and anti-tobacco advocates highlights the need for a new nicotine policy that embraces harm reduction options such as vapor products. (Liberating Nicotine From smoke -attached).

I could share many more studies showing the benefits of vaping as a harm reduction option for the countless number of smokers, as well as additional data diminishing the concerns that students who are experimenting with vapor will end up smoking. Passing an ordinance that raises the age to purchase vapor products not only makes it difficult for those smokers who started young to switch, it also sends the message to adults that smoking and vaping pose the same health risks, when the scientific data simply does not support this.

The truth is that the youth smoking rate not only continues to fall but the rate of smoking overall, when vaping came more prevalent.
Regards,

Cap O'Rourke  
President  
O'Rourke Strategic Consulting  
612.483.1863  
@ORourkesc
E-cigarettes: an evidence update
A report commissioned by Public Health England

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About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

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Published August 2015
PHE publications gateway number: 2015260
Foreword

The role and impact of electronic cigarettes has been one of the great debates in public health in recent years and we commissioned this independent review of the latest evidence to ensure that practitioners, policy makers and, most importantly of all, the public have the best evidence available.

Many people think the risks of e-cigarettes are the same as smoking tobacco and this report clarifies the truth of this.

In a nutshell, best estimates show e-cigarettes are 95% less harmful to your health than normal cigarettes, and when supported by a smoking cessation service, help most smokers to quit tobacco altogether.

We believe this review will prove a valuable resource, explaining the relative risks and benefits of e-cigarettes, in terms of harm reduction when compared with cigarettes and as an aid to quitting.

We will continue to monitor the position and will add to the evidence base and guidance going forward.

Duncan Selbie, Chief Executive, PHE
Key messages

1. Smokers who have tried other methods of quitting without success could be encouraged to try e-cigarettes (EC) to stop smoking and stop smoking services should support smokers using EC to quit by offering them behavioural support.

2. Encouraging smokers who cannot or do not want to stop smoking to switch to EC could help reduce smoking related disease, death and health inequalities.

3. There is no evidence that EC are undermining the long-term decline in cigarette smoking among adults and youth, and may in fact be contributing to it. Despite some experimentation with EC among never smokers, EC are attracting very few people who have never smoked into regular EC use.

4. Recent studies support the Cochrane Review findings that EC can help people to quit smoking and reduce their cigarette consumption. There is also evidence that EC can encourage quitting or cigarette consumption reduction even among those not intending to quit or rejecting other support. More research is needed in this area.

5. When used as intended, EC pose no risk of nicotine poisoning to users, but e-liquids should be in ‘childproof’ packaging. The accuracy of nicotine content labelling currently raises no major concerns.

6. There has been an overall shift towards the inaccurate perception of EC being as harmful as cigarettes over the last year in contrast to the current expert estimate that using EC is around 95% safer than smoking.

7. Whilst protecting non-smoking children and ensuring the products on the market are as safe and effective as possible are clearly important goals, new regulations currently planned should also maximise the public health opportunities of EC.

8. Continued vigilance and research in this area are needed.
Executive summary

Following two previous reports produced for Public Health England (PHE) on e-cigarettes (EC) in 2014, this report updates and expands on the evidence of the implications of EC for public health. It covers the EC policy framework, the prevalence of EC use, knowledge and attitudes towards EC, impact of EC use on smoking behaviour, as well as examining recent safety issues and nicotine content, emissions and delivery. Two literature reviews were carried out to update the evidence base since the 2014 reports and recent survey data from England were assessed.

EC use battery power to heat an element to disperse a solution of propylene glycol or glycerine, water, flavouring and usually nicotine, resulting in an aerosol that can be inhaled by the user (commonly termed vapour). EC do not contain tobacco, do not create smoke and do not rely on combustion. There is substantial heterogeneity between different types of EC on the market (such as cigalikes and tank models). Acknowledging that the evidence base on overall and relative risks of EC in comparison with smoking was still developing, experts recently identified them as having around 4% of the relative harm of cigarettes overall (including social harm) and 5% of the harm to users.

In England, EC first appeared on the market within the last 10 years and around 5% of the population report currently using them, the vast majority of these smokers or recent ex-smokers. Whilst there is some experimentation among never smokers, regular use among never smokers is rare. Cigarette smoking among youth and adults has continued to decline and there is no current evidence in England that EC are renormalising smoking or increasing smoking uptake. Instead, the evidence reviewed in this report point in the direction of an association between greater uptake of EC and reduced smoking, with emerging evidence that EC can be effective cessation and reduction aids.

Regulations have changed little in England since the previous PHE reports with EC being currently governed by general product safety regulations which do not require products to be tested before being put on the market. However, advertising of EC is now governed by a voluntary agreement and measures are being introduced to protect children from accessing EC from retailers. Manufacturers can apply for a medicinal licence through the Medicines and Healthcare products Regulatory Agency (MHRA) and from 2016, any EC not licensed by the MHRA will be governed by the revised European Union Tobacco Products Directive (TPD).

A summary of the main findings and policy implications from the data chapters now follows.
Summary of Chapter 3: UK policy framework

The revised TPD will introduce new regulations for EC or refill containers which are not licensed by the MHRA. The cap on nicotine concentrations introduced by the TPD will take high nicotine EC and refill liquids off the market, potentially affecting heavier smokers seeking higher nicotine delivery products.

The fact that no licensed EC are yet on the market suggests that the licensing route to market is not commercially attractive. The absence of non-tobacco industry products going through the MHRA licensing process suggests that the process is inadvertently favouring larger manufacturers including the tobacco industry, which is likely to inhibit innovation in the prescription market.

Policy implications

- From May 2016, following the introduction of the revised TPD, ECs will be more strictly regulated. As detailed elsewhere in the report, the information we present does not indicate widespread problems as a result of EC. Hence, the current regulatory structure appears broadly to have worked well although protecting non-smoking children and ensuring the products on the market are as safe and effective as possible are clearly important goals. New regulations currently planned should be implemented to maximise the benefits of EC whilst minimising these risks.

- An assessment of the impact of the TPD regulations on the UK EC market will be integral to its implementation. This should include the degree to which the availability of safe and effective products might be restricted.

- Much of England’s strategy of tobacco harm reduction is predicated on the availability of medicinally licensed products that smokers want to use. Licensed ECs are yet to appear. A review of the MHRA EC licensing process therefore seems appropriate, including manufacturers’ costs, and potential impact. This could include a requirement for MHRA to adapt the processes and their costs to enable smaller manufacturers to apply, and to speed up the licensing process. The review could also assess potential demand for the EC prescription market and what types of products would be most appropriate to meet that demand.

Summary of Chapter 4: Prevalence of e-cigarette use in England/Great Britain

Adults: Around one in 20 adults in England (and Great Britain) use EC. Current EC users are almost exclusively smokers (~60%) or ex-smokers (~40%), that is smokers who now use EC and have stopped smoking altogether. EC use among long-term ex-smokers is considerably lower than among recent ex-smokers. Current EC use among
never smokers is very low, estimated to be 0.2%. The prevalence of EC use plateaued between 2013-14, but appeared to be increasing again in 2015.

Youth: Regular EC use among youth is rare with around 2% using at least monthly and 0.5% weekly. EC use among young people remains lower than among adults: a minority of British youth report having tried EC (~13%). Whilst there was some experimentation with EC among never smoking youth, prevalence of use (at least monthly) among never smokers is 0.3% or less.

Overall, the adult and youth data suggest that, despite some experimentation with EC among never smokers, EC are attracting few people who have never smoked into regular use.

*Trends in EC use and smoking:* Since EC were introduced to the market, cigarette smoking among adults and youth has declined. In adults, overall nicotine use has also declined (not assessed for youth). These findings, to date, suggest that the advent of EC is not undermining, and may even be contributing to, the long-term decline in cigarette smoking.

**Policy implications**

- Trends in EC use among youth and adults should continue to be monitored using standardised definitions of use.
- Given that around two-thirds of EC users also smoke, data are needed on the natural trajectory of ‘dual use’, ie whether dual use is more likely to lead to smoking cessation later or to sustain smoking (see also Chapter 6).
- As per existing NICE guidance, all smokers should be supported to stop smoking completely, including ‘dual users’ who smoke and use EC.

**Summary of Chapter 5: Smoking, e-cigarettes and inequalities**

Smoking is increasingly concentrated in disadvantaged groups who tend to be more dependent. EC potentially offer a wide reach, low-cost intervention to reduce smoking and improve health in disadvantaged groups.

Some health trusts and prisons have banned the use of EC which may disproportionately affect more disadvantaged smokers.
Policy implications

- Consideration could be given to a proactive strategy to encourage disadvantaged smokers to quit smoking as quickly as possible including the use of EC, where appropriate, to help reduce health inequalities caused by smoking.

- EC should not routinely be treated in the same way as smoking. It is not appropriate to prohibit EC use in health trusts and prisons as part of smokefree policies unless there is a strong rationale to do so.

Summary of Chapter 6: E-cigarettes and smoking behaviour

Recent studies support the Cochrane Review findings that EC can help people to quit smoking and reduce their cigarette consumption. There is also evidence that EC can encourage quitting or cigarette consumption reduction even among those not intending to quit or rejecting other support. It is not known whether current EC products are more or less effective than licensed stop smoking medications, but they are much more popular, thereby providing an opportunity to expand the number of smokers stopping successfully. Some English stop smoking services and practitioners support the use of EC in quit attempts and provide behavioural support for EC users trying to quit smoking; self-reported quit rates are at least comparable to other treatments. The evidence on EC used alongside smoking on subsequent quitting of smoking is mixed.

Policy implications

- Smokers who have tried other methods of quitting without success could be encouraged to try EC to stop smoking and stop smoking services should support smokers using EC to quit by offering them behavioural support.

- Research should be commissioned in this area including:
  - longitudinal research on the use of EC, including smokers who have not used EC at the beginning of the study
  - the effects of using EC while smoking (temporary abstinence, cutting down) on quitting, and the effects of EC use among ex-smokers on relapse
  - research to clarify the factors that i) help smokers using EC to quit smoking and ii) deter smokers using EC from quitting smoking, including different EC products/types and frequency of use and the addition of behavioural support, and how EC compare with other methods of quitting which have a strong evidence base

- It would be helpful if emerging evidence on EC (including different types of EC) and how to use EC safely and effectively could be communicated to users and health professionals to maximise chances of successfully quitting smoking.
Summary of Chapter 7: Reasons for use and discontinuation

A number of surveys in different populations provide evidence that reducing the harm from smoking (such as through cutting down on their cigarette consumption or helping with withdrawal during temporary abstinence) and the desire to quit smoking cigarettes are the most important reasons for using EC. Curiosity appears to play a major role in experimentation. Most trial of EC does not lead to regular use and while there is less evidence on why trial does not become regular use, it appears that trial due to curiosity is less likely to lead to regular use than trial for reasons such as stopping smoking or reducing harm. Dissatisfaction with products and safety concerns may deter continued EC use.

Policy implications

- Smokers frequently state that they are using EC to give up smoking. They should therefore be provided with advice and support to encourage them to quit smoking completely.
- Other reasons for use include reducing the harm from smoking and such efforts should be supported but with a long-term goal of stopping smoking completely.

Summary of Chapter 8: Harm perceptions

Although the majority of adults and youth still correctly perceive EC to be less harmful than tobacco cigarettes, there has been an overall shift towards the inaccurate perception of EC being at least as harmful as cigarettes over the last year, for both groups. Intriguingly, there is also some evidence that people believe EC to be less harmful than medicinal nicotine replacement therapy (NRT).

Policy implications

- Clear and accurate information on relative harm of nicotine, EC and tobacco cigarettes is needed urgently (see also Chapter 10).
- Research is needed to explore how health perceptions of EC are developed, in relation to tobacco cigarettes and NRT, and how they can be influenced.

Summary of Chapter 9: E-cigarettes, nicotine content and delivery

The accuracy of labelling of nicotine content currently raises no major concerns. Poorly labelled e-liquid and e-cartridges mostly contained less nicotine than declared. EC used
as intended pose no risk of nicotine poisoning to users. However, e-liquids should be in ‘childproof’ packaging.

Duration and frequency of puffs and mechanical characteristics of EC play a major role in determining nicotine content in vapour. Across the middle range of nicotine levels, in machine tests using a standard puffing schedule, nicotine content of e-liquid is related to nicotine content in vapour only weakly. EC use releases negligible levels of nicotine into ambient air with no identified health risks to bystanders. Use of a cigalike EC can increase blood nicotine levels by around 5 ng/ml within five minutes of use. This is comparable to delivery from oral NRT. Experienced EC users using the tank EC can achieve much higher blood nicotine levels over a longer duration, similar to those associated with smoking. The speed of nicotine absorption is generally slower than from cigarettes but faster than from NRT.

Policy implications

- General labelling of the strength of e-liquids, along the lines used for example indicating coffee strength, provides sufficient guidance to consumers.
- Regulatory interventions should ensure optimal product safety but make sure EC are not regulated more strictly than cigarettes and can continue to evolve and improve their competitiveness against cigarettes.

Summary of Chapter 10: Safety of e-cigarettes in light of new evidence

Two recent worldwide media headlines asserted that EC use is dangerous. These were based on misinterpreted research findings. A high level of formaldehyde was found when e-liquid was over-heated to levels unpalatable to EC users, but there is no indication that EC users are exposed to dangerous levels of aldehydes; stressed mice poisoned with very high levels of nicotine twice daily for two weeks were more likely to lose weight and die when exposed to bacteria and viruses, but this has no relevance for human EC users. The ongoing negative media campaigns are a plausible explanation for the change in the perception of EC safety (see Chapter 8).

None of the studies reviewed above alter the conclusion of Professor Britton’s 2014 review for PHE. While vaping may not be 100% safe, most of the chemicals causing smoking-related disease are absent and the chemicals which are present pose limited danger. It has been previously estimated that EC are around 95% safer than smoking. This appears to remain a reasonable estimate.
Policy implications

- There is a need to publicise the current best estimate that using EC is around 95% safer than smoking.
- Encouraging smokers who cannot or do not want to stop smoking to switch to EC could be adopted as one of the key strategies to reduce smoking related disease and death.

Summary of Chapter 11: Other health and safety concerns

There is a risk of fire from the electrical elements of EC and a risk of poisoning from ingestion of e-liquids. These risks appear to be comparable to similar electrical goods and potentially poisonous household substances.

Policy implications

- The risks from fire or poisoning could be controlled through standard regulations for similar types of products, such as childproof containers (contained within the TPD but which are now emerging as an industry standard) and instructions about the importance of using the correct charger.
- Current products should comply with current British Standard operating standards.
- Records of EC incidents could be systematically recorded by fire services.

Summary of Chapter 12: International perspectives

Although EC use may be lower in countries with more restrictions, these restrictions have not prevented EC use. Overall, use is highest among current smokers, with low numbers of non-smokers reporting ever use. Current use of EC in other countries is associated with being a smoker or ex-smoker, similar to the findings in the UK. EC use is frequently misreported with experimentation presented as regular use. Increases in youth EC trial and use are associated with decreases in smoking prevalence in all countries, with the exception of one study from Poland.

Policy implications

- Future research should continue to monitor and evaluate whether different EC policies across countries are related to EC use and to smoking cessation and smoking prevalence.
- Consistent and agreed measures of trial, occasional and regular EC use among youth and adults are urgently needed to aid comparability.
1. Introduction

Despite the decline in smoking prevalence observed over the last few decades, there remain over eight million smokers in England. Most of these are from manual and more disadvantaged groups in society, including those with mental health problems, on low income, the unemployed and offenders. In some such population groups, the proportion who smoke is over two or three times higher than that in the general population, a level of smoking observed in the general population over 40 years ago. For those who continue to smoke regularly, much of their lives will be of lower quality and spent in poorer health than those who don’t smoke, and they will have a one in two chance of dying prematurely, by an average of 10 years, as a direct result of their smoking. Smoking is therefore the largest single contributor to health inequalities as well as remaining the largest single cause of preventable mortality and morbidity in England.

Moving forward, it is therefore important to maintain and enhance England's comprehensive tobacco control strategy in order to motivate and support all smokers in society to stop smoking as quickly as possible, and prevent the recruitment of new smokers. Harm reduction guidance, published by the National Institute for Health and Care Excellence in England in 2013, recognised that some smokers struggled to quit abruptly and that cigarettes were a lethal delivery system for nicotine [1]; it is widely accepted that most smokers smoke for the nicotine but die from the other smoke constituents. Harm reduction has been identified as one of the more promising policy options to reduce smoking induced inequalities in health [2]. All experts agree that a well-resourced comprehensive strategy, involving cessation, prevention and harm reduction should make the goal of a smoke-free society in England quickly achievable.

However, the advent of electronic cigarettes (EC) over recent years has caused controversy. In 1991, Professor Michael Russell, a leading English smoking cessation expert from the Institute of Psychiatry, argued that "it was not so much the efficacy of new nicotine delivery systems as temporary aids to cessation, but their potential as long-term alternatives to tobacco that makes the virtual elimination of tobacco a realistic future target", and he recommended that “tobacco should be rapidly replaced by cleaner, less harmful, sources of nicotine” [3]. Professor Russell was one of the first to recognise the critical role that nicotine played in tobacco use and he identified that whilst there were good ethical and moral reasons not to promote nicotine addiction in society, the harm caused by nicotine was orders of magnitude lower than the harms caused by cigarette smoke. Professor Russell was also a pioneer of new treatments for smoking cessation, in particular, nicotine replacement therapies (NRT). Since then, the number of NRT products has proliferated such that there are now several different delivery routes and modes and countless different dosages and flavours. However, even with a relaxation of the licensing restrictions which increased their accessibility, NRT products have never become popular as an alternative to smoking.
In 2004, the first EC was marketed in China, and EC started to appear in England in 2006/7. The subsequent three years saw a rapid rise in their use. Whilst Professor Russell died in 2009, predating the arrival of these products in England, proponents of EC similarly recognised their potential to contribute towards making a smoke-free society more rapidly achievable [4]. Those against EC, however, believed that they were at best a distraction, at worst a means of undoing decades of progress in reducing smoking [5].

Any new tobacco control strategy for England must therefore incorporate a nicotine strategy, which should include recommendations and an appropriate regulatory framework for EC. This report attempts to inform that strategy by reviewing recent evidence and surveys relating to the use of EC and how they impact smoking behaviour. The focus is England, although we also draw on evidence from elsewhere in the UK and internationally.

**Description of e-cigarettes**

EC use battery power to heat an element to disperse a solution that usually contains nicotine. The dispersion of the solution leads to the creation of an aerosol that can be inhaled by the user. The heated solution typically contains propylene glycol or glycerine, water, nicotine, and flavourings. EC do not contain tobacco, do not create smoke and do not rely on combustion. Whilst EC ‘smoke’ is technically an aerosol, throughout this report we use the established terminology of vapour, vaping and vaper.

There is substantial heterogeneity between different types of EC and the speed with which they are evolving making them difficult to categorise. ECs available in England can be classified into three basic types: (1) EC that are either (a) disposable or (b) use pre-filled cartridges that need to be replaced once emptied. We will refer to these using their most common name, ‘cigalikes’. Most cigalikes resemble cigarettes, although it is important to note that some do not; (2) EC that are designed to be refilled with liquid by the user. We will refer to these using their common name ‘tank systems’. (3) Finally, some EC products, mostly tank systems that allow users to regulate the power delivery from the batteries to the atomizer. These we refer to as mods or ‘variable power EC’.

In the UK, the most prominent brands of cigalikes are now owned by the tobacco industry. To the authors’ knowledge only one tobacco company sells a tank model in the UK, with the rest of the market consisting of non-tobacco industry companies. Some products have also been introduced by the tobacco industry that could be referred to as ‘hybrids’ such that they use pre-filled nicotine cartridges but look like tank models. Additionally, a few EC that are similar to cigalikes in function are also sold that use cartridges that can be refilled, and some users will puncture holes/remove the ends of cigalike cartridges to refill them instead of buying new cartridges.
Studies have validated the ability of EC to deliver nicotine to the user. Blood plasma nicotine concentrations increase after inhalation of EC aerosol [6, 7], and cotinine, a biomarker for nicotine, has been detected in the saliva of EC users [8, 9]. Information about the overall and relative risks of EC in comparison with smoking has also been developing. Using a multi-criteria decision analysis (MCDA) model, the Independent Scientific Committee on Drugs selected experts from several different countries to compare a variety of nicotine products on variables of harm identified by the UK Advisory Council on the Misuse of Drugs [10]. EC were identified as having 4% of the relative harm of cigarettes overall (including social harm) and 5% of the harm to users, although it was acknowledged that there was a lack of hard evidence for the harms of most of the nicotine products on most of the criteria.

Structure of report

Following Chapter 2 on methodology, Chapter 3 assesses the current and future policy framework for EC. Chapters 4 and 5 assess trial and usage in England among adults and youth as well as different socioeconomic groups where evidence permits. Chapter 6 examines the evidence for the impact of EC on smoking behaviour including the use of EC in quit attempts as well as alongside smoking. Chapter 7 assesses reasons for trying and discontinuing EC and Chapter 8 perceptions of relative harms of EC and smoking. Chapter 9 discusses nicotine content and emissions of EC as well as nicotine uptake in users. Chapters 10 and 11 assess different aspects of safety drawing on recent published studies as well as national statistics. Chapter 12 examines international perspectives of EC policies and usage.
2. Methodology

For the present report we have included: (1) a synthesis of recent evidence (published since the two PHE 2014 EC reports) with the earlier evidence in the earlier PHE reports drawing on both national and international literature; and (2) where feasible, an analysis of any relevant national unpublished data available to PHE, KCL and partner organisations from England, Great Britain or the UK, including: i) Smoking Toolkit Study (UCL); ii) Action on Smoking and Health (ASH) Smokefree GB (adult and youth) surveys; iii) Internet Cohort GB survey; iv) Smokers’ surveys 2014 commissioned by ASH from YouGov; and v) the International Tobacco Control (ITC) policy evaluation project.

For the evidence review (1) above, given the short timeframe for this report, a systematic review of the literature was not possible. However, we followed systematic review methods where possible and searched PubMed for studies from 2014 onwards using the following search terms: ("2014/01/01"[Date - Publication] : "3000"[Date - Publication])) AND (((((((e-cigarette) OR Electronic cigarettes) OR e-cig*) OR electronic cig*) OR ENDS) OR electronic nicotine delivery systems) OR electronic nicotine delivery system) OR ((Nicotine) AND Vap*)).

The term ENDS was used as some studies have referred to e-cigarettes as Electronic Nicotine Delivery Systems (ENDS). This search returned 3,452 records. The titles of all records were screened and 798 articles were identified as potentially relevant to the report. The full papers of abstracts considered relevant by two reviewers were retrieved and reviewed as identified in Appendix A.

We wanted to ensure we included the most up-to-date information on EC use and impact in England. In order to do this we used routine national data sources to retrieve measures of EC use prevalence, fires, poisoning and other adverse events. Specifically for (2) above, we assessed, in addition to published papers, unpublished national survey data relevant to this work, identifying where findings are peer reviewed/published. The methods of the surveys that we have accessed are as follows:

**Smoking Toolkit Study (STS, University College London)**

The STS consists of monthly *cross-sectional household interviews* of adults (aged 16 and over) in England that has been running since November 2006. Each month involves a *new nationally representative sample* of about 1,800 respondents. Since 2009, all respondents who smoked in the last year have been asked questions on EC; since November 2013 all respondents complete questions on EC. For more information, see [www.smokinginengland.info](http://www.smokinginengland.info)
ASH Smokefree GB (adult and youth) surveys

**Adult:** ASH has conducted **cross-sectional internet surveys** of adults (aged 18 and over) in Great Britain (GB) since 2007. These surveys cover a wide range of tobacco control policies and smoking behaviour and are carried out on ~12,000 adults each year. Questions on EC were included first in 2010, with new EC questions added in each subsequent survey (2012, 2013, 2014, 2015).

**Youth:** ASH has conducted **cross-sectional surveys of British youth** (aged 11-18) three times to date (2013, 2014, 2015). **Younger** participants are recruited, **online**, through the adult YouGov participants with **older** participants contacted **directly**. It has been used to give a more contemporaneous and comprehensive snapshot of youth attitudes towards smoking and their behaviours (and includes a breakdown of trial and more prolonged use of EC) than UK Government national surveys have been able to.

**Internet Cohort GB survey (King’s College London, University College London)**

A unique longitudinal internet survey of smokers and recent ex-smokers in GB (aged 16 and over) surveyed first in 2012 and then again in December 2013 and 2014. Of the 5,000 respondents in the initial sample, 1,031 respondents (20.7%) used EC at all at the time of the survey in 2012. The prevalence of past-year smoking in this baseline sample was similar to that identified through the STS (which, as stated above, recruited representative samples of the population in England), over a comparable period.

In 2013, 2,182 of the 5,000 were followed up and in 2014, 1,519 were followed up. EC use was 32.8% (n=717) in 2013 and 33.2% (n=505) in 2014. The study sample was recruited from an online panel managed by Ipsos MORI who were invited by email to participate in an online study and were screened for smoking status. The survey included questions on smoking and quitting behaviour and stress and general health as well as detailed questions on EC usage.

**ASH GB Smokers’ survey 2014**

This is an online survey carried out by YouGov for ASH specifically to assess more detailed attitudinal measures concerning nicotine containing products. The 2014 survey involved 1,203 adult smokers and recent ex-smokers selected from the ASH Smokefree adult survey to have roughly equal numbers of smokers who had (n=510) and had not (n=470) tried EC and a smaller number of ex-smokers who had tried EC (n=223).

**ITC Policy Evaluation project**

A longitudinal cohort survey of smokers and recent ex-smokers (aged 18 and over), surveyed by telephone and internet. The ITC UK survey started in 2002 and surveys
have been conducted approximately annually since that time. Probability sampling methods are utilised through telephone surveys using random digit dialling, but in more recent survey waves participants could opt to complete surveys on the internet. The ITC UK study benefits from parallel cohort surveys in Australia, Canada and the United States, enabling comparisons across countries with different tobacco and EC policies. Each wave of the survey includes approximately 1,500 UK respondents. EC questions were added to the last three waves. Data from the last wave (in 2014) were not available for inclusion in this report, but published papers from earlier waves are included. More details of the methodology are available at www.itcproject.org
3. UK policy framework

E-cigarette regulations in England: current and proposed

Regulations have changed little in England since the previous PHE reports. Currently EC are governed by general product safety regulations (UK and EU) which do not require that the products be tested before being put on the market. However, manufacturers can apply for a medicinal licence through the Medicines and Healthcare products Regulatory Agency (MHRA) [11] and from next year any EC not licensed by the MHRA will be governed by the revised European Union Tobacco Products Directive (TPD)[12]. Both the MHRA licensing and the TPD regulatory routes are described below. The TPD regulations are extensive and will have a significant impact on the EC market.

One change from the previous PHE report, which was introduced by the Advertising Standards Authority in October 2014, is that until the TPD comes into force, advertising of EC is governed by a voluntary agreement. This agreement indicates, inter alia, that advertising must be socially responsible, not promote any design, imagery or logo that might be associated with a tobacco brand or show the use of a tobacco product in a positive light, make clear that the product is an EC and not a tobacco product, not undermine quit tobacco messaging, and must not contain health or medicinal claims unless the product is licensed. These guidelines will be reviewed in October 2015 and when more is known about the application of the TPD the role of the Code will be clarified.

A further recent change is the introduction of measures to protect children from EC: an age of sale lower limit of 18 years of age (in line with tobacco cigarettes) is being introduced and a ban on proxy purchasing of EC.

EU Tobacco Products Directive (TPD) route

The revised TPD will introduce new regulations for EC or refill containers (referred to below as products) which are not licensed by the MHRA. We have listed these in detail below because they are wide-ranging and will impose a significant step change for manufacturers, importers and Member State (MS) authorities:

- **notification**: Manufacturers must inform competent authorities of the MS six months before placing new products on the market. For those already on the market by 20 May 2016, the notification needs to be submitted within six months of this date. Each substantial modification of the product requires a new notification
- **reporting obligations** (for which manufacturers/importers might be charged) include:
- details (including quantification) on all the ingredients contained in, and emissions resulting from the use of, the product, by brand name
- toxicological data regarding ingredients and emissions, including when heated, with reference particularly to health of consumers when inhaled including any addictive effect
- information on nicotine doses and uptake when consumed under normal or reasonably foreseeable conditions
- description of the product components, including where appropriate opening and refill mechanisms of product or refill containers
- description of the production process and declaration that it conforms with the TPD
- declaration that manufacturer/importer bear full responsibility for the quality and safety of the product when placed on market and used under normal or reasonably foreseeable conditions

**nicotine-containing liquid** restrictions:
- EC must not contain more than 20 mg/ml of nicotine
- nicotine-containing liquid must be in dedicated refill containers not exceeding 10ml volume, and cartridges or tanks do not exceed a volume of 2ml
- additives are not prohibited but the nicotine-containing liquids cannot contain additives that are otherwise prohibited by the other Articles in the TPD
- high purity ingredients must be used and substances other than those declared should only be present in trace quantities which are unavoidable during manufacture
- ingredients must not pose a risk to health either when heated or not heated
- nicotine doses must be delivered at consistent levels under normal conditions of use

- products are required to be child and tamper proof, protected against breakage and leakage and have a mechanism that ensures refilling without leakage
- products must include a **leaflet with information** on:
  - instructions for use and storage of the product, including a reference that the product is not recommended for use by young people and non-smokers
  - contra-indications
  - warnings for specific groups
  - possible adverse effects
  - addictiveness and toxicity
  - contact details of manufacturer/importer and a legal or natural contact person within the EU

- **outside packaging of products** must include:
  - list of all ingredients contained in the product in descending order of the weight
  - an indication of the nicotine content and delivery per dose
  - batch number
  - recommendation to keep the product out of reach of children
- no promotional element or feature or such that suggests the product is harm reducing (or other features described in Article 13 of the Directive)

health warnings:
- One of the following must be shown:
  - ‘This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers’ or
  - ‘This product contains nicotine which is a highly addictive substance’
- Member States shall determine which health warning to use
- health warnings must comply with regulations concerning specific provisions on position and size

- cross-border advertising and promotion, sponsorship etc of products will be prohibited (unless trade information)
- cross-border sales of products may be prohibited or subject to a registration scheme
- manufacturers/importers of products to submit an annual submission on their products to competent authorities in MS which should include:
  - comprehensive data on sales volumes, by brand name and product type
  - information on preferences of various consumer groups, including young people, non-smokers and the main types of current users
  - mode of sale of the products
  - executive summaries of any market surveys carried out in respect of the above, including an English translation thereof

- MS shall monitor the market developments concerning products, including any evidence that their use is a gateway to nicotine addiction and ultimately traditional tobacco consumption among young people and non-smokers. This information to be made publicly available on a website although the need to protect trade secrets should be taken into account
- MS should on request, make all information relevant to this Article available to the Commission and other Member States who will respect confidential information
- MS shall require manufacturers, importers and distributors of products to establish and maintain a system for collecting information about all of the suspected adverse effects on human health
- corrective action should be taken immediately if economic operators consider or have reason to believe that products are not safe or of good quality or not conforming to the Directive, ensuring conformity or withdrawal or recall from the market. In such cases, operators are required to inform immediately market surveillance authorities of the MS giving details of risk to human health and safety, corrective action taken and results of such corrective action. MS may request additional information from the economic operators on safety and quality aspects or any adverse effect of products
- the Commission will submit a report to the European Parliament and the Council on potential risks to public health by 20 May 2016 and as appropriate thereafter
where a competent authority believes specific products could pose a serious risk to human health it should take appropriate provisional measures, immediately inform Commission and competent authorities of other MS of measures taken and communicate any supporting data. The Commission will determine whether provisional measure is justified informing the MS concerned of its conclusions to enable appropriate follow-up measures to be taken
- the Commission can extend any prohibition to other MS if such an extension is justified and proportionate
- the Commission is empowered to adapt wording of health warnings and ensure factual
- the Commission will give a common format for notification and technical standard for the refill mechanism outlined above

The exact date of implementation in England is yet to be specified but full compliance is likely to be necessary by 2017. One UK company, Totally Wicked, has challenged the UK’s intention to transpose the Directive into UK law. The case rests on whether the TPD was properly made and has been referred to the European Court of Justice for a preliminary ruling. This is expected in late 2015/early 2016.

During implementation, government will need to undertake an impact assessment for the UK market on the final proposals as set out in the Directive and this will be consulted upon. The TPD certainly raises the barrier for bringing EC products to market or continuing to market existing products, and will undoubtedly constrain the EC market. Understanding any unintended consequences of the EU TPD as well as intended ones will be important. For example, the cap on nicotine concentrations introduced by the TPD will take high nicotine EC and refill liquids off the market, potentially affecting heavier smokers seeking higher nicotine delivery products.

**Medicines and Healthcare products Regulatory Agency (MHRA) licensing route**

Following a consultation in 2010, the UK MHRA introduced a mechanism for the licensing of EC and other nicotine containing products as medicines requiring medicinal purity and delivery standards. Such a licence would be required for products to be prescribed on the NHS. As with other licensed nicotine containing products, advertising controls would be applied and VAT of 5% would be imposed.

The licensing process has been described by the MHRA [11]. This regulation was described initially as ‘light touch’ recognising a product that delivered nicotine could be effectively used for harm reduction or cessation purposes, thus implying a relatively speedy route to licensing. This was subsequently changed to ‘right touch’ as it was apparent that the process was more lengthy and costly than originally envisaged. We understand that the MHRA estimated costs for a one-off application of between £252K and £390K with an annually recurring cost of between £65K and £249K, for each
product. This does not include the costs of making manufacturing facilities and products MHRA compliant – estimated at several million pounds.

At the time of writing one non-EC nicotine inhaler product, Voke, developed by Kind Consumer, and to be marketed by British American Tobacco (BAT), had received a medicinal licence, although it is not yet being marketed in England. A further BAT product (an EC) is currently going through the application process. Other EC products are currently in the pipeline with the MHRA but it is not clear at what stage the applications are or what types of products, eg cigalikes or tank models, are involved.

The absence of a licensed product, five years after the MHRA’s consultation took place, suggests that this route to market is not commercially attractive. The fact that the only product at the application stage is a BAT product suggests that the process is very resource intensive. As well as cost, other possible reasons include complexity, a lack of desire to engage with medicinal licensing or the MHRA, the entrepreneurial nature of the EC manufacturers and a possible lack of perceived benefits to acquiring a licence. This could be problematic when the EU TPD is implemented, which is likely to constrain the over-the-counter market. Additionally, having a diverse range of EC on prescription is likely to be beneficial (similar to nicotine replacement tobacco (NRT) products – when new products are introduced, evidence suggests that they do not cannibalise the existing NRT product market but instead expand the use of medications). This means that small manufacturers, particularly non-tobacco industry manufacturers, who may be producing a greater variety or more satisfying EC, will not compete with larger corporations such as the tobacco industry in the prescriptions market. There are several consequences of this which should be explored. These could include an inhibition of innovation and damage public health. Alternatively, given the demand for prescribed EC products is as yet unknown, particularly in the population groups where smoking prevalence is elevated, the medicinal route may not impact public health. The appeal of EC may rest in the fact that they are not medicines. A review of the MHRA licensing process for EC, and its likely impact, is recommended.

**Summary of findings**

The revised TPD will introduce new regulations for EC or refill containers which are not licensed by the MHRA. The cap on nicotine concentrations introduced by the TPD will take high nicotine EC and refill liquids off the market, potentially affecting heavier smokers seeking higher nicotine delivery products.

The fact that no licensed EC are yet on the market suggests that the licensing route to market is not commercially attractive. The absence of non-tobacco industry products going through the MHRA licensing process suggests that the process is inadvertently favouring larger manufacturers including the tobacco industry, which is likely to inhibit innovation in the prescription market.
Policy implications

o From May 2016, following the introduction of the revised TPD, ECs will be more strictly regulated. As detailed elsewhere in the report, the information we present does not indicate widespread problems as a result of EC. Hence, the current regulatory structure appears broadly to have worked well although protecting non-smoking children and ensuring the products on the market are as safe and effective as possible are clearly important goals. New regulations currently planned should be implemented to maximise the benefits of EC whilst minimising these risks.

o An assessment of the impact of the TPD regulations on the UK EC market will be integral to its implementation. This should include the degree to which the availability of safe and effective products might be restricted.

o Much of England’s strategy of tobacco harm reduction is predicated on the availability of medicinally licensed products that smokers want to use. Licensed ECs are yet to appear. A review of the MHRA EC licensing process therefore seems appropriate, including manufacturers’ costs, and potential impact. This could include a requirement for MHRA to adapt the processes and their costs to enable smaller manufacturers to apply, and to speed up the licensing process. The review could also assess potential demand for the EC prescription market and what types of products would be most appropriate to meet that demand.

This chapter assesses the use of EC by adults and young people in England by drawing on recent surveys carried out in England and Great Britain (GB). A later chapter discusses EC prevalence internationally.

Measures used

One of the main issues in measuring EC use is the lack of consistent and appropriate terminology, for example some studies equate ever having used EC with current use of EC which is clearly inappropriate. We recommend that definitions of usage categories should be standardised similar to those used in smoking surveys. Appendix B lists the different measures used in surveys focused on in this report, and gives definitions used in the other studies included in this review.

Use of e-cigarettes by adults

First, we assess e-cigarette use in the adult population in England. We summarise various data sources to provide an overview of EC use among the general population, and then specifically smokers, recent and long-term ex-smokers, and never-smokers. The two main surveys used in this chapter are the Smoking Toolkit Study (STS) and the ASH Smokefree GB surveys. However, in addition to these surveys, findings from the Office for National Statistics Opinions and Lifestyle Survey (ONS survey), a randomised probability sample omnibus survey in GB, have also been included in this section although the exact question used is not available [13]; preliminary released data from Q1 2014 are reported here in advance of the complete data due for publication later in 2015.

Population use of e-cigarettes

Of the available datasets, just two – the Smoking Toolkit Study (STS, England) and the ASH Smokefree GB adult surveys – provide information on population prevalence (Table 1). Using the STS, it is estimated that 5.5% of the adult population of England used EC in the first quarter of 2015 indicating a marked rise from 0.5% in 2011. The measure of use in the STS is compiled from four survey questions and assesses current use for any reason (Appendix B). A very similar estimate is obtained for GB using the 2015 ASH survey, with 5.4% of the population estimated to be current (defined as tried EC and still use them, see Appendix B) EC users. This translates to about 2.6 million EC users in GB in 2015 [14](for comparison there are about nine million tobacco
smokers in GB and as discussed later, most EC users are smokers or ex-smokers). The ASH survey also assessed trial and about 17% of the adult GB population was estimated to have tried EC.

Table 1: Adult EC current use

<table>
<thead>
<tr>
<th>Source (date of data collection)</th>
<th>Population Prevalence</th>
<th>Never smokers</th>
<th>Ex-smokers ('Dual users')</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASH Smokefree GB adult survey (2015 - March)</td>
<td>5.4%</td>
<td>0.2%</td>
<td>6.7%</td>
</tr>
<tr>
<td>Office for National Statistics (2014 - Q1)</td>
<td>N/A</td>
<td>0.1%</td>
<td>4.8%</td>
</tr>
<tr>
<td>Smoking Toolkit Study (2015 – Q1)</td>
<td>5.5%</td>
<td>0.2%</td>
<td>3.3%</td>
</tr>
</tbody>
</table>

1For definitions of current use please see Appendix B. The ONS question is unavailable.
2Figures for never and long-term ex-smokers are derived from n=22489 never and long-term ex-smokers surveyed between November 2013 and March 2015

Never smokers and long-term ex-smokers

All three surveys estimate current EC use among adult never smokers to be very rare at 0.2% or less, and between 3% and 7% among ex-smokers – the latter estimates may vary because in the STS recent ex-smokers (last-year) are not included in this category (Table 1). Prevalence of current EC use among recent ex-smokers in the STS was around 40% in the first quarter of 2015 [15].

The ASH survey estimated that around 1.5% of never smokers and 16% of ex-smokers had ever tried EC.

Smokers

Recent surveys estimate that current EC use among smokers, sometimes referred to as ‘dual users’ of cigarettes and e-cigarettes, is between 12 and 21% (Table 1). The prevalence of EC use among last-year smokers (defined as smokers and recent ex-smokers) using the STS in England is estimated at 22.9% for any use of EC and 14.9% for daily EC use. The ASH 2015 survey indicated that 17.6% of current smokers use EC currently (18% of occasional and 17% of daily smokers); the same survey indicated that a small majority of smokers (59%) have now tried EC.

The Q1 2014 ONS Survey data estimates for current use are considerably lower, suggesting that just under 12% of current smokers used EC in early 2014. The survey question/s used to determine this is/are not available to assess whether different ways of assessing use may be a reason for this discrepancy in findings.
The ASH survey indicates that about 60% of current EC users are current smokers, and about 40% are ex-smokers. The proportion of EC users among never smokers remains negligible.

**Summary**

Around one in 20 of the general adult population in England (and GB) use EC. Current EC users are almost exclusively smokers or ex-smokers. EC use among long-term ex-smokers is considerably lower than among recent ex-smokers.

**Trends in e-cigarette use among adults**

Both the STS and ASH surveys demonstrate that there was a steady increase in EC use in the population from 2011 to 2013.

**Smoking Toolkit Study (STS) data**

The STS data indicate that this increase slowed down, even declining at the end of 2014 from 5.3% in Q3 to 4.5% in Q4 (Figure 1). However, as Q1 data from 2015 show a recent upswing to 5.5%, this decline may have been temporary. The STS data show that alongside the increase in EC use, smoking of tobacco cigarettes declined. Overall nicotine use, ie any consumption via cigarette smoking, NRT use or EC use, has also declined.

**Figure 1: Prevalence of smoking and e-cigarette use among the adult English population (STS)**

From www.smokinginengland.info/latest-statistics/
The overall pattern of EC use in the population is mirrored among last year smokers for whom EC prevalence increased from 2011, but declined from 22% for *any* use and 14% for *daily* use in Q3 2014, to 19% and 11% respectively in Q4 2014; however, any and daily use increased again to 23% and 15% respectively in Q1 2015 (Figure 2).

**Figure 2: Prevalence of e-cigarette use among last year smokers (STS)**

![Graph showing prevalence of e-cigarette use among last year smokers](From www.smokinginengland.info/latest-statistics/)

**ASH Smokefree GB adult survey**

The ASH surveys indicated a slowing down in the increase of EC use in the population between 2014 and 2015 and use among current smokers in 2015 remained at the 2014 level (17.6% of smokers in 2014 and 2015). Use among ex-smokers increased from 1.1% in 2012, to 4.5% in 2014 and 6.7% in 2015, whereas no increase in use was observed among never smokers over the last few years, remaining at 0.2% since 2013. **This means that the increase in EC use observed overall was accounted for by an increase in use by ex-smokers.** It is not clear to what extent this is due to smokers stopping smoking using EC or ex-smokers taking up ECs.

**Summary**

The prevalence of EC use among adults has plateaued. Most of the recent increase in use appears to be among ex-smokers. Cigarette smoking has declined over the period when EC use increased and overall nicotine use has also declined. These findings suggest that the advent of EC is not undermining and may be contributing to the long-term decline in cigarette smoking.
Types and flavours of e-cigarettes used among adults

When those who had tried EC in the 2015 ASH survey were asked about which EC they used first, 24% reported a disposable, 41% a rechargeable with replaceable pre-filled cartridges and 28% rechargeable with tank/reservoir filled with liquids (7% didn’t know/couldn’t remember). The different types were in the same order of popularity for first use regardless of smoking status (Figure 3).

For those still using EC from the same survey, only 5% were now mostly using a disposable, 26% a rechargeable with replaceable pre-filled cartridges and 66% rechargeable with tank/reservoir filled with liquids (2% didn’t know/couldn’t remember). This suggests that a considerable proportion of those who continue to use EC over time switch to the tank models. Among EC users, ex-smokers were particularly likely to use tank models mostly and very few ex-smokers were using disposables (Figure 3). This is in agreement with findings reported in Chapter 6 of this report, where tank models were found to be associated with having quit smoking [16].

Figure 3: Type of e-cigarettes first used and currently used (ASH Smokefree GB data 2015)

The ASH Smokefree GB 2015 adult survey also shows that the most popular flavour was tobacco flavour, followed by fruit and menthol flavours (Figure 4).
Use of e-cigarettes among young people

The main source for estimating smoking prevalence in England among youth is the 'Smoking, drinking and drug use among young people' surveys [17], however, EC use was first assessed in 2014 and these data are not yet available. This section therefore draws on the ASH Smokefree GB youth surveys to assess EC usage in young people, supplemented by a study in the North West of England, two cross-sectional national surveys in Wales and one national survey in Scotland. The measures used are detailed in Appendix B.

In 2015, the ASH survey found that 12.7% of 11 to 18-year olds reported having tried EC; of these, 80.9% had only used one once or twice (10.2% of all respondents). Current EC use was considerably lower: 0.7% had used an EC sometimes but not more than once a month; 1.2% more than once a month but not weekly; and 0.5% weekly (Table 2). The prevalence of EC use (2.4% overall) among people aged between 11 and 18 was therefore lower than among the general population. In comparison, 21% of all 11 to 18-year olds reported having tried cigarettes, of whom 54% only tried once (11.4% of all respondents). Current smoking was reported by a total of 6.7%; 2.7% smoked less than weekly and 4% at least weekly.
Experimentation increased with age: 2.9% of 11-year olds and 20.2% of 18-year olds had tried EC. In comparison, among 11-year olds, 3.9% had tried cigarettes (0.7% current smokers), whereas 40.9% of 18-year olds had tried cigarettes (14.3% current smokers).

Use of EC was very closely linked with smoking status. Among never smokers, 0.3% used EC monthly or more often, compared with 10.0% of ever smokers and 19.1% of current smokers. The majority of EC users had tried tobacco cigarettes first (Table 2).

### Table 2: E-cigarette use among young people

<table>
<thead>
<tr>
<th>Source</th>
<th>Ever tried</th>
<th>Use more than /at least once a month</th>
<th>Use more than once a week</th>
<th>Use (at least monthly) in never smokers</th>
<th>Those using e-cigarettes who had tried tobacco first</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASH Smokefree GB youth survey (11-18 years) (2015 – March)</td>
<td>12.7%</td>
<td>1.9%</td>
<td>0.5%</td>
<td>0.1%</td>
<td>63.7%</td>
</tr>
<tr>
<td>Health Behaviour in School-aged Children, Wales (11-16 years) (Nov 2013 – Feb 2014) [18]</td>
<td>12.3%</td>
<td>1.5%</td>
<td>Not reported</td>
<td>0.3%</td>
<td>Not reported</td>
</tr>
<tr>
<td>CHETS Wales survey (10—11 year olds)[19] 2014</td>
<td>5.8%</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Not reported</td>
</tr>
<tr>
<td>SALSUS Scotland survey (15 and 13 year olds)[20] 2013/2014</td>
<td>12%</td>
<td>0.4%</td>
<td>0%</td>
<td>0%</td>
<td>Not reported</td>
</tr>
</tbody>
</table>

\(^1\) For question on e-cigarette categories please see Appendix B. Use more than/ at least once a month excludes those using more than once a week who are reported separately

\(^2\) N=9055, use defined as at least monthly

Similar findings have been observed in Scotland. A national survey carried out in 283 schools across Scotland in late 2013/early 2014 involved more than 33,000 schoolchildren aged 13 and 15 years old [20]. Seven per cent of 13-year olds, and 17% of 15-year olds, had ever used an EC. Trial was associated with smoking status – 4% of never smokers had tried EC (3% trying them once and 1% having tried a few times) compared with 24% of ever smokers, 39% of ex-smokers, 46% of occasional smokers and 66% of regular smokers. Eleven per cent of regular smokers and 6% of occasional smokers reported using e-cigarettes at least monthly.

Very similar findings have been reported from a survey in Wales (Table 2). A survey of secondary schoolchildren was carried out under the auspices of the Health Behaviour of
School Children (HBSC) study and more than 9,000 participants aged 11–16 from 82 schools were included [18]. Overall, 12.3% had tried EC, 1.5% were monthly users, compared with 12.1% reporting ever having smoked and 5.4% current smokers (reported smoking less than once a week or more frequently). Whilst many experimental EC users had never smoked, most regular EC users had also smoked tobacco. The authors commented that “the very low prevalence of regular use…suggests that e-cigarettes are unlikely to be making a significant direct contribution to adolescent nicotine addiction”.

Additionally, around 1,500 10 to 11-year olds were surveyed in Wales, from 75 schools in the CHETS Wales study [18, 19] (Table 2). Overall, 5.8% (n=87) had ever used an EC; most reported only using once (3.7%, n=55 overall) and only 2.1% (n=32) reported using them more than once. Again, EC use was associated with smoking. Just under half (47.6%) of those who reported having used tobacco had ever used an EC compared with 5.3% of never smokers. Controlling for other variables associated with EC use, parental use of EC and peer smoking remained significantly associated with having ever used an EC. Having ever used an EC was associated with weaker anti-smoking intentions. Parental EC use was not associated with weakened anti-smoking intentions whereas parental smoking was [19]. This study, published prior to the one above, concluded that EC represented a new form of experimentation with nicotine that was more common than tobacco usage. It also commented that the findings added “some tentative support for the hypothesis that use of e-cigarettes may increase children’s susceptibility to smoking”. However, as this was a cross-sectional survey, causal connections cannot be inferred. It is possible that children who had used EC would have smoked cigarettes in their absence and this could explain the relationship between intentions and EC usage (see below).

An additional survey of schoolchildren has been carried out in England. Trading Standards in the North West of England have been running biennial surveys of schoolchildren since 2005. The 2013 findings on EC, smoking and alcohol were published [21]. The survey was not designed to be representative (no compliance or completion rates were collected) but instead “to provide a broad sample of students from a range of community types”. More than 100 schools participated and more than 16,000 participants aged 14–17 years of age were included in the analyses. It is important to acknowledge that the question about EC was “Have you ever bought or tried electronic cigarettes?”, and this study cannot therefore add to knowledge on current usage. Around one in five of the sample had accessed EC, with access being higher in those who had experience of smoking. Around 5% of those who had never smoked cigarettes reported accessing EC; around half of ex-smokers and over two thirds of regular smokers had accessed them. Parental smoking and alcohol use were also associated with EC access.
Summary

Regular use of EC among youth is rare with around 2% using at least monthly and 0.5% weekly. A minority of British youth report having tried EC (national estimates suggest around 12%). Whilst there was some experimentation with EC among never smokers, nearly all those using EC regularly were cigarette smokers.

Trends in e-cigarette use among young people (ASH Smokefree GB youth)

The ASH Smokefree GB youth surveys indicate that awareness of EC has increased markedly, with the proportion of individuals who had never heard of EC falling from 33.1% in 2013 to 7.0% in 2015. Ever having tried EC also increased, from 4.5% in 2013, to 8.1% in 2014, and to 12.7% in 2015. However, the proportion using an EC monthly or more frequently remained virtually unchanged from 2014 (1.6%) to 2015 (1.7%). Over the same period, the proportion of regular smokers (at least weekly) remained at around 4% (2013: 4%, 2014: 3.6%, 2015: 4%).

Type and flavour among youth

The proportion of youth reporting current use was too small to assess the most frequently used types or flavours in current users, so Figures 5 and 6 include everyone who had tried an EC. One third had first used a tank model and the most popular flavours among triers by far were fruit flavours. The responses for adults and youth are not directly comparable given flavours were assessed for adult current EC users, but in the latter group, fruit flavours were less popular than tobacco flavours.
Figure 5: First type of e-cigarette tried by youth, ASH Smokefree GB youth survey, 2015

Note: The proportion of youth reporting current use was too small to assess the most frequently used types.

Figure 6: Last flavour tried by youth, ASH Smokefree GB youth survey, 2015

Note: The proportion of youth reporting current use was too small to assess flavours in current users.
Concerns about impact of e-cigarette use on smoking

Three main concerns raised about EC use are that they might 1) renormalise smoking 2) reduce quitting and 3) act as a ‘gateway’ to smoking or nicotine uptake. An ultimate test for the first concern, and to some extent all three concerns, is the impact of EC use on smoking prevalence nationally which is explored first below. Evidence for effectiveness of EC on quitting smoking is explored in more detail in Chapter 6. Whilst other concerns have been raised such as renormalising the tobacco industry, we are only able to comment on issues pertaining to the objectives of our report.

Recent trends in smoking prevalence

Since EC arrived on the market in England, smoking prevalence has continued to decline among both adults and youth (Figures 1, 7 and 8). Evidence to date therefore conflicts with any suggestion that EC are renormalising smoking. Whilst other factors may be contributing to the decline in smoking, it is feasible that EC may be contributing to reductions in smoking over and above any underlying decline.

Figure 7: Adult smoking prevalence in England 1980–2013

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1 General Lifestyle Survey aged 16+(1980-2010); Integrated Household Survey aged 18+ (2011). Diagram courtesy of ASH.
Figure 8: Prevalence of regular smoking among 11–15 year olds in England 1980–2014

Please note: decimal places were not used in the published data.

Gateway

The gateway theory or hypothesis is commonly invoked in addiction discourse, broadly to suggest that the use of one drug (sometimes a legal one such as tobacco or alcohol) leads to the use of another drug (sometimes an illegal one) but its definition is contested. No clear provenance exists and its origin appears to derive from lay, academic and political models [22]. It is apparent that discussions about the natural progression of drug use observed in longitudinal studies of young people appear to have morphed into implicit conclusions on causality without any evidential backing. Some have argued that the effect could be causal if the use of one drug, biochemically or pharmacologically, sensitises the brains of users to the rewarding effects of other drugs [23] making the dependent use of these other drugs more likely. However, there are many plausible competing hypotheses for such a progression [24] including i) shared networks and opportunities to purchase the drugs; and ii) individual characteristics such as genetic predispositions or shared problematic environment. Academic experts have stated that the gateway concept “*has been one of the most controversial hypotheses…in part because proponents and opponents of the hypothesis have not always been clear about what the hypothesis means and what policies it entails*” [24]. Indeed, a recent analysis of gateway concluded “*Although the concept of*

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the gateway theory is often treated as a straightforward scientific theory, its emergence is rather more complicated. In effect, it is a hybrid of popular, academic and media accounts – a construct retroactively assembled rather than one initially articulated as a coherent theory” [22].

Despite these serious and fatal flaws in the arguments, the use of the term ‘gateway’ is commonplace both in the academic literature and the lay press, particularly in relation to EC use and whether EC are a gateway to smoking. Some have suggested that if EC use increases at the same time as smoking increases then EC are acting as a gateway to smoking. Similarly, it’s been argued that if someone uses an EC first and then initiates smoking, EC are a gateway. These arguments are clearly erroneous. To give one example of the misuse of the gateway concept, a BMJ news item on the Moore et al., 2014 [18] cross-sectional study discussed above commented that “[EC} could be a gateway into smoking” [25].

Kandel recently argued that evidence from mice offers a biological basis for the sequence of nicotine to cocaine use in people [26], but there is limited evidence for this. In reality, the gateway theory is extremely difficult to test in humans. For example, a clean test of the gateway hypothesis in relation to EC and smoking would require randomising people to an environment with EC and one without, and then following them up over a number of years to assess uptake of EC and smoking.

**We strongly suggest that use of the gateway terminology be abandoned until it is clear how the theory can be tested in this field.** Nevertheless, the use of EC and smoking requires careful surveillance in young people. The preferred option is that young people do not use EC but it would be preferable for a young person to use an EC instead of smoking, given the known relative risks of the EC and smoking cigarettes [10].

**Summary**

Since EC were introduced to the market, smoking prevalence among adults and youth has declined. Hence there is no evidence to date that EC are renormalising smoking, instead it’s possible that their presence has contributed to further declines in smoking, or denormalisation of smoking. The gateway theory is ill defined and we suggest its use be abandoned until it is clear how it can be tested in this field. Whilst never smokers are experimenting with EC, the vast majority of youth who regularly use EC are smokers. Regular EC use in youth is rare.

**Summary of findings**

**Adults:** Around one in 20 adults in England (and Great Britain) use EC. Current EC users are almost exclusively smokers (~60%) or ex-smokers (~40%), that is smokers
who now use EC and have stopped smoking altogether. EC use among long-term ex-smokers is considerably lower than among recent ex-smokers. Current EC use among never smokers is very low, estimated to be 0.2%. The prevalence of EC use plateaued between 2013-14, but appeared to be increasing again in 2015.

Youth: Regular EC use among youth is rare with around 2% using at least monthly and 0.5% weekly. EC use among young people remains lower than among adults: a minority of British youth report having tried EC (~13%). Whilst there was some experimentation with EC among never smoking youth, prevalence of use (at least monthly) among never smokers is 0.3% or less.

Overall, the adult and youth data suggest that, despite some experimentation with EC among never smokers, EC are attracting few people who have never smoked into regular use.

Trends in EC use and smoking: Since EC were introduced to the market, cigarette smoking among adults and youth has declined. In adults, overall nicotine use has also declined (not assessed for youth). These findings, to date, suggest that the advent of EC is not undermining, and may even be contributing to, the long-term decline in cigarette smoking.

Policy implications

- Trends in EC use among youth and adults should continue to be monitored using standardised definitions of use.
- Given that around two-thirds of EC users also smoke, data are needed on the natural trajectory of ‘dual use’, ie whether dual use is more likely to lead to smoking cessation later or to sustain smoking (see also Chapter 6).
- As per existing NICE guidance, all smokers should be supported to stop smoking completely, including ‘dual users’ who smoke and use EC.
5. Smoking, e-cigarettes and inequalities

Smoking and inequalities

Whilst smoking prevalence overall has been declining over the past 50 years, smoking has become increasingly concentrated in more disadvantaged groups in society. Over the last decade, the gap between smoking in the different social groups has not narrowed (Figure 9) and some of the most disadvantaged groups in society (such as people with serious mental illness or prisoners) have shown no change in smoking prevalence over time (e.g. Figure 10). Furthermore, among smokers, the level of nicotine dependence increases systematically as deprivation increases [2]. A key challenge in tobacco control is therefore how to encourage smokers from disadvantaged groups to stop smoking.

Whilst quitting cigarettes and all nicotine use should remain the main goal across all social groups, EC are of interest because, as with other cleaner nicotine delivery systems, they potentially offer a wide reach, low-cost, intervention to reduce smoking and improve health in these more deprived groups in society where smoking is elevated [2]. It is therefore important to examine the potential impact of EC on inequalities.

Figure 9: Smoking trends by socioeconomic group status (GHS data)
E-cigarette use and different social groups

Earlier surveys in GB and internationally suggested a social gradient in the use of EC, with smokers of higher income and education being more likely to have used and tried [28, 29]. However, the 2015 ASH Smokefree GB adult 2015 survey indicated only small differences across groups, with lower socioeconomic groups slightly more likely to have tried and be using EC. At the population level, 14.4% of ABC1 groups ('non-manual' occupational groups) had tried EC compared with 19.4% in C2DE groups ('manual' occupational groups); 4.6% of ABC1 were still using EC compared with 6.3% of C2DE groups. Nevertheless, given the higher prevalence of smoking in C2DE groups, when examined within the smoker population by social class, 20.0% of ABC1 smokers compared with 16.0% of C2DE smokers were EC current users.

The STS data surveys show an increase in EC use in all social groups between 2012 and 2014 (Figures 11 and 12) but at a relatively similar rate such that socioeconomic differences are still apparent both for current and daily use of EC.
Figure 11: *Current* use of e-cigarettes by social class among last year smokers (STS data)

![Graph showing current use of e-cigarettes by social class among last year smokers (STS data).](Image)

From www.smokinginengland.info/latest-statistics/

Figure 12: *Daily* use of e-cigarettes by social class among last year smokers (STS data)

![Graph showing daily use of e-cigarettes by social class among last year smokers (STS data).](Image)

From www.smokinginengland.info/latest-statistics/
Nevertheless, EC are penetrating the lower socioeconomic groups. Figure 13 shows the social class breakdown of EC users by quarter over time, also derived from STS data.

**Figure 13: E-cigarette use by social class over time (STS data)**

From www.smokinginengland.info/latest-statistics/

**E-cigarette use in other disadvantaged groups**

There are no GB data, to our knowledge, on EC use among groups where smoking prevalence is known to be very high, such as offenders and people with serious mental illness. There is emerging evidence on the effectiveness of EC in people with mental illness (see Chapter 6). However, to some extent, usage among these groups will be dependent on EC policies being introduced in prisons and mental health settings.

Recent NICE guidance on smoking cessation in secondary care settings [30] recommended the implementation of smokefree policies in these settings, alongside advice to stop smoking and nicotine dependence treatment. Trusts are now implementing this guidance but many prohibit EC usage as well as cigarettes. The rationale for such prohibition is unclear.

The South London and Maudsley NHS Foundation Trust (SLaM) was the second NHS mental health trust to go comprehensively smoke free in England. It has developed an EC policy alongside the smokefree policy which allows EC to be used in private spaces or grounds, although EC are not to be offered as first line treatment or replace tobacco cigarette smoking and can only be used as part of a care treatment pathway [31]. Currently, the use of disposable products or rechargeable models with cartridges is allowed (the latter only under supervision), but tanks are prohibited because of fears
that they might be used for new psychoactive substances (sometimes also known as ‘legal highs’). The basis for this fear is being assessed and the use of tank models may be assessed in a restricted pilot shortly. During the first six months of the policy, the EC policy has been implemented smoothly.

A more general concern has been raised that EC can be used as a vehicle for other drugs. This concern needs exploring and is not something that should be promoted. Nevertheless, if true, EC are likely to offer a less harmful delivery route for the drugs than smoking which could be the subject of research.

Prisons are likely to introduce comprehensive smokefree policies over the next few years [32]. Similar to mental health trusts, it would seem inappropriate to prohibit EC and disposable EC are currently being piloted in at least three prisons [33]. Consideration should also be given to the use of other models of EC in pilots. The use of EC in prisons has been considered in other jurisdictions which should also be informative [34].

Summary of findings

Smoking is increasingly concentrated in disadvantaged groups who tend to be more dependent. EC potentially offer a wide reach, low-cost, intervention to reduce smoking and improve health in disadvantaged groups.

Some health trusts and prisons have banned the use of EC which may disproportionately affect more disadvantaged smokers.

Policy implications

- Consideration could be given to a proactive strategy to encourage disadvantaged smokers to quit smoking as quickly as possible including the use of EC, where appropriate, to help reduce health inequalities caused by smoking.

- EC should not routinely be treated in the same way as smoking. It is not appropriate to prohibit EC use in health trusts and prisons as part of smokefree policies unless there is a strong rationale to do so.
6. E-cigarettes and smoking behaviour

Introduction

Studies examining the relationship between EC use and smoking behaviour have focused on two main questions to date: (1) do EC help people to quit when used on a quit attempt, and, (2) what is the effect of using EC while smoking, on reductions in smoke intake, cigarettes per day, quit attempts, and stopping smoking? Because EC use is a relatively new phenomenon and the products are constantly changing with technological innovation, the studies examining these questions to date are heterogeneous. As mentioned earlier, studies vary in their definitions of EC use, including ever use, which could include one puff, to studies that discriminate between daily and non-daily use. Additionally, it is evident that many of the studies were not originally designed to study the effects of EC use on smoking behaviour due to the absence of rigour and omitted/unmeasured variables.

Current recommendations for use of e-cigarettes to quit

The National Centre for Smoking Cessation and Training (NCSCT) has published current recommendations for practice regarding the use of EC for stopping smoking [35]. The NCSCT recommends that practitioners be open to EC use among smokers trying to quit, particularly if they have tried other methods of quitting and failed. The NCSCT also provides more detailed guidelines for smokers wanting to use EC to quit, including differences in puffing on EC versus regular cigarettes, the need to try different types of EC to find one that works for them, and that multi-sessional behavioural support is likely to improve their success of quitting. Some services have welcomed smokers who wish to stop with the help of EC [36].

The NICE guidelines for tobacco harm reduction cover recommendations for the use of licensed EC for quitting, cutting down (reduction in cigarettes per day), and temporary abstinence [1], similar to NRT. Use for both cutting down and temporary abstinence have been shown to be precursors to quitting among smokers using NRT. As discussed in Chapter 3, no licensed EC are currently available.

Use of e-cigarettes for stopping smoking

STS data have shown that EC have quickly become the most common aid that smokers in England use to help them stop smoking (Figure 14). The rise in the use of EC as a stop smoking aid is occurring despite the fact that no licensed EC are available. Although the most effective way for stopping smoking, currently supported by the research literature [37, 38] is a combination of behavioural support (NHS in Figure 14)
and medication (NRT on prescription or Champix), the problem is that few smokers access these services, limiting their impact on population health.

This section reviews the evidence regarding the use of EC for stopping smoking that has been published since the Cochrane Review [39] on the use of EC for smoking cessation and reduction (cutting down). The Cochrane Review is briefly summarised below.

**Figure 14: Support used in quit attempts**

![Figure 14](image)

N=10078 adults who smoke and tried to stop or who stopped in the past year

From: smokinginengland.info/latest-statistics

**Randomised controlled trials**

To date, two randomised controlled trials (RCTs) have tested the efficacy of EC for stopping smoking, one among smokers wanting to stop and the other among smokers not intending to quit within the next month [40, 41]. Both were among highly dependent smokers. A recent Cochrane Review of these RCTs [39] concluded that they demonstrated that EC with nicotine help smokers reduce their cigarette consumption and stop smoking compared with no nicotine EC (placebo). However, the authors cautioned that there was uncertainty in the findings, and gave their findings a ‘low’ confidence rating using GRADE standards. The Cochrane Review also considered observational studies of EC use and cessation. They concluded that these observational studies were generally consistent with the findings of RCTs. Since the Cochrane Review, one RCT[41], and a secondary analysis of one of the RCTs in the Cochrane Review[42] have been published and are discussed below.
O’Brien et al., 2015 [42] conducted a secondary analysis of the RCT data from Bullen et al., 2013 [43] to examine the effectiveness of EC with and without nicotine compared to the nicotine patch among individuals with mental illness (MI). They identified 86 participants among the original 657 participants (all motivated to quit) using secondary data from the trial on reported use of any medications associated with MI. Overall, when compared to participants without MI, there were no significant differences for those with MI on the primary outcomes of smoking reduction and smoking cessation. One exception was that the six-month quit rate was higher among participants with MI in the patch condition compared to those without MI. Although not a primary outcome, there was evidence of a greater rate of relapse among participants with MI. In the analysis that only included participants with MI, there were no significant differences in quit rates across the three conditions, however participants allocated to 16mg EC showed greater smoking reduction than those allocated to patch. **The authors concluded that EC appear to be equally effective for smoking cessation among individuals with and without MI,** building on other promising research involving EC and people with MI.

Adriaens et al., 2014 [41] conducted an eight-week RCT in Belgium with control where they randomised 48 smokers who did not want to quit to one of two conditions: (1) use of tank model EC, and training on how to use, with no encouragement to quit, and (2) no use of EC. Both groups attended similar periodic lab sessions over an eight-week period where measurements of craving, withdrawal, saliva cotinine, and expired-air CO levels were taken. Adriaens found that after eight weeks of use 34% of those given EC had quit smoking compared to 0% of those not given EC, the EC group also showed substantially greater cigarette reduction. After eight weeks, the group which did not receive EC at baseline was given EC, but no training on how to use the products. At the final eight-month follow-up, 19% of the original EC group and 25% of the control group (given EC at week eight) had quit smoking. Significant reductions in cigarette consumption were also found.

**Population studies**

One problem with RCTs is that because of the time taken to set up and implement trials, the EC used in the trials are often no longer available for sale by the time the research is published. This is problematic because many new EC enter onto the market and it is possible they may be more effective at delivering nicotine than the products used in the trial, and possibly more effective for smoking cessation. Additionally, the controlled environment of RCTs is unable to provide evidence of the effectiveness of EC in the real world where use is much more subject to external forces, such as availability, price and social norms around use. RCTs also reveal little about the attractiveness of the products and thus likely uptake of the products used and what happens after a successful or failed attempt to stop smoking with an EC in the long-term.
Observational and natural history studies are therefore important. Only one population-based survey has examined the effectiveness of EC used during quit attempts. A large cross-sectional study of 5,863 English smokers who attempted to quit in the past year without using professional support [29] found that those who used EC on their last quit attempt were more likely to quit than those who used over the counter NRT – (the most common help sought by smokers after EC, see Figure 14), or no quit aid, controlling for factors related to quitting. This study was, however, unable to explore prospective predictors of quitting, including pre-quit nicotine dependence. Still, this study offers some of the best evidence to date on the effectiveness of EC for use in quit attempts.

Other recent population studies [16, 44, 45] have also examined the association between EC use and quitting. However, because these studies (1) included smokers who were already using EC at baseline, and (2) did not examine the use of EC during a specific quit attempt, we discuss them below in the section on use of EC while smoking.

Pilot studies

Polosa et al., 2014 [46] conducted a six-month pilot study of tank-type EC users with no control group among 72 smokers who did not want to quit (smokers were enrolled after rejecting participation in smoking cessation program at a hospital). At six months, they found significant 50% and 80% reductions in cigarette consumption, and a quit rate of 36% [46]. Another study by Polosa et al., 2014 [47] followed 71 vape shop customers (seven different shops) after their first visit to the shop. The first visit included instructions on how to use EC and encouragement to use their EC of choice to reduce their smoking, along with a telephone number they could call for help. At six and twelve months after their initial visit they found that the smokers reported significant 50% and 80% reductions in cigarettes per day at six and twelve months, and that at six and twelve months, 42.2% and 40.8% had quit smoking.

E-cigarettes and stop smoking services

Some English stop smoking services and practitioners support the use of EC in quit attempts [48], and provide behavioural support for EC users trying to quit smoking. The most recent monitoring data from the stop smoking services show the self-reported success rates for different medications and nicotine-containing products used (Figure 15). Data are not given by validated success rates but overall, 69% of those who self-report stopping smoking are carbon-monoxide validated [49]. Hence, there are limitations with these data as they are self-reported success rates and it is possible that they may vary by treatment used. Additionally, the data are not adjusted for other factors, such as dependence, known to influence success rates, and it is likely that they emanate from a limited number of services who record unlicensed nicotine-containing products and who might therefore be more supportive of their use. Nevertheless, the
evidence is consistent with evidence from trials and other observational data that e-cigarettes are likely to support successful quitting.

**Figure 15: Support used and stop smoking service self-reported quit rates**

![Figure 15: Support used and stop smoking service self-reported quit rates](image)

Note: Figures in brackets represent the number of quit attempts in which each type of support was used. The number of clients with recorded e-cigarette use is very small in comparison to those recorded to have used other types of support.

**Use of e-cigarettes while smoking**

**Population studies**

Two studies using data drawn from a longitudinal population sample of more than 1,500 smokers in GB recently examined the impact of EC use on quitting, considering the effects of frequency of EC used and type of EC. Brose et al., 2015 [45] found that respondents who used EC daily at baseline were more likely to make a quit attempt one year later, but were no more or less likely to quit than those who did not use EC. Daily EC use at follow-up was found to be associated with reduced cigarette consumption since baseline. No effects of non-daily EC use on quit attempts, quitting, or reduction in consumption were found. Using data from the same Internet Cohort GB study, Hitchman et al., 2015 [16] found differences in quitting between baseline and follow-up.

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depending on the type and frequency of EC used at follow-up: compared to no EC use, non-daily cigalike users were less likely to have quit smoking since baseline, daily cigalike or non-daily tank users were no more or less likely to have quit, and daily tank users were more likely to have quit. Overall, the two studies showed that daily use of EC does not lead to lower cessation, and is associated with making quit attempts, cigarette reduction, and if tank-type EC is used, is associated with smoking cessation. Non-daily use of EC is not associated with quit-related outcomes, and may, if cigalike-type EC are used, be associated with lower cessation.

Supporting these findings, using data from a longitudinal population study of smokers in two metropolitan areas in the US, Biener et al., 2015 [44] measured use and intensity of EC use at follow-up in a longitudinal sample of smokers at baseline from two US cities. Biener also found that it was only intensive EC users (used daily for at least one month) that were more likely to quit, less intensive EC users were no more likely to quit than those not using EC.

There are limitations with these studies. For example, an unavoidable methodological problem is that only people who currently smoke are included in these studies meaning that smokers who switched completely to EC and stopped smoking are excluded. The efficacy of EC is thus invariably underestimated.

A longitudinal telephone survey reported by Al-Delaimy et al., 2015 [50] among a sample of 368 current smokers from California at baseline (2011) investigated the relation between ‘ever have used’ versus ‘never will use’ EC, and making a quit attempt, a 20% reduction in cigarettes per month, and quitting for more than one month at follow-up (2012). Al-Delaimy included smokers at baseline who at both baseline and follow-up reported the same EC status: never will use EC at both baseline and follow-up OR ever have used EC at both baseline and follow-up, excluding anyone who gave different responses. Also excluded were respondents who said they might use EC in the future at baseline or follow-up, and respondents who had never heard of EC, reducing sample size from n=980 to n=368. Al-Delaimy concluded that compared to smokers who reported they never will use EC, respondents who had ever used EC were significantly less likely to have reduced their cigarette consumption and quit at follow-up, with no differences reported of quit attempts at follow-up. This study has serious methodological problems that make its conclusions uninterpretable, first, the measure of EC use is ‘ever use’, which could include even a puff on an EC and second, they applied several exclusion criteria that are not clearly justified.

Studies of smokers enrolled in smoking cessation programs

Two recent studies have examined the use of EC among smokers enrolled in smoking cessation programmes in longitudinal studies [51, 52]. Pearson et al., 2015 [51] examined the relation between reporting using an EC for quitting at follow-up and
smoking cessation (30-day abstinence) in a sample of smokers enrolled in a web-based cessation programme in the US with three-month follow-up. Pearson illustrated how the relation between using EC to quit and successful smoking cessation depended on the factors that were adjusted for and how the data were analysed, finding that under some conditions EC use was related to being less likely to quit and in others there was no relationship. The authors concluded that caution needs to be exerted when interpreting observational studies of the effects of EC use on smoking cessation.

Borderud et al., 2014 [52] examined whether any use of EC in the past 30 days was related to smoking cessation outcomes in a group of cancer patients enrolled in a smoking cessation programme in the US. When treating all smokers who dropped out of the study as smoking cessation failures, the authors found that any use of EC in the last 30 days was related to being less likely to quit; however, this treatment of the data may have been problematic because more EC users than non-users dropped out of the study. No relationship between EC use in the last 30 days and smoking cessation was observed when drop-outs were excluded from the analyses. One potential problem with this study is the measure of any EC use in the last 30 days, as this could range from using an EC once in the last 30 days to using an EC daily for the past 30 days. As illustrated [16, 44, 45] and discussed in previous studies [51], measurements of EC use that do not fully capture frequency of use may influence the relation between EC use and smoking cessation. As with studies in the previous section, the Borderud study started with smokers who had tried EC but did not stop smoking. This, of course, seriously reduces the chance of detecting a positive effect.

Summary of findings

Recent studies support the Cochrane Review findings that EC can help people to quit smoking and reduce their cigarette consumption. There is also evidence that EC can encourage quitting or cigarette consumption reduction even among those not intending to quit or rejecting other support. It is not known whether current EC products are more or less effective than licensed stop-smoking medications, but they are much more popular, thereby providing an opportunity to expand the number of smokers stopping successfully. Some English stop smoking services and practitioners support the use of EC in quit attempts and provide behavioural support for EC users trying to quit smoking; self-reported quit rates are at least comparable to other treatments. The evidence on EC used alongside smoking on subsequent quitting of smoking is mixed.

Policy implications

- Smokers who have tried other methods of quitting without success could be encouraged to try EC to stop smoking and stop smoking services should support smokers using EC to quit by offering them behavioural support.
Research should be commissioned in this area including:

- longitudinal research on the use of EC, including smokers who have not used EC at the beginning of the study
- the effects of using EC while smoking (temporary abstinence, cutting down) on quitting, and the effects of EC use among ex-smokers on relapse
- research to clarify the factors that i) help smokers using EC to quit smoking and ii) deter smokers using EC from quitting smoking, including different EC products/types and frequency of use and the addition of behavioural support, and how EC compare with other methods of quitting which have a strong evidence base

It would be helpful if emerging evidence on EC (including different types of EC) and how to use EC safely and effectively could be communicated to users and health professionals to maximise chances of successfully quitting smoking.
7. Reasons for use and discontinuation

Reasons for using e-cigarettes

Reasons for using EC have been assessed for adult smokers and ex-smokers in a number of different ways. Across different populations, help to quit smoking and harm reduction were the top reasons endorsed for using EC [44, 53-57].

In the Internet Cohort GB survey, the list of possible reasons for using EC was extended after the first year (the survey was carried out in 2012, 2013 and 2014). Nevertheless, the most frequently endorsed reasons were health, to cut down and to quit smoking. These were endorsed by approximately 80% of current users at all three time points. The biggest change over time was recorded for ‘they are cheaper’ which appeared to be more popular in 2014 than 2013 (Table 3). Because of the way the question is phrased, a user endorsing a reason does not indicate that current use is for this particular reason, for example, 80% of current users agree that e-cigarettes may help you quit, but this does not mean that 80% of all users were using them in a quit attempt.

Table 3: Internet cohort GB survey, reasons for using e-cigarettes (in order of frequency of endorsement in 2014)

<table>
<thead>
<tr>
<th>Reason</th>
<th>2012 (n=1031)</th>
<th>2013 (n=717)</th>
<th>2014 (n=505)</th>
</tr>
</thead>
<tbody>
<tr>
<td>They may make it easier for you to cut down the number of cigarettes you smoke</td>
<td>81.0</td>
<td>78.1</td>
<td>79.4</td>
</tr>
<tr>
<td>They may not be as bad for your health</td>
<td>81.7</td>
<td>79.8</td>
<td>79.2</td>
</tr>
<tr>
<td>They might help you quit</td>
<td>81.8</td>
<td>79.9</td>
<td>79.0</td>
</tr>
<tr>
<td>No tobacco smoke</td>
<td>not asked</td>
<td>70.9</td>
<td>71.3</td>
</tr>
<tr>
<td>They are cheaper</td>
<td>not asked</td>
<td>36.1</td>
<td>65.5</td>
</tr>
<tr>
<td>The smell or cleanliness</td>
<td>not asked</td>
<td>65.4</td>
<td>65</td>
</tr>
<tr>
<td>So you can use them in places where smoking regular cigarettes is banned</td>
<td>67.2</td>
<td>66.5</td>
<td>61</td>
</tr>
<tr>
<td>They may be more socially acceptable</td>
<td>not asked</td>
<td>55.8</td>
<td>54.3</td>
</tr>
<tr>
<td>Because I enjoy it</td>
<td>not asked</td>
<td>38.6</td>
<td>48.7</td>
</tr>
<tr>
<td>They taste better</td>
<td>28.5</td>
<td>26.1</td>
<td>34.1</td>
</tr>
<tr>
<td>Friends or family use them</td>
<td>not asked</td>
<td>37.0</td>
<td>33.3</td>
</tr>
<tr>
<td>The technology</td>
<td>not asked</td>
<td>34.2</td>
<td>30.3</td>
</tr>
<tr>
<td>A health professional advised you to do so</td>
<td>not asked</td>
<td>16.7</td>
<td>16.4</td>
</tr>
</tbody>
</table>
The ASH Smokefree GB survey similarly found that EC users who were ex-smokers most frequently endorsed that they used or had used EC to help them stop smoking entirely (Table 4). Among smokers, this was the second most frequently endorsed reason, with curiosity being the most frequent reason. Smokers also often reported use to help them cut down on smoked tobacco, which was rarely reported by ex-smokers.

### Table 4: Reasons for use, ASH Smokefree GB adult survey, 2015 (weighted)

<table>
<thead>
<tr>
<th>I use/used electronic cigarettes...</th>
<th>Smokers</th>
<th>Ex-smokers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Just to give it a try</td>
<td>35%</td>
<td>29%</td>
</tr>
<tr>
<td>To help me stop smoking tobacco entirely</td>
<td>30%</td>
<td>44%</td>
</tr>
<tr>
<td>To help me reduce the amount of tobacco I smoke, but not stop completely</td>
<td>29%</td>
<td>9%</td>
</tr>
<tr>
<td>Because I had made an attempt to quit smoking already and I wanted an aid to help me keep off tobacco</td>
<td>27%</td>
<td>35%</td>
</tr>
<tr>
<td>To save money compared with smoking tobacco</td>
<td>24%</td>
<td>22%</td>
</tr>
<tr>
<td>Because I felt I was addicted to smoking tobacco and could not stop using it even though I wanted to</td>
<td>16%</td>
<td>17%</td>
</tr>
<tr>
<td>Because I want to continue to smoke tobacco and I needed something to help deal with situations where I cannot smoke (e.g. workplaces, bars or restaurants)</td>
<td>15%</td>
<td>8%</td>
</tr>
<tr>
<td>To avoid putting those around me at risk due to second-hand tobacco smoke</td>
<td>12%</td>
<td>13%</td>
</tr>
<tr>
<td>Other</td>
<td>1%</td>
<td>3%</td>
</tr>
</tbody>
</table>

A smaller number of surveys specifically assessed reasons for trial and gave the option of selecting curiosity, which was frequently endorsed as an important reason for experimentation in US adults from the general population as well as in a sample of opioid-dependent smokers [58-60].

In youth, reasons for use has rarely been surveyed; one survey on reasons for experimentation among 1,175 students (middle school, high school and college) who had ever tried EC reported that the top three reasons for e-cigarette experimentation were curiosity (54.4%), the availability of appealing flavours (43.8%) and friends’ influence (31.6%). Compared with never smokers, however, ever cigarette smokers (OR=37.5, 95% CI: 5.0 to 283.3) and current cigarette smokers (OR=102.2, 95% CI: 13.8 to 755.9) were many times more likely to say they tried EC to stop smoking [61].
A national survey in New Zealand of 3,127 year 10 students (mostly aged 14 to 15) also showed that the most frequently given reason for first trying EC was curiosity, irrespective of smoking status (64.5% overall) [62].

Reasons *not* to use EC are rarely assessed. The ASH Smokers’ survey 2014 asked current and ex-smokers about advantages and disadvantages of EC. Among those who had never used EC, the three most important disadvantages were “They might be too expensive” (46%), “They might not be safe enough as a product” (39%) and “They might not satisfy my desire to smoke enough” (31%).

**Reasons why trial does not become use**

The rates of ever having tried an EC in the ASH GB Smokefree adult survey are more than three times those of current use; in the ASH GB Smokefree youth survey, about five times as many respondents had tried an EC as were currently using an EC, indicating that **most of those who try EC do not progress to current use.** A small number of surveys assessed why respondents who had tried an EC did not continue use.

In a national sample of 3,878 US adults who reported ever trying EC, two-thirds did not continue to use them and this was linked to the main reason for trying them. Trial turned into continued use for only a minority (19%) of those who did not know their main reason for trying them or whose main reasons were curiosity, friends or family members or advertising. Continued use was more common for those whose main reasons for trial included help to quit smoking or reduce harm. Those who did not continue use were asked for their reasons for stopping. The reason most often given was that they were just experimenting (49%) [58].

In the survey by Kong et al., reported previously, it appears that 98.5% of experimenting students did not continue use. Reasons for discontinuation were assessed but unfortunately the most commonly chosen response was ‘other’ (23.6%, open-ended responses included “I don’t like it”, “I just tried once”) followed by “uncool” (16.3%) and health risks (12.1%) [61].

Some surveys can be used to assess why smokers may not continue to use EC. The ASH Smokers’ survey in 2014 indicates that disappointment with the help EC provide in reducing smoking urges may be an important reason. Among smokers who had tried EC but did not continue using them, 44% said that a disadvantage of the products was that “They might not satisfy my desire to smoke enough”. No other reason got a higher rate of agreement in this group. A high proportion of smokers who were currently using EC also stated this reason (37%), but the proportion was significantly (p<0.05) lower in ex-smokers who had used (32%) or were currently using EC (7%), suggesting that satisfaction with the device/s may be a correlate of stopping smoking.
Of concern is that data suggest that some smokers may not continue to use EC instead of smoking because of a misguided belief that EC would be harmful to their health. In the ASH Smokers’ survey 2014, the second most frequently endorsed disadvantage was “They might not be safe enough as a product” (35%) among smokers who had tried an EC but were not using one anymore. Similarly, in a survey of US respondents, among 227 respondents who had tried EC in the past, were no longer using them but were still smoking cigarettes [44], the most frequently endorsed reason was that EC didn’t feel enough like smoking cigarettes, followed by dislike of the taste and that they were bad for health. It would appear therefore that these respondents stopped EC use in favour of continuing to smoke more deadly cigarettes.

**Summary of findings**

A number of surveys in different populations provide evidence that reducing the harm from smoking (such as through cutting down on their cigarette consumption or helping with withdrawal during temporary abstinence) and the desire to quit smoking cigarettes are the most important reasons for using EC. Curiosity appears to play a major role in experimentation. Most trial of EC does not lead to regular use and while there is less evidence on why trial does not become regular use, it appears that trial due to curiosity is less likely to lead to regular use than trial for reasons such as stopping smoking or reducing harm. Dissatisfaction with products and safety concerns may deter continued EC use.

**Policy implications**

- Smokers frequently state that they are using EC to give up smoking. They should therefore be provided with advice and support to encourage them to quit smoking completely.

- Other reasons for use include reducing the harm from smoking and such efforts should be supported but with a long-term goal of stopping smoking completely.
8. Harm perceptions

Perceptions of the harmfulness of EC are frequently assessed in surveys, most commonly relative to conventional tobacco cigarettes. However, a recent Eurobarometer survey [63] asked smokers in absolute terms whether EC were harmful to the health of those using them. Overall in Europe, 40.6% perceived EC as not harmful (UK: 48.6%), 28.5% as harmful (UK: 14.6%) and 30.9% did not know if they were or were not harmful (UK: 36.8%).

Harm perception relative to cigarettes

In GB, the ASH surveys and the Internet Cohort survey have included questions on the perceived relative harm of EC. These surveys consistently show that compared with conventional tobacco products, EC were perceived as less harmful by a small majority of respondents, but with a sizeable minority inaccurately judging them to be more harmful, about as harmful or being unsure about their relative risks. For example, in the 2015 ASH Smokefree GB adult survey, 2% thought that EC were more harmful than cigarettes, 20% equally harmful, 52% less harmful, 2% completely harmless and 23% did not know.

Harm perception differed by smoking status ($\chi^2=104.05, p<0.001$) and by EC use status ($\chi^2=453.4, p<0.001$) (Figure 15). Overall, smokers were more likely to judge EC to be less harmful compared with cigarettes (63.7%, including 'completely harmless') than ex-smokers (55.6%), whereas never-smokers were least likely to judge EC as less harmful (51.2%, all $p<0.05$). A higher proportion of current EC users (87.4%) thought that they were less harmful compared with cigarettes than those who had tried but were not using (68.8%) or never-users (50.4%), among whom the proportion was lowest (all differences $p<0.05$). Perceptions among youth were similar to adults. For example, in the 2015 ASH Smokefree GB youth survey, 2% thought that EC were more harmful than cigarettes, 21% equally harmful, 67% less harmful and 10% did not know.

In the STS, the proportion believing EC to be less harmful appears to be even lower. Only 44.1% of current smokers in England between November 2014 and March 2015 believed that EC were less harmful than cigarettes [15].
Trends in harm perceptions relative to cigarettes over time

Since 2013, perceptions of the relative harmfulness of EC have become less accurate. Significantly larger proportions perceived EC to be at least as harmful as cigarettes in 2014 than in 2013 both in the Internet Cohort GB surveys (Figure 16) and in the ASH youth surveys (Figure 17 [64]). In the Internet Cohort GB survey, there was no significant change from 2012 to 2013, but from 2013 to 2014 the proportion thinking that EC were less harmful decreased in favour of equally or more harmful (p<0.001). For youth, between 2013 and 2014, the decrease in the proportion endorsing ‘less harmful’ and the increase in the proportion endorsing ‘equally harmful’ were significant (p<0.01). There were no significant changes in the proportion endorsing ‘more harmful’ or ‘don’t know’.

In the ASH adult surveys, data on harm perception are available for 2013 to 2015 (Figure 17). In line with the other GB surveys, this survey found a steep increase in the proportion perceiving EC to be equally harmful as cigarettes (p<0.001).
Figure 16: Perceptions of relative harmfulness of e-cigarettes in comparison with tobacco cigarettes. Internet Cohort GB surveys (N=1,209 respondents with data at all three time points)

Notes: “Less harmful” includes those saying “Electronic cigarettes are completely harmless”. “Not applicable – I do not think regular cigarettes are harmful” not shown (2013: 1.2%, 2014: 0.9%, 2015: 0.8%)

Figure 17: Perceptions of relative harmfulness of e-cigarettes in comparison with tobacco cigarettes. ASH Smokefree GB adult surveys (weighted)

Notes: “Less harmful” includes those saying “Electronic cigarettes are completely harmless”. “Not applicable – I do not think regular cigarettes are harmful” not shown (2013: 1.2%, 2014: 0.9%, 2015: 0.8%)
Surveys from the US also suggest that from 2010 to 2013, the proportion of current smokers aware of EC who believed that EC were less harmful than smoking cigarettes declined considerably [65]. Youth in the US appear to have a less realistic perception of the relative harm of EC compared with cigarettes than UK youth. In the 2012 National Youth Tobacco Survey, of those who were aware of EC, around one-third perceived them to be less harmful than cigarettes and around half were unsure [66, 67].

The ASH Smokefree GB youth survey in 2013 and 2014 further included a question on the harm of EC to persons around a user. Again, the proportion who thought them less harmful than traditional cigarettes decreased from 2013 to 2014 (p<0.05), and the proportion who thought they caused similar levels of harm increased (p<0.01) (Figure 19).
Figure 19: Perceptions of relative harmfulness of e-cigarettes to people around the user. ASH Smokefree GB youth surveys

Harm perception relative to nicotine replacement therapy (NRT)

The ASH Smokers’ survey in 2014 asked respondents about their perception of EC compared with NRT (Table 20). The largest group of respondents thought EC were about as safe. Notably, a higher proportion thought that EC were safer than NRT than believed that NRT was safer than EC. This was particularly pronounced in current EC users.

Table 5: Relative harm perception by e-cigarette use status ASH Smokers’ survey 2014

<table>
<thead>
<tr>
<th>E-cigarette use status</th>
<th>Never (n=470)</th>
<th>Current (n=256)</th>
<th>Ex (n=477)</th>
<th>Total (n=1203)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compared to NRT</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safer</td>
<td>14 (66)</td>
<td>28.1 (72)</td>
<td>22 (105)</td>
<td>20.2 (243)</td>
</tr>
<tr>
<td>About as safe</td>
<td>28.1 (132)</td>
<td>44.1 (113)</td>
<td>35.6 (170)</td>
<td>34.5 (415)</td>
</tr>
<tr>
<td>Less safe</td>
<td>16.2 (76)</td>
<td>6.3 (16)</td>
<td>13 (62)</td>
<td>12.8 (154)</td>
</tr>
<tr>
<td>Don’t know</td>
<td>41.7 (196)</td>
<td>21.5 (55)</td>
<td>29.4 (140)</td>
<td>32.5 (391)</td>
</tr>
</tbody>
</table>

One US survey of 1,400 current and former smokers also assessed expected outcomes of using EC compared with NRT [68]. EC were perceived to be less risky, cost less, cause fewer negative physical feelings, taste better, provide more satisfaction, and be better at reducing craving, negative affect, and stress.
Summary of findings

Although the majority of adults and youth still correctly perceive EC to be less harmful than tobacco cigarettes, there has been an overall shift towards the inaccurate perception of EC being at least as harmful as cigarettes over the last year, for both groups. Intriguingly, there is also some evidence that people believe EC to be less harmful than medicinal nicotine replacement therapy (NRT).

Policy implications

- Clear and accurate information on relative harm of nicotine, EC and tobacco cigarettes is needed urgently (see also Chapter 10).

- Research is needed to explore how health perceptions of EC are developed, in relation to tobacco cigarettes and NRT, and how they can be influenced.
9. E-cigarettes, nicotine content and delivery

Background

We have undertaken a review of available evidence concerning nicotine released by EC. The review is divided into four parts, covering nicotine that EC use (vaping) releases into ambient air, nicotine content of e-liquid, nicotine content in e-vapour, and nicotine delivery to EC users (vapers). The main concern with nicotine in EC relates to the question of whether EC use exposes users or bystanders to the risk of nicotine poisoning. For this reason, we start with a short introductory review of this topic.

Toxicity of nicotine

Nicotine in the form of tobacco and more recently NRT has been available to thousands of millions of people and large numbers of them, including small children, have ingested considerable doses of nicotine. Fatal nicotine poisoning, however, is extremely rare. This fact strongly contradicts the often-repeated claim that an ingestion of 30-60mg of nicotine is fatal. The source of this claim proved difficult to locate – textbooks just cite older textbooks. Eventually, the assertion was found to be based on dubious self-experiments conducted in the 1890s [69].

We are aware of one unconfirmed newspaper report of a fatal poisoning of a two-year old child [70] and of three published case studies of small children who drank e-liquid. A two-year old was admitted to hospital with vomiting, ataxia, and lethargy, and was discharged after 24 hours of observation [71]. In the second report, an 18-month old girl drank 24mg nicotine in e-liquid, vomited and was irritable, and recovered fully within an hour or so [72]. The third article presented a case of a 30-month old child suspected to have ingested e-liquid. The quantity of e-liquid was uncertain and the child was asymptomatic with all clinical observations reported to be normal [73].

With the increase in EC use, there has been an increase in calls to poison centres following accidental exposures but these remain lower than calls following such exposure from tobacco and none resulted in any serious harm [74] (see next chapter for UK data). Serious nicotine poisoning seems normally prevented by the fact that relatively low doses of nicotine cause nausea and vomiting, which stops users from further intake.

Apart from accidental poisoning, nicotine has also been used in suicide attempts. Suicide attempts with large amounts of pesticides containing nicotine sulphate often succeed [75] but completed suicides using e-liquids are extremely rare. Where adults
drank up to 1,500mg of nicotine in e-liquid, the result was vomiting and recovery within a few hours [76]. One fatal outcome was recorded with 3,950mg of nicotine found in gastric content. The victim seems to have drunk three vials of e-liquid totalling over 10,000mg of nicotine [76]. An intravenous injection of unknown quantity of e-liquid also resulted in death [77].

E-liquid normally comes in 10ml bottles containing up to 360mg of nicotine (see below). This poses no risk to vapers if used as intended. The liquid however should be in ‘childproof’ packaging to prevent small children, who may find the flavouring appealing, from drinking it. This seems to have been widely accepted by the EC industry. All e-liquids we have seen so far in the UK and globally were sold in child-resistant packaging.

**Review methods**

We searched the US National Library of Medicine (Pubmed) using the following search terms: (((cotinine OR nicotine) AND (blood OR plasma OR urine OR saliva OR liquid OR aerosol OR pharmacokinetic$)) AND (electronic cigarette$ OR e-cig$ OR ENDS)). This search returned 161 records. The abstracts of all records were screened.

Papers were included if they were peer-reviewed and presented data regarding nicotine in e-liquid, aerosol, or body fluids (blood, saliva or urine). Studies that reported data on blood, salivary, or urine cotinine were also included.

A total of 112 records were excluded as they did not contain any relevant information, leaving 49 records. The full papers of these records were retrieved and reviewed.

From the full text review, 25 studies provided data regarding nicotine content of ambient air, e-liquid and vapour, and 16 provided data on nicotine delivery to users. The remaining eight papers did not contain any relevant information. Three further relevant papers were published during the writing of this report and were also included.

**Nicotine in ambient air, e-liquid and e-vapour**

We identified five studies of nicotine in ambient air, 14 studies of nicotine in e-liquid and nine studies of nicotine vapour. The results are summarised below. We tabulate the results where appropriate and provide a narrative summary where there are only a few studies available. Each section is concluded with a brief summary.

**Passive vaping: Nicotine from e-cigarette use in ambient air**

Four studies examined nicotine exposure from passive vaping. Long et al., 2014 measured nicotine content of EC exhalations. EC exhalations contained eight times less
nicotine than cigarette exhalations [78]. Estimating environmental nicotine exposure, however, has to take into account the fact that side-stream smoke (i.e., the smoke from the lighted end of the cigarette, which is produced regardless of whether the smoker is puffing or not) accounts for some 85% of passive smoking and there is no side-stream EC vapour. A study measuring nicotine residue on surfaces in houses of smokers and vapers reported only negligible levels from vaping, 169 times lower than from smoking [79].

Colard et al., 2015 describe a model for estimating environmental workplace exposure [80]. The model predicts much lower nicotine exposure from vaping than from smoking, at levels negligible in health terms.

Goniewicz and Lee 2014 found that nicotine from EC vapour gets deposited on surfaces, but at very low levels [81]. This poses no concerns regarding exposure to bystanders. At the highest concentration recorded (550 μg/m²), an infant would need to lick over 30 square metres of exposed surface to obtain 1mg of nicotine.

Ballbe et al., 2014 provide the most informative data collected to date as this study measured the actual levels of airborne nicotine in homes of ex-smokers who live either with smokers (N=25) or with vapers (N=5) and also in 24 control homes [82]. The study also measured salivary and urinary cotinine in partners of smokers and vapers. As expected, there was little nicotine in non-smokers’ homes. The air in the homes of vapers contained six times less nicotine than the air in the homes of smokers. There was less of a difference between cotinine levels of partners of vapers and smokers (1.4 to 2 fold difference), most likely due to some ‘ex-smokers’ still occasionally smoking, but even with this possible contamination, the nicotine levels absorbed via passive vaping were negligible. Partners of vapers had mean cotinine concentrations of 0.19 ng/ml in saliva and 1.75 ng/ml in urine, which is about 1,000 times less than the concentrations seen in smokers and similar to levels generated by eating a tomato [83].

Summary

EC release negligible levels of nicotine into ambient air with no identified health risks to bystanders.

Nicotine in e-liquids

Fourteen studies tested more than 400 different e-liquids, mainly to check the accuracy of product labelling. Their results are summarised in Table 6, updated from an earlier review by Cheng et al., 2014 [84].
Table 6: Nicotine in refill solutions, cartridges and aerosols of e-cigarette products
(Adjusted from Cheng et al. 2014)

<table>
<thead>
<tr>
<th>Study</th>
<th>Matrix</th>
<th>Units</th>
<th>Nicotine level</th>
<th>Maximum deviation from label*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Westenberger [85]</td>
<td>Cartridge</td>
<td>mg/cartridge</td>
<td>0.00 to 6.76</td>
<td>N.A.</td>
</tr>
<tr>
<td></td>
<td>Aerosol</td>
<td>μg/100mLpuff</td>
<td>0.35 to 43.2</td>
<td>N.A.</td>
</tr>
<tr>
<td></td>
<td>Refill solution</td>
<td>μg/mL</td>
<td>N.D. to 25.6</td>
<td>N.A.</td>
</tr>
<tr>
<td>Cobb et al [86]</td>
<td>Cartridge</td>
<td>mg/cartridge</td>
<td>3.23±0.5 to 4.07±0.54</td>
<td>−80 to −77%†</td>
</tr>
<tr>
<td></td>
<td>Aerosol</td>
<td>μg/35 mL puff</td>
<td>0.3 for puffs 11 to 50 to 1 for puffs 1 to 10</td>
<td>N.A.</td>
</tr>
<tr>
<td>Trehy et al [87]</td>
<td>Refill solutions</td>
<td>mg/mL</td>
<td>0 to 25.6</td>
<td>−100 to 100%†</td>
</tr>
<tr>
<td></td>
<td>Cartridge</td>
<td>mg/cartridge</td>
<td>0 to 21.8</td>
<td>−100 to 100%†</td>
</tr>
<tr>
<td></td>
<td>Aerosol</td>
<td>μg/100 mL puff</td>
<td>0 to 43.2</td>
<td>N.A.</td>
</tr>
<tr>
<td>Cheah et al [88]</td>
<td>Cartridge</td>
<td>mg/cartridge</td>
<td>0.00 to 15.3</td>
<td>−89 to 105%†</td>
</tr>
<tr>
<td>Pellegrino et al [89]</td>
<td>Cartridge</td>
<td>% W/W</td>
<td>&lt;0.001 to 0.25</td>
<td>N.A.</td>
</tr>
<tr>
<td>McAuley et al [90]</td>
<td>Indoor air</td>
<td>ng/L</td>
<td>538 to 8770</td>
<td>N.A.</td>
</tr>
<tr>
<td>Goniewicz et al [91]</td>
<td>Refill solution</td>
<td>mg</td>
<td>0±0.0 to 25±1.1</td>
<td>−75 to 28%</td>
</tr>
<tr>
<td></td>
<td>Cartridge</td>
<td>mg</td>
<td>0±0.0 to 19±0.5</td>
<td>−89 to 25%</td>
</tr>
<tr>
<td></td>
<td>Aerosol</td>
<td>mg/150 puffs</td>
<td>0.3±0.2 to 8.7±1.0</td>
<td>N.A.</td>
</tr>
<tr>
<td>Etter et al [92]</td>
<td>Refill solution</td>
<td>mg/mL</td>
<td>N.D. to 29.0</td>
<td>−15 to 21%†</td>
</tr>
<tr>
<td>Kirschner et al [93]</td>
<td>Refill solution</td>
<td>mg/mL</td>
<td>14.8±0.2 to 87.2±2.7</td>
<td>−50 to 40%†</td>
</tr>
<tr>
<td>Cameron et al [94]</td>
<td>Refill solution</td>
<td>mg/mL</td>
<td>8.5±0.16 to 22.2±0.62</td>
<td>−66 to 42%†</td>
</tr>
<tr>
<td>Goniewicz et al [95]</td>
<td>Liquids</td>
<td>mg/mL</td>
<td>N.D. to 36.6 (150.3 ‘pure nicotine’)</td>
<td>-92 to 104%</td>
</tr>
<tr>
<td>Geiss et al [96]</td>
<td>Liquids</td>
<td>mg/mL</td>
<td>N.D. to 20.8</td>
<td>-0 to 16%</td>
</tr>
<tr>
<td>Kavvalakis et al [97]</td>
<td>Liquids</td>
<td>%w/v</td>
<td>1.01 to 1.62</td>
<td>-17 to +6%</td>
</tr>
<tr>
<td>Farsalinos et al [98]</td>
<td>Liquids</td>
<td>mg/ml</td>
<td>Labelled 12-18</td>
<td>-21 to +22%</td>
</tr>
</tbody>
</table>

*Deviation from label = (measured value – labelled value) * 100/labelled value.
†Calculation performed by this analysis based on reported data in each study.
N.A. = not available; N.D. = none detected.
A range of analytical methods was used, which may have contributed some variation. There is no established standard and different studies use different approaches. Cheah et al., used gas chromatography coupled with flame ionization detector [88]; Etter et al., gas chromatography coupled with mass spectrometry and ultra high-performance liquid chromatography coupled with diode array detector [92]; McAuley et al., gas chromatography coupled with nitrogen-phosphorus detector [90]; Goniewicz et al., gas chromatography coupled with thermionic specific detector [95]; Trehy et al., high-performance liquid chromatography coupled with diode array detector [87]; Westenberger high-performance liquid chromatography coupled with ultraviolet/visible spectroscopic detector [85]; Kubica et al., liquid chromatography coupled with tandem mass spectrometry [99]; and Kirschner et al., liquid chromatography coupled with time-of-flight mass spectrometry [93].

The data generated so far provide answers to three questions:

**Do e-liquids pose a poisoning hazard?**

The vast majority of vapers use ‘ready-made’ liquids in 10ml bottles, but some aficionados, primarily in the US, buy high concentration nicotine solutions in larger quantities for DIY dilution. An e-liquid was identified labelled as containing 210mg/ml which in fact contained only 150mg/ml [95] but even this may pose risk if ingested in larger volume. DIY liquids are rarely used in Europe, but for spurious reasons, Europe is poised to prohibit sales of products with nicotine concentrations above 20mg/ml. When this happens, the popularity of DIY e-liquids among dependent vapers, who now cannot access the products they need but can mix them themselves at home at low cost, may increase.

‘Ready-made’ e-liquids come in strengths of up to 36mg/ml nicotine, with the highest concentration recorded of 36.6mg/ml. This poses no risk of nicotine poisoning if used as intended. An overenthusiastic vaper, like someone who is over-smoking, receives a reliable warning via nausea. If the 10ml bottle of e-liquid was drunk, it would cause nausea and vomiting but would be unlikely to inflict serious harm. To protect young children from accidental exposure though, e-liquids should be in ‘childproof’ packaging.

**How accurate is product labelling?**

The real content exceeded markedly the labelled concentration only in samples where the declared content was very low (6mg/ml) and the real concentrations ranged up to 12mg/ml (ie still low levels). The most striking examples of inaccurate labelling concerned much lower nicotine levels than those declared in e-liquids confiscated in Singapore where EC are banned, for example, a liquid labelled as containing 24mg of nicotine contained only 3mg [88]. This however was most likely due to samples being several years old. Market competition seems to have led to improved standards as
poorly labelled products are now less common and overall the labelling accuracy has improved. For instance in the latest study which sampled 263 liquids from 13 manufacturers, the correlation between the declared and measured concentrations was $r=0.94$ with the samples ranging from -17% to +6% of the declared value [85]. In another study testing the five most popular EC brands, the consistency of nicotine content across different batches of nicotine cartridges of the same products was found to be within the accuracy required from medicinal nebulisers [100]. Given the generally adequate labelling accuracy and the fact that the actual nicotine intake by vapers is dictated by a host of other factors discussed below, the accuracy of labelling of common e-liquids poses no major concerns.

**Is there a risk from e-liquids inaccurately labelled as containing 0 nicotine?**

All samples labelled as containing 0 nicotine were nicotine free in the newer studies, but three early studies found nicotine in some samples of ‘0 nicotine’ e-liquids. One sample reported in 2011 was clearly mislabelled [87] but in all other cases, only trace contamination was detected (below 1mg/ml). This would have no central effect on users.

**Summary**

Poorly labelled e-liquid and e-cartridges mostly contained less nicotine than declared and so posed no risk to users. The accuracy of product labelling currently raises no major concerns.

**Nicotine in e-vapour**

A number of studies evaluated nicotine in EC vapour generated by puffing machines. A recent experiment [101] has shown that parameters of puffing topography, especially puff duration and puff frequency, have a major influence on nicotine delivery. This poses a serious problem in interpreting the existing studies. The key parameters used by puffing machines differ widely across studies, and may not correspond well or at all with vapers’ behaviour generally and especially with the way individual EC products are used. To illustrate the point, Table 7 below, from Cheng et al. 2014 [84], shows the wide range of settings used in different studies. (Table 7 includes some unpublished studies).

**Table 7. Settings of EC puffing parameters. From Cheng et al 2014 [84].**

<table>
<thead>
<tr>
<th>Study</th>
<th>Puff volume (ml)</th>
<th>Puff interval (s)</th>
<th>Puff duration (s)</th>
<th>Puffs/session</th>
<th>Smoking machine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goniewicz et al [100]</td>
<td>70</td>
<td>10</td>
<td>1.8</td>
<td>15</td>
<td>Palaczbob*</td>
</tr>
<tr>
<td>Pellegrino et al [89]</td>
<td>498</td>
<td>8</td>
<td>3</td>
<td>16</td>
<td>Aspiration</td>
</tr>
</tbody>
</table>
For instance, the average puff duration in experienced vapers is 2.8 seconds [101], but some studies used puffs lasting for up to 4 seconds. This can overheat the e-liquid and provide unrealistically high readings (see Chapter 11).

Although it would be feasible to establish some empirical standards, eg of puff duration and frequency, by observing vapers, any general standard would have to average values across different products. As different products, and especially products from different ‘generations’, are used differently, such a blanket regimen would still provide inaccurate and potentially misleading information.

A recent study discovered another serious problem with trying to make sense of nicotine content in e-vapour. Across five common e-liquids with middle ranges of strength, the actual nicotine concentration in the e-liquid had almost no relationship with the nicotine content in vapour when the devices were puffed on by a machine at a standard rate [100]. The e-liquid of course had to contain a certain minimal level of nicotine as with little or no nicotine in e-liquid, there would be little or no nicotine in vapour. This finding concerning machine testing also does not mean that nicotine levels in e-liquids are irrelevant for EC users. Although EC technology is developing to maximise nicotine delivery, a vaper seeking high blood nicotine levels is likely to struggle to achieve them with a weak e-liquid. The reason for the low correlation between nicotine in e-liquid and in e-vapour is that the battery output, type of wicks, ventilation holes and other mechanical characteristics of each individual EC product determine how much vapour and nicotine is released – before the individual puffing style and preferences generate yet another key determinant of nicotine delivery to users.
These findings have an important implication. Above the necessary minimum level of nicotine, nicotine concentrations in e-liquid and even the concentrations in vapour, if measured by standard puffing schedules, are of limited relevance. For light smokers, 18mg/ml ‘mild’ e-liquid may be sufficient, but they may also prefer a stronger liquid and take shorter and less frequent puffs. A heavy smoker who would be expected to prefer a 28mg/ml ‘strong’ liquid may in fact chose a ‘moderate’ strength if they favour long and frequent puffs.

In real-life use, vapers have no way of knowing in advance what liquid strength and product characteristics they will prefer. As with other consumer products of this type, such as cigarettes, coffee and soft drinks, vapers have to try several EC models and different e-liquids before settling on a preferred product that matches their preferences.

For practical purposes, general labelling of the strength of e-liquid, along the lines used for indicating coffee strength, may provide sufficient information for consumers. The current vapers’ preferences suggest as a rough rule of thumb that ‘mild’ equates to 16–20mg/ml, ‘medium’ to 21–26mg/ml and ‘strong’ to 27–36mg/ml.

Translating these findings into regulatory recommendations, it would seem that regulation to enforce standard nicotine delivery may not be needed because nicotine delivery is influenced by a host of factors, including user puffing preferences, and because consumer preferences differ. EC products will hopefully continue to evolve guided by differential market success, with the result that more smokers find EC helpful and switch to them.

**Summary**

Across the middle range of nicotine levels, nicotine delivery to vapour is determined primarily by mechanical and electrical characteristics of EC products and by the duration and frequency of puffs. General labelling of the strength of e-liquids, along the lines used for indicating coffee strength (eg mild, medium and strong), is likely to provide sufficient information for consumers.

**Nicotine delivery to e-cigarette users**

To assess nicotine intake from EC, a number of studies took blood samples from smokers during and after vaping. Table 8 summarises data from 17 studies that investigated nicotine delivery from EC in humans. The narrative description of the studies and additional details concerning their findings are presented in Appendix C.

The two key questions in this field are:

a) How much nicotine EC deliver compared to cigarettes, and
b) How fast EC deliver nicotine compared to cigarettes.
As in every new field, methodological problems limit the usefulness of some of the data collected so far. Two problems in particular are prominent.

1) Almost all studies used prescribed puffing regimes, sometimes derived from observations of smokers rather than vapers. We described above the evidence that puffing schedules have a major influence on nicotine delivery to vapour. Puffing schedules that do not correspond with vapers’ behaviour are thus unlikely to provide realistic nicotine delivery data. Only three studies allowed vapers to puff ad-lib on first use.

2) Regarding the question of the speed of nicotine delivery, all existing studies started blood sampling only after five minutes of vaping. Cigarettes provide peak nicotine plasma levels very quickly (eg peak arterial nicotine concentrations of around 20ng/ml nicotine are reached within 20 seconds of starting to puff on an cigarette [107]). Data collected so far do not allow an appraisal of whether EC are approaching cigarettes in this key parameter.

Despite these limitations, the studies above have generated several strands of useful information on how much nicotine vapers obtain over time and how this compares with nicotine intake from cigarettes.

Cotinine is a metabolite of nicotine with a long half-life which shows nicotine exposure over time. Cotinine data are thus not influenced by the laboratory puffing schedules. Some studies suggest that experienced vapers can, over time, reach nicotine levels comparable to those obtained from smoking [108-110], although others have found plasma or salivary cotinine levels that are still lower than those observed in daily smokers [111-113].

Cigalike EC deliver lower levels of nicotine than cigarettes [114-116], especially to novice users [117-119]. Vapers obtain slightly more nicotine from them with practice, but nicotine delivery is comparatively low and slow [115]. Experienced users can obtain a rise in blood nicotine concentration of between 8 and 16ng/ml [120, 121]. Tank systems deliver nicotine more efficiently than cigalikes and somewhat faster [120, 122, 123].

Overall, the data indicate that within five minutes of use of a cigalike EC, blood nicotine levels can rise by approximately 5ng/ml. For comparison, after chewing a piece of 2mg nicotine chewing gum, peak plasma concentrations of 3–5ng/ml are observed within approximately 30 minutes [124, 125]. For experienced users of tank systems the increase in blood nicotine concentration within five minutes of use can be 3–4 times higher.
Speed of nicotine delivery seems important for smokers' satisfaction. Cigarettes deliver nicotine very fast via the lungs. It is likely that to out-compete cigarettes, EC will need to provide nicotine via the lungs as well. Although some EC products may already provide a degree of lung absorption, most nicotine is probably delivered via a much slower route through buccal mucosa and upper airways, in a way that is closer to the delivery from nicotine replacement medications than to the delivery from cigarettes.

This tallies with two other observations. Vapers feel they are less dependent on EC than they were on cigarettes [126]; and non-smokers experimenting with EC do not find them attractive and almost none progress to daily vaping [127]. This contrasts with the fact that about half of adolescents who experiment with cigarettes progress to daily smoking [128].

In addition to mechanical characteristics of EC and user puffing behaviour discussed in previous sections, the composition of the chemicals used to produce the vapour, typically vegetable glycerol and/or propylene glycol (PG), may also influence nicotine delivery. E-liquid with a mix of vegetable glycerol/PG was associated with better nicotine delivery than a vegetable glycerol-only e-liquid with the same concentration of nicotine [129]. The presumed effect is that PG vaporises at a faster rate than vegetable glycerol when heated in the EC and so is able to carry more nicotine to the user.

If EC continue to improve in the speed of nicotine delivery, they are likely to appeal to more smokers, making the switch from smoking to vaping easier. It may be important in this context to note that if the smoking-associated risk is removed, nicotine use by itself, outside pregnancy, carries little health risk and in fact conveys some benefits.

Table 8: Studies examining nicotine intake in vapers

<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>EC Device</th>
<th>Methods</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vansickel et al 2012 [119]</td>
<td>20 smokers naive to EC</td>
<td>Vapor King (cigalike), 18mg/ml nicotine</td>
<td>Overnight abstinence, baseline blood sample, after 5 mins 10 puffs, 30 sec inter-puff interval, 5 mins after last puff blood sample. Repeated 5x, 30 mins in between</td>
<td>At end of last puffing bout plasma nicotine increased from 2.2 ng/ml at baseline to 7.4 ng/ml</td>
</tr>
<tr>
<td>Vansickel &amp; Eissenberg 2012 [121]</td>
<td>8 vapers using EC for average of 12 months</td>
<td>Own EC 1 used 9 mg/ml 6 used 18 mg/ml 1 used 24 mg/ml</td>
<td>Overnight abstinence, Baseline blood, after 5 mins 10 EC puffs at 30 sec intervals, 5 and 15 mins after first puff blood sample, 60 min ad-lib vaping</td>
<td>Increase in plasma nicotine from 2.0 ng/ml to 10.3 ng/ml in 5 mins. Cmax = 16.3 ng/ml at end of ad-lib period</td>
</tr>
<tr>
<td>Yan &amp; D'Ruiz 2014 [129]</td>
<td>23 smokers</td>
<td>4 types of Blu (cigalike) EC (1.6% to 2.4%) Marlboro cigarette</td>
<td>Randomised 6 sessions 7-days get used to EC, 36 h abstinence. EC = 50x5 sec puffs, 30 sec</td>
<td>During controlled puffing Cmax (ng/ml): EC 10.3 to 18.9; cig 15.8</td>
</tr>
<tr>
<td>Study</td>
<td>Participants</td>
<td>EC Device</td>
<td>Methods</td>
<td>Results</td>
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<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Vansickle et al 2010</td>
<td>32 smokers</td>
<td>Own brand cig, NJOY EC (18mg), Crown 7 EC (16mg), Sham (unlit cig) EC were cigalike</td>
<td>Randomised crossover, overnight abstinence. Baseline blood, EC – 10 puffs at 30 sec intervals, blood at 5, 10, 15, 30, 45, 60 mins.</td>
<td>Tmax: 30 mins for EC and 5 mins for cig. During ad lib use. Cmax (ng/ml): EC 13.7 to 22.42; cig 29.3.</td>
</tr>
<tr>
<td>Van Staden et al 2013</td>
<td>13 smokers</td>
<td>Twisp eGo (18mg/ml nicotine)</td>
<td>Provided with EC and asked to use this and stop smoking for two weeks.</td>
<td>Cotinine ng/ml Baseline: 287, at 2 weeks 97 (p=0.0011)</td>
</tr>
<tr>
<td>Spindle et al 2015</td>
<td>13 vapers &gt; 3 months, e-liquid ≥12mg/ml</td>
<td>Own EC (all tank systems)</td>
<td>Overnight abstinence, two sessions. Baseline blood, EC – 10 puffs at 30 sec interval. Blood at 5 and 15 min.</td>
<td>Plasma nicotine at Baseline: 2.4 ng/ml 5 mins: 19.2 ng/ml 10 mins: 10.2 ng/ml</td>
</tr>
<tr>
<td>Bullen et al 2010</td>
<td>8 smokers</td>
<td>Ruyan V8 (cigalike) 16mg/ml (puff for 5 mins), Inhalator 10mg (puff for 20 mins), Own brand cig (puff for 5 mins)</td>
<td>Randomised crossover, overnight abstinence. Baseline blood, product use, blood at 5, 10, 15, 30, and 60 mins.</td>
<td>Cmax (ng/ml): EC=1.3; Inh=2.1; Cig=13.4 Tmax (mins): EC=19.6; Inh=32.0; Cig=14.3</td>
</tr>
<tr>
<td>Flouris et al 2013</td>
<td>15 smokers</td>
<td>Giant (cigalike) 11mg/ml</td>
<td>Smoked 2 cigs, puffed EC to match smoking. Cotinine immediately and 1 h after puffing.</td>
<td>No difference between products</td>
</tr>
<tr>
<td>Caponnetto et al 2013</td>
<td>Sample size not stated</td>
<td>Categoria (cigalike) 7.2mg for 12 weeks</td>
<td>RCT – 12 weeks of EC use</td>
<td>Salivary cotinine 6 weeks: 42 ng/ml; 12 weeks: 91 ng/ml 6 weeks: 68 ng/ml; 12 weeks: 70 ng/ml</td>
</tr>
<tr>
<td>Etter &amp; Bullen 2011</td>
<td>30 vapers</td>
<td>Own brand EC</td>
<td>Ad libitum use</td>
<td>Salivary cotinine 322 ng/ml</td>
</tr>
<tr>
<td>Dawkins &amp; Corcoran 2014</td>
<td>14 vapers, 7 dual users</td>
<td>Skycig (cigalike) 18mg/ml</td>
<td>10 puffs in 5 mins, then 1 hour ad lib</td>
<td>After 10 mins: 0.74 – 6.77 ng/ml After ad lib: 4.35-25.6 ng/ml</td>
</tr>
<tr>
<td>Study</td>
<td>Participants</td>
<td>EC Device</td>
<td>Methods</td>
<td>Results</td>
</tr>
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<td>------------------------------</td>
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<td>-------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Nides et al 2014 [116]</td>
<td>29 smokers, 55% used EC in past</td>
<td>NJOY® King Bold (cigalike) 26mg</td>
<td>EC ad lib 1 week, 12 h abstinence. 2x10 puffs (30 sec inter-puff interval) 60 mins apart Blood before and 5, 10, 15, 30 minutes after</td>
<td>N=16 had no baseline plasma nicotine Rise 5 min after first puffs: 3.5 ng/ml; after second puffs: 5.1 ng/ml</td>
</tr>
<tr>
<td>Norton et al 2014 [112]</td>
<td>16 smokers</td>
<td>Smoke 51 TRIO (cigalike) 11 mg/ml</td>
<td>Day 1: own brand, saliva sample Given EC and stopped smoking. Saliva at day 5. Analysis of 16 who abstained from smoking for 72 hours</td>
<td>Significant decrease in saliva cotinine between baseline (338.0 ng/ml) and day 5 (178.4 ng/ml), p&lt;0.001</td>
</tr>
<tr>
<td>Hecht et al 2014 [111]</td>
<td>28 vapers (median 9 months), 96% daily users</td>
<td>Average nicotine 12.5 +/- 7.0 mg/ml</td>
<td>Measured toxicants, carcinogens, nicotine and cotinine in urine</td>
<td>Nicotine: 869 ng/ml Cotinine: 1880 Smokers normally Nicotine: 1380 ng/ml, cotinine: 3930 ng/ml</td>
</tr>
<tr>
<td>Hajek et al 2014 [115]</td>
<td>40 smokers,</td>
<td>Greensmoke (cigalike) EC (2.4% nicotine)</td>
<td>Overnight abstinence Baseline blood, first EC use ad-lib 5 mins, blood at 5, 10, 15, 20, 30 and 60 mins. Repeated after 4-weeks of ad lib use</td>
<td>Baseline: Cmax: 4.6, Tmax: 5, AUC: 96 4-weeks: Cmax: 5.7, Tmax: 5, AUC: 142</td>
</tr>
</tbody>
</table>
| Farsalinos et al 2014 [122]  | N=23 vapers (19 months use)                        | A: V2 (cigalike)                    | Abstained for 8 hrs Blood baseline and after 10 puffs over 5 mins, 1 h ad lib, blood every 15 mins | A:5 mins: 4.9 ng/ml 1h: 15.8 ng/ml  
B: 5 mins: 6.6 ng/ml 1h: 23.5 ng/ml |
| Oncken et al 2015 [123]      | N=20 smokers given EC for 2 weeks                  | Menthol or non-menthol tank system with 18mg/ml liquid | Blood baseline, 5 min ad lib vaping, blood at 5,10,15,20,30 min | At 5 min nicotine increased by 4-5 ng/ml |

**Summary of findings**

The accuracy of labelling of nicotine content currently raises no major concerns. Poorly labelled e-liquid and e-cartridges mostly contained less nicotine than declared. EC used as intended poses no risk of nicotine poisoning to users. However, e-liquids should be in ‘childproof’ packaging.
Duration and frequency of puffs and mechanical characteristics of EC play a major role in determining nicotine content in vapour. Across the middle range of nicotine levels, in machine tests using a standard puffing schedule, nicotine content of e-liquid is related to nicotine content in vapour only weakly. EC use releases negligible levels of nicotine into ambient air with no identified health risks to bystanders. Use of a cigalike EC can increase blood nicotine levels by around 5ng/ml within five minutes of use. This is comparable to delivery from oral NRT. Experienced EC users using the tank EC can achieve much higher blood nicotine levels over a longer duration, similar to those associated with smoking. The speed of nicotine absorption is generally slower than from cigarettes but faster than from NRT.

Policy implications

- General labelling of the strength of e-liquids, along the lines used for example indicating coffee strength, provides sufficient guidance to consumers.

- Regulatory interventions should ensure optimal product safety but make sure EC are not regulated more strictly than cigarettes and can continue to evolve and improve their competitiveness against cigarettes.
10. Safety of e-cigarettes in the light of new evidence

Introduction

PHE commissioned a review of EC in 2014, which covered EC safety [131]. The review found that the hazard associated with use of EC products currently on the market “is likely to be extremely low, and certainly much lower than smoking” and “the health risks of passive exposure to electronic cigarette vapour are likely to be extremely low”.

These conclusions tally with a review by an international team of experts, which estimated the risks of vaping at less than 5% of the risks of smoking [10] and a comprehensive review of relevant literature by another international team which concluded that “EC aerosol can contain some of the toxicants present in tobacco smoke, but at levels which are much lower. Long-term health effects of EC use are unknown but compared with cigarettes, EC are likely to be much less, if at all, harmful to users or bystanders” [132].

Over the past few months, however, several reports have suggested that EC may pose more risks than previously thought [133-137].

We were asked to review these studies to see if in the light of this new evidence, the conclusions of the PHE 2014 review need to be adjusted. We present below the details of these studies together with any additional data that may assist with their interpretation.

Aldehydes in vapour from e-cigarettes

Two recent reports raised a possibility that under certain conditions, EC may release high levels of aldehydes. Aldehydes, including formaldehyde, acrolein and acetaldehyde, are released in tobacco smoke and contribute to its toxicity. Aldehydes are also released with thermal degradation of propylene glycol and glycerol in e-liquids. Previous studies detected the presence of aldehydes, especially formaldehyde, in the vapour from some EC, but at levels much lower than in cigarette smoke [138]. Across brands, EC released 1/50th of the level of formaldehyde released by cigarettes. The highest level detected was six times lower than the level in cigarette smoke [138].

In November 2014, following a press release from Japan [136], major media around the world reported variations of a headline: “E-cigarettes contain 10 times the carcinogens of regular tobacco”. This was based on a Japanese researcher reporting at a press conference that during tests on a number of EC brands, one product was identified
which released 10 times more formaldehyde than cigarettes. The press release states that the formaldehyde was released when the e-liquid was over-heated. The study has not been published yet and so no further details are available, but the two experiments described below provide the explanation for this finding.

In January 2015, a similar report was published as a research letter to the New England Journal of Medicine (NEJM) [133]. In this study, negligible levels of formaldehyde were released at lower EC settings, but when a third generation EC (EC with variable power settings) was set to the maximum power and the apparatus was set to take puffs lasting 3–4 seconds, this generated levels of formaldehyde that, if inhaled in this way throughout the day, would exceed formaldehyde levels in cigarette smoke between five and 15 times.

The EC was puffed by the puffing machine at a higher power and longer puff duration than vapers normally use. It is therefore possible that the e-liquid was overheated to the extent that it was releasing novel thermal degradation chemicals. Such overheating can happen during vaping when the e-liquid level is low or the power too high for a given EC coil or puff duration. Vapers call this phenomenon ‘dry puff’ and it is instantly detected due to a distinctive harsh and acrid taste (it is detected by vapers, but not by puffing machines) [139]. This poses no danger to either experienced or novice vapers, because dry puffs are aversive and are avoided rather than inhaled.

A study has just been published testing the hypothesis that the NEJM report used dry puffs [140]. An equivalent EC product was set to the same or normal settings and used by seven vapers. The vapers found it usable at normal settings, but all received dry puffs and could not use the device at the settings used in the NEJM report [133]. The product was then machine tested. At the dry puff setting, formaldehyde was released at levels reported in the NEJM letter and the Japanese press release. At normal settings, there was no or negligible formaldehyde release.

We are aware of two studies that examined aldehyde levels in vapers. In a cross-sectional study, vapers had much lower levels of acrolein and crotonaldehyde in urine than smokers [111]. The other study, funded by the Medicines and Healthcare products Regulatory Agency (MHRA), examined changes in acrolein levels in smokers who switched to exclusive EC use and in those who continued to smoke while also using EC. As both EC and cigarettes release acrolein, there was a concern that ‘dual users’ may increase their acrolein intake compared to smoking only. The results showed a substantial decrease in acrolein intake in smokers who switched to EC, but it also found a significant decrease in acrolein intake in dual users (ie people that were both smoking and vaping). This was because they reduced their smoke intake as indexed by exhaled CO levels. Normal vaping generated negligible aldehyde levels [141].
Although e-liquid can be heated to a temperature which leads to a release of aldehydes, the resulting aerosol is aversive to vapers and so poses no health risk.

**Summary**

There is no indication that EC users are exposed to dangerous levels of aldehydes.

**Effects of e-cigarette vapour on mice lungs**

A paper published in February 2015 [135] generated worldwide media coverage with claims that it linked EC to lung inflammation, lung infection, and even lung cancer.

Groups of mice were put in a small container exposing them to vapour from six EC (‘Menthol Bold’ 1.8% nicotine) puffed on a rotating wheel at six puffs per minute for 1.5 hours, twice daily, over two weeks. The control mice were not exposed to this treatment.

Animals were infected with either streptococcus pneumonia via intranasal instillation and killed 24 hours later, or with tissue culture influenza virus and monitored for weight loss, mortality, and lung and airways inflammation. Compared to the control group, the experimental animals had an increase in pro-inflammatory cytokines, diminished lung glutathione levels, higher viral titre, and were more likely to lose weight and die. The study identified free radicals in EC vapour as the potential culprit.

There are several problems with the study and with the way its results have been interpreted.

EC vapour is inhaled as a replacement for tobacco smoke, but the study attempted no comparison of the effects on the lungs from smoke and vapour exposures. This makes a meaningful interpretation of the results difficult. A comparison was made, however, of the levels of free radicals. Even at the very high vapour density generated by the study procedure, the level of free radicals identified in vapour was “several orders of magnitude lower than in cigarette smoke”.

In addition to this, the mice in the experimental group were exposed to a much higher level of stress than the control group, and stress affects bacterial and viral response. Long and repeated containment in the small and crowded smoke chamber emitting an overpowering smell is a stressor in itself, but the animals also suffered repeated nicotine poisoning. The mice showed an average cotinine concentration of 267ng/ml. Cotinine is the primary metabolite of nicotine and in humans the amount of nicotine needed to give similar cotinine levels are tolerated by heavy smokers, but highly aversive to non-smokers, who would be expected to feel sick and vomit at this level of exposure. Mice are much more sensitive to nicotine than humans (LD50 in mice is 3mg/kg, in humans
6.5–13mg/kg [69]). Accelerated weight loss, reduced immunity and early death in the experimental group were much more likely the result of protracted stress and nicotine poisoning than the result of exposure to free radicals (which were in any case 1,000 times lower than from cigarettes).

A similar study from 2015 [134] reported oxidant reactivity (which is linked to free radicals) of e-liquid and cytokine release in exposed lung tissue and in mice exposed to EC vapour. Again, no comparison with exposure to smoke was reported.

Human studies do not corroborate any of the findings reported here. A case study of lipoid pneumonia, which could have been caused by EC flavouring, received worldwide attention in 2012 [142] but despite extensive interest in the phenomenon, no further cases were published. Adverse effects of vaping are primarily local irritation and dry mouth [132]. A study that monitored asthma patients who switched from smoking to vaping found significant improvements in symptoms and in respiratory function [143]. The recent Cochrane Review found no significant adverse effects associated with EC use for up to 1.5 years [39].

Summary

The mice model has little relevance for estimating human risk and it does not raise any new safety concerns.

Particles in e-cigarette vapour

For completeness we are including information on another recent report which was interpreted as showing that EC may be dangerous to bystanders. At an EC Summit conference in London in November 2014, Harrison and McFiggans reported on particles present in EC vapour. Their presentation was reported in the British Medical Journal under the title “E-cigarette vapour could damage health of non-smokers” [137]. McFiggans and Harrison requested a retraction of the piece because their findings did not concern any health risks. It is the content of the particles rather than their presence or size which has health implications [144].

Impact of media reports that e-cigarettes are dangerous

Together with previous health scares, the articles reviewed here may be having a significant impact on public perception of EC safety. In the US, 82% of responders believed that vaping is safer than smoking in 2010, but the figure has shrunk to 51% in 2014 [65]. A perception that EC pose as much risk as smoking is the most likely explanation of the recent decline in adoption of EC by smokers [145].
Summary of findings

Two recent worldwide media headlines asserted that EC use is dangerous. These were based on misinterpreted research findings. A high level of formaldehyde was found when e-liquid was over-heated to levels unpalatable to EC users, but there is no indication that EC users are exposed to dangerous levels of aldehydes; stressed mice poisoned with very high levels of nicotine twice daily for two weeks were more likely to lose weight and die when exposed to bacteria and viruses, but this has no relevance for human EC users. The ongoing negative media campaigns are a plausible explanation for the change in the perception of EC safety (see Chapter 8).

None of the studies reviewed above alter the conclusion of Professor Britton’s 2014 review for PHE. While vaping may not be 100% safe, most of the chemicals causing smoking-related disease are absent and the chemicals that are present pose limited danger. It had previously been estimated that EC are around 95% safer than smoking [10, 146]. This appears to remain a reasonable estimate.

Policy implications

- There is a need to publicise the current best estimate that using EC is around 95% safer than smoking.
- Encouraging smokers who cannot or do not want to stop smoking to switch to EC could be adopted as one of the key strategies to reduce smoking related disease and death.
11. Other health and safety concerns

There have been a number of newspaper reports about the hazards of EC use including e-liquid ingestion/poisonings, fires, battery explosions etc [147-149]. In this chapter we review available national data on these issues to endeavour to quantify the risk.

Poison reports

Data on e-liquid exposures in the UK are available from the National Poisons Information Service (NPIS)[150]. The NPIS provides information about poisoning to NHS staff and publishes data based on enquiries made by phone, using their online database TOXBASE, and by consultant referrals. The NPIS report for 2013/14 [150] details 204 enquiries related to the liquid content of EC and their refills, most of which reported accidental exposure, however 21 enquiries were related to intentional overdoses using e-liquids. Most incidences concerned ingestion of the liquid in EC or their refills (n=182) although small numbers of inhalation (n=17), eye contact (n=13) and skin contact (n=12) enquiries were also reported. The NPIS further reported that the number of enquiries about e-liquids has increased since 2007 (Figure 20) broadly reflecting the increasing popularity of EC.

A large proportion of exposures to e-liquids were in children under five years old (Figure 21), a finding that is replicated in a US study on calls to poison centres [151]. However, the concentration of events concerning children is not unique to e-liquids. Children under five years old appear to be more vulnerable than adults to accidental poisoning in general (Figure 22).
Figure 20: Number of telephone enquiries to National Poisons Information Service (NPIS) about e-cigarettes over time

Figure 21: Number of enquiries about e-cigarettes to NPIS by age
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Figure 22: Age of poisoned patients overall reported in telephone enquiries to NPIS 2013/4

Exposures to poisonous liquid among children are of concern; however they should be taken in context. The same report from the NPIS recorded 208 exposures to liquid in reed diffusers, 1,168 exposures to pesticides and more than 600 to paracetamol. E-liquids seem to contribute towards domestic poisoning incidents but regulations, such as child safety caps, could limit this risk.

The clinical outcomes of exposures to e-liquids, as detailed in the NPIS report, were predominantly either ‘no toxicity’ or ‘mild toxicity’. There were two reported cases of ‘moderate toxicity’ and one ‘severe’ case that required treatment in an intensive care unit. Toxicity symptoms included conjunctivitis, irritation of the oral cavity, anxiety, vomiting, hyperventilation and changes in heart rate.

Fire

A number of news articles report the risk of fire and explosions from EC [147, 149, 152]. These reports suggest that faulty or incompatible chargers are the main causes of EC related fires along with faults relating to lithium batteries [152]. In order to assess the risks of fire we used the two data sources below:

1) In 2014, the BBC made Freedom of Information requests to UK fire services [153] and reported that there were 43 recorded call outs for fires related to EC in 2013 and 62 between 1 January 2014 and 15 November 2014. They added that call outs to EC related fires were rising in frequency. This report was based on responses from 43 out of 46 fire services in the UK [153, 154]
2) The official reporting statistics for the UK [155] do not specifically report EC as a cause of fire. There were 2,360 accidental fires between April 2013 and March 2014 where the source of ignition was “smokers’ materials” causing 80 fatalities and 673 non-fatal casualties. Additionally, there were 3,700 fires from faulty appliances and electrical leads causing 19 fatalities and 820 non-fatal casualties. It is not clear what proportion of these were caused by EC.

Regulations covering chargers and quality standards of production could help reduce the risk of fire and explosion in EC. An unpublished Department for Business, Innovation and Skills (BIS) funded market surveillance exercise in 2013/14 found that six out of 17 EC had no instructions for charging, and that eight out of 17 EC did not have a charging cut-off device and therefore did not meet the requirements of BS EN 62133:2013 ‘Safety requirements for portable sealed secondary cells and batteries for use in portable devices’[^4]. It seems likely that the risk of fire and electrical fault is similar to other domestic electrical products, indicating that EC should be subject to the same guidelines and safety mechanisms.

**Summary of findings**

There is a risk of fire from the electrical elements of EC and a risk of poisoning from ingestion of e-liquids. These risks appear to be comparable to similar electrical goods and potentially poisonous household substances.

**Policy implications**

- The risks from fire or poisoning could be controlled through standard regulations for similar types of products, such as childproof containers (contained within the TPD but which are now emerging as an industry standard) and instructions about the importance of using the correct charger.

- Current products should comply with current British Standard operating standards.

- Records of EC incidents could be systematically recorded by fire services.

12. International perspectives

Overview

Internationally, countries have taken a wide variety of approaches to regulating EC [156]. Current approaches range from complete bans on the sale of any EC, to applying existing laws on other products to EC (poison, nicotine, and/or tobacco laws), to allowing EC to be sold under general consumer product regulations. Similarly, within countries, different laws have also been applied at the state/provincial level, along with municipal by-laws, extending into areas including taxes on EC, and bans on use in places where smoking is banned. Furthermore, several nuances in laws exist, making it difficult to make broad statements about the regulations in a given country. This section focuses on presenting (1) studies that have compared the use of EC internationally across countries using representative samples and comparable methods, (2) a brief review of adolescent surveys internationally, and (3) the cases of Australia and Canada, two countries that have very similar tobacco control policies to the UK but very different policies relating to EC.

Use of e-cigarettes among adults internationally

Three studies have compared the use of EC internationally: (1) International Tobacco Control Project (described in the Methodology section), (2) Eurobarometer study and (3) Global Adult Tobacco Survey.

The International Tobacco Control Project compared EC use (use defined as less than monthly or more often) among smokers and ex-smokers across 10 countries [157]. Gravely et al., 2014 found significant variability in use across countries, but data were gathered across different years. Gravely et al., 2014 concluded that the study provided evidence of the rapid progression of EC use globally, and that variability was due partly to the year the survey was conducted, but also market factors, including different regulations on EC. Notably, EC use was highest in Malaysia at 14%, where a ban on EC was in place.

Two studies using secondary data from the 2012 Eurobarometer 385 survey have examined EC use. Vardavas, et al., 2014 [158] examined ever use (tried once or twice) of EC among smokers, ex-smokers and never smokers aged 15 years and over across 27 EU countries. The study found wide variation in ever EC use among smokers and non-smokers, with ever use varying from 20.3% among smokers, 4.4% among ex-smokers, and 1.1% among never smokers. Of those who had tried, 69.9% reported using EC once or twice, and 21.1% and 9% reported ever using or currently using occasionally or regularly (use or used regularly or occasionally). It is important to note that the question asked about ever using or currently using occasionally or regularly,
and thus would overestimate actual current use. Overall, being a smoker was the strongest predictor of ever using an EC, younger age was also predictive. Respondents who were uncertain about the harmfulness of EC were less likely to have tried an EC. Among current smokers, those who had a made a quit attempt in the past year were most likely to have ever used EC, along with heavier smokers. With regards to use as a smoking cessation aid, 7.1% of smokers who had ever made a quit attempt reported having used EC, compared to 65.7% who used no help, 22.5% who used nicotine replacement therapy, and 7.3% who received behavioural counselling. Geographical differences in EC use noted by the authors included higher ever use in Northern and Eastern Europe compared to Western Europe. The study did not go into detail on occasional or regular users of EC because the numbers were too low for any detailed analyses.

A 2012 study using the same Eurobarometer 385 survey data gave further detail on ever having used or currently using EC occasionally or regularly among smokers and non-smokers [63]. The study found that regular/occasional use was highest in Denmark at 4.2% and lowest in Lithuania and Portugal at 0.6%, and 2.5% in the UK [63].

The Global Adult Tobacco Survey [159] published findings on EC use in Indonesia (2011), Malaysia (2011), Qatar (2013) and Greece (2013) among smokers and non-smokers, the first countries with available data. Of those respondents who were aware of EC, they asked, “Do you currently use e-cigarettes on a daily basis, less than daily, or not at all?” and considered those who said they used ‘less than daily’ or ‘daily’ to be current EC users.

Overall, awareness of EC was highest in Greece (88.5%), followed by Qatar (49%), Malaysia (21%), and Indonesia (10.9%). Use of EC among smokers was highest in Malaysia (10.4%), followed by Qatar (7.6%), Indonesia (4.2%) and Greece (3.4%). Use of EC among non-smokers was highest in Greece (1.3%), followed by the other three countries, Malaysia (0.4%), Indonesia (0.4%) and Qatar (0.4%). Similar to findings from the ITC Project, these numbers are likely influenced by timing of the survey, due to the rapid progression of use of EC globally, and other market factors. Together with the findings from Gravely et al., 2014 [157] they show the rapid global progression of EC use across both high income and lower middle income countries.

**Use of e-cigarettes among youth internationally**

Whilst there are very few international or European studies which use consistent methodology, there is a rapidly growing body of research on the prevalence of EC use in young people at the country level, as well as reviews in this area [eg [160]]. However, much of this literature on EC use among adolescents is incomparable because of inconsistent measurements of use (confusing ever use, trial, current use), and different age ranges involved. In addition, many of the studies have been poorly reported. For
example, much has been made of the increase in EC observed in the US using the cross-sectional Centers for Disease Control & Prevention (CDC) National Youth Tobacco Surveys [161-163]. These reports and press coverage have been heavily criticised [164-166]. The most important feature of the NYTS data was the fall in smoking prevalence over the same period (as observed in the UK, France [167] and elsewhere).

The CDC findings indicated that past 30-day use of EC increased among middle and high school students. For example, the 2014 data indicated that among high school students use increased from 4.5% to 13.4% between 2013 and 2014. Among middle school students, current EC use increased from 1.1% in 2013 to 3.9% in 2014. However, cigarette smoking had continued to decline during this period (high school students: 15.8% to 9.2%; middle school students: 4.7 % to 2.5%) such that smoking was at a 22-year low in the US. These findings strongly suggest that EC use is not encouraging uptake of cigarette smoking.

Whilst most of the recent studies examining youth EC use emanated from North America, the common pattern emerging worldwide is of a very high awareness of EC and an increase in trial of these products among young people [168-178]. Nevertheless, estimates of prevalence of current use of EC vary widely with the highest being reported in Poland at around 30% [174] and Hawaii (29% tried, 18% current) [178]. Most other estimates indicate that a very small minority of youth, less than 3%, currently or recently used EC. Whilst EC experimentation is increasing, regular or current use of EC appears to be largely concentrated in those already smoking conventional cigarettes. The most recent Europe-wide data indicated that 1.1% of never-smokers aged 15 and above had ever tried an EC [158]. Yet little research has focused on how EC are being used among young people, with limited qualitative research studies in this area [179, 180]. Other findings relate to the influence of parents who smoke on EC experimentation in youth [eg [170] and associations between EC experimentation and other substance use [eg [170, 181]. Several studies have also found an association between EC use and openness to cigarette smoking [eg [182] or intentions to smoke cigarettes [eg [168].

The cases of Australia and Canada

Australia has applied existing laws on poisons, therapeutic goods, and tobacco products to EC. Very broadly speaking, the current laws in Australia have resulted in a ban on the sale and importation of EC with nicotine (although there is a mechanism for legal import as an unapproved medicine with a doctor’s prescription). There are no national level prevalence data on EC use in Australia available at this time. One study comparing trends in awareness, trial, and use of EC among nationally representative samples of smokers and ex-smokers (use defined as less than monthly or more often) in Australia and the UK in 2010 and 2013 found reported EC use in Australia in 2013 at 6.6% and use in the UK at 18.8% [183]. Although the use of EC was found to be
significantly lower in Australia than in the UK in 2013, the use of EC increased at the same rate in Australia and the UK between 2010 and 2013 [183].

**Canada** took a similar approach to regulating EC as Australia by prohibiting the sale of EC with nicotine through existing laws. However, a recent House of Commons report stated that the current regulatory approach was not working to restrict access to EC with nicotine [184]. Canada has now put forward recommendations to develop a new legislative framework for EC that would most likely allow the sale of EC with nicotine [184]. There has been only one population-level survey of EC use in Canada. The 2013 Canadian Tobacco, Alcohol and Drugs Survey (CTADS) of Canadians 15 years and older found that 9% had ever tried an EC, with trial being higher among young people aged 15–19 years at 20% [185]. Use in the past 30 days was lower at 2%, with past 30 day use being higher among young people aged 15–19 years at 3%. Of those who tried an EC, 55% stated the EC did not contain nicotine, while 26% reported it did contain nicotine, with 19% reporting uncertainty. Whether the EC they tried contained nicotine is uncertain given (1) the ban on the sale of EC with nicotine, and (2) reports that many EC sold and bought in Canada are labelled as not containing nicotine but actually contain nicotine [184]. Although it is difficult to make comparisons due to different survey methods and questions, the percentage of young people (15–19 years) who have tried EC in Canada (20%) is roughly similar to the percentage who have tried EC in GB in 2014 (reported at 8%, 15%, 18%, and 19%, for ages 15 to 18, respectively).

**Summary of findings**

Although EC use may be lower in countries with more restrictions, these restrictions have not prevented EC use. Overall, use is highest among current smokers, with low numbers of non-smokers reporting ever use. Current use of EC in other countries is associated with being a smoker or ex-smoker, similar to the findings in the UK. EC use is frequently misreported, with experimentation presented as regular use. Increases in youth EC trial and use are associated with decreases in smoking prevalence in all countries, with the exception of one study from Poland.

**Policy implications**

- Future research should continue to monitor and evaluate whether different EC policies across countries are related to EC use and to smoking cessation and smoking prevalence.

- Consistent and agreed measures of trial, occasional and regular EC use among youth and adults are urgently needed to aid comparability.
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Declaration of interests

Professor Ann McNeill leads the Nicotine Research Group at the Institute of Psychiatry, Psychology & Neuroscience (IoPPN), King’s College London (KCL). She is a Deputy Director of the UK Centre for Tobacco and Alcohol Studies (UKCTAS), President-Elect of the Society for Research on Nicotine and Tobacco European Chapter and a member of the Royal College of Physicians tobacco advisory group. She is a trustee of the Society for the Study of Addiction, a Member of the Board of Tobacco Free Futures and of the Advisory Council of Action on Smoking and Health, and Senior Editor for the journal Addiction. She has no financial or other conflicts of interest and no links with any tobacco or e-cigarette manufacturers.

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Robert Calder is a research assistant and PhD student at the IoPPN, KCL, and has no financial or other conflicts of interest and no links with any tobacco or e-cigarette manufacturers.

Dr Sara Hitchman is a Lecturer in Addictions in the Nicotine Research Group, IoPPN, KCL and a member of the UKCTAS. She has no financial or other conflicts of interest and no links with any tobacco or e-cigarette manufacturers.

Professor Peter Hajek is director of Health and Lifestyle Research Unit at Wolfson Institute of Preventive Medicine, Queen Mary University of London (QMUL). He provided consultancy to and received research funding from manufacturers of stop-smoking medications including Pfizer, GSK and Johnston and Johnston. His research into safety and effects of e-cigarettes was funded by MHRA and NIHR. He has no links with any tobacco or e-cigarette manufacturers.

Dr Hayden McRobbie is a researcher at QMUL and Director of the Dragon Institute for Innovation (New Zealand), which has no links with any tobacco or e-cigarette manufacturers. He contributed to educational sessions sponsored by Pfizer and Johnson & Johnson, manufacturers of stop-smoking medications, and received investigator-led research funding from Pfizer. He was an investigator on a study of e-cigarettes (EC) produced by Ruyan Group, Beijing and Hong Kong. Ruyan sponsored Health New Zealand Ltd. who provided funding to the University of Auckland to conduct the trial, independently of Ruyan. He was also an investigator on an EC trial funded by the Health Research Council of New Zealand that used EC supplied at no charge by PGM international, a retailer of EC.

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References

E-cigarettes: an evidence update


25. Wise, J., *Children are three times as likely to try e-cigarettes as tobacco products, study finds*. BMJ, 2014. 349: p. g7508.


E-cigarettes: an evidence update


71. Shawl, L. and L.S. Nelson, *Smoking cessation can be toxic to your health.* EMERGeNCy MEDICInE, 2013.


76. Christensen, L.B., T. van't Veen, and J. Bang. Three cases of attempted suicide by ingestion of nicotine liquid used in e-cigarettes. in Clinical Toxicology. 2013. INFORMA HEALTHCARE 52 VANDERBILT AVE, NEW YORK, NY 10017 USA.


126. Farsalinos, K.E., et al., Evaluating nicotine levels selection and patterns of electronic cigarette use in a group of “vapers” who had achieved complete substitution of smoking. Substance abuse: research and treatment, 2013. 7: p. 139.


140. Farsalinos, C., E-cigarette aerosols generates high levels of formaldehyde only in ‘dry puff’ conditions. Addiction, (in press).


167. Houezec, J., According to a new survey, youth smoking decreased during the last 4 years while e-cig used increased. 2014.


APPENDIX A: PRISM Flow Diagram

Records identified through database searching (n = 3459)

Additional records identified through other sources (n = 1)

Records after duplicates removed (n = 3453)

Records screened by title

Records excluded by title

Records screened by abstract (n = 446)

Records excluded by abstract (n = 336 (+16 foreign language or abstract missing))

Full-text articles assessed for eligibility (n = 94)

Additional reports, news stories etc (n = 10)

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Please note that we did not carry out a full systematic review for this report but followed systematic review methods. We assessed 94 papers and 9 additional reports included those that were relevant to our objective of describing the use of e-cigarettes and how they impact smoking behaviour, with a particular focus on the UK.
APPENDIX B: Measures of e-cigarette use

Measures of EC use in studies referenced, in most cases respondents were only asked about EC use if they first answered yes to ever trying an EC/had heard of EC.

Surveys

These questions in all surveys below may have been slightly altered from year to year as the EC market evolved and awareness grew.

Smoking Toolkit Study (STS)

The following four questions are used to assess current use of e-cigarettes: (if already responded they are cutting down)

Q632e37. Which, if any, of the following are you currently using to help you cut down the amount you smoke?
Nicotine gum
Nicotine replacement lozenges\tablets
Nicotine replacement inhaler
Nicotine replacement nasal spray
Nicotine patch
Electronic cigarette
Nicotine mouthspray
Other (specify)

Q632e1. Do you regularly use any of the following in situations when you are not allowed to smoke?
Nicotine gum
Nicotine lozenge
Nicotine patch
Nicotine inhaler\inhalator
Another nicotine product
Electronic cigarette
Nicotine mouthspray
Other (specify)

NEWW53a. Can I check, are you using any of the following either to help you stop smoking, to help you cut down or for any other reason at all?

Nicotine gum
Nicotine lozenge
Nicotine patch
Nicotine inhaler/inhalator
Another nicotine product
Electronic cigarette
Nicotine mouthspray
Other (specify)

QIMW86_1. Can I check, are you using any of the following?
PROBE FULLY: Which others? PROBE UNTIL RESPONDENT SAYS ‘NO OTHERS’
PLEASE TYPE IN OTHER ANSWERS CAREFULLY AND USE CAPITAL LETTERS
Nicotine gum
Nicotine lozenge
Nicotine patch
Nicotine inhaler/inhalator
Another nicotine product
Electronic cigarette
Nicotine mouthspray
Other (specify)

ASH Smokefree GB adult survey

Which of the following statements BEST applies to you?
  o I have heard of e-cigarettes and have never tried them
  o I have heard of e-cigarettes but have never tried them
  o I have tried e-cigarettes but do not use them (anymore)
  o I have tried e-cigarettes and still use them
  o Don’t know

The fourth option constitutes ‘current use’

ASH Smokefree GB youth survey

An e-cigarette is a tube that looks like a normal cigarette, has a glowing tip and puffs a vaour that looks like smoke but unlike normal cigarettes, they don’t burn tobacco.
Have you ever heard of e-cigarettes?
  o Yes, I have
  o No, I haven’t

All those who have heard of e-cigarettes: Which one of the following is closest to describing your experience of e-cigarettes?
  o I have never used them
  o I have tried them once or twice
  o I use them sometimes (more than once a month)
I use them often (more than once a week)
Don’t want to say

Internet cohort survey

Have you ever heard of electronic cigarettes or e-cigarettes? These are electronic devices that contain nicotine in a vapour and are designed to look like cigarettes, but contain no tobacco.
Yes/No/Don’t know

If Yes, Have you ever tried an electronic cigarettes?
Yes/No/Don’t know

If Yes, How often if at all, do you currently use an electronic cigarette? (PLEASE SELECT ONE OPTION)
1. Daily
2. Less than daily, but at least once a week
3. Less than weekly, but at least once a month
4. Less than monthly
5. Not at all
6. Don’t know

Other studies

Amrock et al., 2015 (US)

Which of the following tobacco products have you ever tried, even just one time?” to which they could select, “electronic cigarettes or e-cigarettes, such as Ruyan or NJOY” alongside other tobacco products. A related question asked if students used e-cigarettes on at least one of the past 30 days.

Biener & Hargraves, 2014 (US)

At baseline, three questions were asked about e-cigarettes: whether the respondent had “ever heard of electronic cigarettes, also known as e-cigarettes”; if so, whether he/she had ever used an e-cigarette even one time, and if so, on how many of the past 30 days the respondent had used an e-cigarette. To assess how intensively and for how long the respondent had used e-cigarettes during the period between interviews, the follow-up interviews included questions to describe e-cigarette usage. Those who were not aware of e-cigarettes at baseline were asked if they had heard of them at follow-up. Those who had not tried e-cigarettes at baseline were asked if they had done so by follow-up. All respondents who reported ever trying them by follow-up were asked
whether they currently used e-cigarettes every day, some days or not at all. If not at all, they were asked if they ever used e-cigarettes “fairly regularly.” If not, whether they had used only once or twice or more often than that. All who had used more than once or twice, were asked a series of questions about their patterns of use: for how long they had used e-cigarettes (less than a month, 1–6 months, more than 6 months); whether they had ever used e-cigarettes daily for at least one week; if so for how long they had used e-cigarettes daily. From these variables, a 3-level measure of intensity of e-cigarette usage was computed: 3 = intensive (used daily for at least 1 month); 2 = intermittent (more than once or twice but not daily for a month or more); 1 = non-use or at most once or twice.

Borderud et al., 2014 (US)

Patients were asked if they had used E-cigarettes within the past 30 days, with the response options being yes or no.

Brose et al, 2015 and Hitchman et al., 2015 (GB)

How often, if at all, do you currently use an electronic cigarette? [Asked of respondents who had ever heard of e-cigarettes and had ever tried one.]
1. Daily
2. Less than daily, but at least once a week
3. Less than weekly, but at least once a month
4. Less than monthly
5. Not at all
6. Don't know

What electronic cigarette equipment do you currently use the most?
1. A disposable electronic cigarette (non-rechargeable)
2. A commercial electronic cigarette kit which is refillable with pre-filled cartridges
3. A commercial electronic cigarette kit which is refillable with liquids
4. A modular system (I use my own combination of separate devices: batteries, atomizers, etc.)
5. Don't know

Brown et al., 2014 (England)

Which, if any, of the following did you try to help you stop smoking during the most recent serious quit attempt?
1. E-cigarettes
2. NRT bought over-the-counter
3. No aid
Canadian Tobacco, Alcohol and Drugs Survey 2013 (CTADS)

Trial
Have you ever tried an electronic cigarette, also known as an e-cigarette?
1. Yes
2. No
3. Refused
4. Don’t know

Last 30 day use
In the past 30 days did you use an electronic cigarette, also known as an e-cigarette?
1. Yes
2. No
3. Refused
4. Don’t know

CDC/NYTS and Dutra and Glantz

During the past 30 days, on how many days did you use electronic cigarettes or e-cigarettes such as Blu, 21st Century Smoke, or NJOY?

Gravely et al., 2014 (Republic of Korea, US, UK, Canada, Australia, and Malaysia); Yong et al., 2014 (UK and Australia)

How often, if at all, do you currently use an electronic cigarette? (dichotomised into current use and non-current by combining any use responses vs. not at all)
1. Daily, Less than daily but at least once a week
2. Less than weekly but at least once a month
3. Less than monthly
4. Not at all

Gravely et al., 2014 (Netherlands)

How often do you currently use an electronic cigarette? (dichotomised into current use and non-current by combining any use responses vs. have you stopped altogether)
1. Daily
2. Less than daily, but at least once a week
3. Less than weekly, but at least once a month
4. Less than monthly versus, or
5. Have you stopped altogether?
Gravely et al., 2014 (China)

Are you currently using an electronic cigarette at least weekly? (Yes vs. No)
   1. Yes
   2. No

Hughes et al., 2014 (Trading Standards NW Study)

“Have you ever bought or tried electronic cigarettes?”

Hummel et al., 2014 (Netherlands)

Respondents who had ever tried e-cigarettes were asked how often they currently used an e-cigarette (daily, at least once a week, at least once a month, less than monthly, or stopped altogether)

Lee et al., 2014 (US)

E-cigarette use questions were:

Have you ever used e-cigarettes?
   1. yes
   2. no

Have you used e-cigarettes in the past 30 days?
   1. yes
   2. no

Moore et al., 2014 (Welsh study 10-11 year olds)

“Have you heard of e-cigarettes before this survey?”
‘Have you ever used an e-cigarette? with response options of ‘no’, ‘yes, once’ or ‘yes, more than once’

Moore et al., 2015 (Welsh study HBSC)

Asked whether they had ever used an e-cigarette with response options of:
   o I have never used or tried e-cigarettes
   o I have used e-cigarettes on a few occasions (1-5 times);
   o I regularly use e-cigarettes (at least once a month)’.
Palipudi et al., 2015 (Global Adult Tobacco Survey)

“Do you currently use e-cigarettes on a
1. Daily basis,
2. Less than daily,
3. Or, not at all?”

Pearson et al., 2014 (US)

Participants were asked which methods they had used to quit in the past 3 months and were presented a list of common quit methods. Participants were considered e-cigarette users if they selected “e-cigarettes” in response to this question or if they entered terms like “vapors,” “vaping,” “vape,” or “ecigs” in the “other quit methods” open-ended response option.

Pepper et al., 2014 (US)

Have you ever used an e-cigarette, even one puff?
Do you now use e-cigarettes every day, some days, or not at all?

Richardson et al., 2014 (US)

Please indicate whether you have ever heard of these products, if you have ever tried them and if you have ever purchased them. Products included ENDS; dissolvables; chew, dip, or snuff (assessed in 1 question); and snus, each presented with brand names to increase validity of responses. Respondents could choose multiple options from the following choices: (1) heard of; (2) tried; (3) purchased; (4) never heard of, tried, or purchased (for those to whom options 1, 2, and 3 were not applicable); (5) refused; and (6) don’t know.

Rutten et al., 2014 (US)

Do you now use e-cigarettes (eg BluCig, NJoy, V2, Red Dragon, etc)? [Picture of three different e-cigarettes included]
1. Every day
2. Some days
3. Not at all
Schmidt et al., 2014 (US)

Have you ever used an electronic cigarette, even just one time in your entire life? Do you now use electronic cigarettes every day, some days, rarely, or not at all?

Vardavas et al., 2014 (Eurobarometer 27 countries), dichotomised into regularly, occasionally, tried once or twice vs. otherwise; Agaku et al., 2014 (Eurobarometer, 25 countries), dichotomised into regularly or occasionally vs. otherwise;

Have you ever tried any of the following products? (Electronic cigarettes)
   1. Yes, you use or used it regularly.
   2. Yes, you use or used it occasionally.
   3. Yes, you tried it once or twice.
   4. No.
   5. Don’t Know.

White et al., 2015, New Zealand national youth tobacco use survey in 2012 and 2014

Ever use: Have you ever tried electronic cigarettes?
Appendix C: Narrative summary of studies on nicotine delivery from e-cigarettes

Early studies

Two studies, both published in 2010, examined nicotine delivery from cigalike EC.

Bullen et al., 2010 used a cross-over design to compare nicotine delivery of a 16mg/ml Ruyan V8 EC with a 0mg/ml EC, a nicotine inhalator (10mg) and a conventional cigarette among 8 smokers who abstained from smoking overnight [43]. Participants puffed on their cigarettes and EC ad libitum over 5 minutes, and on the inhalator over 20 minutes. The nicotine containing EC had similar pharmacokinetic parameters to the inhalator (Cmax: 1.3 vs. 2.1 ng/ml; Tmax: 19.6 vs. 32.0 mins), and both were outperformed by a conventional cigarette (Cmax 13.4 ng/ml; Tmax 14.3 mins).

Vansickel et al., 2010 also used a cross-over design and tested nicotine delivery of two EC (NJOY EC (18mg) and Crown 7 EC (16mg) and participants own brand cigarette[118]. Participants abstained overnight and then took 10 puffs on the EC with a 30 sec inter-puff interval. Only the conventional cigarette produced a significant rise in plasma nicotine, from baseline 2.1 ng/ml (SD 0.32) to a peak at 5 minutes 18.8 ng/ml (SD 11.8).

The poor nicotine delivery of these EC was likely to be due to several factors. The EC tested were some of the first to market. The EC used in the Bullen 2010 study were noted to leak and the vaporising component did not always function. Both of these early studies recruited EC naïve smokers, without opportunity to practice using the EC prior to experimentation.

There are other factors that are associated with nicotine delivery, which we have summarised below.

1) More intensive vaping regimens

Vansickel et al., examined nicotine delivery associated with the use of Vapor King (cigalike EC with 18mg/ml nicotine) in 20 smokers naïve to EC [119]. After overnight abstinence, participants used the EC for 5 minutes on a total of six occasions (10 puffs, 30 sec inter-puff interval) 30 minutes apart. A significant increase in plasma nicotine was observed after the fourth bout of puffing, and mean blood nicotine levels had increased from 2.2 ng/ml (SD 0.78) at baseline to 7.4 ng/ml (SD 5.1) at the end of the last bout of puffing.

2) Experience with EC

Vansickel & Eissenberg (2012) report nicotine pharmacokinetics in eight vapers who had been using EC for average of 11.5 (SD 5.2) months [7]. They used their own EC and e-liquid (the majority used an e-liquid with a concentration of 18 mg/ml).
Participants attended the laboratory after overnight abstinence and used their EC under a standardised vaping regimen (10 puffs with a 30 second inter-puff interval) and then a 60 minutes period of *ad lib* vaping. The PK analyses showed a significant increase in plasma nicotine from baseline 2.0 ng/ml to 0.3 ng/ml within five minutes of the first puff. At the end of the ad-lib vaping period the maximum plasma nicotine concentration was 16.3 ng/ml.

Dawkins and Corcoran (2014) examined nicotine delivery associated with the used of the Skycig 18 mg Crown tobacco bold cartridges in 14 vapers, who had been vaping for almost 5 months on average[6]. Using a similar methodology to Vansickel & Eissenberg (2012), the analysis of plasma nicotine from the seven participants that provided a full blood set, showed that levels had increased from 0.74 to 6.77 ng/ml in 10 minutes. However there was individual variation (2.5 ng/ml to 13.4 ng/ml). After an hour of *ad lib* use the maximum nicotine concentration reached was 13.91 ng/ml, again with a wide range of levels observed between individuals (4.35-25.6 ng/ml).

Spindle et al., 2015 studied 13 experienced EC users (> 3 months, with the majority 9/13 using e-liquid strength of 24mg/ml and all using tank systems)[120]. Taking 10 puffs over 5 minutes resulted in an increase in mean blood nicotine levels from 2.4 ng/ml baseline to 19.2 ng/ml at 5 minutes.

Practice in EC use also results in a modest increase in blood nicotine levels. Hajek et al., 2014 tested Greensmoke EC (a cigalike EC with 2.4% nicotine) in 40 smokers, naïve to EC[115]. Participants abstained from any nicotine use overnight and after a baseline blood sample was collected used the EC, *ad lib*, for 5 minutes. This procedure was undertaken twice, on first use and then again after 4 weeks of use. The maximum plasma concentrations increased from 4.6 ng/ml (range 0.9-9.0) to 5.7 ng/ml (range 1.9-11.0), although this increase was not significant. The area under the curve (AUC), however, did show a significant increase, from 96 (range 12-198) to 142 (range 56-234). The time to maximum plasma concentration (5 minutes) did not change.

Nides et al., 2014 provided EC to participants (29 smokers, mean cigarette consumption of 20 cpd, and of 55% of whom had used EC in past) but also allowed them to practice using the EC (NJOY®King Bold, a cigalike EC, with 26mg nicotine) for a week prior to undertaking a PK analysis [116]. Participants (who abstained from all nicotine products for at least 12 hours) then were asked to use EC (10 puffs with a 30 second inter-puff interval) on two occasions 60 minutes apart. Pharmacokinetic (PK) analyses were undertaken in 16 participants who had no detectable plasma nicotine at baseline. The mean rise in blood nicotine was 3.5 ng/ml (range 0.8-8.5 ng/ml) at 5 minutes after the first round of puffing and 5.1 ng/ml (range 1.1 – 7.1 ng/ml) at 10 minutes after the second.
3) Nicotine concentration and chemical composition of e-liquid
Yan & D’Ruiz (2014) examined nicotine delivery from Blu cigalike EC with differing levels of nicotine (2.4% and 1.6%), glycerin/propylene glycol (75% glycerin and 50% glycerin/20% propylene glycol), and flavours (classic tobacco and menthol)[129]. Participants (23 smokers) were randomized to 5 different EC conditions and smoking a regular cigarette in a cross over design. They were given 7 days to familiarize with EC use, and then abstain from all nicotine products for 36 hours prior to test days. On test days participants were asked to take 50 x 5 second puffs on EC at 30 sec intervals (in the cigarette arm they smoked 1 cigarette with usual puff duration at 30 sec intervals). After the controlled puffing testing ppts were allowed 60 minutes of ad lib use.

Peak plasma nicotine concentrations were reached sooner for cigarettes (5 minutes) than for EC (30 minutes). During the 30 minutes controlled puffing phase, within EC conditions the highest Cmax was seen with the 2.4% nicotine, 50% glycerin/20% PG (18.09 ng/ml, SD=6.47 ng/ml). The lowest Cmax was observed in the 1.6% nicotine, 75% glycerine (10.34 ng/ml SD=3.70 ng/ml). The Cmax associated with smoking one conventional cigarette was 15.84 ng/ml (SD = 8.64 ng/ml). At the end of the ad lib period, the highest Cmax was seen with the conventional cigarette (29.23 ng/ml SD = 10.86 ng/ml), followed by the 2.4% nicotine, 50% glycerin/20% PG EC (22.42 ng/ml; SD = 7.65ng/ml). The glycerine/PG mix resulted in better nicotine delivery than the 75% glycerine solution, which was confirmed in the bench top tests that measured nicotine content in vapour using the Canadian Intense regimen. The high nicotine content in vapour is a likely consequence of the lower boiling point of PG (187.6 degrees Celsius) compared with glycerine (290 degrees Celsius).

4) Type of EC device
Although many vapers start off with using a cigalike EC experienced vapers are more likely to be using tank systems or variable power EC. One of the reasons for this observation is that the tank systems and variable power ECs deliver nicotine more nicotine to the user.

Farsalinos et al., (2014) examined plasma nicotine levels in experienced vapers (n=23) who used a cigalike (V2 with cartomiser) and a new generation (EVIC set at 9 watts with EVOD atomizer) EC with standardized flavour and nicotine concentration (18mg/ml) in a cross-over design[129]. Participants’ abstained from EC use for at least 8 hours before completing a bout of 10 puffs over 5 minutes followed by one hour of ad lib use. Use of the cigalike EC was associated with an increase in blood nicotine from 2.80 ng/ml at baseline, to 4.87 ng/ml at 5 minutes and 15.75 ng/ml at the end of ad lib use. Significantly greater increases were observed with use of the new generation EC from 2.46 ng/ml to 6.59 ng/ml to 23.47 ng/ml at baseline, 5 minutes and at the end of the ad lib period.
Oncken et al., (2015) also examined nicotine delivery in a tank system EC (Joye eGo-C with 18 mg/ml nicotine e-liquid) in 20 smokers who were asked to use an EC for two weeks[123]. Participants were asked to use the EC for 5 minutes ad lib in two laboratory sessions where blood samples were taken for PK analysis. Blood nicotine concentrations increased, significantly, by 4 ng/ml (Cmax 8.2 ng/ml) at the first session and 5.1 ng/ml (Cmax 9.3 ng/ml) at the second session. These levels were reached at five minutes.

Studies that examine cotinine as a measure of nicotine replacement in vapers

We found eight studies that reported on cotinine in urine, blood or saliva as a marker of nicotine exposure in people using EC.

In an RCT of nicotine containing EC versus placebo Caponnetto and colleagues (2013) measured salivary cotinine in participants who had stopped smoking cigarettes, but were still vaping EC (Categoria 7.5mg/ml)[40]. After 12 weeks of use the mean salivary cotinine concentration was 67.8 ng/ml, which is at the lower end of what is typically observed in smokers (eg 66.9-283.7 ng/ml).

In a study that randomised 48 smokers unwilling to quit to one of two tank system EC (18mg/ml nicotine) or to continue to smoke found that at 8 month follow-up mean salivary cotinine did not significantly differ between those who had stopped smoking but were vaping (428.27 ng/ml), achieved a ≥50% reduction in cigarette consumption (356.49 ng/ml) and those who continued to smoke (545.23 ng/ml, SD = 46.32)[41].

Van Staden et al., (2013) examined the change in serum cotinine in 13 smokers who were asked to stop smoking and instead use a Twisp eGo (18mg/ml nicotine) tank system EC for two weeks[113]. There was a significant decrease in cotinine from baseline 287.25 ± 136.05 to two weeks 97.01 ± 80.91 ng/ml suggesting that the EC used did not provide as much nicotine as participants usual cigarettes.

Norton et al., (2014) observed a similar result in 16 abstinent smokers who used a cigalike EC (11 mg/ml) for five days, finding a significant decrease in saliva cotinine between baseline (338.0 ng/ml) and day five (178.4 ng/ml)[112].

Flouris et al., (2013) measured serum cotinine in 15 smokers, who had abstained overnight, after smoking two of their usual cigarettes over 30 minutes and after 30 minutes of vaping a cigalike EC (Giant, 11mg/ml)[130]. EC and cigarettes produced similar effects on serum cotinine levels (60.6 ± 34.3 versus 61.3 ± 36.6 ng/ml). However measurement of cotinine would not give an accurate indicator of exposure in an acute study such as this.
Experienced vapers, using their own devices, however obtain much better nicotine substitution. Etter and Bullen (2011) measured salivary cotinine concentrations in 30 vapers who had been using EC for approximately 3 months on average and no longer smoking[9]. The mean nicotine content of e-liquid was 18mg/ml. Mean salivary cotinine was found to be 322 ng/ml indicating a high level of nicotine replacement via EC.

Similarly Etter (2014) found mean cotinine levels of 374 ng/ml (95% CI: 318-429) in 62 vapers who had not used any other nicotine containing products in the last 5 days [8].

Hecht et al., 2014 measured nicotine and cotinine in urine of 28 EC users (median use of 9 months, using tank system EC with e-liquid containing, on average 12.5 ± 7.0 mg/ml)[111]. Nicotine and cotinine levels in urine were 869 ng/ml (95% CI: 604-1250) and 1880 ng/ml (95% CI: 1420-2480) respectively, although these levels are lower than what are typically observed in smokers (eg nicotine 1380 ng/ml 95% CI: 1190-1600 and cotinine 3930 ng/ml; 95% CI: 3500-4400).
Nicotine without smoke
Tobacco harm reduction
A report by the Tobacco Advisory Group of the Royal College of Physicians

April 2016
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The Royal College of Physicians
The Royal College of Physicians (RCP) plays a leading role in the delivery of high-quality patient care by setting standards of medical practice and promoting clinical excellence. The RCP provides physicians in over 30 medical specialties with education, training and support throughout their careers. As an independent charity representing 32,000 fellows and members worldwide, the RCP advises and works with government, patients, allied healthcare professionals and the public to improve health and healthcare.

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The Royal College of Physicians (RCP) exists to improve the care of individual patients, and the health of the population. As tobacco smoking generates more illness and premature death than any other avoidable cause, preventing smoking has been a high priority for the RCP since the health harm of smoking was first recognised over 60 years ago. In the more than 50 years since our first report, *Smoking and health*, in 1962, we have argued consistently for more and better policies and services to prevent people from taking up smoking, and help existing smokers to quit.

Smoking is far less prevalent today than it was in 1962, but remains common, particularly among more disadvantaged individuals in our society. There are still almost nine million smokers in the UK, half of whom will die prematurely unless they quit. The evidence in this report demonstrates sustained progress over recent decades in preventing young people from becoming smokers, but also shows that much more must be done to increase the number of existing smokers who succeed in stopping smoking.

In 2007 the RCP published a report, *Harm reduction in nicotine addiction*, which argued for the application of harm-reduction strategies to tobacco dependence. We suggested that making effective, affordable, socially acceptable, low-hazard nicotine products available to smokers as a market alternative to tobacco could generate significant health gains, by allowing smokers to stop smoking tobacco, without having to stop using the nicotine to which they are addicted. Our report was published just as the prototypes of a new consumer alternative to tobacco, the electronic cigarette (e-cigarette), were first appearing on the UK market.

The rapid growth in use of e-cigarettes by smokers since 2007 demonstrates that many smokers want reduced-harm products, and it is also clear that many smokers have succeeded in quitting simply by substituting electronic for tobacco cigarettes. However, e-cigarettes have also proved to be highly controversial, attracting much criticism as well as support within medicine and public health, and indeed in wider society.
Tobacco harm reduction

This report therefore aims to provide a fresh update on the use of harm reduction in tobacco smoking, in relation to all non-tobacco nicotine products but particularly e-cigarettes. It concludes that, for all the potential risks involved, harm reduction has huge potential to prevent death and disability from tobacco use, and to hasten our progress to a tobacco-free society. With careful management and proportionate regulation, harm reduction provides an opportunity to improve the lives of millions of people. It is an opportunity that, with care, we should take.

Professor Jane Dacre
President, Royal College of Physicians
## Abbreviations

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<th>Abbreviation</th>
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<tr>
<td>ASA</td>
<td>Advertising Standards Authority</td>
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<td>ASH</td>
<td>Action on Smoking and Health</td>
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<td>BAT</td>
<td>British American Tobacco</td>
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<td>BSI</td>
<td>British Standards Institute</td>
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<td>CO</td>
<td>carbon monoxide</td>
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<tr>
<td>COP</td>
<td>FCTC Conference of the Parties</td>
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<td>COPD</td>
<td>chronic obstructive pulmonary disease</td>
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<td>CTADS</td>
<td>Canadian Tobacco, Alcohol and Drugs Survey</td>
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<td>CYP2A6</td>
<td>cytochrome P450 2A6 enzyme</td>
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<tr>
<td>e-cigarette</td>
<td>electronic cigarette</td>
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<td>ECITA</td>
<td>Electronic Cigarette Industry Trade Association</td>
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<td>EFTA</td>
<td>European Free Trade Association</td>
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<td>ENDS</td>
<td>electronic nicotine delivery system</td>
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<td>EU</td>
<td>European Union</td>
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<td>FCA</td>
<td>Framework Convention Alliance</td>
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<td>Framework Convention on Tobacco Control</td>
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<td>FDA</td>
<td>US Food and Drug Administration</td>
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<td>FMO3</td>
<td>flavin-containing monooxygenase 3</td>
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<td>GABA</td>
<td>γ-aminobutyric acid</td>
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<td>GRPs</td>
<td>gross rating points</td>
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<td>Health Action Zones</td>
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<td>Institute for Global Tobacco Control</td>
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<td>ITC</td>
<td>International Tobacco Control policy evaluation project</td>
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<td>MAO</td>
<td>monoamine oxidase</td>
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<td>Medicines Control Agency</td>
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<td>UK Medicines and Healthcare products Regulatory Agency</td>
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<td>MMC</td>
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<tr>
<td>MPOWER</td>
<td>Monitor, Protect, Offer, Warn, Enforce, Raise</td>
</tr>
<tr>
<td>nAChR</td>
<td>nicotinic acetylcholine receptor</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute for Health and Care Excellence</td>
</tr>
<tr>
<td>NMR</td>
<td>nicotine metabolite ratio</td>
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<tr>
<td>NNN</td>
<td>N′-nitrosonornicotine</td>
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### Tobacco harm reduction

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tr>
<td>NNS</td>
<td>nicotine nasal spray</td>
</tr>
<tr>
<td>NO</td>
<td>nitric oxide</td>
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<tr>
<td>NRT</td>
<td>nicotine replacement therapy</td>
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<tr>
<td>ONS</td>
<td>Office for National Statistics</td>
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<tr>
<td>PET</td>
<td>positron emission tomography</td>
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<tr>
<td>PHE</td>
<td>Public Health England</td>
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<tr>
<td>PMI</td>
<td>Philip Morris International</td>
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<tr>
<td>RCP</td>
<td>Royal College of Physicians</td>
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<tr>
<td>SALSUS</td>
<td>Schools Adolescent and Lifestyle and Substance Use Survey</td>
</tr>
<tr>
<td>SES</td>
<td>socio-economic status</td>
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<td>SHARE</td>
<td>Smoking Harm Reduction Education Programme</td>
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<td>SHS</td>
<td>second-hand smoke</td>
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<td>SPECT</td>
<td>single-photon emission computed tomography</td>
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<td>SSS</td>
<td>Stop Smoking Service</td>
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<tr>
<td>STS</td>
<td>Smoking Toolkit Study</td>
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<tr>
<td>TAPA</td>
<td>UK Tobacco Advertising and Promotion Act 2002</td>
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<td>TPD</td>
<td>EU Tobacco Products Directive</td>
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<tr>
<td>TSNAs</td>
<td>tobacco-specific nitrosamines</td>
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<tr>
<td>UGT</td>
<td>uridine diphosphate (UDP) glucuronosyltransferase</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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Harm reduction is a strategy used in medicine and social policy to minimise harm to individuals and/or wider society from hazardous behaviours or practices that cannot be completely avoided or prevented. Examples include providing clean needles and syringes to intravenous drug users to reduce the risk of infection, promoting condom use by sex workers, drink-driving laws, protective clothing in sport, and motor vehicle safety measures and emission controls. Sometimes by appearing to condone or perpetuate hazardous behaviours that could in theory be prevented, harm-reduction approaches can be controversial, particularly in medicine. To their proponents, however, they represent pragmatic solutions to a range of otherwise intractable causes of avoidable death and disability.

Tobacco smoking is addictive and lethal. Half of all lifelong smokers in the UK die as a direct consequence of their smoking, and smokers lose an average of about 3 months of life expectancy for every year smoked after the age of 35; in sustained smokers this amounts to a total loss of around 10 years of life. Tobacco smoking harms others, through passive exposure of both adults and children to exhaled and sidestream smoke, while smoking in pregnancy impairs fetal growth and development, in some cases to the point of fetal death. Tobacco smoking causes fires and litter, reduces economic productivity and social engagement, and exacerbates poverty. Together these effects make smoking responsible for more loss of quality and quantity of life in the UK than any other avoidable cause. As smoking is strongly related to social disadvantage, the burden of ill health caused by smoking falls particularly on the most disadvantaged individuals, making smoking the largest cause of social inequalities in health in the UK.

Smoking is completely preventable, yet, more than half a century after the health harm of smoking first became widely known, almost 1 billion people worldwide still smoke. They do so primarily because they are addicted to the nicotine in tobacco smoke and, as this addiction can be extremely difficult to overcome, many will continue to smoke until they die. Conventional tobacco control policies, embodied in the World Health Organization’s (WHO’s) Framework Convention on Tobacco Control (FCTC) and MPOWER policy framework
(Monitor tobacco use and prevention policies, Protect people from tobacco smoke, Offer help to quit tobacco use, Warn about the dangers of tobacco, Enforce bans on tobacco advertising, promotion and sponsorship, and Raise taxes on tobacco)\textsuperscript{12} aim to prevent the uptake of smoking and to help as many existing smokers to quit as possible. These approaches have contributed to a 50% reduction in UK smoking prevalence in the past 35 years,\textsuperscript{13} as well as increasing global success in smoking prevention.\textsuperscript{9,14} However, although smoking prevalence in the UK is now down to 18%,\textsuperscript{15} this figure translates into around 8.7 million current smokers\textsuperscript{16,17} sustaining significant harm from smoking. Harm reduction provides an additional strategy to protect this group, and their counterparts in other countries, from the burden of disability and early death that will continue to accumulate until and unless they stop smoking.

In 2007 the RCP published a report promoting the principle of harm reduction in nicotine addiction,\textsuperscript{18} arguing that, as most of the harm caused by smoking arises not from nicotine but from other components of tobacco smoke, the health and life expectancy of today’s smokers could be radically improved by encouraging as many as possible to switch to a smoke-free source of nicotine. While recognising the primacy of complete cessation of all tobacco and nicotine use as the ultimate goal to prevent harm from smoking, the report argued that promoting widespread substitution of cigarettes and other tobacco combustion products would, for smokers who made the change, achieve much the same thing.\textsuperscript{18} Harm reduction, as a complement to conventional tobacco control policies, could therefore offer a means to prevent millions of deaths among tobacco smokers in the UK alone.\textsuperscript{18} This argument was accepted and integrated into national tobacco control strategies published by the then Labour and subsequent coalition governments in 2010 and 2011,\textsuperscript{19,20} through the extension of the licence for nicotine replacement therapy (NRT) to include harm reduction by the Medicines and Healthcare products Regulatory Agency in 2010,\textsuperscript{21} and in guidance issued by the National Institute for Health and Care Excellence in 2013.\textsuperscript{22}

At the time of the 2007 report, the product categories available as potential smoking substitutes comprised smokeless tobacco, the least hazardous forms of which were then and still are illegal in the UK,\textsuperscript{18} and conventional NRT, which, although effective as a smoking cessation therapy, has proved to have limited appeal to many smokers.\textsuperscript{18} E-cigarettes, which appeared in the UK at around the time the 2007 report was published, have transformed this market, becoming the most popular choice of product for smokers hoping to quit or cut down on their smoking\textsuperscript{23,24} (see Chapter 5). In the UK and many other countries, however, e-cigarettes have proved highly controversial, attracting both widespread concern and disapproval, and strong support, from individuals and organisations both within and outside medicine. Policies on e-cigarettes vary widely between countries with some, such as the UK, currently allowing their sale as consumer products whereas others, eg Australia, prohibit the product\textsuperscript{25} (see Chapter 10).
Harm reduction, and in particular the role of e-cigarettes, has probably split global and, to some extent, national opinion on tobacco control more than any other issue. This report therefore aims to provide an update on harm reduction in the UK, particularly but not exclusively in relation to the role of e-cigarettes.

1.1 The harm of smoking

The harm that smoking causes to individuals and society is extensive and has been reviewed comprehensively in reports published by the RCP over the past 15 years,3,4,10,26 by the US surgeon general27–30 and by many other authorities. The main effects of smoking on health and wellbeing, particularly in the context of the UK population, are as follows.

1.1.1 Mortality

The most recent detailed analysis of mortality caused by smoking in the UK uses data from 2010, when tobacco smoking caused an estimated 122,000 deaths in adults, equivalent to more than one in six of all deaths, in the UK.31 Although due to a wide range of diseases, 70% of these deaths were from three causes: lung cancer, chronic obstructive pulmonary disease (COPD) and vascular disease (Fig 1.1).

Fig 1.1 Deaths attributable to smoking by disease in men and women, UK, 2009.31 (Data for figure from Peto et al.31)
Deaths caused by passive smoking are more difficult to estimate with precision, but in 2003 over 10,000 adults in the UK were estimated to have died from lung cancer, cardiovascular disease or COPD caused by passive smoking. The figure today is likely to be lower, as a result of declining smoking prevalence and legislation making UK public places and workplaces smoke free. Among children, around 40 cases of sudden infant death syndrome are caused by smoking in the UK each year, whereas passive exposure of the fetus arising from maternal smoking during pregnancy causes over 5,000 fetal or perinatal deaths each year.

1.1.2 Morbidity

Smoking during pregnancy accounts for around 2,000 premature births and 19,000 cases of low birth weight each year, and increases the risk of fetal anomalies. Among children, passive smoking has been estimated to cause around 165,000 new cases of disease, predominantly middle-ear disease and respiratory infections in 2008, generating over 300,000 primary care consultations and 9,500 hospital admissions in the UK each year. In adults, combined morbidity and mortality from smoking accounted for the loss of around 2 million disability-adjusted life years in the UK in 2010. In 2014 smoking caused over 450,000, or about 4% of all, admissions to hospitals in England. Most of these admissions were for cancer, or respiratory or vascular disease.

1.1.3 NHS and wider societal costs

Smoking costs the NHS more than £2 billion in direct costs, or more than 2% of the total NHS budget, every year. Costs of inpatient and primary care caused by passive smoking in children in 2007 exceeded £20 million. The total cost of smoking to society, including healthcare, social care, lost productivity, litter and fires, was conservatively estimated in 2015 to be around £14 billion per year.

1.1.4 Smoking and deprivation

Smoking prevalence is strongly and directly related to all measures of deprivation. Smoking prevalence among those in higher managerial and professional occupations in the UK is now close to 12%, whereas among those in routine and manual occupations the figure is over 28%. Among unemployed people, almost 40% smoke, as do around 40% of people with longstanding mental health problems and more than 70% of people who are homeless or imprisoned.
1.1.5 Normalisation effects

Smoking harms the health of others through behavioural effects, independent of tobacco exposure. It was estimated that, in the UK in 2011, over 200,000 11- to 15-year-olds started smoking and, although smoking rates have since fallen, it is still the case that, every day, hundreds of children become smokers. These new smokers are more likely to come from households that include a smoker or to have been exposed to smoking behaviour in the media or in their wider social environment. These effects tend to perpetuate addiction to smoking among successive generations of families and social groups, and hence also the consequent inequality in quantity and quality of life in disadvantaged groups.

1.2 Principles of tobacco harm reduction

Tobacco smoke contains thousands of constituents that determine the flavour and other characteristics of the smoke; but, crucially, they also combine to deliver nicotine to the lung in an aerosol, with physical properties that allow rapid absorption into the pulmonary circulation. Although other components of tobacco smoke may enhance the addictiveness of tobacco smoke, the main driver of tobacco smoking is addiction to nicotine. The mechanisms of nicotine addiction are complex, but it is evident that smokers experience an initial sensation of reward from exposure to nicotine; after sustained use and consequent desensitisation to nicotine’s effects, smokers seek nicotine primarily to relieve the symptoms of nicotine withdrawal. Regular nicotine use also confers rewards in some of the stimuli and behaviours associated with nicotine delivery, such as the sense of smoke in the throat, and the physical acts that are integral to smoking, such as unwrapping, sharing or handling cigarettes.

Nicotine is not, however, in itself, a highly hazardous drug (see Chapters 4 and 5). It increases heart rate and blood pressure, and has a range of local irritant effects, but is not a carcinogen. Of the three main causes of mortality from smoking, lung cancer arises primarily from direct exposure of the lungs to carcinogens in tobacco smoke, COPD from the irritant and proinflammatory effects of smoke, and cardiovascular disease from the effects of smoke on vascular coagulation and blood vessel walls. None is caused primarily by nicotine. For practical purposes, as argued by Mike Russell in the 1970s, ‘smokers smoke for nicotine but are killed by tar’. Although the nature and extent of any long-term health hazard from inhaling nicotine remain uncertain, because there is no experience of such use other than from cigarettes, it is inherently unlikely that nicotine inhalation itself contributes significantly to the mortality or morbidity caused by smoking. The main culprit is smoke and, if nicotine could be delivered effectively and acceptably to smokers without smoke, most if not all of the harm of smoking could probably be avoided.
It is also clear that many smokers would prefer not to have to smoke to get nicotine, provided that they can access the drug in doses and formulations that they find satisfying and acceptable. The availability and use of an oral tobacco product known as snus in Sweden, documented in more detail in our 2007 report (and revisited in Chapter 7), demonstrates proof of the concept that a substantial proportion of smokers will, given the availability of a socially acceptable and affordable consumer alternative offering a lower hazard to health, switch from smoked tobacco to the alternative product. Particularly among men, the availability of snus as a substitute for smoking has helped to reduce the prevalence of smoking in Sweden, which is now by far the lowest in Europe. The magnitude of the contribution made by the availability of snus over and above conventional tobacco control measures is difficult to quantify, but a recent study of the effect of withdrawal of snus from the market in Finland in 1995, when both Finland and Sweden joined the EU, but only Sweden was allowed to continue its use, estimates that over the following 10 years the availability of snus reduced smoking prevalence in Sweden by an additional 3.7 percentage points. Trends in snus use in Norway are similar to, and perhaps stronger than, those in Sweden, and there the use of snus is strongly associated with quitting smoking.

### 1.3 Role of harm reduction in tobacco control policy

In 1962, the RCP’s *Smoking and health* report promoted a range of smoking prevention measures, including a list of policies that, under the heading ‘Possible action by the government’, probably represented the first published comprehensive tobacco control strategy. The core components – preventing tobacco advertising, increasing prices, making public places smoke free, providing treatment for smokers, educating the public and restricting young people’s access to cigarettes – remain at the centre of modern tobacco control strategy as promoted by the WHO and the FCTC.

These policies are effective and, when countries and states adopt them comprehensively, the prevalence of smoking falls, slowly. Australia, Canada and the UK have implemented increasingly extensive ranges of tobacco control policies over recent decades and, in these countries, over the past 10 years or so, prevalence has fallen respectively by around 0.6, 0.75 and 0.7 percentage points per year. Adult smoking prevalence is now below 20% in all of these countries, but, even if these rates of decline can be sustained, it will take more than two decades before rates start to approach zero. Meanwhile, substantial numbers of people in these countries continue to smoke: nearly 9 million in the UK, 4.6 million in Canada and 3 million in Australia remain exposed to the harm of smoking. Tobacco control policies may have a greater effect when introduced together for the first time in a high-prevalence setting: in Uruguay,
Introduction

for example, a comprehensive package of tobacco control measures was introduced in 2005, when adult smoking prevalence was around 34%, and led to a reduction in smoking prevalence of around 1.1 percentage points per year for the next 6 years. However, even if this rate of decline can be sustained, it will take three decades to eradicate smoking, during which most current smokers will continue to be harmed or killed by their addiction. It is therefore important to complement this approach with strategies to reduce or prevent harm in those who will otherwise continue to smoke.

To date, harm-reduction strategies have tended to focus on reducing emissions and absorption of toxins from conventional cigarettes, eg through the use of filters and attempts to limit tar yields, although the latter proved to be more of a marketing device for the tobacco industry than a genuine reduction in harm potential. More radical strategies, such as promoting alternative sources of nicotine as a sustained substitute for smoking, have until recently been pursued only in the context of therapies for individual smokers attempting to quit. The potential for more widespread nicotine product substitution at a population level, with the primary objective of changing the source of nicotine used by smokers rather than ending all nicotine use, has not to date been widely adopted as a public health policy. The evidence from Sweden suggests that the harm reduction could add a further 0.4 percentage points per year to the rate of decline in smoking prevalence, and hence make a substantial contribution to public health.

1.4 Developments since the publication of the 2007 RCP report and the need for this update

When the RCP published its last report on harm reduction in 2007, options for alternative nicotine products for use in a population-level harm-reduction strategy were limited to smokeless tobacco, the supply of which in the UK is subject to severe constraints under the terms of legislation passed in 1992, and medicinal NRT products, which many smokers find unsatisfactory as a long-term substitute for smoking. However, the nicotine harm-reduction landscape has since been transformed by the emergence of e-cigarettes which, as documented later in this report, have demonstrated a popularity among smokers akin to that of snus in Sweden. The emergence of e-cigarettes has also provoked substantial controversy among those involved in tobacco control, wider public health policy and practice, and the general population, and a spectrum of regulatory responses in different countries that range from free market access to outright prohibition. This report has been produced to review developments relevant to tobacco harm reduction since the publication of the 2007 RCP report Harm reduction in nicotine addiction, to look in particular at the effect that this new product category has had on smoking and nicotine use in the UK, and to make further developments.
recommendations as to how the potential for this approach to prevent death and disability from tobacco use might be realised, within an appropriate and proportionate regulatory framework.

1.5 Summary

- Tobacco smoking is addictive, and causes an extensive range of harm to health and wellbeing in individuals and wider society.
- Tobacco smoking contributes more to social inequalities in health, and to overall death and disability, than any other avoidable cause.
- Smoking is preventable, and smoking prevalence falls progressively when countries implement a comprehensive range of tobacco control policies.
- The rate of decline is slow, however, with millions of smokers in the UK alone continuing to be exposed to the immediate and long-term hazards of smoking.
- Harm reduction aims to reduce or prevent harm in those smokers who do not respond to conventional tobacco control approaches by quitting smoking.
- Harm reduction works by providing smokers with the nicotine to which they are addicted without the tobacco smoke that is responsible for almost all of the harm caused by smoking.
- E-cigarettes are a new product class that has proved popular with smokers and offers a viable harm-reduction option.
- E-cigarettes have proved highly controversial and have provoked widely different regulatory responses in different countries.
- It is therefore important to look carefully at the role that these and other novel nicotine products might play in helping to prevent death and disability caused by smoking, and to consider how regulation should be applied proportionately to maximise this benefit.

References

4 Royal College of Physicians. Going smoke-free: the medical case for clean air in the home, at work and in public places. A report on passive smoking by the Tobacco Advisory Group of


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41 Maki J. The incentives created by a harm reduction approach to smoking cessation: Snus and smoking in Sweden and Finland. *Int J Drug Policy* 2014;26:569–74.


2.1 Recent trends and current prevalence of smoking in the UK

Reliable national data on the prevalence of smoking among adults in Britain were collected from 1972 to 2011 in the General Household Survey, and since that date in the Opinions and Lifestyle Survey and the Integrated Household Survey. Data from these sources demonstrate that, over the more than four decades for which survey data are available, smoking prevalence fell from 51% of men and 41% of women in 1972, to 21% of men and 16% of women in 2014 (Fig 2.1). Applying age- and gender-specific smoking rates to the 2013 population estimates of the Office for National Statistics (ONS), there are approximately 8.7 million adult smokers in the UK, of whom 4.8 million are men and 3.9 million women.

Fig 2.1 Smoking prevalence in men and women in Britain, 1972–2013 and 2014 (Adapted with permission from the Office for National Statistics under Open Government Licence.)
Smoking has always been more common among men than women, and is also related to age and socio-economic status. Especially over the past two decades, smoking tends to be most common among young adults, and least so among older people, but is following a predominantly downward trend in all age groups (Fig 2.2).

Fig 2.2  Smoking among men and women in Britain, by age 1974–2013.¹
(Adapted with permission from the Office for National Statistics¹ under Open Government Licence.)
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Cross-sectional prevalence data by age demonstrate that smoking is currently most common among young adults, and particularly among men aged 25–34 (Fig 2.3). Age-group data also demonstrate marked falls in smoking prevalence.

Fig 2.3 Prevalence of smoking by age group and gender in Britain, 2014.2 (Adapted with permission from the Office for National Statistics2 under Open Government Licence.)

Fig 2.4 Smoking in Britain by age group, 20041 and 2014.2 (Adapted with permission from the Office for National Statistics1,2 under Open Government Licence.)

Cross-sectional prevalence data by age demonstrate that smoking is currently most common among young adults, and particularly among men aged 25–34 (Fig 2.3). Age-group data also demonstrate marked falls in smoking prevalence.
over the decade from 2004 to 2014 in all age groups, but particularly in younger adults (Fig 2.4).

Smoking among children is also falling, even more markedly than among young adults. Figure 2.5 shows that the proportion of children aged 11–15 in England who report that they currently smoke at least one cigarette a week has fallen by around two-thirds since the 1990s, to figures of 4% and 3%, respectively, in girls and boys. Over the past 10 years the prevalence of smoking in all people aged 11–15 has fallen from 9% to 3%, with smoking among the youngest participants (those aged 11 and 12) falling to almost zero (Fig 2.6). Similarly substantial declines in smoking prevalence among young people have also occurred in Scotland.

### 2.2 Smoking and disadvantage

Smoking is strongly associated with socio-economic disadvantage, however defined or measured. Figure 2.7 shows prevalence trends over time in Britain according to occupational socio-economic status, and demonstrates a falling prevalence in all groups since 2001, but also prevalence that is twice as high, and falling more slowly, among those in routine and manual occupations relative to the managerial and professional group.
A more detailed breakdown of smoking by occupation, from the Integrated Household Survey, demonstrates a clear and direct relationship between smoking occupation and health.
prevalence and occupational social group, being highest in the least skilled occupations (Fig 2.8).

In 2013, smoking in Britain was almost twice as prevalent among unemployed people (35%) as among those in employment (19%), and in those with incomes below £20,000 per year (23%) than those with incomes greater than £40,000 (11%). Smoking is about twice as prevalent among those with a long-standing mental health condition than in those without (Fig 2.9), and similar among those with schizophrenia or other psychosis in 2010 to those in the general population in the 1970s. Among other severely deprived groups, such as those who are homeless, imprisoned, or dependent on other drugs or other substances, most smoke. The strong relationship between smoking and deprivation means that passive exposure to tobacco smoke, particularly in children, tends to be much higher among children living in relatively deprived households.

Socio-economically disadvantaged people not only are more likely to be smokers, but also tend to be more heavily dependent on smoking. Levels of cotinine, a metabolite of nicotine (see Chapter 4) and a marker of nicotine dependence, are consistently higher among relatively disadvantaged smokers across all age groups (Fig 2.10).

![Fig 2.8 Smoking by occupation in Britain 2014.](Adapted with permission from the Office for National Statistics under Open Government Licence.)
Fig 2.9 Smoking prevalence among people with a long-standing mental health problem, and in the general population, UK 1993–2013. (Updated for this report from the RCP.6)

Fig 2.10 Saliva cotinine levels in smokers in relation to age and deprivation (data from 1998 to 2003).8 (Adapted with permission from Action on Smoking and Health.8)
2.3 Trends in the uptake and progression of smoking in the UK

2.3.1 Smoking uptake

Most smokers in the UK start smoking during their teenage or early adult years. In Britain in 2011, the most recent year for which data are accessible, 68% of male and 65% of female current smokers, respectively, reported that they started smoking before age 18, and 95% and 93%, respectively, before age 25.9 Children in lower socio-economic status households tend to start smoking at an earlier age: 43% of smokers in 2011 who grew up in households in which the main wage earner was employed in a manual or routine occupation took up smoking before age 16, compared with 31% of those from professional and managerial households.9 Uptake after age 25 is rare in men and women, and in all socio-economic groups.9

Smoking status in young people tends to be less dichotomous than in adults, because much early use is occasional and experimental, with a relatively low likelihood of leading to sustained smoking. Comparison of smoking behaviour between children and adults is also complicated by the different survey questions used to define smoking in national surveys in these groups. Thus, by the age of 15 in 2014, 35% of children in England had tried smoking at least once, 5% had smoked occasionally but less than once per week and 8% were smoking regularly, which in this survey is defined as smoking at least once a week.4 From age 16, the question used to define regular smoking changes to ‘Do you smoke cigarettes at all nowadays?’10 and by this definition 17% of those aged 16–19 in 2014 were regular smokers.2 Among those aged 20–24, smoking prevalence was 25% (see Fig 2.4).

However, these are cross-sectional data, so the prevalence of smoking in those aged 20–24 in 2014 will not necessarily apply to younger cohorts when they reach that age. As Figs 2.6 and 2.7 demonstrate, uptake of smoking among children and young people is falling rapidly, indicating that children born since the early 1990s may be substantially less likely than their predecessors to take up smoking, at least in their teens; and, unless these cohorts take up smoking in their 20s to a much greater degree than has typically been the case in the past, it appears that today’s children and young people in the UK are much less likely than their predecessors to become smokers. The marked decline in smoking prevalence among 11- to 15-year-olds began in 2006 (see Fig 2.6) and is likely to be attributable primarily to the major tobacco control interventions of the decade: the phased removal of tobacco advertising in the UK from 2002 and smoke-free legislation, which was in place across the UK by the end of 2007.

2.3.2 Quitting

The proportion of people who have smoked regularly in the past but do not smoke now increases progressively with age. Taking data for 2011,9 around 2% of
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men and 4% of women aged 16–19 describe themselves as ex-smokers, whereas, of those aged 60 and over, the respective proportions are 45% and 30%. Although the latter figures are likely to be biased upwards by the higher mortality in continuing smokers, this bias will be less marked among those aged 50–59. In this age group in 2011, 27% of men and 24% of women were ex-smokers, whereas 20% and 18%, respectively, were still smoking. These data therefore indicate that over half of those who had ever been regular smokers quit before they reached the age of 60, but that over 40% continue to smoke beyond that age.

2.3.3 Uptake and quitting within birth cohorts

Cross-sectional data on current smoking prevalence and past quitting are not representative of trends within cohorts of UK individuals born at different times. Figure 2.11 shows General Household/General Lifestyle Survey data from 1972 to 2011, provided by the UK Data Service, analysed to estimate smoking prevalence within 5-year birth cohorts over the duration for which data are available. Figure 2.11 demonstrates that, in more recent birth cohorts, smoking prevalence tends to be highest at around 25 years of age, but also that the peak within-cohort
prevalence has fallen progressively in successive cohorts from almost 50% in those born between 1951 and 1955, to under 30% in those born since 1986. Peak prevalence levels in earlier cohorts are not known, but the steady downward trend in prevalence in all of them indicates that they were probably substantially higher. After age 24 the prevalence of smoking declines in all cohorts, and this decline is likely to be attributable primarily to quitting smoking during mid-adult life, and also to earlier mortality among smokers in older age groups. The rate of this decline in smoking prevalence within recent cohorts is of the order of 1 percentage point per year, which, if sustained, indicates that, by the time today’s 20- to 24-year-olds reach the age of 50, their smoking prevalence is likely to have fallen from around 30% (see Fig 2.4) to about 5%.

2.4 Current and expected future mortality and morbidity from smoking

Mortality from smoking tends to lag behind smoking prevalence by several decades, and reached a peak of around 151,000 deaths per year in the UK in the mid-1980s (Fig 2.12).\textsuperscript{11} This total has since declined progressively to 103,000 in 2009.\textsuperscript{11} Data for England since 2009 suggest that this trend has continued, with an estimated 78,200 people,\textsuperscript{12} equivalent to about 93,000 in the UK, killed by smoking in 2014.\textsuperscript{12} The decline has to date been due predominantly to a relatively marked fall in cardiovascular mortality (Fig 2.13), although modest
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Fig 2.13 Deaths from smoking in England, by cause, 2003–13.12 (Adapted with permission from the Health and Social Care Information Centre12 under Open Government Licence.)

declines in all causes of premature mortality among smokers are expected over the coming decades.

Generating estimates of morbidity from smoking is a more complex process and direct data are not available. However, figures on hospital admissions attributable to smoking provide a proxy for morbidity, and demonstrate a sustained rise over the past decade, from 1.38 million in 2003–4 to 1.63 million in 2013–14.12

2.5 Summary

- Smoking prevalence has been falling for several decades in the UK, in all age groups, in both men and women.
- Smoking prevalence has fallen particularly markedly since 2007 among children and young people.
- Smoking remains much more prevalent among socio-economically disadvantaged individuals and those with mental health problems.
- Uptake of smoking appears to be falling progressively, whereas quit rates appear to be remaining relatively constant across successive cohorts.
- Smoking remains most prevalent among disadvantaged individuals, and addiction to nicotine tends to be higher in more disadvantaged smokers.
This means that the approximately 8.7 million smokers in the UK today include a high proportion of the most disadvantaged individuals in society, who as a result of higher levels of addiction are likely to find it particularly difficult to quit smoking.

Smoking is likely to be rare among today’s young people as they approach older age, but continuing efforts to reduce child uptake of smoking are vital.

However, smoking continues to cause significant mortality and morbidity, in part as a consequence of higher smoking rates in past decades.

Helping disadvantaged smokers to quit or else reduce the harm caused by smoking is therefore a key priority to prevent current and future death and disability.

References


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3 Effectiveness of current and future tobacco control policy

3.1 Background

In 1962, when most men and almost half of all women in the UK were regular smokers, the RCP’s report, *Smoking and health*, identified tobacco smoking as the primary cause of the twentieth-century global epidemic of lung cancer and proposed a range of policies to reduce smoking prevalence.¹ Progress with implementation of these policies remained slow, however, until the first comprehensive UK tobacco control policy document, *Smoking kills*, was published in 1998.² *Smoking kills* recognised the devastating effect of tobacco smoking on UK public health, and committed to reduce smoking in children and young people, help adults to stop smoking, prioritise reducing the prevalence of smoking in manual occupational groups as a means of decreasing health inequalities, and offer particular help to pregnant smokers. Drawing heavily on the policy recommendations of *Smoking and health*, *Smoking kills* defined a package of tobacco control policies including the following:

- a ban on tobacco advertising and sponsorship
- tobacco tax rises
- enforcement of underage sales laws
- reducing point-of-sale tobacco advertising
- introducing smoking cessation services
- facilitating access to smoking cessation medication
- voluntary measures to reduce passive smoke exposure in public places and workplaces.

Shortly after *Smoking kills* was published, powers for key policy areas, including health, were devolved to the newly established Scottish Parliament, Welsh Assembly and Northern Ireland Assembly, although some powers relevant to tobacco, such as fiscal policy (via the Treasury), remained within the remit of the Westminster government. However, *Smoking kills* had set the scene for tobacco policy changes throughout the UK and, in the years that followed, the main policies it recommended were implemented throughout England and the devolved nations. These new measures included comprehensive smoke-free
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legislation, which was implemented in Scotland in 2006 and throughout the rest of the UK by the end of 2007. Each of the UK nations has since produced their own tobacco control strategies, with some variation in emphasis and the timing of how policies were introduced. The core strategies are, however, broadly similar and articulated in the most recent tobacco control plan for England, which was published in March 2011. This plan committed to:

- implementing legislation to end tobacco displays in shops
- considering and consulting on plain packaging of tobacco products
- continuing to defend tobacco legislation against legal challenges by the tobacco industry
- continuing to follow a policy of using tax to maintain the high price of tobacco products
- promoting effective local enforcement of tobacco legislation
- encourage more smokers to quit by using the most effective forms of support, through local stop smoking services
- publish a 3-year marketing strategy for tobacco control.

Progress has been made on all these objectives, particularly in ending point-of-sale tobacco displays and passing legislation mandating standardised packaging for tobacco products. The plan also proposed adopting a harm-reduction strategy based on helping tobacco users who cannot or are unwilling to quit smoking to substitute alternative safer sources of nicotine for tobacco, to be supported by guidance from the National Institute for Health and Care Excellence (NICE), which was in development at the time but published in due course in 2013, and undertook to encourage the development of new, affordable and acceptable nicotine products. The UK government elected in 2015 has committed to a new tobacco strategy, although a publication date has not been set.

In addition to national and devolved government actions, tobacco control policy in the UK is significantly influenced by international treaties and initiatives. UK tobacco policy is shaped by the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC), a global health treaty ratified by most of the world’s countries, including the UK, that defines a comprehensive range of tobacco control policies and practices that all political parties undertake to implement. At the European level, European Union (EU) single market rules have also been a driver of significant policy initiatives across all EU member states in recent years, including legislation banning tobacco advertising (2003/33/EC) and mandating health warnings on tobacco packs (2001/37/EC, known as the Tobacco Products Directive, or TPD). A revision of the TPD (2014/40/EU), which comes into force in 2016, will impose a minimum pack size of 20 cigarettes (and 50 g hand-rolling tobacco), require combined pictorial and text health warnings to cover 65% of the front and back of the pack, and end
cigarette flavouring. The new TPD will also set out product standards and regulations on the sale of e-cigarettes (see Chapter 9). UK tobacco control policy thus continues to be shaped by both national initiatives and international agreements and legislation. The combination of these processes has led to the UK becoming the European leader in tobacco control policy implementation.

3.2 Tobacco control policy effectiveness and implementation in the UK

3.2.1 Increasing the price of tobacco products

Fiscal measures, including tobacco taxation, are a key element of tobacco control. In the UK, tobacco tax increased in the mid- to late 1990s, through an escalator of 3% above inflation from 1993 to 1997 and 5% above inflation from 1997 to 2000. From 2001 to 2008 taxes rose in line with inflation, until, in 2009, a tax escalator was reintroduced, which is currently set at 2% above inflation, a commitment that runs until the end of the current parliament in 2020. Overall, between 1980 and 2012 the affordability of tobacco declined by 28%, although, relative to the 1960s’ prices, tobacco was approximately 50% more affordable in 2006 than when Smoking and health was published in 1962, and remains more affordable today. The price of the most popular price category cigarettes, a metric that initially reflected the price of the most popular brand or brands on the market, but now typically represents the prices of the more expensive (premium-brand) cigarettes, has increased consistently over the last three decades (Fig 3.1), with the result that the UK now has some of the highest premium-brand prices in Europe. However, the price of cigarettes in the ultra-low price category favoured by younger and more disadvantaged smokers has remained virtually static in recent years, thus undermining the effects of tobacco tax rises.

The World Bank suggests that price increases through higher taxation are the single most effective and cost-effective tobacco control measure. Its estimates from the late 1990s suggested that a price increase of 10% typically decreases adult consumption by around 4% in developed countries. A 1996 study in the UK produced an estimate consistent with the World Bank figure, with a price increase of 10% reducing consumption by 5% and with evidence that lower socio-economic groups were more responsive than those in higher socio-economic groups to changes in the price of cigarettes. These figures were disputed in a recent paper by HM Revenue and Customs (HMRC), which estimated that the price elasticity of demand for cigarettes increased in the period from 1982 to 2009, suggesting that a 10% increase in price now reduces consumption by 10%. However, this study included duty-paid manufactured cigarettes only, and did not take into account other types of tobacco, such as
Evidence from a wide range of settings consistently demonstrates the effectiveness of price increases as a tobacco control measure. From 1990 to 2005, France tripled inflation-adjusted cigarette prices by raising taxes 5% or more every year in excess of inflation and, during the same period, cigarette consumption halved and smoking prevalence fell by a quarter. Comparable price increases in South Africa achieved similar reductions in consumption. However, the available evidence relates predominantly to the effects of relatively small, incremental price rises over time; the effects of sudden large price rises are less well defined. Data from France indicate that a single large increase in tobacco taxation in 2003, which caused the price of a packet of premium-brand cigarettes to rise in real terms by almost 20%, resulted in a 13.5% decline in sales. This implies that sudden large price increases may be more effective than repeated smaller rises.

There is also consistent international evidence that raising taxes to increase the price of tobacco reduces smoking among young people, who as a group are more responsive than adults to price increases. The US surgeon general’s report on preventing youth smoking concluded that increases in cigarette prices reduce
initiation, prevalence and intensity of smoking among both children and young adults.\textsuperscript{23} Evidence from developed countries indicates that a 10% increase in price reduces youth consumption by between 5 and 12%.\textsuperscript{24} There is also evidence from high-income countries that low socio-economic status (SES) groups are more responsive to price increases, indicating that tobacco price increases have a key role to play in reducing inequalities in health caused by tobacco use.\textsuperscript{25} Two systematic reviews have recently assessed the equity impact of tobacco control in high-income countries, in terms of differential impact on SES groups, in both young people and adults.\textsuperscript{26,27} The reviews found that the clearest and most consistent evidence of a positive equity impact (ie reduced inequalities in smoking) for all types of tobacco control in adults, and to a lesser extent in young people (as there are fewer studies on this), related to price increases.

Although UK tobacco prices increased throughout the 1990s, the effects of increasing taxation during this period were undermined by, among other things, a rapid increase in the market share for illicit cigarettes, which rose from 3% in 1996–7 to 21% by 2000–1.\textsuperscript{28,29} This meant that smokers were switching to cheap, illicit cigarettes rather than quitting in response to price rises. This and a relative absence of other tobacco control measures during this period resulted in little change in UK smoking prevalence, despite year-on-year price rises. From 2000, however, a comprehensive anti-smuggling strategy reduced the supply of illicit cigarettes from 21% in 2000–1 to 9% in 2012–13. This included, from 2006, legislation imposing substantial fines on manufacturers who failed to prevent their products from being smuggled into the UK.\textsuperscript{28} Since then, however, tax increases have been undermined by new developments in tobacco industry pricing strategy, with the creation of a range of ultra-low-price cigarettes and the practice of ‘overshifting’ tax on to more profitable premium brands, leaving ultra-low brand prices relatively unchanged.\textsuperscript{12} The consequence of this strategy is that many smokers who might otherwise quit smoking or else reduce their consumption in response to price rises now ‘downtrade’ to lower-price brands, or indeed switch to hand-rolling tobacco.

### 3.2.2 Restrictions on smoking in public places, workplaces and cars

The health effects of passive smoke exposure are well documented\textsuperscript{30} and, to protect workers and the public from these effects, bans or restrictions on smoking in public places and workplaces are a key component of tobacco control policy. In the UK, smoke-free legislation was introduced first in Scotland in March 2006, in Wales and Northern Ireland in April 2007, and in England in July 2007.

There is now extensive international and UK evidence that smoke-free laws are effective in reducing passive exposure to smoke. Before the 2007 smoke-free legislation, the highest levels of occupational passive exposure to smoke in the
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UK occurred in serving staff in bars and pubs.31 A study of bar workers in England, Scotland and Wales showed that their exposure was reduced on average by between 84% and 93% after introduction of the legislation.32 Children are particularly vulnerable to the effects of tobacco smoke, and research in Scotland, Wales and Northern Ireland found that passive exposure of children to smoke declined after the introduction of the legislation in these countries.33 Between 1998 and 2012 in England, passive smoke exposure among children declined by 79%, and the most rapid decline occurred in the period immediately before smoke-free legislation came into force, thus coinciding with national mass media campaigns highlighting the dangers of passive smoke exposure.34 Smoke-free legislation in the UK has also had positive effects on child and adult health, with substantial reductions in preterm deaths, childhood admissions to hospital with asthma and adult admissions for myocardial infarction.35–38

Smoke-free legislation also acts as an incentive to smokers to quit smoking. The Smoking Toolkit Study found that, at the time of the legislation in England, the number of smokers trying to quit smoking increased significantly, with approximately 300,000 additional quit attempts made.39 Scottish data suggest that quit attempts increased in the 3 months leading up to Scotland’s smoke-free legislation,40 after which there was a temporary fall in prevalence in addition to the secular reducing trend.40 A further study has suggested that, although smoke-free legislation was not associated with additional reductions in smoking prevalence, existing decreasing trends continued in the 18 months following implementation of the ban.41

Two systematic reviews have recently assessed the equity impact of smoke-free policy in high-income countries on young people and adults.26,27 A youth review found that, of the six studies that had looked at the equity impact of comprehensive smoke-free legislation, two had a neutral effect and four were negative in terms of second-hand smoke (SHS) exposure.26 Declines in SHS exposure occurred predominantly among children who had low SHS exposure before smoke-free legislation, and who were from more affluent families. Thus, the substantial SES gradients in children’s SHS exposure levels remained unchanged. Welsh data showed that, although there was a significant decline among high-SES children perceiving adult smoking as the norm, there was no change among children from low-SES households.42 Thus, SES disparities in children’s perceptions of adult smoking as normative increased, which is of concern because social norms are important influences on smoking uptake. An adult equity systematic review found that comprehensive national smoke-free legislation was much more likely to have a neutral or positive equity impact than voluntary partial policies.27

Following the success of smoke-free legislation in the UK, there are continuing efforts to extend smoke-free policies to other settings. Some cities are considering
extending smoke-free laws to outdoor public places including parks or other open spaces. Since October 2015 it has been illegal for drivers in England and Wales to smoke in private cars in the presence of children, and Scotland and Northern Ireland are in the process of introducing similar legislation. Recent UK research suggests that around one-fifth to one-third of 11- to 15-year-olds are exposed to SHS in cars sometimes or often, and that this is concentrated among those from more deprived backgrounds. Around three-quarters of adolescents reported disliking being exposed to SHS in cars. Around one-third of 8- to 15-year-olds who reported ever being exposed to SHS in cars felt too embarrassed or frightened to ask someone smoking in a car when they were present to stop. Most children, adults and adult smokers in the UK support a ban on smoking in cars where children are present.

3.2.3 Mass media campaigns

Tobacco control mass media campaigns (MMCs) use television, radio, newspapers and other media channels to reach large numbers of smokers and encourage them to quit smoking, reduce harm to self or others from tobacco use, and prevent young people from taking up smoking. Large-scale MMCs have been a key component of UK tobacco control strategy since the early 2000s, and there is strong evidence that tobacco control MMCs can increase adult smoking cessation and reduce youth uptake. Campaigns in England have varied in informational content; approximately half of the adverts between 2004 and 2010 warned of the negative consequences of smoking, whereas half contained information on how to quit smoking. In April 2010, the government ceased spending on national public health MMCs in England. A tobacco control MMC was reintroduced in England in September 2011, but at a much lower rate of funding. Mass media are also used to promote the ‘Stoptober’ campaign, which has run every year since 2012 and encourages smokers to quit for the month of October. Examples are shown in Fig 3.2.

The magnitude of the independent effect of MMCs on smoking behaviour is difficult to establish when, as is usually the case, they are used together with other tobacco control policies. However, several recent studies have assessed the impact of MMCs on a range of measures of quitting behaviour in England (and, to a lesser extent, Wales), including quit-line calls, hits on the national Smokefree website, and measures of cigarette consumption and smoking prevalence. Over the period from 2002 to 2009, when adult smoking prevalence in Britain fell from 26% to 21%, an estimated 13.5% of this decline was attributable to the effect of MMCs. A further study showed that positive emotive campaigns – predominantly those promoting the use of NHS Stop Smoking Services – and negative emotive campaigns – generally those containing negative health effects messages – played a statistically indistinguishable role in
triggering this effect. More recently, the annual English Stoptober campaign, which aims to create a positive quitting trigger around a specific call to action – stopping for 28 days – and which uses a combination of traditional and new ways to support quitting.

Fig 3.2 Examples of imagery from recent UK smoking mass media campaigns (MMCs). (a) Toxic cycle MMC: launched in December 2013, and aimed at reminding smokers of the physical damage caused by tobacco use, while also offering support to help them quit by urging them to go online to get information about stopping smoking, and order a free support pack (Quit Kit), Smokefree app, text and emails, and information on how to contact local NHS Stop Smoking Services. (b) Stoptober: launched in 2012; runs annually. Uses traditional and new media to set people the challenge of staying smoke free for 28 days starting on 1 October. The call to action is reinforced by the positive message that smokers achieving this goal are at least five times more likely to become permanent ex-smokers.
Media, was estimated to have generated an additional 350,000 quit attempts and 9,000 permanent quitters in October 2012.63

Research from Australia has suggested that the level of exposure to MMCs required to obtain a detectable reduction in smoking prevalence is the equivalent of four exposures per person per month (390 gross rating points, known as GRPs).47 Between 2004 and the spring of 2010, campaign exposure in England exceeded this threshold in around 40% of months; in other months, exposure was lower, with no campaign at all during 1 in every 5 months.54 A recent study found that, below 400 GRPs per month, there was little impact of campaigns on quit-line calls in England, and that the effect increased significantly above the 400 GRP threshold,59 suggesting that efforts should be made to maintain exposure above this level.

The US surgeon general’s report on prevention of smoking in youth concluded that MMCs can be one of the most effective strategies in changing social norms and preventing youth smoking.23 The surgeon general concluded that the characteristics of effective campaigns included evoking strong negative emotions (eg health effects, deceptiveness of the tobacco industry), an appealing format, clear messages, intensity and adequate repetition (at least four advertising exposures per month over a 4-month period). There was strong evidence that MMCs aimed at adults also decreased smoking among young people.

Two recent systematic reviews have looked at the equity impact of MMCs on youth and adults. The youth equity review found only one study that had assessed the equity impact of MMCs on young people by SES.26 This was an evaluation of the US Truth campaign, which had mixed equity effects depending on the outcome measure used.65 The adult review found 30 studies that had looked at the equity impact of MMCs.27 These studies included a diverse range of approaches and messages, including some aimed at increasing quit motivations and/or attempts, and some aimed at increasing calls to quit-lines or uptake of free nicotine replacement therapy (NRT). The equity impact of these campaigns was inconsistent. This is perhaps not surprising given the diversity of messages, media formats and levels of exposure. There was some evidence that certain types of message, such as those with a higher emotional narrative, are more effective with low-SES smokers. A previous review also found that the impact of campaigns can vary by SES depending on the type of message, media format and mechanisms of engagement.66,67

3.2.4 Health warnings

Health warnings on tobacco packages are a means of communicating the risks of tobacco use to smokers. Text warnings became a legal requirement in the UK in
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1971, and since 2008 graphic pictorial warnings covering 40% of the back of the pack, and text warnings covering 30% of the front of the pack, have been required (Fig 3.3). The new EU TPD will see a further increase in the prominence of health warnings, with picture and text warnings covering at least 65% of the front and back of tobacco packaging by May 2016.

Studies from a wide range of countries indicate high levels of awareness of pack health warnings among both smokers and non-smokers. Large text warnings have been shown to be linked to increased knowledge about the health risks of smoking and increased motivation to quit. In the UK, a study of text-only warnings found that they were noticed by over half of smokers, and that those noticing warning labels were more likely to know about the health risks of smoking. Pictorial warnings are likely to be most effective because they are more likely to be noticed, improve memory for the health message, and are associated with stronger beliefs about the risks of smoking and increased motivation to quit.

Determining whether exposure to health warnings is causally related to changes in smoking behaviour has been difficult, owing to the challenges of disentangling their effect from those of other interventions. Research has suggested that pictorial health warnings increase the likelihood of a quit attempt, and that health warnings can help to prevent relapse. Some studies have investigated the effect of health warnings on smoking prevalence, with some suggesting positive effects, although other factors may also have contributed. The US surgeon general’s report on prevention of smoking in youth concluded that small text-only health warning labels have limited impact on youth and

Fig 3.3 Examples of UK text and graphic health warnings. (Adapted from Department of Health under Open Government Licence; Crown copyright.)
young adults, but that larger text or pictorial warnings that elicit strong emotional reactions are significantly more effective at discouraging tobacco use.\textsuperscript{23}

Systematic reviews of the equity impact of tobacco control policies found no studies that had assessed the equity impact of health warnings in young people,\textsuperscript{26} and five studies of the effect of health warning labels in adults.\textsuperscript{27} EU text-only health warnings and the addition of a quit-line number to new pictorial health warnings were found to have had a greater impact on low-SES groups, and the rest were equity neutral.

3.2.5 Comprehensive bans on the advertising and promotion of all tobacco products, logos and brand names

Prohibiting advertising and promotion of tobacco products is a key element of tobacco control. Television advertising for tobacco products was banned in the UK in 1965 under the Television Act 1964, almost 25 years earlier than an EU directive that prohibited television advertising across the EU in 1989 (Television without Frontiers Directive (89/552/EEC)).\textsuperscript{85} This directive was replaced by the Audiovisual Media Services Directive (2007/65/EC) adopted in December 2007.\textsuperscript{86} Subsequently, the UK Tobacco Advertising and Promotion Act 2002 (TAPA) banned print media and billboard advertising from February 2003, tobacco direct marketing from May 2003 and sponsorship within the UK in July 2003.

Advertising bans have been shown to reduce smoking uptake in children by lessening its social desirability, and also to reduce tobacco consumption in adults. The introduction of comprehensive advertising bans in Norway, Finland and France resulted in significant reductions in tobacco sales in the period following the introduction of the legislation.\textsuperscript{87} The US surgeon general’s report on prevention of smoking among youth concluded that there is a causal relationship between tobacco advertising and promotion, and the initiation and progression of smoking in young people.\textsuperscript{23} It also concluded that comprehensive cigarette advertising bans reduce youth smoking. The World Bank has estimated that comprehensive advertising bans can reduce consumption by around 7%.\textsuperscript{88}

A recent systematic review found four studies that had assessed the equity impact of restrictions and bans on advertising and promotion, all of which had a neutral equity effect.\textsuperscript{27} A similar review on the equity impact on young people found four US studies indicating that, when there is no enforced control of advertising, promotion or marketing of tobacco, there is the potential for increased inequality in youth smoking.\textsuperscript{26}

The main exclusions from TAPA, and hence the key remaining forms of promotion, were displays of tobacco packs at the point of sale in shops, and the
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Legislation ending both of these exclusions has now been passed in the UK. Point-of-sale displays were removed from large retailers such as supermarkets in England, Northern Ireland and Wales from April, October and December 2012, respectively, and April 2013 in Scotland. Point-of-sale displays in smaller shops were prohibited across the UK from April 2015 (Fig 3.4). Studies of the removal of point-of-sale displays in Iceland and Ireland suggest that the policy is supported by the public and that there are signs that prohibition helps to denormalise smoking. A recent systematic review of the impact of point-of-sale promotion on youth smoking found that there was a positive association between exposure and smoking-related outcomes, including smoking and smoking susceptibility. The review also found that point-of-sale bans may contribute to a shift in youth perceptions about peer smoking prevalence, but found no evidence of short-term population-level impacts on smoking.

Fig 3.4 Examples of tobacco point-of-sale displays in small retailers in England, before and after prohibition.
Legislation to introduce standardised tobacco packaging in the UK was approved in March 2015, and from May 2016 imposes a standard plain dark-green/brown design and a large graphic health warning on all tobacco packaging, and limits branding to a name and descriptor in a specified and standard plain font (Fig 3.5). A systematic review published in 2012 found that plain packs were rated as less attractive than branded equivalent packs, or unattractive, by young people.91 An independent review into standardised packaging published in 2014 concluded that the measure is likely to lead to a modest but important reduction in smoking, including among children.92 Public support for the measure is also reported to be high: in January 2015, a YouGov survey conducted for Cancer Research UK found that 72% of those polled supported standardised packaging.93

In 2012, Australia became the first country to introduce standardised packaging, and early evaluations suggest that the removal of branding from packaging has reduced the ability of the tobacco industry to use the pack to communicate to...
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young people and adults, and made products less appealing.\textsuperscript{94–96} There is also evidence that standardised packaging has increased both thoughts about quitting and quit attempts in adult smokers, and reduced smoking prevalence.\textsuperscript{97,98} Concerns that standardised packaging would lead to reductions in the price of cigarettes and increases in illicit tobacco consumption appear not to have been borne out.\textsuperscript{99,100}

With point-of-sale and standardised packaging legislation complementing TAPA, there are few remaining means by which smoking can be promoted in the UK. However, tobacco and related imagery remains prevalent in the media, including films, television programmes, magazines and social media. Although paid-for product placement is illegal under the terms of TAPA, smoking imagery remains common in popular films, computer games and on prime-time UK television.\textsuperscript{101,102} Evidence suggests that there is a clear association between exposure to such imagery in the media and young people starting smoking.\textsuperscript{103} Smoking in the media thus remains a major driver of smoking uptake among children and young people, and needs to be addressed.

3.2.6 Restricting young people’s access to tobacco products

Measures to reduce young people’s access to tobacco have been recommended as a means of reducing uptake of smoking. Evidence arising mostly from the USA indicates that reducing youth access to tobacco by implementation of the minimum age-of-sale laws reduces smoking prevalence among young people, although this is highly dependent on levels of enforcement and access to alternative non-retail sources of cigarettes.\textsuperscript{104,105} European evidence indicates that access to cigarette-vending machines was significantly associated with regular smoking by young people.\textsuperscript{106}

Across the UK, the minimum age at which young people are permitted to purchase tobacco was raised from 16 to 18 in 2007, and legislation prohibiting vending machines was implemented between 2011 and 2013.\textsuperscript{107} The increase in minimum purchase age in England was associated with a significant reduction in regular smoking among 11- to 15-year-olds\textsuperscript{107} and a decline in smoking prevalence among 16- to 17-year-olds.\textsuperscript{108} The percentage difference in current smoking pre- and post-legislation was significantly greater among those under 18 than in older age groups. However, the effect of the legislation is undermined by substitution of other means of access, particularly proxy purchasing by adults.\textsuperscript{109,110} Scotland banned such sales in 2010 and England from 2015, although the Scottish legislation appears not to have been successful in reducing proxy sales.\textsuperscript{111}

A recent systematic review of the equity impact of tobacco control policies found only five studies that have assessed the equity impact of such measures on
Two were equity positive (greater impact on low-SES youth), two neutral (no difference by SES) and one negative (greater impact on high-SES youth). Thus, no overall conclusion can be drawn about their equity impact. However, stronger (ie comprehensive and enforced) US state-level, age-of-sale laws were associated with lower smoking initiation and a reduction in low-SES adolescent girls moving on to regular smoking. In England, raising the age of sale from 16 to 18 was associated with a significant reduction in regular smoking among those aged 11–15 years, with no difference by SES (measured by eligibility for free school meals).112 However, although the percentage of high-SES pupils who found it difficult to buy cigarettes from a shop increased, this was not the case for low-SES pupils.

3.2.7 Treatments to help dependent smokers stop, including increasing access to medications

Evidence-based smoking cessation treatments typically comprise behavioural interventions, delivered as brief advice from healthcare professionals, telephone quit-lines, more intensive one-to-one or group counselling, and pharmacotherapies, including NRT, bupropion and varenicline.113 The UK was one of the first countries to make these services easily available to all smokers as a tobacco control policy. In England and Wales, NHS Stop Smoking Services (NHS SSSs), free at the point of use, were launched in areas of high deprivation defined as Health Action Zones (HAZs) in 1998–9, and extended to the rest of England and Wales in 2000–1. The number of people using NHS SSSs grew year on year, rising to over 800,000 in 2011–12, although they have fallen each year since then to a total of 450,582 in 2014–15.114

These services, which use evidence-based guidelines115 and strongly recommend the use of pharmacotherapy, have been shown to be effective over a number of years. A national evaluation conducted in the early years after their establishment found that 53% of attendees confirmed abstinence at 4 weeks, with 15% still abstinent at 1 year.116 This study has recently been updated, and 1-year abstinence rates are now lower, at 8%;117 however, some of this change may be attributable to the growth of less intensive and hence less effective forms of support, such as one-to-one interventions in pharmacies rather than individual or group behavioural support delivered by smoking cessation specialists.117 In the UK, cessation support is also available to smokers through stop smoking helplines and websites where smokers can speak to or converse online with a trained expert adviser. In a recent trial using the NHS Stop Smoking helpline, approximately 20% of smokers who agreed to set a quit date were abstinent at 6 months.118 The number of calls to the NHS quit-line is small, however, averaging 20,000 per month between 2005 and 2010.60
Pharmacological therapies such as NRT, bupropion and varenicline are highly effective when delivered with behavioural support (see Chapter 5), and initiatives to increase access to these treatments by smokers should improve the success of quit attempts. Making cessation therapies available on reimbursable prescriptions and NRT products available on general sale, which occurred in the UK between 1999 and 2002, resulted in a rapid increase in the proportion of quit attempts supported by medication from 28% to 61%. However, a great deal more could be done to extend delivery of stop smoking interventions, particularly by making intervention a component of all NHS care delivery, including secondary care.

Smoking cessation services tend to be more effective in adults than in young smokers. The US surgeon general’s report on prevention of smoking in youth concluded that several cessation programmes for youth are efficacious in the short term but that, in contrast to adults, there is little evidence of the efficacy of pharmacotherapies in youth cessation. Data from the NHS SSSs indicate that relatively few under-18-year-olds access these services, and that those who do have lower quit rates than other age groups. A recent systematic review found only two studies that had assessed the equity impact on youth of cessation services. Participants in both studies were mobile phone owners in their late teens / early 20s, who were motivated to quit and received text messaging support. Only one study demonstrated a long-term effect on quitting and this was significant only in low-SES intervention participants.

The contribution of NHS SSSs to the reduction in smoking prevalence over recent years has been estimated at between 0.1 and 0.3% above the background quit rate per year. Although the impact on prevalence of policies and initiatives to improve access to treatment is modest, these interventions have been successful in reaching smokers in the most disadvantaged areas, who tend to be more addicted and have the most difficulty stopping. A recent systematic review of cessation studies concluded that untargeted smoking cessation interventions across Europe are, on balance, likely to have increased inequalities in smoking. However, the same review found that the comprehensive UK stop smoking services, which are targeted at low-SES smokers, have reduced inequalities in the harm caused by smoking, because higher reach among low-SES smokers compensates for lower quit rates.

### 3.3 Cumulative impact of conventional tobacco control policies and future challenges

Although evidence of the impact of individual interventions on smoking prevalence is limited by the difficulty of separating out the independent effects on smoking prevalence of individual components from a wider package of measures, the multi-component approach adopted in the UK appears to be
Effective, for both adults and young people. The effectiveness of comprehensive packages of tobacco control policies has been further demonstrated in a recent study of the association between MPOWER policies – a list of measures developed by the WHO that are intended to assist in the implementation of interventions required by the FCTC (Monitor tobacco use and prevention policies, Protect people from tobacco smoke, Offer help to quit tobacco use, Warn about the dangers of tobacco, Enforce bans on tobacco advertising, promotion and sponsorship, and Raise taxes on tobacco) – and changes in prevalence, by scoring countries according to their implementation of MPOWER measures. The study showed that countries with higher MPOWER composite scores experienced greater decreases in current tobacco smoking between the years 2006 and 2009, and therefore underlines the need to implement the widest possible range of policies. The study also assessed the effect of changes in each MPOWER measure on changes in current tobacco smoking, and confirmed existing evidence that price increases are the most effective tobacco control measure.

Figure 3.6 demonstrates the declines that have occurred in smoking prevalence among adults and young people in Britain since Smoking kills was published in 1998, in relation to the timeline of policies introduced. The reduction of adult smoking prevalence has been marked by the implementation of key policies, including bans on tobacco advertising, minimum ages for purchase of tobacco, and the launch of NHS Stop Smoking Services. The diagram illustrates the impact of these interventions on smoking rates in adults and young people, showing improvements over time as policies were implemented.
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Fig 3.7 Adult smoking prevalence in Scotland by Index of Multiple Deprivation: 1999 to 2011 (actual), 2012–2036 (target projections).\textsuperscript{127} (Adapted from ASH Scotland\textsuperscript{127} under Open Government Licence.)

smoking by around one-third, and by almost twice that proportion among young people, represents a substantial success for tobacco control policy. However, these figures also demonstrate that, despite this progress, smoking remains a significant public health problem in the UK, with around one in five adults still smoking regularly.\textsuperscript{61,128} These smokers, who are increasingly predominantly from the more deprived SES groups in UK society,\textsuperscript{61} have by definition proved resistant to policies applied to date, and also by definition are in desperate need of measures to help them stop smoking.

The Scottish Government has recently set a target for Scotland to become ‘tobacco free’, defined as a smoking prevalence below 5%, by 2034. Figure 3.7 demonstrates how challenging it will be to meet this objective given current trends in smoking prevalence, particularly among low-SES groups, and it will be equally challenging in the rest of the UK. If such an ambition is to be realised, new tobacco control approaches that can bring about substantial declines in smoking among the most deprived individuals in society are urgently needed.

3.4 Developing a more effective tobacco control policy approach

There are many ways in which existing UK tobacco control policies could be improved and complemented to achieve faster declines in smoking
prevalence. In addition to policy measures already in place, greater investment in innovative MMCs, reversing declines in the uptake of SSSs and wider integration of smoking cessation interventions into NHS service delivery, extending smoke-free policies to a wider range of public places, preventing smoking promotion through media imagery and other loopholes in advertising and promotion legislation, and tighter measures to prevent youth access would all make contributions to this end.

However, the most effective policy measure is price. Repeated substantial increases in tobacco price, and removal of the price differentials for premium cigarettes, budget cigarettes and hand-rolling tobacco, would have a substantial impact, particularly among low-SES groups. The effect of taxes can be further enhanced if some of the revenue generated is used to support comprehensive tobacco control strategies. However, the negative effect of price rises on the incomes of those who continue to smoke, as well as the need to do more in general to provide smokers with alternative means to stop smoking, demands additional alternative approaches. Making non-tobacco nicotine products available to smokers, as envisaged in the Tobacco Control Plan for England and advocated in this report, could not only reduce the prevalence of smoking but also offset the negative effect of increased tax on continuing smokers by providing a more affordable and acceptable alternative product.

### 3.5 Summary

- Increasing the price of cigarettes reduces smoking prevalence, particularly among young and relatively disadvantaged smokers.
- Price increases may be more effective if introduced in single large rather than multiple small increments.
- The effect of price increases is undermined by the availability of illicit tobacco, and the option for smokers to downtrade to ultra-low-price cigarettes and hand-rolling tobacco.
- Smoke-free legislation has reduced passive exposure of children and adults to smoke, and may also have generated some further reduction in smoking prevalence.
- MMCs reduce smoking in all age groups and are an important factor in enhancing the effectiveness of other interventions, but are effective only if sufficiently well funded.
- Graphic health warnings on packs discourage smoking uptake, and encourage and sustain quit attempts.
- Removal of tobacco advertising is particularly effective in reducing smoking uptake, and both point-of-sale display prohibition and standardised packaging of tobacco products further reduce exposure to tobacco branding.
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> Smoking imagery in the media, both branded and unbranded, remains a strong promotional driver of smoking, particularly among young people.
> Raising the minimum age of sale, and prohibiting vending machine sales, reduces smoking among young people.
> Providing cessation support to smokers helps them to quit smoking and, if widely available, increases the rate at which smoking prevalence declines.
> Smokers from low-SES groups are particularly likely to respond to price increases and graphic health warnings.
> Existing tobacco control policy could be enhanced by: further reducing the affordability of tobacco, particularly of budget cigarettes and hand-rolling tobacco; investing in MMCs; preventing smoking imagery in the media, including social media; and extending smoke-free policies to outdoor areas.
> NHS SSSs need to be expanded, and appropriately funded to be integrated and actively promoted in clinical care pathways.
> However, even with all such measures in place, millions of people in the UK will continue to smoke for the foreseeable future. Alternative approaches, particularly for young and disadvantaged smokers, are urgently needed.
> Promoting the use of alternative, acceptable and more affordable nicotine products as a harm-reduction strategy has the potential to complement existing tobacco control policy, and in particular to offset the potentially regressive nature of tobacco tax rises.

References


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44 Laverty A, Millett C. Smoking ban in cars will benefit disadvantaged children most. *BMJ* 2014;348:g1720.


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provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities. www.wipo.int/wipolex/en/details.jsp?id=7882 [Accessed 22 February 2016].


94 Miller C, Ettridge K, Wakefield M. Research paper: ‘You’re made to feel like a dirty filthy smoker when you’re not, cigar smoking is another thing all together.’ Responses of Australian cigar and cigarillo smokers to plain packaging. Tob Control 2015;24:i58–65.


96 White V, Williams T, Wakefield M. Has the introduction of plain packaging with larger graphic health warnings changed adolescents’ perceptions of cigarette packs and brands? Tob Control 2015;24:i42–9.

97 Durkin S, Brennan E, Coomber K et al. Short-term changes in quitting-related cognitions and behaviours after the implementation of plain packaging with larger health warnings: findings from a national cohort study with Australian adult smokers. Tob Control 2015;24:26–32.


99 Scollo M, Bayly M, Wakefield M. Did the recommended retail price of tobacco products fall in Australia following the implementation of plain packaging? Tob Control 2015;24:90–3.

100 Scollo M, Zacher M, Durkin S et al. Use of illicit tobacco following introduction of standardised packaging of tobacco products in Australia: results from a national cross-sectional survey. Tob Control 2015;24:i76–81.


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127 Duffy, S. Creating a generation free from tobacco: how far have we come and where to next? Powerpoint presentation to University of Aberdeen Global Health Seminar, March 27 2015. Edinburgh: ASH Scotland.


Nicotine pharmacology and pathophysiology

4.1 Nicotine chemistry and absorption

Nicotine is a naturally occurring alkaloid present in the leaves of the tobacco plant, and is the major psychoactive compound and mediator of addiction to tobacco use. Nicotine absorption across cell membranes is highly pH dependent, because only non-ionised nicotine can cross biological membranes and be absorbed into the bloodstream. Nicotine is a weak base with a $pK_a$ of approximately 8, so, in the relatively acidic medium of cigarette smoke with a pH typically ranging from 6.0 to 7.8, more than half of the nicotine in tobacco smoke is protonated and cannot be absorbed. Manipulating the pH of tobacco smoke to make it more alkaline thus increases nicotine absorption.

The average nicotine content of commercially available manufactured cigarettes is around 10 mg, but, as a result of loss in sidestream smoke, retention in the cigarette stub and delivery of nicotine in ionised form, only about 1 mg is absorbed from each cigarette smoked. When tobacco smoke is inhaled, nicotine passes through the alveolar membranes of the lung into the pulmonary venous circulation. It is then carried into the heart, and then directly into the arterial system, reaching the brain within 10–20 s. The rate of increase in arterial nicotine concentration achieved by inhaling nicotine is thus faster even than that achieved by intravenous administration, with peak arterial concentrations occurring at around 20 and 30 s, respectively. After smoking a single cigarette, arterial nicotine concentrations differ according to the type of cigarette and the way in which it is smoked. Thus, one study reported arterial levels of only about 20 ng/mL, but some smokers can achieve arterial nicotine concentrations of about 60 ng/mL with just a few puffs and arterial concentrations of 100 ng/mL have been reported after smoking a single cigarette. The arterial blood nicotine levels achieved by inhaling nicotine are much higher than in the venous circulation (Fig 4.1). As the rate at which an addictive drug reaches the brain influences its addictive potential, the fast absorption and delivery of nicotine after inhaling tobacco smoke underpin the rapid behavioural reinforcement of smoking.
In contrast, when nicotine is swallowed, it is absorbed from the gastrointestinal tract into blood that flows into the portal veins and hence to the liver, where it undergoes substantial first-pass metabolism. Oral nicotine therefore generates very low and similar systemic venous and arterial blood levels. Conventional nicotine replacement therapy (NRT) products avoid this first-pass metabolism by delivering nicotine via the skin, mouth or nose, blood from which drains directly into the systemic venous system. NRT thus generates higher arterial nicotine levels than those achieved by gastrointestinal absorption, but levels in arterial blood are similar to those in venous blood and much lower than those achieved by inhalation. There are also marked differences in venous plasma concentrations of nicotine achieved, depending on the form and dose of NRT used (Fig 4.2). The variation in time to reach maximal nicotine plasma concentration is due, in part, to differences in administration duration as well as absorption time that occur with each route of delivery.

The relatively slow delivery of nicotine to the brain achieved by NRT is much less reinforcing, and hence much less likely to generate dependence, than cigarette smoking. However, forms of NRT that deliver nicotine relatively quickly, such as the nasal spray, are thought to be more likely to generate dependence than others. Overall, however, the addictive potential of cigarettes is much higher than that of NRT or other non-inhaled nicotine products. Clinically, very few users of NRT become dependent on it.
4.2 Nicotine metabolism

Around 70–80% of absorbed nicotine is metabolised to cotinine, and around 90% of this metabolism is via the hepatic cytochrome P450 (CYP) 2A6 enzyme. The majority of cotinine is then further metabolised to 3′-hydroxycotinine in a reaction mediated exclusively by CYP2A6. Both nicotine and its metabolites are excreted in urine. As most nicotine clearance occurs via metabolic (ie non-renal) means, variability in nicotine metabolism is likely to cause substantial variation in the rate of nicotine clearance between individuals. The ratio 3′-hydroxycotinine:cotinine is known as the nicotine metabolite ratio (NMR), which serves as a phenotypic indicator of CYP2A6 enzymatic activity. As CYP2A6 represents the major route of nicotine clearance, the NMR is also strongly correlated with the rate of nicotine clearance.

Fig 4.2 Venous plasma nicotine concentrations achieved over 1 h by a single cigarette and by single doses of various forms of nicotine replacement therapy (NRT – nicotine nasal spray (NNS), 2 and 4 mg gum, and nicotine patch). Inset: nicotine levels after a 16- and 24-h course of nicotine patch treatment over a 24-h period. (Reproduced from: Schneider NG, Olmstead RE, Franzon MA, Lunell E. The nicotine inhaler: clinical pharmacokinetics and comparison with other nicotine treatments. Clinical Pharmacokinetics 2001;40:661–84. With permission from Springer.)
Variation in the CYP2A6 gene, which has an impact on the functionality of the CYP2A6 enzyme, is common and associated with alterations in the rate of nicotine clearance, together with a variety of smoking behaviours. Slower nicotine metabolism, as inferred from CYP2A6 genotypes or as measured directly by the NMR, is associated with lower cigarette consumption, lower nicotine dependence, lower smoking-related reward and lower risk of being a current smoker. Slower nicotine metabolism is also associated with an increased likelihood of unaided cessation (ie cessation without behavioural or pharmacological support) and cessation in clinical trials, in which slow metabolisers are typically more likely to achieve abstinence on both placebo and NRT. A separate study that used an alternative CYP2A6 phenotype measure also found associations between slow nicotine metabolism and higher abstinence rates. The prevalence of slower nicotine metabolism differs according to ethnicity, predominantly owing to interethnic variability in patterns of CYP2A6 allele expression. The frequency of CYP2A6 alleles conferring reduced or loss of CYP2A6 activity is generally higher in African and East Asian populations than in European populations, as reflected by a higher prevalence of reduced nicotine metabolism in populations of African and East Asian descent (approximately 40–50%) versus European descent (approximately 10–25%).

In addition to CYP2A6-mediated nicotine inactivation, nicotine can be inactivated through N-glucuronidation and N'-oxidation, through metabolism by uridine diphosphate (UDP) glucuronosyltransferase (UGT) 2B10 and flavin-containing monooxygenase (FMO) 3, respectively. The resulting minor nicotine metabolites, nicotine N-glucuronide and nicotine N'-oxide, account for up to 5% and 7% of a nicotine dose that can be recovered from urine, respectively. In individuals with no functional CYP2A6 activity, FMO3- and UGT-mediated nicotine metabolism may be more important for nicotine clearance; however, reduced FMO3 function did not substantially affect nicotine metabolism in individuals with reduced CYP2A6 activity. UGT2B10 can also metabolise cotinine to cotinine N-glucuronide, comprising 12–17% of a nicotine dose recovered from urine. A second UGT enzyme, UGT2B17, metabolises 3'-hydroxycotinine to 3'-hydroxycotinine O-glucuronide, and accounts for about 9% of a nicotine dose recovered from urine.

Several of these minor enzymes involved in the nicotine and cotinine metabolic pathway (FMO3, UGT2B10 and UGT2B17) are highly polymorphic, with some genetic variants leading to altered activity of these enzymes. Variation in FMO3 is associated with minor alterations in nicotine metabolism, but appears to be of insufficient magnitude to alter cigarette consumption or total tobacco dose in light smokers of African-American ancestry. In heavy smokers of European ancestry, variation in FMO3 has little effect on consumption, unless restricted to those with faster CYP2A6 activity (a difference of about three cigarettes a day). The influence of UGT genetic variation, tested to date on variation in nicotine
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metabolism, is also relatively modest and does not appear to alter smoking behaviours substantially.\(^{35,36}\) Although UGT2B17 genetic variation is associated with altered 3′-hydroxyccotinine metabolism,\(^{36}\) variation in genes for UGTs that alters cotinine and 3′-hydroxyccotinine metabolism is unlikely to affect smoking behaviours because cotinine and 3′-hydroxyccotinine are essentially inactive metabolites of nicotine.

4.3 Systemic and central nervous system effects

4.3.1 Nicotinic acetylcholine receptors

Nicotine exerts its pharmacological effects through binding to nicotinic acetylcholine receptors (nAChRs). These receptors are universally expressed in cells throughout the body,\(^{37}\) including the central and peripheral nervous systems, where they play a key role in mediating nicotine dependence and addiction. The nAChRs are ligand-gated ion channels composed of five transmembrane subunit proteins arranged around a central pore. Neuronal nAChRs consist of \(\alpha (\alpha_2-\alpha_{10})\) and \(\beta (\beta_2-\beta_4)\) subunits,\(^{38}\) each of which is encoded by a single gene (denoted with a ‘CHRN’ prefix), and may be homomeric or heteromeric in terms of subunit composition. Different combinations of subunits result in receptors differing in pharmacological and physiological profiles.\(^{39,40}\) Individual subtypes differ, eg in their affinity for nicotine, and sensitivity to upregulation and desensitisation after nicotine exposure.\(^{40}\)

Each nAChR subtype has a distinct distribution profile within the brain, which can be determined through assessment of subunit mRNA using techniques such as in situ hybridisation, and through imaging techniques such as positron emission tomography (PET) and single-photon emission computed tomography (SPECT), using subtype-selective radioligands.\(^{40}\) The differential expression of specific subunits, with distinct biological functions in brain regions mediating specific behaviours, allows nicotine to exert a broad range of effects.\(^{41}\) The \(\alpha_4\beta_2\) receptor is the most commonly expressed subtype in the human brain, and historically has been implicated through animal models as critical to the experience of nicotine’s reinforcing effects (eg Picciotto et al\(^{42}\)). In recent years, however, the importance of the less studied \(\alpha_3\) - and \(\alpha_5\)-receptor subunits in mediating nicotine dependence has been recognised. The \(\alpha_5\)-receptor subunit appears to play a key role in determining aversive responses to high doses of nicotine.\(^{43}\)

4.3.2 Systemic and central nervous system effects

Nicotine, at relatively low doses, is a stimulant. It increases heart rate, and has been reported to have beneficial effects on cognition and performance,
improving attention, memory and fine motor skills. Tolerance to nicotine can develop rapidly (within a few days of use), and cessation of use then results in the experience of withdrawal symptoms, both somatic and affective, such as anxiety, restlessness, inability to concentrate, irritability and change in appetite. Chronic exposure to nicotine results in a number of neuroadaptions, including desensitisation of nAChRs and upregulation in their expression, both of which are linked to nicotine tolerance and withdrawal.

4.3.3 Mechanisms of effect

Nicotine exerts its complex effects (including arousal, mood modulation and pleasure) via several neurotransmitter pathways. Once bound to neuronal nAChRs, nicotine facilitates the release of dopamine, serotonin and a host of other neurotransmitters including γ-aminobutyric acid (GABA), glutamate, noradrenaline, acetylcholine and endorphins. The mesolimbic dopamine pathway has, perhaps, been the most widely studied in relation to nicotine dependence. Dopamine release in the nucleus accumbens, resulting from nicotinic stimulation of dopaminergic neurons in the ventral tegmental area, is crucial to the processing of rewarding and reinforcing the effects of nicotine. Indeed, dopamine release in the nucleus accumbens appears to be critical in the experience of the rewarding effects of many drugs of abuse. Continued pairing of the rewarding/reinforcing effects of nicotine with specific sensory and environmental stimuli (which could include, for example, the smell of tobacco smoke or the sight of a pack of cigarettes – smoking-related behaviours) results in these stimuli also acquiring reinforcing properties. These cues (conditioned reinforcers) have been linked to the maintenance of smoking, smoking-related cravings and relapse.

4.4 Toxicity and potential hazards

4.4.1 Toxicity of nicotine

Although nicotine is a toxic compound, overdosing on nicotine products used as directed is almost impossible, given the individual ability to titrate dose and the short half-life of nicotine (see Development of addiction below – Section 4.5). However, ingestion of high doses (purposeful or accidental) can be fatal. Historically, the lethal dose of nicotine for a human adult has consistently been stated to be about 60 mg, corresponding to an oral median lethal dose (LD₅₀) of approximately 0.8 mg/kg. However, this figure has recently been disputed in the light of reports of non-fatal suicide attempts or accidents involving nicotine ingestion, leading to an estimate that the lower dose limit for fatal outcomes is likely to be 500–1,000 mg ingested nicotine, equivalent to an oral LD₅₀ of 6.5–13 mg/kg.
4.4.2 Potential hazards of short- and long-term nicotine use

At commonly used dose levels, short-term nicotine use does not result in clinically significant harm. The safety of NRT products, which have typically been used for days or weeks in the context of an attempt to quit smoking, is well established49 (see Chapter 5 for further detail), with no evidence of any increase in the risk of heart attack, stroke or death.50,51

Evidence about long-term nicotine or NRT use is relatively scarce, and concerns have been raised that long-term NRT use may increase cancer risk, in part owing to endogenous formation of carcinogens such as N\textsuperscript{-}nitrosonornicotine (NNN).52 However, studies carried out in experimental animals largely indicate that nicotine alone is not carcinogenic.53 In vivo and in vitro studies in animals do, however, suggest that nicotine can have tumour-promoting effects through activation of intracellular signalling pathways. Such effects include cell proliferation, enhanced angiogenesis and decreased apoptosis.37,49 However, it is important to note that many studies in this area have used nicotine at higher doses than those achieved in heavy smokers.54 In vitro research suggests that nicotine can have a negative impact on the function of some cells within the cardiovascular system,55 and adverse effects on glucose metabolism.56 However, robust evidence on the safety of long-term nicotine use in humans from the 5-year Lung Health Study, in which participants were actively encouraged to use NRT for several months and many continued to consume NRT for a much longer period, demonstrates no association between sustained NRT use and the occurrence of cancer (lung, gastrointestinal or any cancer) or cardiovascular disease.57,58 In addition, a recent clinical trial comparing 8, 24 and 52 weeks of NRT treatment found that treatment duration was not associated with any adverse effects, further supporting the safety of long-term NRT use.59

Although there is little evidence on the safety of using nicotine for periods longer than 5 years, and no data on the safety of long-term use of nicotine by inhalation other than when delivered by tobacco smoke, it is widely accepted that any long-term hazards of nicotine are likely to be of minimal consequence in relation to those associated with continued tobacco use. Notably, and in recognition of this fact, the UK Medicines and Healthcare products Regulatory Agency (MHRA) recently approved an extension to the indication of NRT to include ‘harm reduction’,60 defined as ‘for use as a substitute or partial substitute for smoking tobacco, both for those making an attempt to quit and those not currently intending to make a quit attempt, without any restriction on its duration of use’.61 Guidelines on harm-reduction approaches to smoking from the National Institute for Health and Care Excellence (NICE) further state that ‘it is safer to use licensed nicotine-containing products than to smoke’ and ‘there is reason to believe that lifetime use of licensed nicotine-containing products will be considerably less harmful than smoking’.62
Research from animal studies suggests that fetal exposure to nicotine may lead to adverse postnatal health consequences\textsuperscript{63} and that cognitive function and development are adversely affected by nicotine exposure during both the fetal and the adolescent periods.\textsuperscript{64} The relevance of these findings to human brain development remains uncertain, however. There is evidence that smoking in adolescence is associated with cognitive and attentional impairments in later life, and possibly an increased risk of mental health problems,\textsuperscript{65} but it is difficult to exclude the effects of confounders of this association in the observational studies available.\textsuperscript{66}

\section*{4.5 Development of addiction}

Nicotine is the primary addictive component in cigarettes and other tobacco products. It establishes and maintains addiction, thereby sustaining use, through a range of complex actions on brain neurochemistry, which have been reviewed in detail elsewhere.\textsuperscript{67,68} However, the addictiveness of any nicotine-containing product depends on several factors beyond merely the presence of nicotine. These factors primarily include the rate at which nicotine is absorbed and delivered to the brain, and the dose of nicotine delivered. Other factors, such as the speed at which the drug is metabolised and how soon withdrawal symptoms occur, play a role. This is particularly relevant to nicotine, given its short half-life (about 2 h), but this is a feature of the drug more than the product delivering the drug. A nicotine-containing product will therefore be more or less addictive depending on the dose and rate at which the nicotine is delivered. Essentially, a product that delivers a high dose rapidly will have a greater liability for addiction than one that delivers a low dose slowly. In this section, we describe the importance of these factors.

\subsection*{4.5.1 Dose effects on addiction potential}

Dose is an important factor in the development of nicotine dependence. Animal models clearly demonstrate an inverted-U relationship between nicotine dose and self-administration, although there is interindividual variability in the shape of this curve, some of which is under a genetic influence.\textsuperscript{43} Therefore, increasing the dose is associated with increased self-administration up to a point, after which higher doses become increasingly aversive and ultimately toxic. One advantage of the short half-life of nicotine is, however, that it enables consumers to self-titrate their achieved dose. The dose (ie plasma concentration) of nicotine achieved via use of different nicotine-containing products varies considerably (see Fig 4.1 – the total dose achieved is reflected by the area under the curve for each product). Figure 4.1 also illustrates the considerable variability in speed of delivery across these products which, as discussed above, also contributes to addiction liability.
4.5.2 Rate of nicotine clearance

Nicotine is metabolised principally in the liver, with a half-life for elimination of approximately 2 h (although, as discussed above, this varies considerably between individuals). As a result of this short half-life, plasma nicotine concentrations drop rapidly after nicotine administration, leading to withdrawal symptoms, prompting further nicotine administration in regular users, eg in a typical heavy, dependent smoker, nicotine levels increase rapidly after smoking a cigarette (by about 5–30 ng/mL), then drop before increasing again after smoking the next cigarette. Over the course of a day, plasma nicotine concentrations rise gradually to a steady state of between about 10 and 50 ng/mL. The combination of a short half-life and regular administration via frequent smoking (eg hourly) results in a distinctive pattern of nicotine concentrations, as represented in Fig 4.3. Critically, overnight abstinence leads to the almost-complete elimination of nicotine from the body, leading to marked withdrawal on waking, and the need to consume nicotine in order to reverse these symptoms.

Fig 4.3 Simulated plasma nicotine concentrations obtained after smoking a cigarette every hour for 16 h. (Adapted and reprinted from Le Houezec with the permission of the International Union Against Tuberculosis and Lung Disease. Copyright © The Union.)
4.6 Smoke constituents influencing the addictive potential of cigarette smoke

The addictive potency of cigarettes (and indeed other tobacco products) is influenced by not only their nicotine content but also other aspects of product design, including substances added to the cigarette to enhance nicotine delivery and absorption. Monoamine oxidase (MAO) inhibitors in tobacco smoke increase the levels of amines in the brain, such as dopamine and serotonin, and may subsequently potentiate the reinforcing effects of nicotine. Indeed, animal studies have demonstrated that MAO inhibitors facilitate nicotine self-administration and enhance its motivational properties. These findings may also contribute to the strong reinforcing properties of nicotine from cigarettes.

Sugars and polysaccharides are commonly added to tobacco products to increase the formation of aldehydes, including formaldehyde and acetaldehyde, in tobacco smoke. Acetaldehyde itself has addictive potential, as demonstrated through self-administration experiments in animals, but it also enhances the addictive potential of nicotine. The interaction between these compounds also generates a rewarding effect that exceeds the additive effects of either component in rodent studies.

Menthol and other flavourings (including cloves and liquorice) increase the palatability of cigarette smoke and, in the case of menthol and cloves, facilitate deeper inhalation and therefore a higher nicotine dose (owing to their cooling/local anaesthetic effects). These are widely added at levels below those used in what are conventionally considered to be ‘flavoured’ cigarettes. Flavours may also become conditioned reinforcers in themselves, as a consequence of their repeated pairing with nicotine. In addition, menthol inhibits metabolism of nicotine to cotinine, purportedly through inhibition of CYP2A6 enzyme activity, thus increasing the effect of nicotine. Cocoa and chocolate, which contain theobromine, are also common additives in tobacco. Theobromine is a bronchodilator, and thus has been proposed to enhance nicotine absorption in the lungs. However, the theobromine content of cigarettes was deemed too low to exert bronchodilatation in a recent review. Levulinic acid is an additive with a sweet caramel taste, but it also alters the pH and so reduces the ‘harshness’ of inhaled smoke. This, similarly to menthol, facilitates a higher nicotine dose.

Alkaline additives such as ammonia compounds are among the most common additives used in cigarette manufacture. These substances are added to cigarettes (and other tobacco products) to manipulate the pH. As discussed above, increasing the pH increases the proportion of non-ionised, or freebase, nicotine, which is more physiologically active than the ionised form, crossing biological membranes more readily. Tobacco industry scientists have extensively investigated the potential of pH manipulation to optimise nicotine delivery (see...
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Hurt and Robinson. Curing methods used in the production of tobacco can also influence the pH of tobacco smoke. In particular, air-cured tobacco, as used in cigars, generates nicotine at a relatively high pH, facilitating absorption from oral and upper airway mucosa. Cigarette tobacco is largely flue cured, resulting in nicotine at a lower pH and lower upper airway absorption, hence requiring inhalation into the much larger surface area of the lung alveoli to achieve significant absorption.

4.7 Impact of cigarette design characteristics on nicotine delivery

A number of physical characteristics of cigarettes have been engineered to influence nicotine delivery, including cigarette dimensions, filtration, ventilation, paper porosity and tobacco shred size. Ventilation, for example, serves to manipulate nicotine, tar and carbon monoxide levels through dilution of tobacco smoke, and is achieved through the introduction of holes in both the filter and the paper wrap. Ventilation technology was used in the production of ‘light’ or ‘low-tar’ cigarettes, which were promoted by the tobacco industry as healthier alternatives to full-strength cigarettes. However, these descriptions have been shown to be misleading and for this reason have been banned in the UK. Although smoking machine assessments give readings indicating that these cigarettes yield lower doses of nicotine, studies in humans have shown that smokers compensate by altering their smoking topography (ie the way in which people smoke their cigarettes). Thus, smokers use deeper inhalation, increased number of puffs per cigarette, etc when smoking these cigarettes, in order to achieve the same dose of nicotine attained when smoking stronger brands. This results in equivalent levels of exposure to the harmful constituents of tobacco smoke.

Smoking topography also affects nicotine delivery. Smokers can make changes to their blood nicotine levels by altering depth and frequency of inhalation and volume of smoke inhaled. A 20-a-day smoker can halve the number of cigarettes that they smoke, but sustain the same plasma nicotine levels by taking larger and deeper puffs. It is this compensatory behaviour that leads to a lack of association between machine-determined nicotine levels in cigarettes and the nicotine dose and quantity of toxic smoke inhaled by a smoker (see below). This may be why reductions in the amount individuals smoke, although making it easier for them to go on to quit, have a relatively limited impact on health outcomes compared with quitting altogether. There are also sex differences in smoking topography (women typically take smaller puffs than men) and ethnicity (African-American individuals typically smoke more of their cigarette than people of European descent). Mood may also affect the way in which people smoke, with positive effect being associated with a greater increase in blood nicotine levels.
4.8 Lessons from cigarette design for harm-reduction product development

Nicotine is the primary addictive component sustaining tobacco use, but is not the cause of the vast majority of harm associated with tobacco use. Therefore, a product that delivers nicotine in the absence of other constituents of tobacco will be associated with dramatically less harm. The safety of NRT demonstrates this and, although long-term use is relatively uncommon, there is sufficient evidence to conclude that any harm from long-term nicotine use will still be negligible compared with the harm of tobacco use. However, nicotine-containing products such as NRT, although very low in harm, are also substantially less satisfying to smokers than, for example, cigarettes, as evidenced by their modest efficacy as smoking cessation products. As discussed above, this is due to the favourable nicotine delivery characteristics and unique range of behavioural reinforcers associated with cigarette smoking. The ideal harm-reduction device should therefore deliver nicotine in a manner as similar as possible to cigarettes, while at the same time maximising palatability and nicotine delivery to approximate the experience of cigarette smoking more closely.

4.8.1 Targeting the determinants of addictiveness

The principal determinants of the addictiveness of a nicotine-containing product are the dose that it delivers, and the speed with which the dose is delivered. Given that most cigarette smokers are dependent (at least to some degree) on nicotine, targeting these determinants is a critical requirement of any harm-reduction product. The use of additives in tobacco products and the design of the cigarette are both engineered to enhance nicotine delivery from the cigarette, by modifying both the palatability of the cigarette smoke (and therefore the ease with which it can be inhaled, facilitating rapid delivery and self-titration) and the bioavailability of the nicotine contained within it. Other factors, such as the taste and smell of cigarette smoke, and the behavioural action of smoking, can themselves become conditioned reinforcers over time and, although secondary to the effects of nicotine, are important drivers of continued smoking.

4.8.2 E-cigarettes and harm reduction

E-cigarettes meet many of the criteria for an ideal tobacco harm-reduction product. Although nicotine delivery from e-cigarettes depends on a number of factors, including level of user experience and device characteristics, they can in principle deliver a high dose of nicotine, in the absence of the vast majority of the harmful constituents of tobacco smoke (or at least at negligible levels), in a way that enables accurate self-titration (see Chapter 5). They also provide some of the
cues associated with cigarette smoking, such as taste and throat rasp, as well as behavioural actions such as hand-to-mouth movement. At present therefore, although little is known of the kinetics of nicotine uptake from e-cigarettes into arterial blood, e-cigarettes offer a substitute to smoking that is more likely, on theoretical grounds, to prove satisfying and acceptable to smokers than NRT.

4.9 Summary

- Nicotine is the primary addictive component of tobacco smoke.
- When inhaled into the lungs, nicotine from tobacco smoke is absorbed and delivered to the brain much more quickly, and in higher doses, than can be achieved by other routes of absorption.
- This rapid delivery of repeated high doses of nicotine to the brain is thought to underpin the addictive nature of cigarettes.
- Nicotine is metabolised quickly, causing blood levels to fall rapidly after dosing. People who metabolise nicotine more slowly, and therefore maintain more constant blood levels, tend to be less heavily addicted.
- Nicotine is a stimulant that improves concentration and fine motor skills. However, once tolerance is acquired, unpleasant withdrawal symptoms occur when nicotine blood levels fall.
- Sustained use of nicotine is reinforced by some of the co-stimuli of smoking, such as the taste and sensation of tobacco in the throat, and the smells and behaviours associated with smoking.
- The tobacco industry has manipulated other constituents and additives in tobacco to enhance the addictiveness of nicotine in smoke.
- NRT products may not be effective in some smokers because they replicate few of the delivery, sensory or behavioural characteristics of cigarettes.
- E-cigarettes have the capacity to replace more of the characteristics of tobacco cigarettes than conventional NRT, and therefore have potential as effective smoking substitutes.

References

5 Kozlowski LT, Mehta NY, Sweeney CT et al. Filter ventilation and nicotine content of tobacco in cigarettes from Canada, the United Kingdom, and the United States. Tob Control 1998;7:369–75.


Gu DF, Hinks LJ, Morton NE, Day IN. The use of long PCR to confirm three common alleles at the CYP2A6 locus and the relationship between genotype and smoking habit. Ann Hum Genet 2000;64(Pt 5):383–90.
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5 Non-tobacco nicotine products

5.1 Introduction

For many years, the range of non-tobacco nicotine products available in the UK has been dominated by nicotine replacement therapy (NRT) products, developed and licensed as medicines to aid smoking cessation. The range of NRT products available has grown to include transdermal patches, chewing gum, lozenges, nasal spray, oral pouch, oral spray, oral strips and the ‘inhalator’, a device that provides a nicotine vapour for oral absorption. In recent years the licences for these products have been extended in several countries, including the UK, to include use to assist smoking reduction and temporary abstinence.

There is strong evidence from randomised controlled clinical trials that NRT can be an effective smoking cessation therapy. A Cochrane review carried out in late 2012 identified 150 such trials, and concluded that all commercially available forms of NRT increase the likelihood of successful cessation among smokers making a quit attempt.¹ NRT products also have a very good safety record.² The products differ in the speed of nicotine delivery and the degree of behavioural replacement for smoking that they provide, but are fairly similar in the amount of nicotine that their strongest formulation delivers. Some require specific techniques for correct use (e.g. chewing gum and nasal spray), whereas others (e.g. the transdermal patch) are very simple to use. None, however, reproduces the rapid delivery of high doses of nicotine achieved by inhaling tobacco smoke, and few smokers find them enjoyable or satisfying.

NRT products have traditionally been produced and marketed by the pharmaceutical industry, but in recent years tobacco companies have also begun to acquire or develop products manufactured to standards similar to those of NRT products. Examples of these ‘clean’, non-tobacco nicotine products include Zonnic nicotine gum, marketed by Niconovum, part of Reynolds American Inc, and Verve nicotine-containing discs marketed by NuMark, part of Philip Morris. In the past 5 years, however, the non-tobacco nicotine market has been transformed by the emergence of e-cigarettes, which are now the most widely used form of non-tobacco nicotine. Unlike NRT, they have been marketed as...
consumer products rather than therapeutic goods, and also, unlike most forms of NRT, they retain several important features of smoking other than nicotine delivery, including similar hand-to-mouth movements, behavioural rituals, an inhaled sensory stimulus and a range of flavours. These characteristics make e-cigarettes attractive to a wide range of smokers, including many who do not or would not use NRT; hence, they provide a potentially viable, lower-hazard market competitor to tobacco cigarettes. As consumer products, they are subject to varying degrees of regulation in different countries, and are evolving quickly as the technology improves. Most e-cigarettes are marketed by independent companies importing products from China, but some production is now based in the UK. Several leading brands have now been bought by tobacco companies (see Chapter 8).

The non-tobacco nicotine market in the UK and many other countries is thus in a state of rapid change, with use of e-cigarettes already eclipsing that of pharmaceutical NRT (see Chapter 7), and an increasingly wide range of new products that deliver nicotine at or close to medicinal standards, some of them marketed by the tobacco industry, becoming available. Indeed the status quo of the nicotine market, whereby medicines have to date been made exclusively by pharmaceutical companies, has recently been challenged by the award of medicines licences to two new products: a nicotine-metered dose inhaler (Voke), and an e-cigarette (E-Voke), both of which are being brought to market by Nicoventures, a subsidiary of British American Tobacco.

This chapter provides a summary of currently available non-tobacco nicotine products, their pharmacokinetic profile, safety, addiction potential and trends in their use. Where blood or plasma nicotine levels are given, they relate to those in venous blood (see Chapter 4) unless stated otherwise.

5.2 NRT products

5.2.1 Transdermal nicotine

5.2.1.1 Doses and pharmacokinetics

Commercially available transdermal nicotine patches provide nicotine at a controlled rate for absorption through the skin into the systemic venous circulation. Products vary in dose from around 7 to 25 mg per patch, and deliver nicotine for either 16 or 24 h. High-dose examples include patches that deliver 25 mg over 16 h, or 21 mg over 24 h; lower doses, which are intended for weaning some weeks after smoking cessation, deliver (for example) 15 or 10 mg over 16 h, or 14 or 7 mg over 24 h. The rationale behind the 24-h patch is that it delivers nicotine during sleep and thus provides some protection against urges to smoke immediately after waking. The occasional drawback of 24-h delivery,
which is avoided by 16-h formulations, is that nicotine can cause vivid dreams or otherwise disturbed sleep.

The rate of absorption of nicotine from transdermal patches is slow, although there are some differences in pharmacokinetic profile between available products. In general, after application of the patch there is a delay of up to 2 h before plasma nicotine levels start to rise. High-dose products can generate maximum venous plasma concentrations of 16–18 ng/mL at around 6–12 h.\textsuperscript{3,4} Plasma nicotine levels at 24 h are about 11 ng/mL with the 24-h patch, and 3 ng/mL with the 16-h patch.\textsuperscript{3} During use a small reservoir of nicotine accumulates in the skin under the patch, which means that nicotine continues to be absorbed into the blood for an hour or so after the patch has been removed.

5.2.1.2 Safety profile

The nicotine patch has a good safety profile, even when more than one high-dose patch is applied simultaneously.\textsuperscript{5} In addition to the generic nicotine effects outlined briefly in Chapter 4, which apply to all the products described in this section, the most common side effects of the nicotine patch are insomnia, abnormal dreams, and skin irritation at the application site. There were early case reports of cardiovascular adverse effects, but more robust reviews suggest that these were not caused by NRT.\textsuperscript{6}

5.2.1.3 Addiction potential

The addiction potential of nicotine products is generally related to the speed of nicotine delivery, with faster delivery systems more likely to be used long term.\textsuperscript{7,8} As transdermal patches deliver nicotine very slowly, long-term dependence is not expected to be a problem, and empirical evidence confirms that this is indeed the case.\textsuperscript{7,9}

5.2.2 Oral and nasal nicotine

5.2.2.1 Doses and pharmacokinetics

Oral and nasal NRT products deliver nicotine more rapidly than nicotine patches, typically achieving peak plasma nicotine concentrations within 30–60 min. However, this kinetic profile is due in part to the sustained-release formulations used in many oral products, and faster absorption is possible. Formulations that spray nicotine solutions directly on to the mouth or nasal linings are among the most quickly absorbed NRT products, achieving peak levels within about 10 min of dosing. Nicotine absorption is influenced by the pH of the oral lining, being faster in relatively alkaline conditions. As with all oral or nasal products, nicotine that is swallowed undergoes extensive first-pass
metabolism (see Chapter 4) and makes no appreciable contribution to levels of nicotine in the blood.

Nicotine gum

Nicotine gum is available in two strengths, 2 mg and 4 mg, with the higher dose recommended for more dependent smokers. The nicotine contained within the gum is released on chewing and absorbed through the tissues lining the mouth. After chewing a single 2-mg piece of gum, peak plasma concentrations of 3–5 ng/mL are observed within 30–60 min, and chewing a 2-mg piece of gum every hour results in plasma nicotine concentrations of between 12 and 16 ng/mL. The maximum concentration ($C_{\text{max}}$) for a single dose of 4-mg gum is around 10 ng/mL, and regular dosing can generate plasma nicotine concentrations of between 27 and 32 ng/mL.

Nicotine oral disc

A recently developed nicotine oral disc has similar characteristics to the gum. It is a non-dissolving polymer disc containing 1.5 mg tobacco-derived nicotine, which is released when it is chewed. Chewing for 15 min results in an increase in plasma nicotine concentration of around 2 ng/mL.

Nicotine oral pouch

The nicotine in this product is in a powder, contained in a small pouch designed to be held in the mouth. A single 4-mg pouch, if held against the inner lining of the cheek for 30 min, produces a peak plasma concentration of approximately 10 ng/mL.

Nicotine lozenges and sublingual tablets

Products in this NRT category differ in how quickly they dissolve in the mouth, and in their dose and pharmacokinetic profile. A single 1-mg lozenge creates a peak plasma concentration of around 2 ng/mL, a 2-mg lozenge between 4 and 5 ng/mL and a 4-mg lozenge about 10 ng/mL, all within about 60 min. A study of a 2.5-mg nicotine lozenge showed that single use resulted in a maximum plasma concentration of 10.8 ng/mL in 30 min. Regular use of lozenges (eg one every 1–1.5 h) results in plasma nicotine concentrations of between 10 and 15 ng/mL for the 1- and 2-mg lozenges and 20 and 26 ng/mL for the 4-mg lozenge. The pharmacokinetic profile of the 2-mg sublingual tablet is similar to that of the 2-mg lozenge.

Nicotine oral film

This product contains 2.5 mg nicotine in a thin film, designed to be applied to the roof of the mouth, where it dissolves in less than 5 min. Use of a single strip
produces a peak plasma nicotine concentration, similar to the 2-mg lozenge and gum, of between 4 and 5 ng/mL.

**Nicotine inhalator**

The nicotine inhalator consists of a plastic tube holding a replaceable cartridge containing either 10 or 15 mg nicotine. When the user inhales through the device, nicotine vapour is generated, which deposits on and is absorbed through the lining of the mouth. Although used by inhalation, this product does not achieve appreciable pulmonary delivery or absorption, and the pharmacokinetic profile is similar to that of other oral NRT products. After 20 min intensive use, around 2 mg nicotine is released from the device, resulting in peak plasma concentrations of up to 8 ng/mL and, if this use is repeated hourly for 10 h, levels of around 20–25 ng/mL are achieved. Most users do not, however, use the device with this level of intensity, so lower plasma levels, similar to those achieved by 2-mg gum, are more typical. Nicotine release from this device decreases with ambient temperature so, in cold conditions (<15°C), users should be advised to keep the inhalator warm.

**Nicotine nasal and mouth sprays**

The nasal spray delivers nicotine solution to the nasal mucosa and, after a single 1-mg dose (two sprays containing 0.5 mg nicotine), a peak plasma nicotine concentration of about 5–6 ng/mL is observed within 10–15 min. Taking an hourly dose results in a steady-state plasma concentration of about 10 ng/mL. Although one of the fastest-acting NRT products, the nasal spray is also one of the most aversive to use initially.

The nicotine mouth spray also delivers nicotine quickly. Each spray delivers 1 mg nicotine and results in a peak plasma concentration of around 3–4 ng/mL within 10 min. A 2-mg dose gives a plasma concentration of around 5–6 ng/mL. Another mouth spray formulation has shown higher maximum plasma concentration (10 ng/mL) with a 2-mg dose, but with a slightly longer time (15 min) to reach this.

**5.2.2.2 Safety profile**

Similar to the nicotine patch, oral and nasal nicotine products have a good safety profile. The most commonly reported adverse effects are related to mouth and throat irritation, and hiccups. The nasal spray is a local irritant to the nasal lining.
5.2.2.3 Addiction potential

Some 5% of smokers who use oral nicotine products to stop smoking will continue to use them for a year or longer.\(^9\) With the nicotine nasal spray, this figure is closer to 10%,\(^9\) which probably reflects the faster nicotine delivery of this product. Long-term users are usually people who were highly dependent on nicotine from their cigarettes and who would be relatively unlikely to maintain long-term abstinence from smoking without such help.\(^21\) There are no documented cases of non-smokers becoming dependent on NRT.

5.2.3 Dual use of NRT and smoked tobacco products

NRT appears to be safe and well tolerated when used together with smoking.\(^22,23\) Randomised placebo-controlled trials of dual use indicate that the occurrence of expected symptoms of nicotine overdose, such as nausea and palpitations, is uncommon.\(^24,25\) A meta-analysis of NRT use before quitting found no increase in adverse events in patch users compared with those on placebo.\(^26\) No reported concerns over the use of NRT while smoking have arisen from post-marketing surveillance. Smokers who also use NRT (known as ‘dual users’) are approximately twice as likely in the following months to make a quit attempt, and to quit smoking, than those who do not.\(^27,28\)

5.3 E-cigarettes

E-cigarettes provide nicotine for inhalation in a vapour generated by heating a solution containing water, nicotine, propylene glycol, vegetable glycerine and typically also some flavouring. E-cigarettes were developed and first marketed in China in around 2003, and appeared on the market in the UK about 4 years later. The quality of early devices was variable, as was the consistency of the nicotine solutions (e-liquid) that they contained\(^29\) and their ability to deliver nicotine, which, in some cases at least, was poor.\(^30\) Newer studies have demonstrated some improvements in quality, at least in relation to declared nicotine content.\(^31,32\)

The many brands and models of e-cigarettes available can be grouped into three broad categories of different appearance (Fig 5.1). The original or first-generation e-cigarettes were designed to be of similar size and appearance to a conventional cigarette, and hence are sometimes known as ‘cigalikes’. These devices typically comprise two components: a battery and a ‘cartomiser’, a section of the device that contains nicotine solution and a vaporiser. Although some cartomisers are refillable, most are disposable, ie designed for single use and replacement when empty. Second-generation e-cigarettes are larger,
Fig 5.1 The three generations of e-cigarettes: (a) first generation; (b) second generation; and (c) third generation. (Images provided by Anna Phillips.)
typically the size of a large fountain pen, and incorporate a more powerful battery linked to a permanent vaporiser, and a tank system that users can refill with nicotine solution. Third-generation devices are typically larger still, with a still more powerful battery, usually with two heating elements (coils), and allow users to vary power and sometimes also the draw resistance of the device. Third-generation devices are also designed to allow modifications and substitution of individual components according to preference. Second- and third-generation devices generally deliver nicotine more effectively than first-generation devices (see below). The nicotine, propylene glycol, glycerine and flavourings of e-liquids also vary substantially, particularly in relation to nicotine content (with some being nicotine free), and in the ratio propylene glycol:glycerine.

5.3.1 Pharmacokinetics

Nicotine delivery from e-cigarettes is influenced by the concentration of nicotine and other constituents of the e-liquid, and the puffing (‘vaping’) technique used, and has generally increased with successive generations of the technology. The earliest first-generation devices delivered little or no nicotine, eg two early products containing a 16 mg/mL nicotine solution; when tested in smokers who had not previously used e-cigarettes, it was found that the devices delivered either very little nicotine, achieving a maximum blood level of 1.3 ng/mL at 20 min, or none at all. However, with improved technology and more experienced users, nicotine delivery is improved, eg whereas one study found that, among naive users, 5 min free use of an e-cigarette containing 24 mg/mL nicotine produced a peak plasma concentration of 4.6 ng/mL within 5 min, after 4 weeks’ practice the same users were achieving levels of 5.7 ng/mL. A study of a more advanced first-generation e-cigarette containing 18 mg/mL nicotine, and using a longer puffing (vaping) regimen (10 puffs 30 s apart on six occasions every 30 min), resulted in a maximum plasma nicotine concentration of 7.4 ng/mL at 2.5 h after the first puffing bout. In experienced users, using the same 10 puffs in a 5-min regimen, plasma nicotine levels can rise by around 8–16 ng/mL within 5 min of the first puff.

Use of higher nicotine concentrations in the e-liquid increases nicotine delivery, as does the inclusion of propylene glycol. In a study that examined nicotine delivery from a first-generation e-cigarette containing either 16 or 24 mg/mL nicotine, in either 75% glycerine or a 50% glycerine:20% propylene glycol e-liquid, peak plasma nicotine concentrations after 30 min of controlled puffing were highest (18 ng/mL) with the 24 mg/mL nicotine in the mixed glycerine:propylene glycol formulation, and lowest (10 ng/mL) with the 16 mg/mL nicotine in 75% glycerine solution. The propylene glycol:glycerine mix formulation delivered more nicotine at either dose than the
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75% glycerine solution. This higher delivery is thought to result from the lower boiling point of propylene glycol (187.6°C) than of glycerine (290°C).

Nicotine delivery is generally better from second- and third-generation devices, eg in a direct comparison with first-generation devices using a prescribed 5-min puffing regimen, second-generation e-cigarettes produced significantly higher rises in plasma nicotine concentration (by 4 ng/mL vs 2 ng/mL) at 5 min⁴¹ (Fig 5.3), and with repeated use these devices can sustain venous blood levels comparable with those expected in smokers.⁴² In a study examining the nicotine delivered by a third-generation device, experienced vapers were able to achieve a greater rise in blood nicotine levels than naive users under the same prescribed 5-min puffing regimen (5.8 ng/mL vs 2.7 ng/mL at 5 min),⁴³ although the speed of nicotine delivery remains much slower than from cigarettes.

Levels of the nicotine metabolite cotinine, which reflect nicotine intake over the past 3–4 days,⁴⁴ are similar in experienced e-cigarette users to those observed in smokers,⁴⁵–⁴⁷ indicating that e-cigarettes are capable of delivering

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Fig 5.3 Nicotine absorption from first- and new-generation e-cigarettes.41 (Reproduced from: Farsalinos KE, Spyrou A, Tsimopoulou K et al. Nicotine absorption from electronic cigarette use: comparison between first and new-generation devices. Scientific Reports 2014;4:4133.41)

total doses of nicotine similar to those from cigarettes. However, because, at the time of writing, available data relate only to venous blood levels, the extent to which e-cigarettes deliver nicotine for absorption into the pulmonary circulation, and hence reproduce the high arterial levels achieved by cigarettes, remains uncertain.

5.3.2 Safety profile

E-cigarettes are generally well tolerated. Similar to oral NRT products, reported short-term adverse effects relate predominantly to mouth and throat irritation, and tend to be self-limiting.29,48,49 As with all new products, however, long-term or rare adverse effects will remain uncertain until e-cigarettes have been in widespread use for several decades. Discussion of the potential long-term adverse effects of e-cigarette use is therefore limited to consideration of the likely effects of sustained inhalation of the known constituents of e-cigarette vapour.

Analysis of vapour generated by e-cigarettes has identified a number of potentially harmful constituents delivered alongside the nicotine and other
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e-liquid components. These include volatile organic compounds, carbonyls, aldehydes, tobacco-specific nitrosamines (TSNAs) and metal particles, but all at much lower levels than in cigarette smoke.50–64 Levels of formaldehyde and other aldehydes can be relatively high when vaporisation occurs at high temperatures,65,66 although in practice this overheating generates an aversive taste known as a ‘dry puff’, which vapers avoid.66,67 Recent reviews of the health effects of toxins inhaled during normal use of e-cigarettes have expressed concerns over potential adverse effects based on the presence of these contaminants,68–70 but not their levels, which are generally the more important determinant of toxicity. In normal conditions of use, toxin levels in inhaled e-cigarette vapour are probably well below prescribed threshold limit values for occupational exposure,71 in which case significant long-term harm is unlikely. Some harm from sustained exposure to low levels of toxins over many years may yet emerge, but the magnitude of these risks relative to those of sustained tobacco smoking is likely to be small. However, consideration of the potential harm of long-term e-cigarette use should serve as a guide to evidence-based product development, regulation and monitoring.

5.3.3 Areas of potential concern over hazards arising from vapour exposure

Areas of potential concern over the long-term effects of e-cigarette use include the effects of vapour constituents depositing in the mouth, upper airway and lungs, and systemic effects of vapour components absorbed as a result of swallowing or inhalation. The vapour constituents to be considered consist of those that should be present in e-liquids, and hence also the vapour, including: nicotine, propylene glycol, glycerine and flavours; those arising from impurities and contaminants in the e-liquid, which vary between batches and suppliers;72 and toxins, particles and other components created by the vaporisation process. The long-term adverse effects of nicotine are likely to be minimal73 (see also Chapters 4 and 7), although it is acknowledged that the effects of sustained inhalation of nicotine, in isolation from tobacco smoke and as opposed to absorption by another route, have not been studied. There are, however, no grounds to suspect that inhaled nicotine will have an appreciably different risk profile from nicotine delivered via other routes of absorption. The following discussion therefore relates to the effects of other constituents of e-cigarette vapour.

Inhaled vapours deposit first, and often substantially, in the mouth and upper airway. Much of this deposition is then swallowed, absorbed from the gastrointestinal tract and excreted, mostly in urine, either unchanged or after metabolism. This process of deposition, absorption and excretion of TSNAs and other carcinogens in tobacco smoke probably accounts for the increased risks of
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cancer of the oropharynx, stomach, bladder and other organs involved in the absorption and excretion process in smokers. The presence of carcinogens in e-cigarette vapour therefore increases the risk of similar outcomes but, in view of the very low levels of exposure generated by e-cigarette vapour, the magnitude of any increase in risk, in either relative or absolute terms, is likely to be low.

After passing through the mouth and upper airway into the lungs, larger particles and droplets in inhaled vapours deposit substantially throughout the intrapulmonary airways, to be either absorbed and excreted as above, or expectorated. Vapour components <5 µm in diameter reach the alveoli, where they either deposit and are then absorbed or cleared through phagocytosis or other processes, or are exhaled. In tobacco smoking, the deposition of carcinogens carried in tobacco smoke results in an increased risk of lung cancer, whereas oxidants and other toxins and irritants in smoke cause direct and inflammation-induced damage to lung tissues, which leads to chronic bronchitis and emphysema (chronic obstructive pulmonary disease (COPD)) and to pulmonary fibrosis. Smoke components absorbed from the lung, including particles and carbon monoxide, contribute to the increased risk of cardiovascular disease in smokers and, together with local effects, to an increased risk of infection. Although e-cigarette vapour contains a far less extensive range of toxins, and those present are typically at much lower levels, than in tobacco smoke, it is appropriate to consider potential hazards of e-cigarettes in relation to this spectrum of harm.

5.3.3.1 Generic effects of vapour

Data on the effects of e-cigarette vapour on the airways are limited to studies of short-term exposure. Use of an e-cigarette in healthy individuals for 5 min has been shown to reduce exhaled nitric oxide (NO) and increase airway resistance, consistent with an irritant effect on the airways resulting in mucosal oedema, smooth muscle contraction or increased production of lung secretions in response to the vapour. Another study reported a reduction in exhaled NO after inhaling vapour from an e-cigarette, with or without nicotine, of an order of magnitude similar to that provoked by conventional cigarette smoke. However, short-term e-cigarette use has been found to have no effect on spirometric markers of lung function, and another study found no difference in reported adverse events over 12 weeks’ use of an e-cigarette with or without nicotine, or conventional NRT. It is therefore far from clear whether these short-term airway effects will translate into long-term airway damage. Furthermore, as smoking cessation is associated with a reduction in respiratory symptoms in people with respiratory disease, many smokers who switch to an e-cigarette are likely to experience improvements in respiratory symptoms. This is illustrated in a study that followed a small cohort of patients with asthma, in whom improvements in symptoms and respiratory function were observed after
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switching from smoking to vaping. These observations therefore provide reassurance about short-term use of e-cigarettes in relation to adverse respiratory effects. One survey from Hong Kong has reported a higher prevalence of respiratory symptoms among Chinese adolescents who were ex- or never-smokers, and reported any use of an e-cigarette in the preceding month. However, e-cigarettes were used by only 1.1% of the total sample and 0.1% of never-smokers and, as use of e-cigarettes was not quantified, there is no evidence that those reporting symptoms were using the product regularly.

E-cigarette vapour has been reported to influence resistance to infection, and to delay recovery from influenza infection, in an animal model, although the validity of these findings and relevance to the effects in humans are far from clear. At the time of writing we are not aware of any published evidence on cardiovascular effects of e-cigarette use other than those attributable to nicotine. It is known, however, that the vapour does not deliver appreciable amounts of carbon monoxide, which represents a significant advantage relative to tobacco smoke. A study of carcinogen excretion in participants’ urine after use of e-cigarettes or tobacco cigarettes found significantly lower levels of TSNAs, benzene and polyaromatic hydrocarbons with e-cigarettes, demonstrating systemic absorption of these carcinogens and hence some degree of potential cancer risk, although clearly much less than that associated with smoking.

5.3.3.2 Propylene glycol and glycerine

Propylene glycol is an active ingredient of the solutions used to generate the synthetic smoke widely used in the performing arts and nightclubs, and in this context is generally considered to be safe. In animal studies, a month of exposure to propylene glycol vapour produced no apparent tissue toxicity of the lung, liver or kidney in beagles or rats, although 90 days’ nasal inhalation in rats was associated with an increase in the number of goblet cells and mucin production in the nasal mucosa at levels of exposure >1.0 mg/L. An early study examined long-term exposure to propylene glycol vapour over 12–18 months in rats and monkeys, and identified no lung or other adverse effects. However, acute exposure to propylene glycol has been shown to induce airway irritation and cough in humans, together with minor airflow obstruction. One study also found an association between levels of propylene glycol exposure in the home, and asthma and rhinitis in children.

Evidence on the adverse effects of inhaled glycerine is limited to a single case report of lipoid pneumonia with onset of symptoms associated with commencing e-cigarette use. The pneumonia was attributed to glycerine-based oils in the e-liquid, although commentators pointed out that glycerine is an alcohol and not a lipid. There have been no further reported cases of this
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outcome. Studies of repeated inhalation in rats found no evidence of damage to the lungs.97,98

5.3.3.3 Flavours

Although the flavours used in the e-cigarette liquid are generally those considered safe when ingested orally, some are irritant to the airways and the safety of most flavours after heating and inhalation is unknown.99 Diacetyl is an example of a flavour used in popcorn, and some other foods, that is safe for oral consumption but which, when heated and inhaled in large doses over long periods of time, can cause irreversible bronchiolitis.100 Vapour produced from e-liquids containing flavours has been demonstrated to be more cytotoxic than unflavoured vapour101 and, although both are far less so than tobacco smoke, this exposure may increase airway inflammation.102 In vitro experimental studies have also reported increased susceptibility of airway cells to viral infection after direct contact with e-liquid103 and evidence of cytotoxicity from cinnamon flavours, although the relevance of direct effects of contact with e-liquid, as opposed to vapour, is unclear.50 Although no study so far shows any clear hazards of flavours in e-cigarette vapour, those derived from flavours seem the most likely to pose appreciable health risks from long-term use.

5.3.3.4 Components generated by vaporisation

Heating propylene glycol or glycerine can cause decomposition to low-molecular-mass carbonyl compounds including formaldehyde and acetaldehyde, which can be carcinogenic in large doses.104 A study investigating the effect of varying the heating element voltage in e-cigarettes found that, at low voltage, levels of these compounds were up to 800-fold lower than in tobacco smoke, but that, at higher voltage (4.8 V), the levels were similar.56 In a study involving a third-generation – or variable-voltage – e-cigarette, negligible levels of formaldehyde were generated at lower (normal) power settings, but, when used at maximum power with 3- or 4-s puffs, levels 5–15 times higher than those found in cigarette smoke were observed.65 However, in a study simulating this ‘dry puff’ use, generating high levels of formaldehyde (up to 355 µg), acetaldehyde (up to 206 µg) and acrolein (up to 210 µg), experienced vapers were easily able to detect dry puffs and none could tolerate them.66 Under normal conditions of use, the levels were negligible.66

Two studies have examined urinary levels of aldehydes in vapers. One was a cross-sectional study that demonstrated considerably lower levels of urinary acrolein and crotonaldehyde in vapers than in smokers.89 The other was a cohort study that examined the change in urinary acrolein level when smokers switched to vaping. Significant decreases in acrolein concentrations were observed in smokers who switched completely to e-cigarettes as well as in those who were
both smoking and vaping, showing that 'dual use' of tobacco cigarettes and e-cigarettes leads to a reduction in smoke intake.88

In addition to the vaporised liquid, e-cigarette devices include metals, ceramics and rubber, all of which may become aerosolised in the process of vapour generation,62,105,106 eg copper particles of respirable size (0.450–2.02 µm) have been demonstrated in e-cigarette vapour at a level six times that seen in conventional cigarette smoke;57 levels of nickel and silver that are also higher than those in tobacco smoke have been noted.60 Whether these exposures comprise a significant health hazard remains uncertain. Potential toxicity of metal and other fine particles include carcinogenicity, cardiovascular disease and diseases such as COPD and interstitial lung disease, which are characterised by sensitisation, chronic inflammation or tissue remodelling.107 Inhalation of small particles, over both the short and the long term, also increases the risk of cardiovascular events.108 However, this is probably not a major concern because levels of exposure are well below recognised safety thresholds,109 and could be reduced still further by improving manufacturing processes and standards.

5.3.3.5 Hypersensitivity reactions

Hypersensitivity pneumonitis has been described in response to a range of inhaled organic materials. Allergy to nickel, which can be present in very small amounts in e-cigarette vapour, is a relatively common problem in clinical practice,110 although there has been no reported case of this problem in e-cigarette users. A case of eosinophilic pneumonia has been reported in a smoker who tried an e-cigarette,111 but again this has not been replicated and hence is of uncertain relevance.

5.3.3.6 Relevance to potential long-term harms

The above observations indicate that e-cigarettes deliver a much smaller range of toxins at much lower concentrations than cigarettes, and therefore indicate that harm from e-cigarette use is likely to be far less than that from smoking. They also demonstrate a possibility that some harm from long-term e-cigarette use cannot be dismissed. From first principles, we would expect repeated and sustained inhalation of the generally low concentrations of particulates, oxidants, carcinogens and other constituents to pose some risks to health, particularly in relation to COPD and lung cancer. However, the absolute magnitude of any risk attributable to e-cigarette use is likely to be very small in absolute terms, and hence substantially smaller than that arising from tobacco smoking. A recent evidence review concluded that e-cigarette vapour can contain some of the toxins present in tobacco smoke, but at much lower levels, and that the long-term health effects of e-cigarette use, although unknown, are likely to be much less, if
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at all, harmful to users or bystanders than cigarette smoke. An analysis based on expert opinion quantified the likely harm to health and society of e-cigarettes at about 5% of the burden caused by tobacco smoking, and a recent report by Public Health England supported this conclusion.

With appropriate product standards to minimise toxin and contaminant exposure in e-cigarette vapour, it should be possible to reduce risks of physical health still further. It is also possible, although unlikely, that other, unexpected harm from inhaling e-cigarette vapour over the longer term might yet emerge. Although it is not possible to quantify the long-term health risks associated with e-cigarettes precisely, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure.

5.3.3.7 Effects of passive exposure to e-cigarette vapour

Users of e-cigarettes exhale the vapour, which may therefore be inhaled by others, leading to passive exposure to nicotine. There is, so far, no direct evidence that such passive exposure is likely to cause significant harm, although one study has reported levels of polycyclic aromatic hydrocarbons that were outside defined safe-exposure limits. It is clear that passive exposure will vary according to fluid, device and the manner in which it is used. Nicotine from exhaled vapour can be deposited on surfaces, but at such low levels that there is no plausible mechanism by which such deposits could enter the body at doses that would cause physical harm.

5.3.4 Addiction potential

Speed of nicotine delivery seems to be important for smokers’ satisfaction and addiction potential. As outlined in Chapter 4, as a consequence of pulmonary absorption, cigarettes deliver nicotine to the brain very quickly. Although there are no available data on arterial nicotine levels after e-cigarette use, its venous delivery kinetics appear similar to those of products delivering to the mouth or upper airway, suggesting that pulmonary absorption from currently available e-cigarettes is low. In addition to this, the addictiveness of cigarettes is probably also related to other chemicals in tobacco smoke that enhance nicotine’s effects. These observations tally with other evidence, eg e-cigarette users report that they feel less dependent on them than on tobacco cigarettes, and empirical evidence from adolescent use suggests that, although adolescents experiment with e-cigarettes, few – if any – never-smokers who do so become regular e-cigarette users. The addiction potential of currently available e-cigarettes is therefore likely to be low. NRT and e-cigarettes may satisfy smokers who are already using nicotine, but they have little appeal for never-smokers. This may
change in the future, however, if e-cigarette and other nicotine inhalation technology improves sufficiently to achieve significant pulmonary absorption.

5.3.5 Dual use of e-cigarettes and tobacco cigarettes

Observational population-level evidence indicates that dual users of both tobacco and e-cigarettes are more likely to make an attempt to stop smoking than smokers who do not also use e-cigarettes, but it is not yet clear whether they are more likely to succeed\textsuperscript{119,120} (see Chapter 6). Some researchers have found a lower subsequent cessation rate among smokers who tried e-cigarettes but continued to smoke than among smokers who did not try e-cigarettes, but this could be explained by self-selection and exclusion of smokers who switched completely to e-cigarettes. One study found that daily users of the more advanced models had a higher cessation rate.\textsuperscript{120} Experience with NRT suggests that e-cigarette use is likely to increase the proportion of smokers making a quit attempt, but appropriate evidence on this effect is not yet available. A recent study has shown that dual users maintain their intake of nicotine, but reduce their intake of smoke and related toxins significantly.\textsuperscript{88} Obtaining nicotine from an alternative source leads to a reduction in smoking.\textsuperscript{22}

5.3.6 Use to inhale other drugs

Refillable e-cigarettes can be used to inhale other materials including cannabis oil or narcotics. Although such use is outside the scope of this report, use of e-cigarettes to deliver cannabis is likely, as is the case for nicotine, to be substantially less hazardous than conventional inhalation of cannabis smoke either alone or mixed with tobacco.

5.4 Products in development

At the time of writing there is a range of non-tobacco nicotine products in development, most of which are variations on the formulations outlined above, but some of which represent genuinely novel approaches, with the potential to deliver nicotine by inhalation with significant pulmonary absorption. As this is the route of absorption that generates the fastest increases in arterial blood levels, this range of products may prove to be the most effective, and also possibly the most addictive, smoking substitutes.

A metered-dose inhaler using propellants to deliver small droplets of nicotine to the respiratory tract has been developed.\textsuperscript{121} Ten puffs of a 50-µg nicotine/puff inhaler, inhaled via a spacer, resulted in peak plasma nicotine concentrations of
12.5 ng/mL within 6 min of finishing the 10 puffs. A 100-µg dose was also tested and resulted in slightly lower peak nicotine concentrations (9.4 ng/mL), most probably owing to the greater adverse effect of coughing at the higher dose. Voke is an inhaler device that is similar in shape and size to a conventional cigarette; it is charged and recharged with an aerosol containing nicotine, propylene glycol and a propellant from a small pressurised canister (similar to those used in asthma inhalers), housed in a pack about the size of a pack of 20 cigarettes. Inhalation of the entire contents of the device provides 0.45 mg of nicotine to the user, with nicotine measurable in arterial blood (mean 2.06 ng/mL) within 2 min of the first inhalation, suggesting at least some pulmonary absorption. A $C_{\text{max}}$ of 3.7 ng/mL in arterial blood was reached in 7 min. A $C_{\text{max}}$ in venous blood of approximately 3 ng/mL was reached within 15–20 min. Hourly use results in steady-state plasma nicotine levels of between 8 and 10 ng/mL. The product has now been awarded a medicines licence, and hence is likely to be brought to market, although at the time of writing no date has been set.

Nicotine pyruvate is formed from the combination of nicotine and pyruvic acid. Its salts are small (similar in size to the particulate matter in cigarette smoke) and so can be carried deeper into the respiratory tract in the process of inhalation, and are less harsh than pure nicotine to inhale. An inhaler has been developed that contains pyruvic acid and nicotine, which are combined when the user draws air through the device. In participants taking 10 controlled inhalations over 5 min, plasma nicotine levels rose to 5 ng/mL within 5 min when using a dose of 20 µg nicotine pyruvate per puff, and to 8.3 ng/mL with a 30-µg dose. This technology was purchased by Philip Morris International Inc in 2011, but has not yet been brought to market.

The Aradigm AERx system, which was developed for inhalation of insulin, has also been tested for nicotine delivery. There are limited published data about nicotine delivery, but those that are available on the company website suggest that nicotine delivery is rapid. The product has not, however, yet been commercialised.

### 5.5 Summary

- The market in non-tobacco nicotine products in the UK has been dominated for several decades by NRT.
- NRT is licensed as a medicine to help smokers quit smoking, and there is strong clinical trial evidence of effectiveness in this role.
- NRT is also licensed for use to help smokers cut down on smoking, and for temporary abstinence.
- NRT products have an excellent safety profile and present negligible risks to users.
- However, NRT products do not reproduce the rapid, high-dose delivery of...
tobacco smoke, and reproduce few if any of the behavioural components of tobacco smoking.

- The dominance of NRT has been challenged in recent years by a growing range of consumer nicotine products, some of which are made to high standards of purity but not necessarily licensed as medicines, and by e-cigarettes, which are now more widely used than NRT.
- Unlicensed nicotine products made to high standards of purity are also likely to have very little risk for users.
- Currently available e-cigarettes are manufactured to variable standards, and many are therefore likely to be more hazardous than NRT.
- Nicotine delivery from e-cigarettes is variable and, with some first-generation devices, very low.
- However, e-cigarette design is evolving quickly, with newer models delivering higher doses of nicotine than their predecessors, and hence being more satisfying for smokers.
- Some of the carcinogens, oxidants and other toxins present in tobacco smoke have also been detected in e-cigarette vapour, raising the possibility that long-term use of e-cigarettes may increase the risks of lung cancer, COPD, cardiovascular and other smoking-related diseases.
- However, the magnitude of such risks is likely to be substantially lower than those of smoking, and extremely low in absolute terms.
- These potential health risks arise primarily from contaminants and components generated by the vapourisation process, which should be amenable to reduction through technological and purity improvements.
- New nicotine products in development are likely to extend the range of choices available to smokers further, increasing purity and safety, and, in those achieving greater pulmonary absorption, addictiveness.
- Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure.

References

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85 Wang MP, Ho SY, Leung LT, Lam TH. Electronic cigarette use and respiratory symptoms in Chinese adolescents in Hong Kong. JAMA Pediatr 2015;9;1–2.


93 Robertson OH, Loosli CG. Tests for the chronic toxicity of propylene glycol and triethylene glycol on monkeys and rats by vapor inhalation and oral administration. J Pharmacol Exp Ther 1947;91:52–76.


110 Fabbro SK, Zirwas MJ. Systemic contact dermatitis to foods: nickel, BOP, and more. *Curr Allergy Asthma Rep* 2014;14:463.


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6 Quitting smoking

6.1 Introduction

Quitting smoking is the most effective means by which smokers can avoid the premature death and disability caused by smoking. This chapter describes current patterns of smoking cessation in the UK, to provide context in which to consider the position and role of harm-reduction policies. As in Chapter 5, data are again drawn from the Smoking Toolkit Study (STS: www.smokinginengland.info), the only national survey within the UK that provides detailed data on smoking cessation behaviour in a representative general population sample. Although limited to smokers in England, STS data are likely to be broadly representative of trends across the UK. This chapter uses STS and other data to explore recent trends in quitting behaviour, and the association between e-cigarette use and smoking prevalence, and to consider approaches to increasing the number of quit attempts made. It also describes patterns of use of e-cigarettes among young people.

6.2 Quit attempts and quit success

STS data indicate that the proportion of smokers making at least one quit attempt each year has fallen over the past 8 years, from 43% in 2007 to 32% in the first 9 months of 2015 (Fig 6.1). This overall trend was reversed in 2012 and 2013, when 34% and 39% made quit attempts, but has since fallen again.

These attempts were slightly more likely to occur in women and younger adults and, in 2014 and 2015, among those in non-manual occupations (Fig 6.2).

The proportion of these attempts that are successful in the short term, which can be identified as survey responses from individuals reporting that they have made a quit attempt in the past year and are now not smoking, is around 16%, a slight increase since 2011 (Fig 6.3). There were no marked differences in the proportion of successful attempts in relation to age or gender, but success was more likely among those in higher occupational groups (Fig 6.4).
Fig 6.1 Proportion of people who have smoked in the past year who made at least one serious quit attempt in that year\(^1\) (data from 42,386 people who smoked in the past 12 months; 2015 figures based on January to September data). (Adapted from the Smoking Toolkit Study\(^1\) with permission.)
Fig 6.2 Proportions of people who have smoked in the past year making at least one serious quit attempt in that year, by gender, age and occupational group (data details as per Fig 6.1).1 (Adapted from the Smoking Toolkit Study1 with permission.)
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Fig 6.3 Proportion of people who have tried to stop in the past year and are currently not smoking\(^1\) (data from 15,720 people who tried to stop smoking in the past 12 months; 2015 figures based on January to September data). (Adapted from the Smoking Toolkit Study\(^1\) with permission.)

Fig 6.4 Proportion of people who have tried to stop in the past year and are currently not smoking by occupational social group (data details as per Fig 6.3).\(^1\) (Adapted from the Smoking Toolkit Study\(^1\) with permission.)
6.3 Methods used to quit

The methods chosen by smokers in England to help them to quit, reported in the STS study between 2007 and 2015, are represented in Fig 6.5. Until 2013, the most commonly used aid to cessation was nicotine replacement therapy (NRT) bought over the counter, but NRT has been displaced as the most popular choice by a rapid increase in the use of e-cigarettes in England since 2012 (see also Chapter 5). The proportion of smokers who use no aid to cessation has fallen progressively over recent years, but remains above 40%.

![Graph showing percentage of smokers using different aids to cessation](image)

**Fig 6.5** Percentage of smokers using different aids to cessation in at least one quit attempt in the past year\(^1\) (data from 15,720 people who tried to stop smoking in the past year; 2015 figures based on January to September data; respondents may use more than one method per quit attempt). NRT OTC = nicotine replacement therapy bought from a shop; NRT Rx = nicotine replacement therapy obtained on prescription; Varen = varenicline (Champix) prescribed therapy; Bupr = bupropion (Zyban) prescribed therapy; E-cig = e-cigarette; Behav’l support = one-to-one sessions with an adviser or group support; None = none of the aforementioned. Use of other methods such as telephone quit-lines is very low. (Adapted from the Smoking Toolkit Study\(^1\) with permission.)

Evidence from randomised trials\(^2\) and English population data\(^3\)–\(^6\) indicate that there are three main categories of quit attempt in terms of aids used; these are grouped below in relation to their relative likelihood of success.
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6.3.1 Lowest likelihood of success

The approaches to quitting associated with the lowest likelihood of success are those that are unaided, including use of over-the-counter NRT and use of NRT without professional support. STS data suggest that there is little or no difference in the likelihood of quitting using either of these methods. This observation contrasts with randomised trial evidence that NRT can increase the likelihood of cessation, and suggests that trial procedures, and perhaps in particular an element of professional instruction and follow-up, may be crucial to NRT effectiveness. This, in turn, indicates that providing even minimal behavioural support to purchasers of NRT could improve the likelihood of successful quitting. As one in five smokers who tried to quit smoking in 2015 did so using NRT purchased from a shop or pharmacy, the low effectiveness of this approach represents a considerable lost opportunity to promote cessation.

6.3.2 Intermediate likelihood of success

Quit attempts among STS participants are around 50% more likely to succeed if they involve NRT, varenicline or bupropion obtained on prescription (and hence involving at least some contact with a health professional), or an e-cigarette bought from a shop. These methods are typically used by more heavily addicted smokers who would otherwise be expected to have a lower chance of success than those using the methods of lowest effectiveness. The fact that NRT obtained on prescription yields higher success rates than over-the-counter NRT suggests that, again, with this product, some form of clinical supervision or involvement is required for NRT to have an effect. This may be because without supervision smokers use NRT incorrectly, eg by using too little, or use the therapy for too short a time. However, this in turn raises the question of why use of e-cigarettes, which in the limited clinical trials available to date appear to be of similar efficacy to NRT, appears to be effective even without this supervision. There are, however, a number of possible explanations, as follows.

6.3.2.1 Nicotine delivery kinetics

Although early-generation e-cigarettes delivered relatively little nicotine, experienced e-cigarette users, particularly when using a later-generation product, can achieve venous blood levels similar to those obtained from smoking (see Chapter 5). Although this is also possible with NRT, it generally requires very frequent dosing with a short-acting product used in combination with a nicotine transdermal patch, and few consumers of NRT are likely to be aware of the need to follow this kind of dosing regimen. It is therefore possible that users...
adopting e-cigarettes without direction on optimal use are more likely to achieve satisfactory nicotine substitution than those choosing NRT.

6.3.2.2 Duration of use

There is a tendency for e-cigarettes to be used for longer than NRT. Although some smokers who use NRT to stop smoking continue to use NRT for months or even years after quitting, they are in a minority; most discontinue the product within a few weeks. In contrast, many users of e-cigarettes continue using the product both before and after quitting smoking, and for a longer period after quitting than most NRT users.12–15

6.3.2.3 Sensory replacement

Unlike NRT, e-cigarettes replicate many of the sensory characteristics of smoking. As outlined in Chapter 4, nicotine addiction is sustained not only by the rewarding characteristics of nicotine itself, but also by reward given to the stimuli and behaviours associated with nicotine delivery.16 As sensory replacement can reduce tobacco withdrawal symptoms,17 the sensation of vapour in the back of the throat, the plume of exhaled vapour, the hand-to-mouth action, and various other sensory and behavioural similarities with cigarettes may help to make e-cigarettes a closer sensory substitute for tobacco smoking than NRT products.

6.3.2.4 Cultural acceptability

Particularly among smokers, e-cigarettes are a socially and culturally accepted direct substitute for smoking. E-cigarette users can still share smoking breaks with and be accepted by other smokers, thus sustaining a social identity as a smoker, but can also tap into the enthusiasm, knowledge sharing and social support for e-cigarette use generated via online user groups and vaping websites. Also, unlike NRT, e-cigarettes are not medicalised, and use does not imply rejection of smoking or a commitment to quitting.

6.3.2.5 Confounding

People who choose to purchase e-cigarettes may differ from those who choose NRT in relation to factors that also influence the likelihood of successful quitting. Although STS analysis suggests that differences in characteristics known to predict smoking cessation outcome, including nicotine dependence, age, social grade and recent history of quit attempts, do not account for the difference in quit rates between those using e-cigarettes and those using NRT,3–6 it is still possible that unmeasured confounding variables could account for the apparent advantage of e-cigarettes.
Clarifying whether and why over-the-counter e-cigarettes appear to be more effective than NRT purchased in the same way clearly requires further research, comparing e-cigarettes and other cessation pharmacotherapy in head-to-head pragmatic trials, and exploring the importance of sensory replacement and other characteristics of the products involved.

6.3.3 Highest likelihood of success

STS data indicate that the greatest improvement in quit rates comes from use of NRT, varenicline or bupropion together with multi-session, face-to-face specialist behavioural support from a qualified stop smoking adviser. This method tends to be used by the most heavily addicted smokers, who would therefore be expected to have the lowest success rates of the three categories but, after adjustment for characteristics associated with likelihood of cessation, this approach appears to increase success rates by between two- and threefold. As NHS Stop Smoking Services (SSSs) have only recently started to support quit attempts using e-cigarettes, the available data on success rates are limited, but early experience estimates quit rates to be at least as high as among those using other medication. In the year to March 2015 in England, only 2,221 SSS users made a quit attempt using an unlicensed nicotine product (ie an e-cigarette), from a total of 445,979 setting a quit date. The average quit rate in all smokers using SSSs was around 51%, and among e-cigarette users it was 66%; although factors other than the product itself are likely to be involved in this difference, the finding is certainly consistent with high efficacy as a cessation therapy.

6.3.4 Trends in uptake of different quitting methods over time

Figure 6.6 shows the proportions of quit attempts using these three groups of quitting methods among smokers in England from 2009 to 2015. It demonstrates that use of specialist services is rare among smokers and that, although most of those making a quit attempt still use the least effective methods to do so, the proportion using methods of intermediate effectiveness is increasing, largely as a consequence of increased use of e-cigarettes.

Through use of estimates of relative effectiveness based on Cochrane reviews of trials of medication and behavioural support, supplemented by the data from smokers in England described above, the growth in use of intermediate effectiveness methods between 2012 and 2015 from 18% to 40% is likely to have generated many thousands of additional successful quit attempts by 2015; the figure for 2014 is likely to be around 19,000. However, these trends also demonstrate that much more needs to be done to increase the number of smokers attempting to quit, and to increase the proportions...
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6

using the more effective approaches. The data available from NHS SSSs indicate that there is no reason to believe that the integration of e-cigarettes into treatment support would reduce quit rates.

6.4 What motivates smokers to try to quit and what are the obstacles?

Smokers make a quit attempt when the desire to quit and confidence in success reach an action threshold. Environmental factors can trigger a quit attempt by either momentarily raising motivation above this threshold or reducing the level of the threshold. In this context, the environment includes social norms about the desirability of smoking, as well as triggers such as health campaigns or advice on smoking from health professionals.

Survey data suggest that, in Britain, motivation to quit is driven primarily by health concerns and the financial cost of smoking, whereas factors such as
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concern about the effect of smoking on one’s family, not liking being addicted to smoking and feeling stigmatised are present but less frequently cited.\textsuperscript{26,27} The most important environmental trigger identified from smokers’ reports is health professional advice.\textsuperscript{26} Mass media campaigns can also play an important role,\textsuperscript{28} although this does not appear to be explicitly recognised by smokers.\textsuperscript{26} The introduction of a comprehensive ban on smoking in indoor public areas appears to have had a short-term, but not a sustained long-term, effect on quitting.\textsuperscript{29}

The main personal barriers to making an attempt to quit smoking appear to be enjoyment of smoking, having a positive smoker identity and low confidence in success.\textsuperscript{27,30} Motivation may also be reduced by smoking among other people who are important to the smoker, such as a partner or friends, colleagues and wider family, although evidence for this influence is less strong.\textsuperscript{27}

6.5 Why do more smokers not try to quit and how could the numbers be increased?

The figures outlined in this chapter thus far relate to the approximately one in three smokers who make a quit attempt each year. Although it is essential to ensure that as many of those as possible succeed in quitting, it is at least as important to increase quit attempts among the remaining majority of smokers who do not make a quit attempt in any given year. Measures are therefore required to increase the proportion of smokers making any attempt to quit smoking, as well as to increase the likelihood of success among those who try.

Chapter 3 outlined the population measures that can influence both quitting and uptake of smoking, and identified price rises and media campaigns as among the most effective. As studies of smokers also identify that the main drivers of motivation to quit are concerns about the health consequences of smoking and the cost of smoking,\textsuperscript{26,27} the evidence is consistent in indicating that the most effective approaches to increase quit attempt numbers in the UK are likely to comprise price rises and media campaigns using health messages. However, advice from a health professional is also identified by smokers as a key trigger for quit attempts,\textsuperscript{26} and it would appear that a great deal more could be done to increase the delivery of such advice. Figure 6.7 shows the proportion of smokers in England who report having received advice to stop smoking from their GP in the past year during 2010–15, and reveals that fewer than 40% of smokers recall having received advice to quit; of these, only two-thirds recall having received an offer of help with quitting. Equivalent data from people accessing NHS secondary care services are not available, but anecdotal evidence suggests that delivery of smoking cessation advice and support is also low. As over 1 million
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smokers are admitted to hospitals in the UK each year, this also represents a substantial missed opportunity to initiate and support quit attempts.

These findings indicate that guidance from the National Institute for Health and Care Excellence (NICE), which recommends that health professionals should offer help to quit at every opportunity, and support of harm-reduction initiatives among those unwilling to quit, is not being implemented sufficiently widely. Clinical trial evidence also suggests that, although simple advice from a physician to quit is effective, offers of support are more effective, generating quit attempts in around 40% of those receiving the offer. Therefore, there is substantial scope for healthcare professionals to increase the rate of quit attempts by integrating advice and support to quit smoking in all healthcare consultations.

Since 2004, GPs in the UK have received financial incentives to record smoking status and provide advice on smoking, which, although unspecified, is generally interpreted as advice to quit. This scheme applied initially only to smokers with smoking-related conditions and people with serious mental health disorders, but in 2012 was extended to cover everyone who smokes. Moreover, in 2012, the contracted requirement was changed from an offer of advice to an offer of pharmacotherapy and referral for smoking cessation support. Early evidence on the scheme demonstrated that it led to marked increases in the recording of both

Fig 6.7 Proportion of people who smoked in the past year who reported receiving any advice on stopping or offer of help with stopping from their GP (data from 27,000 smokers; 2015 figures based on January to September data). (Adapted from the Smoking Toolkit Study with permission.)
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smoking status and delivery of advice, but no increase in the prescription of pharmacotherapy\(^36\) over the background trend.\(^37\) A later evaluation of the 2012 change showed a similar result for all smokers, with increased recording by GPs of smoking status, delivery of advice to quit and referral to smoking cessation services, but no actual increase in prescription of pharmacotherapy.\(^38\) A similar scheme that rewarded hospitals for ensuring that opportunistic advice on smoking was given to patients was introduced in 2012, and there is also no evidence that this initiative has had any effect.\(^39\) Reform of these schemes would therefore appear appropriate.

6.6 How could changes in the availability of nicotine products influence quitting behaviour?

Evidence from time-series analyses indicates that increasing the availability of NRT, and introducing new smoking cessation medications to the market, increases the use of these products by smokers trying to stop smoking, but does not increase the proportion of smokers attempting to quit.\(^40\)

Evidence from placebo-controlled trials indicates that use of an NRT product while continuing to smoke can increase the likelihood of a quit attempt (see Chapter 5), and that this effect is due to the nicotine in the products rather than being a placebo response.\(^41\) Population-level data confirm that smokers who use an NRT product while smoking are more likely to try to stop, and eventually to succeed in quitting.\(^42\)\(^-\)\(^45\) Although the mechanism for this effect does not appear to involve increased confidence in quitting,\(^43\) it is possible that nicotine from the NRT product interferes with the maintenance of the association between smoking and nicotine reward, and hence reduces the motivation to smoke. It is also possible that encouraging smokers to experiment with nicotine products, including e-cigarettes, would generate more quit attempts and hence increase smoking cessation. The limited available evidence on this indicates that quit attempts are indeed more common among daily e-cigarette users who continue to smoke, but that successful quitting using the early-generation ‘cigalike’ devices is less common.\(^46\)\(^,\)\(^47\) Research into methods of increasing quit rates among people experimenting with alternative nicotine sources, perhaps by finding ways to deliver quitting advice and behavioural support, is therefore needed.

6.7 Summary

> Approximately one in three smokers in the UK currently attempts to quit each year, but only about one in six of those who try to quit remains abstinent for more than a few weeks or months.
Most smokers who try to quit do so without accessing professional help, preferring either to use no help or support, or else to use NRT or e-cigarettes bought over the counter.

Those who use over-the-counter NRT appear to be no more likely to quit than those getting no help.

Smokers who use over-the-counter e-cigarettes or prescribed medications are more likely to succeed.

The greatest increase in the chances of stopping successfully occurs with prescribed medications used together with specialist behavioural support.

The effectiveness of e-cigarettes used with behavioural support is uncertain, but early data demonstrate a relatively high quit rate.

Smokers are motivated to make a quit attempt in particular by cost and health concerns.

Price rises, media campaigns and brief advice from health professionals are therefore likely to increase the numbers of smokers trying to quit.

Health professional advice and support to quit smoking should be offered as a routine component of healthcare consultations.

Smokers who use nicotine products as a means of cutting down on smoking are more likely to make quit attempts. Promoting wider use of consumer nicotine products, such as e-cigarettes, could therefore substantially increase the number of smokers who quit.

New research is needed to improve the effectiveness of over-the-counter NRT, and to find ways of providing behavioural support to smokers who choose e-cigarettes.

References

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11 Le Houezec J. Role of nicotine pharmacokinetics in nicotine addiction and nicotine 
12 Etter JF, Bullen C. Electronic cigarette: users profile, utilization, satisfaction and perceived 
13 Zhang B CJ, Bondy SJ, Selby P. Duration of nicotine replacement therapy use and smoking 
14 Silva K, Beard E, Shahab L. Characterization of long-term users of nicotine replacement 
15 Biener L. A longitudinal study of electronic cigarette use among a population-based sample 
of adult smokers: association with smoking cessation and motivation to quit. _Nicotine Tob 
16 Rose JE, Behm FM, Westman EC, Johnson M. Dissociating nicotine and nonnicotinic 
17 Buchhalter AR, Acosta MC, Evans SE, Breland AB, Eissenberg T. Tobacco abstinence 
symptom suppression: the role played by the smoking-related stimuli that are delivered by 
18 Hartmann-Boyce J, Stead LF, Cahill K, Lancaster T. Efficacy of interventions to 
combat tobacco addiction: Cochrane update of 2013 reviews. _Addiction_ 2014;109: 
1414–25.
19 Health and Social Care Information Centre. _Statistics on NHS Stop Smoking Services in 
20 Cahill K, Stead LF, Lancaster T. Nicotine receptor partial agonists for smoking cessation. 
22 Hughes JR, Stead LF, Hartmann-Boyce J, Cahill K, Lancaster T. Antidepressants for smoking 
23 Lancaster T, Stead LF. Individual behavioural counselling for smoking cessation. 
24 West RBJ, Shahab L. Estimating the population impact of e-cigarettes on smoking cessation 
25 West R, Sohal T. ‘Catastrophic’ pathways to smoking cessation: findings from national 
26 Vangeli E, West R. Sociodemographic differences in triggers to quit smoking: findings from 
27 Vangeli E, Stapleton J, Smit ES, Borland R, West R. Predictors of attempts to stop smoking 
and their success in adult general population samples: a systematic review. _Addiction_ 
2011;106:2110–21.
28 Durkin S, Brennan E, Wakefield M. Mass media campaigns to promote smoking cessation 
29 Hackett L, McEwen A, West R, Bauld L. Quit attempts in response to smoke-free 
30 Tombor I, Shahab L, Brown J, West R. Positive smoker identity as a barrier to quitting 
smoking: findings from a national survey of smokers in England. _Drug Alcohol Depend_ 


Trends in use of non-tobacco nicotine in Britain

7.1 Sources of data

Although detailed data on the prevalence of smoking in Britain have been collected for some decades (see Chapter 2), sources of survey data on the use of nicotine replacement therapy (NRT) or unlicensed nicotine products are relatively limited. The most detailed source is the Smoking Toolkit Study (STS: www.smokinginengland.info), a monthly, household, face-to-face survey of representative samples of the population of England aged 16 and over, in operation since 2007. Data on all smoking and non-tobacco nicotine-containing products, including e-cigarettes, have been collected since 2007 for smokers, since 2011 for recent ex-smokers (<1 year), and since 2013 for never-smokers and long-term (>1 year) ex-smokers. Other large national surveys have added questions on e-cigarettes much more recently, eg in 2014 in the Opinions and Lifestyle Survey and Scottish Health Survey. Data on use of e-cigarettes by children have also begun to be collected only relatively recently in national surveys in England, Scotland and Wales. Action on Smoking and Health (ASH) UK has commissioned annual surveys of e-cigarette use among adults since 2010 and children since 2013, and these extend beyond simple measures of prevalence to include reasons for use, and a range of other factors. The STS is the only source of data on NRT use. This chapter draws on all these sources to review trends in use of NRT and e-cigarettes in Britain over recent years. Most of the data presented are drawn from samples of smokers and recent ex-smokers participating in the STS.

7.2 Trends in the use of non-tobacco nicotine products among adults

Before the widespread uptake of e-cigarette use began in around 2011, NRT was being used by between 15% and 20% of smokers in England (Fig 7.1). However, use of non-tobacco nicotine products has risen sharply since 2011, primarily as a result of a marked increase in e-cigarette use, which has more than offset a more sustained decline in use of licensed NRT. In 2015 about 28% of smokers were
using at least one non-tobacco nicotine product, and more than 20% an e-cigarette (Fig 7.1).

Among recent (<1 year) ex-smokers, use of non-tobacco nicotine products also rose between 2012 and 2015, despite a fall in the use of NRT (Fig 7.2). In 2015 more than half of all recent ex-smokers were using a non-tobacco nicotine product, with more than 40% of these being e-cigarette users.

**Fig 7.1** Prevalence of use of NRT, e-cigarettes or any non-tobacco nicotine products among current cigarette smokers in England 2007–151 (data from 36,896 cigarette smokers; 2015 figures based on January to September data). (Adapted from the Smoking Toolkit Study9 with permission.)

**Fig 7.2** Prevalence of use of NRT, e-cigarettes or any non-tobacco nicotine products among recent ex-smokers in England 2011–141 (data from 2,318 people who stopped smoking in the past year; 2015 figures based on January to September data). (Adapted from the Smoking Toolkit Study9 with permission.)

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Data for longer-term (>1 year) ex-smokers, which are available since 2013, show a slightly different pattern, with generally lower levels of prevalence of use and stable NRT prevalence, whereas e-cigarette use has increased (Fig 7.3).

The explanation for these trends is not certain, but is likely to be mainly due to continued e-cigarette use among people who have used them to quit smoking, because the proportion of smokers in England who have stopped smoking but then take up an e-cigarette within a year of stopping is only about 10%.1 The ASH survey in 2015 found that the principal reasons given by ex-smokers who are currently vaping are ‘to help me stop smoking entirely’ (61%) and ‘to help me keep off tobacco’ (53%). The principal reasons given by current vapers who still smoke are ‘to help me reduce the amount of tobacco I smoke, but not stop completely’ (43%) and ‘to help me stop smoking entirely’ (41%).7 Whether some of these individuals would otherwise have relapsed back to cigarette smoking, had e-cigarettes not been available, is not clear. Exploration of the explanations for these trends is an important area for future research.

Among never-smokers, non-tobacco nicotine use is extremely uncommon. In 2015, 0.1% of never-smokers were using NRT and 0.3% an e-cigarette, and these figures have remained virtually unchanged since 2013 (Fig 7.4).

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Fig 7.3 Prevalence of use of NRT, e-cigarettes or any non-tobacco nicotine products among long-term ex-cigarette smokers in England 2013–151 (data from 6,487 long-term ex-smokers; 2015 figures based on January to September data). (Adapted from the Smoking Toolkit Study9 with permission.)
Among current smokers and recent ex-smokers, e-cigarettes tend to be used by a slightly higher proportion of younger than older smokers (Fig 7.5), but this use does not differ by socio-economic status (Fig 7.6) or gender.

**Fig 7.4** Prevalence of use of NRT, e-cigarettes or any non-tobacco nicotine products among never-smokers in England, 2013–15 (data from 24,041 never-smokers; 2015 figures based on January to September data). (Adapted from the Smoking Toolkit Study with permission.)

**Fig 7.5** Age distribution of e-cigarette or NRT users in 2013–15 (data from 11,186 smokers and <1 year ex-smokers; 2015 figures based on January to September data). (Adapted from the Smoking Toolkit Study with permission.)
Fig 7.6 Social grade distribution of e-cigarette and NRT users in 2013–15\(^1\) (from 11,186 smokers and <1 year ex-smokers; 2015 figures based on January to September data). AB, professional managerial; C1, clerical; C2, skilled manual; D, semi-skilled manual; E, unskilled manual/unemployed. (Adapted from the Smoking Toolkit Study\(^9\) with permission.)

Fig 7.7 Proportion of adults in Scotland in 2014 who had ever used an e-cigarette, by age and sex.\(^3\) (Adapted from the Scottish Government\(^3\) with permission under Open Government Licence.)
The Opinions and Lifestyle Survey estimated that, in the first quarter of 2014, e-cigarettes were being used by 11.8% of smokers, 4.8% of ex-smokers and 0.14% of never-smokers. Data from Scotland indicate that, in 2014, around 15% of men and women reported ever having used an e-cigarette, and about 5% reported current use. This current use was entirely restricted to current smokers (of whom 15% were current e-cigarette users) and ex-smokers (7%). Of never-smokers, 1% reported ever using an e-cigarette, and none were current users.

‘Ever use’ was much more prevalent among younger people (Fig 7.7).

Annual surveys by ASH demonstrate data consistent with STS findings, with almost 60% of smokers in Britain ever having tried an e-cigarette, and just under 18% reporting current use in 2015. Similar to the STS findings, current use had remained unchanged between 2014 and 2015 after rapid growth since 2010 (Fig 7.8).

As in the Scottish data, however, this use of e-cigarettes has occurred almost entirely among current and ex-smokers; in 2015, the prevalence of current use of e-cigarettes among never-smokers was 0.2%. The most frequently reported reasons for using e-cigarettes were to quit smoking, to help maintain abstinence having already quit and, among dual users, to cut down on smoking. The ASH survey in 2015 also explored the type of e-cigarettes that respondents were using, and demonstrated that most had started use with first-generation disposable or ‘cigalike’ devices, but then migrated to second- and third-generation refillable or tank designs (Fig 7.9).
Over 80% of e-cigarette users surveyed by ASH in 2015 were using flavoured e-liquids. Tobacco was the most popular flavour (35% of users), but fruit (25%) and menthol (19%) were also popular.7

### 7.3 Trends in the use of non-tobacco nicotine products among children

Data on the use of non-tobacco nicotine among children are limited to e-cigarette use. Annual surveys by ASH of young people in the UK since 2013 demonstrate that awareness of e-cigarettes has grown substantially, such that, in 2015, only 7% of young people reported no knowledge of these products, and the proportion of young people who had tried e-cigarettes increased over these three surveys from 5% to 13% (Fig 7.10).8

However, of the 13% of young people who reported in 2015 ever having tried an e-cigarette, most (80%) had done so only once or twice.8 Only 2.4% of all participants in the survey had used e-cigarettes once or more a month, and 0.5% once or more a week. The Scottish SALSUS (Schools Adolescent and Lifestyle and Substance Use Survey) study5 reported similar findings among 13- and 15-
year-olds in 2013, with 7% and 17%, respectively, reporting ever having tried to use or used an e-cigarette, and only 1% in each age group using the product more than ‘once or a few times’. In 2014, the Welsh Health Behaviour in School-aged Children survey of 11- to 16-year-olds in Wales reported that 12.3% of participants had ever used an e-cigarette, and 1.5% were using e-cigarettes at least once a month. The 2014 Smoking, Drinking and Drug Use survey of children aged 11–15 in England found that 22% of participating children had ever used an e-cigarette, but only 1% reported regular use. Regular use of e-cigarettes among young people in the UK thus appears to be very rare. As in adults, it appears that it occurs predominantly among those who are using, or have used, tobacco cigarettes. In 2013 in the Scottish study, all of those who reported having used e-cigarettes more than a few times had been, or were still, smokers (Fig 7.11).

The 2014 Welsh survey reports very similar findings, with young people aged 11–15 who had ever used an e-cigarette being over 20 times more likely than never-users to have ever smoked; those using e-cigarettes more than once a month were more than 100 times more likely to be smoking cigarettes at least once a week. The 2015 ASH survey also reports a strong association between use of e-cigarettes and tobacco cigarettes (Fig 7.12), with almost all e-cigarette users either being current smokers, or having tried or been regular smokers in the past. Regular e-cigarette use in the 2014 English Smoking, Drinking and Drug Use survey was exclusive to children who had at least tried smoking.
Of those using e-cigarettes in the ASH survey, most used a tank or other refillable device, and most used e-liquids with fruit (42%), tobacco (23%) or menthol (13%) flavours.8

![Graph showing use of e-cigarettes by smoking status in Scotland in 2013.](image1)

**Fig 7.11** Use of e-cigarettes, by smoking status, among 13- and 15-year-olds in Scotland in 2013.5 (Adapted from NHS National Services Scotland5 with permission under Open Government Licence.)

![Graph showing use of e-cigarettes by smoking status among young people in the UK in 2015.](image2)

**Fig 7.12** Young people aged 11–18 who have ever tried an e-cigarette, by smoking status, UK, 2015.8 (Adapted from ASH8 with permission under Open Government Licence.)
7.4 Summary

- Use of e-cigarettes among adults in the UK was rare before 2010, but has since increased to the point that up to one in five smokers now uses an e-cigarette, more than twice as many as use NRT.
- The proportion of smokers using NRT has fallen by about half over this period, but the proportion using any non-tobacco nicotine product has increased to just under 30%.
- These trends are similar but more marked among recent ex-smokers, 40% of whom use an e-cigarette.
- Use of e-cigarettes among adults who have never been regular smokers is very rare.
- There is a slightly greater likelihood that younger adult smokers will use e-cigarettes than NRT; in Scotland, younger men are more likely to use them.
- Adult regular e-cigarette users tend to use tank or other refillable devices, rather than first-generation ‘cigalikes’, and tobacco-, fruit- or menthol-flavoured nicotine.
- The proportion of young people in Britain aged <18 who have ever used an e-cigarette is increasing, but remains low.
- Most use among young people appears to be single or very occasional experimentation. Use more than once a month is relatively rare and more than once a week extremely rare.
- Regular use is almost exclusively limited to young people who are already either regular or occasional smokers, or have experimented with smoking in the past.
- Young regular users of e-cigarettes also favour later-generation devices, and fruit, tobacco or menthol flavours.
- In adults and young people in the UK, therefore, use of e-cigarettes is limited almost entirely to those who are already using, or have used, tobacco.

References

Tobacco harm reduction


8.1 The need for harm reduction

Prevention of smoking is vital to public health, and much progress has been made in reducing the prevalence of smoking in the UK over recent decades (see Chapter 2). However, the data presented in Chapter 2 also demonstrate that this success has been achieved primarily by reducing uptake of smoking among younger people, more than improvements in the rate at which established smokers quit smoking. It is, however, these established smokers in middle and older age who will generate most of the population burden of morbidity and premature mortality caused by smoking over the next two decades.1,2 As established smokers today are more likely to be socio-economically disadvantaged or to have mental health problems (see Chapter 2), this burden of disease will fall disproportionately on these groups who, as a result of higher levels of addiction to nicotine, also find it particularly difficult to quit smoking.

Increasingly powerful incentives for existing smokers to try to quit smoking, and strong support to help them succeed, are therefore urgently required. Further application and extension of the conventional policy options summarised in Chapter 3 might be expected, at best, to sustain the decline in smoking prevalence of close to 0.7 percentage point per year achieved over the past decade in the UK (see Fig 2.1, Chapter 2), the consequence of which will be that most of the current smokers in the UK, and particularly the most heavily addicted smokers, will continue to smoke for several decades. The public health imperative in relation to smoking is, however, to reduce prevalence as much and as quickly as possible, for example, to achieve the widely agreed objective of a ‘tobacco-free’ society (comprising smoking rates of 5% or less in all socio-economic groups) by 2035,3 and this requires the addition of new strategies. Harm reduction offers the potential to add significantly to the current rate of decline in smoking prevalence among all population groups. The availability of alternatives to tobacco, as a source of nicotine for the most heavily addicted smokers, also allows the application of much higher levels of taxation on tobacco without necessarily exacerbating poverty in those smokers who find themselves unable to quit in response to increases in tobacco prices. In Sweden,
Tobacco harm reduction

the availability of snus has been estimated to have added around 0.4 percentage point per year to the rate of decline in smoking prevalence.\(^4\) E-cigarettes, and other non-tobacco nicotine products, surely have the potential to achieve at least the same in the UK.

Harm-reduction approaches, by promoting substitution of tobacco with less hazardous sources of nicotine, thus represent a potentially powerful complement to existing prevention policy, particularly among the relatively highly addicted and typically disadvantaged smokers who are likely to find it most difficult to quit.\(^5,6\) However, pursuing a harm-reduction strategy also carries risks of unwanted effects in society. This chapter explores some of the harms caused by tobacco smoking in different periods of life, and the probable balance of risks and benefits of harm-reduction approaches based on substitution with NRT or other non-tobacco nicotine products, particularly e-cigarettes.

8.2 Potential hazards of harm reduction

Although harm-reduction approaches have the potential to reduce the hazard of nicotine use among the current smoking population, they also bring potential hazards to wider public health. For example, a product that is half as damaging to health as tobacco smoking has the potential to halve the harm caused by smoking in society, if used exclusively and completely as a substitute for tobacco by current smokers, and young people who would otherwise have become smokers. That benefit would be reduced or even reversed, however, if the new product came to be sufficiently widely used among non-smokers that the benefits to smokers were eclipsed by harm sustained by non-smokers. The benefit of harm reduction to smokers would also be offset at population level if use of harm-reduction products increased the risk of smoking uptake (known as gateway progression, see below), undermined existing tobacco control measures by making the act of smoking socially acceptable again (renormalisation) or discouraged quitting by being used as a partial substitute for tobacco smoking (‘dual use’), without progression to complete substitution among smokers who would otherwise have quit. These processes are discussed in more detail below.

8.2.1 Renormalisation

In relation to tobacco smoking, renormalisation refers to processes that undermine or reverse a progressively increasing perception in society that smoking is not a normal or desirable behaviour.\(^5\) For much of the 20th century smoking was part of the fabric of British life, and children grew up perceiving
smoking to be something that many, if not most, adults did. In recent years, however, the acceptability of smoking has changed, particularly as a consequence of prohibition of tobacco advertising, smoking in enclosed public places and point-of-sale displays, and other measures. Although smoking remains relatively common, and hence relatively normal, in some communities or social groups, this is no longer the case in general. Examples of renormalisation might include: the use of e-cigarettes in areas where smoking is prohibited, thus creating an impression that smoking is acceptable; advertising or other imagery that evokes tobacco smoking through e-cigarette use; behavioural modelling from use of e-cigarettes by parents, siblings, peers, friends, celebrities or others; or other processes that in some way make smoking more appealing.6,7

8.2.2 Gateway progression

Gateway progression is a process by which, in relation to tobacco smoking, use of non-tobacco nicotine is proposed to cause uptake of smoking that would not otherwise have occurred. Gateway theory has its origins as a descriptive model for progression from use of soft drugs to use of hard drugs, and a recent review of evidence from animal models concluded that nicotine exposure may indeed increase susceptibility to other drug use, independent of other determinants of common liability.8 In nicotine use, however, the gateway theory has also been applied as a predictive model proposing that use of non-tobacco nicotine is likely to cause progression to use of nicotine through tobacco smoking,9 and therefore that use of e-cigarettes by non-smokers, and particularly by children, could cause smoking uptake independent of other determinants of smoking initiation. Similar concerns have in the past been expressed in relation to nicotine replacement therapy (NRT) and smokeless tobacco.9

8.2.3 Dual use

Dual use refers to the concomitant use of non-tobacco nicotine by smokers who continue to smoke tobacco. As outlined in Chapter 5, reasons for dual use include relief of nicotine withdrawal symptoms at times when smoking is not allowed, or a desire to cut down on smoking without necessarily a commitment to quit. However, concerns have been expressed that dual use may inadvertently sustain smoking by making it easier to abstain when smoking is prohibited and the smoker might otherwise have quit, and that smokers who could otherwise have quit elect for dual use instead, in the mistaken belief that this generates significant health gains. There are particular concerns that the tobacco industry will promote dual use of e-cigarettes as a means of sustaining, rather than cutting down or quitting, tobacco smoking in their customers10 (see Chapter 9).
8.3 Harm to health and wellbeing of self and others from smoking at different stages of life

Smoking directly damages the health of all who smoke (see Chapter 1), increasing the risk of a wide range of fatal and non-fatal illnesses\textsuperscript{11} and causing over 120,000 deaths in the UK in 2010.\textsuperscript{12} However, the adverse effects of smoking extend well beyond this direct harm to the individual smoker, and are not limited to the later period of life when the increased mortality in smokers becomes more acute. Through the life course of any individual from the point of conception, maternal smoking (and hence fetal exposure \textit{in utero}) impairs fetal growth and development, and increases rates of fetal and neonatal death, low birth weight, preterm birth and developmental anomalies.\textsuperscript{13} Passive maternal smoking during pregnancy increases the risk of stillbirth and developmental anomalies\textsuperscript{14,15} and reduces birth weight.\textsuperscript{16} In childhood, passive exposure to tobacco smoke causes sudden infant death, respiratory infections, middle-ear disease and exacerbation of asthma.\textsuperscript{13} Passive exposure to others’ smoke during adulthood causes transient symptoms such as eye and throat irritation at all ages, and in later life contributes to higher mortality from lung cancer, cardiovascular disease and chronic obstructive pulmonary disease (COPD).\textsuperscript{17}

Harm from smoking is not limited to that arising from inhaling tobacco smoke. Probably through behavioural modelling and opportunities for experimentation, children whose parents or other household members smoke are more likely to take up smoking themselves,\textsuperscript{18} thus perpetuating smoking and its consequent harm in successive generations. Smoking rates in the wider communities and environments that children grow up in also influence smoking uptake, because children whose peers smoke, and those exposed to smoking imagery in the media, are more likely to become regular smokers.\textsuperscript{19} Smoking is a significant drain on family budgets, exacerbating poverty,\textsuperscript{20} and a drain on wider society, which suffers the opportunity cost of funding over £3.3 billion in direct healthcare and social care costs in the UK, and over £10 billion in lost productivity and other societal costs.\textsuperscript{21} Thus, although smoking has little direct effect on the personal health of individual smokers during early adult life,\textsuperscript{22,23} the risks to others, especially children, are substantial.

As outlined above, all or almost all of these harms could be prevented or else much reduced by substitution of smoked tobacco with a less hazardous source of nicotine. The potential benefits and risks to individual and societal health of doing so are now considered in relation to the two main options currently available in the UK: conventional NRT products and unlicensed non-tobacco nicotine products, including e-cigarettes.
8.4 Harm reduction with conventional NRT products

8.4.1 Health harms

As use of nicotine alone in the doses used by smokers represents little if any hazard to the user, complete substitution of smoking with conventional NRT products is, for practical purposes, the equivalent of complete cessation in almost all areas of harm to the user. NRT products do not emit vapour and so are not a source of passive exposure for adults or children. Packaging and dose restrictions render accidental poisoning in children highly unlikely. Questions remain about the safety of nicotine in pregnancy and potential effects on fetal development and mortality, although one recent study has reported a lower occurrence of developmental abnormality among children whose mothers used NRT in pregnancy than in those whose mothers did not.

8.4.2 Renormalisation of and gateway to smoking

Only the Nicorette inhalator bears any resemblance to a cigarette, so users of most NRT products provide no behavioural modelling that could encourage primary uptake of, or sustain, tobacco smoking by others. Use of NRT among never-smokers is rare at all ages and, despite early concerns to the contrary, there is no reported evidence that use of the inhalator or any other NRT product in young people has ever acted as a gateway to smoking.

8.4.3 Dual use and gateway from smoking

NRT was developed as a smoking cessation therapy for use after an abrupt and complete cessation of tobacco smoking. The efficacy of NRT used in this way is well established. More recently, however, NRT has been licensed in the UK for use together with continued smoking, to relieve withdrawal symptoms during temporary abstinence from smoking, or to cut down on smoking, for dual use. Before the advent of e-cigarettes, up to 15% of current smokers in England used NRT in this way, although the proportion is now closer to 5% (Fig 8.1). Although cutting down on smoking achieves relatively little in terms of health benefits, use of NRT together with tobacco smoking does appear to reduce compensatory smoking to a modest extent and, among smokers with no intention to quit, to increase, by as much as twofold, the likelihood of a subsequent quit attempt. It also protects those around the smoker from the harmful effects of passive smoking. For this and other reasons, dual use of NRT and tobacco smoking is licensed by the Medicines and Healthcare products Regulatory Agency (MHRA) and recommended by the National Institute for Health and Care Excellence.
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8.4.4 Population health effects of substitution of smoking by NRT

With the possible exception of use during pregnancy, complete substitution of smoking by NRT achieves much the same in health terms as quitting both smoking and all nicotine completely. Widespread uptake of NRT by non-smokers would therefore result in little harm to public health, but is in any case rare. Gateway progression from NRT to smoking among those who have never smoked does not, for practical purposes, occur. Dual use results in a modest reduction in tobacco smoking of little or no significance to health, but promotes quitting. Promotion of NRT as a reduced harm substitute for smoking is therefore unequivocally good for health. Economic analysis of the use of NRT in a harm-reduction strategy, including a range of scenarios in which opting to cut down rather than quit detracted to different degrees for those who would otherwise have quit, found that all options were cost-effective in relation to preventing major disease costs to the NHS, and hence were acting in favour of population health.
8.5 Substitution with e-cigarettes

8.5.1 Health harm

As e-cigarettes have been in widespread use in the UK and most other countries for less than a decade, the health effects of long-term use are as yet unknown. As outlined in Chapter 5, there is very little evidence that short-term use of e-cigarettes causes any appreciable harm to users or to others, but information on long-term health effects of repeated and sustained inhalation of e-cigarette vapour is of necessity limited to inference, based on knowledge of the vapour’s constituents. The oxidant, particulate, carcinogen and other toxin contents summarised in Chapter 5 would be expected, from first principles, to increase the risk of lung cancer, COPD, cardiovascular disease and other diseases caused by smoking, but at much lower levels of risk. For the less common health sequelae of smoking, levels of increased risk are likely to be negligible. The risks attributable to long-term inhalation of nicotine in isolation from tobacco smoke, and of the propylene glycol, glycerine and other components unique to e-cigarettes, are also uncertain but likely to be low. The health harm to long-term users of e-cigarettes is therefore likely to be marginally greater than for those who use conventional NRT.

Harm to others from vapour exposure is negligible (see Chapter 5). The effects of maternal use on the fetus are unknown but, on the grounds of the very low levels of toxins in vapour, are probably close to those of NRT. Accidental poisoning in children from ingestion of e-cigarette solutions, which has been reported and typically results in nausea and vomiting, are preventable through the use of childproof fasteners.

8.5.2 Renormalisation and gateway to smoking

First-generation e-cigarettes were designed to resemble tobacco cigarettes in approximate shape and size, and hence their use provides a behavioural model similar to smoking, which could appeal to young people or smokers trying to quit smoking, appear to undermine smoke-free policy, and be used by the tobacco industry to cross-promote smoking imagery and hence tobacco products through e-cigarette advertising (see Chapter 9). However, even first-generation products are visually distinct from cigarettes, and exhaled vapour easily distinguishable from tobacco smoke in terms of appearance, smell and irritancy, making confusion unlikely between e-cigarettes and tobacco cigarettes in areas covered by smoke-free legislation. Later-generation e-cigarettes have less or no physical resemblance to tobacco cigarettes. Use of e-cigarettes to generate smoking imagery in advertisements is prevented under UK advertising codes of practice.
Data from Wales indicate that children whose parents or peers use e-cigarettes are more likely to experiment with e-cigarettes themselves, and to intend to smoke in the future, than children without this exposure. However, as parental e-cigarette use occurs almost exclusively among current or former smokers, children in these households would be expected to have higher smoking intentions, and it is unclear whether this risk is either increased or decreased by the availability of e-cigarettes as opposed to tobacco cigarettes.

The prevalence data on the use of e-cigarettes by both adults and children presented in Chapter 7 demonstrate that e-cigarette use in Britain is, to date, almost entirely restricted to current, past or experimental smokers. As with NRT, there is no evidence thus far that e-cigarette use has resulted, to any appreciable extent, in the initiation of smoking in either adults or children; the extremely low prevalence of use of e-cigarettes among never-smoking adults and children indicates that, even if such gateway progression does occur, it is likely to be inconsequential in population terms.

8.5.3 Dual use and gateway from smoking

Office for National Statistics data indicate that, in the first quarter of 2014, 11.8% of smokers, 4.8% of ex-smokers and 0.14% of never-smokers in Britain used e-cigarettes; smoking prevalence data from the same source indicate that these proportions represented approximately 2.2%, 2.6% and 0.08% of the total adult population, respectively. On these figures, therefore, about 45% of e-cigarette users in Britain are using them together with smoking, which is about twice as many as do so with NRT. As dual use of NRT is recommended as a means of increasing the likelihood that smokers will attempt to quit smoking, and early-generation e-cigarettes appear to be approximately as effective as NRT as a cessation aid, it follows that the same is likely to apply to e-cigarettes.

Observational data from England confirm that smokers who use e-cigarettes at least daily are indeed twice as likely to make a quit attempt, or else to reduce their smoking, than those who do not, although in this study the likelihood of success among those attempting to quit was not increased by e-cigarette use. Independent clinical trials and observational data from the Smoking Toolkit Study indicate that e-cigarette use is associated with an increased chance of quitting successfully, but further longitudinal and trial data would be helpful to define any such effect more precisely.
These findings suggest, however, that, among smokers, e-cigarette use is likely to lead to quit attempts that would not otherwise have happened, and in a proportion of these to successful cessation. In this circumstance, e-cigarettes act as a gateway from smoking. However, it is not yet known whether, or by how much, e-cigarettes are being dually used by smokers who would otherwise have quit completely, and hence act as a barrier or delay to cessation. It is also not known whether or by how much a preference to try to quit using e-cigarettes is displacing uptake of the more effective conventional NHS Stop Smoking Services (SSSs) or other services combining pharmacotherapy with behavioural support, and hence reducing overall quit numbers, or whether this effect is counteracted by the much broader reach and uptake of e-cigarettes relative to NHS SSSs.

It seems likely that the chance of successful quitting with e-cigarettes would be increased if smokers who chose to use them, whether for cutting down or quitting, could also receive additional behavioural support, and perhaps, given the evidence that the combination of two nicotine products is more effective than one alone, were encouraged to combine e-cigarette use with a nicotine transdermal patch. Research and development of methods are clearly needed to engage and support smokers who start to use e-cigarettes, for whatever reason, to increase the likelihood of successfully quitting.

8.5.4 Population health effects of substitution of smoking with e-cigarettes

Thus far, the availability of e-cigarettes appears to have been positive for UK public health. Uptake has been rapid among adults and limited almost entirely to smokers, and has contributed to a continued downward trend in UK smoking prevalence. Use by children who would not otherwise smoke appears to be minimal. In many ways, therefore, their availability and adoption as a consumer alternative to smoking share many parallels with the use of snus as a consumer harm-reduction product in Sweden. Although long-term safety remains a concern, it appears likely that the combined influences of impending regulatory controls (see Chapter 10) and technological advances will lead to significant improvements in the probable long-term hazard profile of these products in the near future. These developments mean that unlicensed e-cigarettes are likely, in the near future, to approximate to NRT in terms of long-term hazard. The arrival on the market of licensed products, whether e-cigarettes or other novel designs, will make that prospect even more of a reality. In that case, e-cigarettes are likely to share the efficacy of NRT as a harm-reduction option under most circumstances.

However, the creation of models of these beneficial effects for products available today, and also those of potentially adverse influences such as widespread uptake
by non-smokers, gateway effects into smoking and sustaining dual use rather than quitting among established smokers, is difficult and inevitably dependent on assumptions about the probable magnitude of these influences. At the time of writing, we are aware of only two published attempts to do so. A proof-of-concept study applying Markov modelling to a cohort of adults aged 18–24 in the USA developed two models of smoking and e-cigarette use, the more conservative of which predicted that the prevalence of adult cigarette smoking within the cohort would increase from 15% at baseline to 21% after 10 years.\textsuperscript{52} These figures do not therefore appear applicable to the UK, where a 6 percentage point increase in smoking prevalence after the age of 25 has not happened in over 40 years (see Fig 2.11). A Monte Carlo analysis approach, modelling various scenarios of relative uptake by smokers and non-smokers, and at levels of harm relative to smoking ranging from 1% to 50%, predicted population benefits as long as use of e-cigarettes is concentrated among those who already smoke, or would otherwise have become smokers.\textsuperscript{53} As the true magnitude of e-cigarette harm is likely to lie at the low end of that modelled range, and experience to date indicates that use of e-cigarettes is almost entirely confined to smokers, these predictions support the notion that e-cigarettes, within the context of a regulatory environment designed to discourage use among youth and never-smokers, are likely to benefit public health.

8.6 Summary

- Uptake of smoking is falling in the UK, but most current smokers are likely to continue smoking for many years.
- Most of the morbidity and mortality caused by smoking in the short- and near-term future will occur in people who are smoking now.
- More effective measures to help existing smokers to quit smoking, as soon as possible, are therefore urgently needed.
- Harm reduction has the potential to complement conventional tobacco control policy by offering an alternative means for smokers to stop smoking tobacco.
- Substituting medicinal nicotine (NRT) for tobacco almost completely prevents any further damage to self or others from nicotine use.
- Although the long-term hazards of e-cigarette use are not yet clearly defined, e-cigarettes are probably close to NRT in the harm that their use confers on the user and others.
- The long-term hazard associated with e-cigarette use is likely to fall, as a result of regulatory and technological developments.
- There is no evidence that either NRT or e-cigarette use has resulted in renormalisation of smoking.
- None of these products has to date attracted significant use among adult never-smokers, or demonstrated evidence of significant gateway progression into smoking among young people.
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> NICE guidance recommends dual use of NRT for harm reduction, largely because dual users are more likely eventually to quit smoking.
> Evidence on the natural history of smoking among dual users of e-cigarettes is less well established, but a similar effect is likely.
> Promotion of the use of non-tobacco nicotine, including e-cigarettes, as widely as possible as a substitute for smoking, in the context of a regulatory framework designed to discourage use among youth and never-smokers, is therefore likely to generate significant health gains in the UK.

References

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31 Moore D, Aveyard P, Connock M et al. Effectiveness and safety of nicotine replacement...
therapy assisted reduction to stop smoking: systematic review and meta-analysis. BMJ 2009;338:b1024.


Tobacco harm reduction


9 E-cigarettes, harm reduction and the tobacco industry

9.1 Introduction

In 2013, the investment bank Goldman Sachs identified e-cigarettes as one of eight emergent themes in the global economy capable of ‘creative destruction’, representing a new technology that could offer consumers a significantly superior proposition and potentially ‘forcing established companies and business models to either adapt or die’.1 In the same year, The Economist newspaper similarly asked whether the rise of e-cigarettes represented the tobacco industry’s ‘Kodak moment’ – ‘its version of the point at which the world’s leading maker of camera film realised that consumers had gone digital, and it was too late to chase them’.2 The continuing profitability of the tobacco industry, which arises overwhelmingly from sales of tobacco cigarettes,3–6 suggests that such reports of the industry’s demise are at best premature. However, these claims do highlight the substantial degree of uncertainty about the commercial implications of e-cigarettes for the future of the tobacco industry and therefore for the strategic development of tobacco control.

The disruptive effect of e-cigarettes is not confined to the tobacco industry. The chairman of the pharmaceutical giant GlaxoSmithKline, for example, has acknowledged that, in response to the declining performance of their nicotine replacement therapies (NRTs), the company considered manufacturing e-cigarettes before concluding that such a step would be ‘just too controversial’.7 Leading tobacco companies have, perhaps predictably, made a different decision, implementing a rapid programme of investment in and acquisition of vapour devices. The public health implications of such developments remain uncertain and contested, and reflect broader debates about the role of harm reduction in general. At one end of the spectrum, harm-reduction advocates and researchers see advantages in engaging an industry skilled in marketing nicotine in the promotion of products that could offer a potential exit strategy from selling cigarettes: identifying, for example, the ‘need to create a situation in which there are incentives for tobacco companies to gradually become nicotine companies … [such] that their long-term profits are going to be in other products than cigarettes’.8 At the other end of the spectrum are those who see no such prospect,
claiming, for example, that ‘only the most naive or captured advocates for vaping could fail to acknowledge that the tobacco industry wants people who vape to smoke and vape, not vape instead of smoking’. This chapter explores the motives for and potential consequences of the tobacco industry’s engagement in harm reduction and, in particular, the emerging e-cigarette market.

9.2 The tobacco industry and e-cigarettes

E-cigarettes have emerged as a significant component of the market in nicotine products with astonishing rapidity, both in the UK and globally. The market research company Nielsen identified e-cigarettes as the fastest-growing product in British supermarkets during 2014, with sales across large grocers increasing by almost 50%. A report on the UK market in nicotine vapour devices by the industry analysts Euromonitor suggested even greater growth, with a category that was worth only £25 million as recently as 2011 having reached overall sales of £459 million in 2014. This growth also reflected changing consumer preferences, with first-generation (‘cigalike’) devices (see Chapter 5) being displaced in the UK by the rapid expansion of tank systems and of e-liquids, which experienced value growth of 110% and 145% respectively in 2014. This shift is also strongly evident in other leading western European markets, although ‘cigalikes’ retain majority shares in both Russia and the USA. The UK e-cigarette market is now estimated to be the world’s second largest, being exceeded only by the USA, whereas global sales of an estimated $US6.5 billion now dramatically outstrip the declining international market for NRT (US$2.4 billion), and are equivalent in value to cigarette sales in the world’s 20th-largest cigarette market.

Having perhaps been taken by surprise by the rise of e-cigarettes, the transnational tobacco companies have all now committed to major initiatives in this emergent industry. A key moment was the April 2012 acquisition of the e-cigarette brand blu™ by the US-based cigarette manufacturer Lorillard for $US135 million, marking the tobacco industry’s first major foray into the e-cigarette market. In December 2012, British American Tobacco (BAT) became the first leading tobacco company to buy a British e-cigarette manufacturer through its purchase of CN Creative, the maker of Intellicig. This complemented BAT’s earlier formation of what was billed as a stand-alone start-up company, Nicoventures, to ‘focus exclusively on the development and commercialisation of innovative regulatory approved nicotine products’. All of the leading international cigarette manufacturers have now made substantial acquisitions or launched strategic initiatives in nicotine products, principally in e-cigarettes. Altria and Philip Morris International (PMI) manage vapour brands including Mark Ten, Nicotines and the heat-not-burn product iQOS; BAT brands include Vype, Intellicig and an inhaled nicotine device called Voke; Japan
Tobacco International have purchased E-Lites and launched Ploom; RJ Reynolds have developed Vuse and Revo, whereas Imperial Tobacco launched Puritane through its Fontem Ventures subsidiary and, in July 2014, obtained the blu™ brand that was sold as part of Reynolds’ takeover of Lorillard.11–12,17

These investments have, to date, been weighted heavily towards first-generation ‘cigalikes’, which mimic tobacco cigarettes more closely, but tend to deliver lower doses of nicotine than, later-generation devices (see Chapter 5), and it has been suggested that this is a deliberate strategy to avoid promoting products likely to be effective in aiding cessation.18 Recent developments suggest diversification, with tobacco companies looking beyond ‘cigalikes’: the Vivid Vapours e-liquid brand has become increasingly prominent in the UK after its acquisition by PMI, and the blu™ product range is expanding via its e-liquid portfolio.19 Investments in heat-not-burn technology (positioned as reducing risks associated with combustion by electronically heating tobacco rather than burning it6), as well as in non-tobacco nicotine products (see Chapter 5), further increase the diversity of tobacco company initiatives in reduced risk products, and PMI’s launch of its iQOS Heatsticks, under its flagship Marlboro brand in test markets in Japan and Italy, suggests that this development is of major strategic importance to PMI.20 It does appear that tobacco industry efforts to build a market for reduced-risk products are now centred on vapour devices, as epitomised in July 2015 by PMI announcing the dissolution of its snus joint venture with Swedish Match while extending its international strategic collaboration with Altria in vaping products.21

The engagement of the tobacco industry in the reduced-risk product sector is thus changing rapidly, and in relation to e-cigarette products is likely to continue to do so, given, among other things, the expected changes in regulatory context, new patterns of ownership and investment, the currently fragmented market, absence to date of dominant brands, and continuing technological innovation and shifting consumer preferences. Such uncertainties notwithstanding, however, rapid growth in the e-cigarette market is predicted to continue over the next few years, with Euromonitor suggesting that the global market for vaping products could reach US$50 billion by 2030. This is clearly a substantial and enticing prospect from a commercial perspective, although it needs to be interpreted alongside an expectation that it will remain a fraction of the market in tobacco products, with cigarettes remaining the dominant product category.22

9.3 E-cigarette marketing

The first television advertisement for an e-cigarette, promoting the then independently owned E-Lites brand, was broadcast in the UK in January 2013.11 This was followed a year later by advertisements for Vype, an e-cigarette...
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marketed by BAT and representing the first overt paid-for television advertisement by a tobacco company in over two decades,23 and then, later in 2014, by advertisements showing the act of vaping for the VIP e-cigarette brand.24 Such developments occurred amid considerable ambiguity about how and whether existing regulatory frameworks applied to reduced-risk nicotine products. This led to a public consultation by the Committees of Advertising Practice,25 followed by the issuance of specific guidance25,26 intended to govern the period until the implementation of more stringent regulation of advertising, sponsorship and promotion under the 2014 revision of the EU Tobacco Products Directive 2014/40/EU.

The development of television advertising campaigns forms one strand of an extensive array of marketing, sponsorship and promotional efforts that have contributed to the rapid growth of the e-cigarette market. Sports sponsorship deals, for example, have included Nicolites partnering with Birmingham City Football Club, whereas E-Lites secured distribution deals and designated vaping areas in Celtic and Rangers football stadiums in Glasgow, and invoked the strong association between tobacco and motorsport in announcing its sponsorship of the British Superbike Championship.27–29 E-Lites secured the first product placement for e-cigarettes in a music video by the artist Lily Allen. Packaging innovations have included ‘smart packs’ produced by blu™ e-cigarettes that vibrate and flash a blue light when within 50 feet of other users, and which can transmit to Facebook and Twitter profiles, whereas Vapestick has created a retro-style computer game named Electronic cigarette wars. PMI also offered retailers free retail display shutter cases heavily branded with its Vivid e-liquid and Nicolites e-cigarettes, in preparation for the second stage of UK point-of-sale display legislation, which prohibited point-of-sale display of any tobacco product from April 2015.30

Such high-profile activity is indicative of the recent rise of e-cigarette promotions across multiple fields, driven by rapidly escalating expenditure. During 2013, around £8.4 million was spent in the UK promoting five leading brands (E-Lites, Vype, SkyCig, NJOY King and Gamucci) across press, television, radio, the internet and outdoor media, figures that were to be dwarfed in 201431 with BAT’s television advertising for Vype as part of a £3.6 million marketing campaign and Skycig announcing investment in a £20 million marketing campaign.27 A similar surge in marketing spending has occurred in the USA, where a study of advertising spending across television, print, radio and the internet found that expenditure in the second quarter of 2013 amounted to $US28 million, some eight times more than that for the equivalent period in 2012.32

This escalation of marketing expenditure reflects the increased resources available following the wave of investments in e-cigarettes by the tobacco industry, with the latter’s engagement in marketing raising distinct concerns.
Looking at the future development of the market in vapour devices from a commercial perspective, this represents both opportunity and risk, because leading tobacco companies ‘have the capital to turn e-liquid brands into household names but also the reputational impairment to attract draconian regulation to the category’. In this context, discussions about how to regulate the marketing of e-cigarettes are inevitably coloured by the tobacco industry’s long-standing global reliance on advertising and marketing to promote and maintain cigarette consumption, particularly by targeting young people. Health campaigners have raised concerns about the extent to which some e-cigarette advertising has sought to replicate imagery and themes that have long been central to marketing cigarettes. Magazine adverts for e-cigarettes in the USA have, for example, been seen as depicting equivalents to the rugged masculinity of the Marlboro Man or the glamorous independence of the Virginia Slims woman, sponsorship of sports and music events, and the development of sweet flavours are seen as enhancing appeal among youth, and blu® e-cigarettes’ use of a cartoon ‘Mr Cool’ evoked the notorious Joe Camel cartoons. In the UK, rules on advertising limit such opportunities and the Advertising Standards Authority recently upheld complaints about an advert for VIP e-cigarettes that showed a woman vaping ‘in a sultry and glamorous way’, creating a strong association with traditional smoking and thereby ‘indirectly promoting the use of tobacco products’. Complaints about a UK advert for Vape Nation were upheld as encouraging use of e-cigarettes among ex-smokers.

Maintenance of extensive marketing freedom and potentially controversial promotional strategies for e-cigarettes has been defended as likely to appeal to smokers, and it has been argued that excessive regulation is likely to protect the market monopoly of tobacco cigarettes by inhibiting competition from e-cigarettes. Analyses from a social marketing perspective, however, have emphasised risks associated with e-cigarette marketing in general, and the role of tobacco companies within such activities in particular. In presenting the promotion of e-cigarettes as a reinvention of tobacco marketing, de Andrade et al highlight the active promotion of dual use, in which marketing activities are identified to have been ‘promoting long term use as a permanent alternative to tobacco, and a temporary one in public places where smoking is banned’. An analysis of the marketing strategy of tobacco company-owned e-cigarettes for Cancer Research UK was organised around a distinction between marketing targeted at potential consumers and those activities oriented towards ‘stakeholders’, such as policymakers and public health agencies (Table 9.1).

Although debate about the potential for such campaigns to renormalise or inadvertently promote smoking continues, attention is increasingly focused on the tobacco industry’s use of e-cigarettes and the wider harm-reduction agenda to rebuild its links with policymakers, and public health and other key stakeholders.
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9.4 Undermining tobacco control

The recognition of a fundamental conflict between public health objectives and tobacco industry interests has become a central tenet of tobacco control, epitomised by Article 5.3 of the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC), which requires countries to protect the setting and implementation of tobacco control policies from the industry’s commercial and other vested interests. The emergence of a distinctive model of

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Table 9.1 Tobacco-owned e-cigarettes – the marketing strategy

<table>
<thead>
<tr>
<th>Marketing challenge</th>
<th>Marketing strategy</th>
<th>Stakeholders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who Consumers</td>
<td>Objective</td>
<td>Responsibility, legitimacy, credibility, access to policymakers/regulatory processes, public–private partnership, scientific proof</td>
</tr>
<tr>
<td></td>
<td>Long-term sales of tobacco through ‘next-generation’ product (especially in developed countries), profit maximisation</td>
<td></td>
</tr>
<tr>
<td>What</td>
<td>Reduced-harm product, safer alternative to cigarettes, used for pleasure, lifestyle products</td>
<td></td>
</tr>
<tr>
<td>How</td>
<td>Product: safe nicotine, used anywhere, flavoured lifestyle products</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Price: financial – affordable; psychological – safer and glamorous</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Promotion: where tobacco products cannot be advertised, lifestyle and celebrity</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Place: everywhere tobacco is available, company websites, point-of-sale displays</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Positioning: safer smoking alternative, necessity, capitalise on consumer’s preference</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Product: harm reduction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Price: financial – priceless, saving lives; psychological – it would be negligent to ignore this offering</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Promotion: health bodies/experts, charities, politicians, regulators</td>
<td></td>
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<tr>
<td></td>
<td>Place: regulated space</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Positioning: differentiation from NRT products, reframe perceptions of nicotine use, alternative for those who cannot or will not quit</td>
<td></td>
</tr>
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</table>
E-cigarettes, harm reduction and the tobacco industry

Health governance, centred on minimising engagement with the industry, has led to tobacco companies experiencing increasing political marginalisation and difficulty obtaining access to policy elites. In this context, investments in harm reduction and e-cigarettes offer potential opportunities to claim legitimacy in re-engaging with policymakers, and even to rehabilitate what has become a pariah industry. If realised, these opportunities may therefore undermine tobacco control.

Tobacco companies have long sought to redress the challenge of a toxic reputation by seeking to establish partnerships or common ground with public health researchers and advocates. A key element of PMI's 'Project Sunrise' in the mid-1990s, for example, was to 'enhance our credibility' by linking with 'moderate' tobacco control organisations on issues such as youth access legislation. Tobacco companies' interest in the concept of harm reduction increased markedly following a 2001 Institute of Medicine report, driven by recognition of a dual opportunity to both '(re-)establish dialogue with and access to policymakers, scientists and public health groups and to secure reputational benefits via an emerging corporate social responsibility agenda. The emergence of pure nicotine alternatives to traditional forms of tobacco consumption has thus created increased opportunities for both interaction with policymakers and the depiction of common ground with public health. In the context of a public consultation on the future of the NHS, for example, Imperial Tobacco met with the then minister for public health, and subsequently made a submission in which the company invoked its interests in harm reduction to argue against exclusion from policymaking and to position itself as a potential partner for the government. Several tobacco industry submissions to a Department of Health consultation on the future of tobacco control similarly used interests in harm reduction as a basis for suggesting that it could positively contribute to the challenge of reducing health inequalities.

Exploiting such opportunities was a key part of the remit of Nicoventures following its establishment by BAT. In 2012, Nicoventures initiated a medical education plan named the Smoking Harm Reduction Education Programme (SHARE), holding a series of meetings with healthcare professionals, including a round table at the Royal Society of Medicine, and publishing proceedings in GP and Pharmacy Magazine. In June 2013, Nicoventures approached public health officials across various regions in the UK to discuss harm reduction and regulation, with a sales representative describing the company as complying with the regulatory standards required of a pharmaceutical company. BAT also appointed Dr Richard Tubb to their board of directors in January 2013, describing this former physician to the president of the USA and ex-director of the White House Medical Unit as 'a prominent and well respected expert in the field of tobacco harm reduction' whose appointment 'further demonstrates our commitment to putting science at the heart of our business'. The company...
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devoted its 2013 sustainability focus report to the issue of harm reduction, depicting BAT as a potential partner in a public health revolution; this included an endorsement of the group’s strategy by Dr Delon Human, a global health consultant and former head of the International Food and Beverage Alliance, as having the expertise and public commitment to harm reduction to suggest that ‘BAT could become part of the solution to addressing the epidemic of tobacco-related disease’. The report claims that ‘(m)ore collaboration between the tobacco industry, academia and tobacco research centres is … key to establishing an evidence-based regulatory framework to assess new products.

Alongside such examples of formal endorsements, tobacco companies have also opportunistically cherry-picked statements from leading public health organisations and researchers so as to imply common ground and a shared perspective. The harm-reduction section of the PMI website cites a 2014 report from Public Health England (PHE) as recognising a need for ‘appropriate regulation, careful monitoring, and risk management’ for harm-reduction products; the citation is presented under a headline claim that the ‘public and private sectors are starting to embrace the public health opportunity new products provide’, but does so without noting that the PHE report highlights the involvement of the tobacco industry among ‘potential hazards, unintended consequences, (and) harms to public health’.

A key element of the strategic value of harm-reduction discourse to tobacco companies is its ability to polarise opinions held by those involved in tobacco control policy, fracturing the remarkable degree of political consensus that has characterised the tobacco control movement and been central to its success. PMI’s ‘Project Sunrise’ centred on the recognition of unity as a key strength of tobacco control, and promoting division was seen as critical to combating the movement’s success. The company’s strategy sought to exploit latent tensions between groups that it labelled ‘moderates’ and ‘prohibitionists’, and this finds strong contemporary echoes in the depiction of competing wings of tobacco control comprising ‘pragmatists’ who favour harm-reduction approaches being opposed by ‘idealists’ or ‘zealots’.

In this context, the very public dispute in 2014 between competing perspectives on harm reduction via ‘duelling letters’ from public health researchers and practitioners to the director-general of WHO, Dr Margaret Chan, appears very welcome from a tobacco industry perspective. The initial open letter of 24 May 2014 with 53 prominent signatories was prompted by a concern that harm reduction was being ‘overlooked or even purposefully marginalised’ in preparing for the forthcoming sixth Conference of Parties of the WHO FCTC. The letter began to receive significant media coverage on 29 May 2014 and on the same day BAT issued a press release calling ‘for tobacco harm reduction to be adopted as a progressive public health policy’.

A quotation from a
subsequent letter remains prominent on the harm-reduction pages of BAT’s website, emphasising ‘the importance of dispassionate presentation and interpretation of evidence’ and the challenge to find ‘an appropriate framework’ of regulation balancing opportunities and risks. These twin themes are also repeatedly invoked in the company’s subsequent 2014 harm-reduction report. Its introduction by chief executive Nicandro Durante suggests that ‘the challenge is that these are new products which many governments are still unsure how to regulate’ and cites ‘the growing weight of evidence and arguments in support of harm reduction’. The report highlights a call from a paper by three of the letter’s signatories for regulatory decisions to be ‘proportional, based on evidence, and incorporate a rational appraisal of likely risks and benefits’, presenting a variation on BAT’s long-standing claim to ‘support sensible regulation’.

Although neither the reputational management nor policy engagement opportunities afforded by harm reduction have yet been exploited with success that can be considered transformational, a number of strategically valuable ‘wins’ for the tobacco industry can be identified. Notable here is the success of BAT’s Nicoventures in securing marketing authority from the UK Medicines and Healthcare products Regulatory Agency (MHRA) for its nicotine inhaler Voke, a success has been described as ‘an important waypoint on the industry’s journey to self-rehabilitation’. Vype, also owned by BAT’s Nicoventures, is marketed as a ‘pharmaceutical-grade product’ and sold via Lloyds Pharmacy, whereas Puritane e-cigarettes, owned by the Imperial Tobacco subsidiary Fontem, are exclusively available in Boots. Such distribution deals are inconsistent with advice from the Royal Pharmaceutical Society, and both bring reputational benefits of association with prominent high-street chemists and create strategic opportunities. Puritane’s deal with Boots is seen as leaving it well placed to benefit from any reclassification of e-cigarettes to ‘directly rival smoking cessation aids’.

9.5 E-cigarettes and the future of the tobacco industry

Tobacco companies’ investments in e-cigarettes, as with earlier incarnations of the harm-reduction debate, have been characterised by considerable uncertainty, false starts and fluctuations, and there is nothing to suggest that the recent developments outlined above constitute a fixed and settled strategic direction, whether for specific companies or for the industry as a whole. There is, however, now a sufficient basis to draw some preliminary conclusions informed by marketing campaigns, investor presentations and stated strategic priorities. Such conclusions need to be informed by the historical experience of how and why tobacco companies viewed earlier reduced-risk products, with which striking similarities are becoming evident. One potential parallel has recently been drawn
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in light of the history of NRT, via tension between two competing conceptions of NRT as a therapeutic device to aid cessation and as a cigarette alternative capable of delivering nicotine in the ‘right way’. This analysis highlights the dangers of the potential of e-cigarettes being ‘easily compromised in the hands of tobacco companies, reflected by their tendency for imagining nicotine replacements … as creatively complementing rather than creatively destroying the market for combustible tobacco products.’

More broadly, the tobacco industry’s recent involvement with e-cigarettes carries echoes of its earlier rise to dominance of the Swedish snus market via acquisitions and joint ventures between 2001 and 2009, eg an analysis of BAT corporate documents from this period yielded no substantive evidence of the company encouraging smokers to switch permanently to smokeless tobacco, but indicated instead that these were essentially defensive investments that protected the status quo and the dominance of the cigarette by shifting ‘snus from a threat (a product that may have competed with cigarettes) to a major opportunity’ that presented common interests with public health and an alternative future amid long-term decline in cigarette sales.

One significant difference that emerges from comparison with the snus experience is the prominence afforded e-cigarettes and reduced-risk products in contemporary investor presentations. This contrasts with a near absence of snus from earlier BAT and PMI presentations, which suggest that snus was not central to business strategy. The reformulation of BAT’s vision statement to become ‘the world’s best at satisfying consumer moments in tobacco and beyond’ indicates newfound strategic centrality for nicotine projects, mirrored in PMI’s designation of reduced-risk products as ‘our greatest growth opportunity’. Although the reputational and stakeholder engagement advantages of e-cigarettes for tobacco companies are clearly considerable, this does seem also to represent a consumer market in which growth prospects are being taken seriously.

The extent to which this constitutes a transformation of the strategic landscape for tobacco companies should not, however, be overstated. To return to the image of creative destruction, the emphasis seems to be very much on e-cigarettes creatively complementing conventional products within an expanded portfolio, not on displacing the industry’s ongoing reliance on the conventional cigarette. Hence BAT has been unequivocal that their ‘ambition remains to lead the global tobacco industry’, retaining confidence in the growth of the global tobacco business and developing their portfolio of ‘beyond tobacco products’ within a single integrated view of the consumer. New products are therefore positioned alongside traditional cigarettes, combustible innovations and non-combustible offers in creating multiple satisfying ‘consumer moments’. Similarly, PMI chairman Louis Camilleri’s speech to the company’s 2015 annual meeting emphasised that ‘we expect our combustible products to be the core of our
profitability growth for many years to come’, notwithstanding the significance attached to investing in and developing reduced-risk products. The decision to launch the company’s heat-not-burn iQOS system under the Marlboro brand is also consistent with ongoing concerns that tobacco companies are using e-cigarette marketing to promote dual use, thereby complementing and sustaining rather than challenging the future dominance of the cigarette.

Any suggestion that tobacco companies are using investments in e-cigarettes as a vehicle to secure their long-term exit from the cigarette market therefore looks like misplaced optimism. Their engagement in harm reduction is likely to be better understood in terms of exploring an emerging opportunity that can buttress their core business, and promise the maintenance of both their licence to operate and the prospect of rehabilitation. Appraising the implications of this perspective for the broader role of harm reduction within the future of tobacco control remains contentious, but it does serve to highlight the ongoing importance of protecting health policy from tobacco industry interference and of maximising compliance with guidelines for the effective implementation of WHO FCTC Article 5.3. Although the most optimistic interpretations of increased tobacco industry interests in reduced-risk products might suggest the prospect of some degree of shared interest with public health, the economic and political contexts within which such products are being promoted suggests that any such appraisal is dangerously naive and holds the potential significantly to undermine tobacco control policy and practice internationally. Interests in e-cigarettes and other reduced-risk products create important strategic opportunities for the tobacco industry, and therefore compound the complexities confronting public health in dealing with the harm-reduction agenda. The appropriate response is therefore to strengthen and broaden protections against conflicts of interest, protecting ‘tobacco control activities from all commercial and other vested interests related to [e-cigarettes], including interests of the tobacco industry’.

9.6 Summary

- The e-cigarette market has demonstrated massive growth in value and, until relatively recently, has been driven by independent e-cigarette companies.
- This success represents a potential challenge to the traditional business model of the tobacco industry, but also creates important commercial and political opportunities.
- After some delay the tobacco industry is now engaging in the e-cigarette market, and the possible reasons for doing so include:
  - promotion of low-efficacy products that are likely to fail and hence minimise the threat to tobacco sales
  - use of intellectual property rights to bring legal challenges against competitors
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- ensuring a share in the emerging e-cigarette market to harness a new, disruptive technology
- using these products to sustain tobacco smoking by promoting them as a complement rather than an alternative to tobacco
- using the products also to promote smoking through advertising and promotion to adults and children
- attracting customers who currently use competitors’ tobacco products
- creating justification to re-engage with policymakers, hence undermining the WHO FCTC (Article 5.3)
- exploiting harm reduction to build credibility in corporate social responsibility initiatives
- using harm reduction as a pretext to engage with and disrupt the activities of scientists and advocates in tobacco control.

The engagement of the tobacco industry in the e-cigarette market thus represents a significant potential threat to UK national and global tobacco control.

References


10 Smithers R. Electronic cigarettes and sports nutrition products lead grocery sales boost.
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18 Torjesen I. Tobacco industry is investing in electronic cigarette types least likely to help smokers quit. BMJ 2015;350:h2133


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35 Campaign for Tobacco-free Kids. 7 ways electronic cigarette companies are copying big tobacco's playbook, 2 October 2013 (online). www.tobaccofreekids.org/tobacco_unfiltered/post/2013_10_02_ecigarettes [Accessed 15 August 2015].


46 Peeters S, Gilmore AB. Understanding the emergence of the tobacco industry’s use of the term tobacco harm reduction in order to inform public health policy. *Tob Control* 2015;24:182–9.


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10.1 What does nicotine product regulation need to achieve?

Products are regulated to ensure that they are safe and fit for purpose; the general product regulations that apply to all consumer products sold in the UK, and their equivalents in other countries, are intended to achieve this for general consumer goods. In the case of products for which safety is particularly important, these general product regulations are often supplemented or superseded by higher levels of specific safety regulation, with medicines, for example, being required to meet especially high standards of manufacturing, safety, product information and efficacy. The overall purpose of all of this regulation is, however, to ensure that consumers can access products that serve their purpose within reasonable bounds of safety, quality and efficacy.

The rationale for regulating nicotine products is the same as for any other, but is complicated by the fact that the market leader in nicotine products in the 20th and 21st centuries, the cigarette, is so intrinsically hazardous that it is beyond the scope of conventional general product regulations, and as an addictive product is too entrenched in society to be amenable to prohibition. It is therefore important that the approach to regulating non-tobacco nicotine products recognises the need not only to meet the general requirements of safety and fitness for purpose, but also to encourage the development and uptake of competitive alternatives to the fatally toxic product currently chosen by most habitual nicotine users. Therefore, although regulation of all products should be proportionate to their potential hazard, proportionality in nicotine regulation must also incorporate the consideration that regulation that discourages or delays the development and use of non-tobacco nicotine is likely, in effect, to sustain tobacco smoking and hence perpetuate harm to smokers and wider society.

This report has argued that nicotine use, of itself, presents relatively little risk to users or wider society, and that most of the harm that arises from nicotine use is attributable to the vehicle of delivery, with tobacco smoke being by far the most hazardous. It therefore follows that, although the ideal course of action for any smoker is to quit smoking and all nicotine use, quitting smoking by long-term
substitution with a less hazardous nicotine source is the next best option. Nicotine regulation should therefore be designed to make non-tobacco nicotine a more attractive, available and affordable option for smokers than cigarettes, to prevent, as far as possible, uptake of nicotine use by never-smokers, particularly children, and to make smoked tobacco products as unappealing as possible.

When the RCP last reported on nicotine regulation in 2007, the range of available nicotine products fell into three classes: smoked tobacco, smokeless tobacco and nicotine replacement therapy (NRT). We argued then that the prevailing regulatory structure intrinsically favoured smoked tobacco over both NRT, which was regulated as a medicine, and smokeless tobacco, of which the lowest-hazard product, Swedish snus, is prohibited in the UK. The emergence of e-cigarettes has added a whole new product class to this range, and this spectrum of choice is likely to be increased still further by new technologies in development (see Chapter 5). The nicotine regulatory framework has also undergone substantial change since 2007.

This chapter describes recent developments and impending changes in UK nicotine regulation, identifies key areas of concern, and discusses alternative approaches that might increase the public health benefit accrued from the emergence of e-cigarettes and other non-tobacco nicotine. The discussion is based in the UK setting and pertains to the three broad types of nicotine product available on the UK market: tobacco, unlicensed nicotine products (predominantly e-cigarettes) and nicotine products that are licensed as medicines.

10.2 Current regulation of tobacco, and licensed and unlicensed nicotine products

10.2.1 Tobacco products

Since 1998, a comprehensive tobacco control strategy has been introduced in the UK, the component measures of which are discussed in more detail in Chapter 3. Regulatory approaches have included: reducing affordability by increasing taxation and reducing the size of the cheap and illicit market; imposing packaging and labelling requirements (including the implementation of standardised packaging legislation from May 2016); prohibiting all advertising, promotion and sponsorship; restrictions on where, how and to whom tobacco products can be sold; and smoke-free policies determining where tobacco can be used. After unsuccessful attempts to regulate the cigarette itself by restricting tar levels, regulation of product contents and emissions has not been extensively pursued, other than to prevent fires by reducing ignition propensity. The overall package of tobacco control policies in place in the UK is one of the most...
advanced in the world, with the UK currently highest in the European tobacco control league table. The new EU Tobacco Products Directive (TPD) will, from May 2016, impose a range of new restrictions on tobacco products, which include a minimum pack size of 20 cigarettes (and 50 g hand-rolling tobacco), restrictions on the shape of packs, combined pictorial and text health warnings that cover 65% of the front and back of the pack, and prohibition of flavourings including, after a delay, menthol.

10.2.2 Unlicensed nicotine products

E-cigarettes (most of which contain nicotine) and other unlicensed nicotine products are currently regulated in the UK by the EU General Product Safety Directive. This has recently been supplemented by legislation in England imposing a minimum purchase age of 18 years, which is currently in the process of being introduced elsewhere in the UK. General product regulations do not require products to be tested before being put on the market, but do allow retrospective action to remove products found to be faulty or harmful. In July 2015, the British Standards Institute (BSI) published a fast-track voluntary standard for e-cigarettes (PAS 54115), which was sponsored by the Electronic Cigarette Industry Trade Association (ECITA (EU) Ltd) and facilitated by the BSI. This standard gives guidance on the manufacture, import, labelling, marketing and sale of vaping products, including e-cigarettes, e-shishas and e-liquid mixing kits. However, at the time of writing it is not clear how widely this standard is being adopted by manufacturers and importers.

E-cigarette marketing in the UK has to comply with compulsory advertising codes administered by the Advertising Standards Authority (ASA). Although those codes contain general rules that apply to all advertising, concerns about the promotion of e-cigarettes led the ASA to introduce sector-specific rules in November 2014. These require the following of e-cigarette advertising: to be socially responsible; not to promote any design, imagery or logo that might be associated with a tobacco brand or show the use of a tobacco product in a positive light; to make clear that the advertised product is an e-cigarette and not a tobacco product; not to undermine quit smoking messages; and not to contain health or medicinal claims unless the product holds a medicines licence. There is a commitment to review progress with these rules after 12 months.

Although not subject to the smoke-free legislation that prohibits tobacco smoking in enclosed public places and workplaces, some businesses and organisations prohibit e-cigarette use in places where this legislation already prohibits smoking. Given the lack of evidence on the harmfulness of e-cigarette vapour to others (see Chapter 5), it would be inappropriate for national legislation to prohibit their use in public places and workplaces. At the time of
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going to press, an attempt by the Welsh government to legislate to ban the use of e-cigarettes in some enclosed places and workplaces had failed and was considered unlikely to be reintroduced in the next parliament after the elections in May.8

There are some circumstances, such as prisons and mental health settings, where tobacco smoking is particularly prevalent. The option to use e-cigarettes where tobacco smoking is banned could help to introduce and sustain fully smoke-free policies, eg the South London and Maudsley NHS Foundation Trust implemented a policy that allows some types of e-cigarette to be used, as part of a care treatment pathway, in private spaces or grounds where smoking is prohibited.9 Prisons in England and Wales have made single-use e-cigarettes available for sale to prisoners as a smoking substitute, in preparation for implementing fully smoke-free policies across the prison estate which started in late 2015.10

10.2.3 Licensed nicotine products

Nicotine products licensed as medicines, generally known as nicotine replacement therapy (NRT), have been available in the UK since 1980. They were initially licensed by the Medicines Control Agency (MCA) for use to relieve nicotine withdrawal symptoms during attempts to quit smoking, and were subject to an extensive range of cautions and contraindications that arose from the use of comparison of adverse effects with those of placebo, rather than continued smoking.

The MCA was replaced in 2003 by the UK Medicines and Healthcare products Regulatory Agency (MHRA), which was established with a wider remit, including a new objective to make ‘an effective contribution to public health’. In 2005 the MHRA made some substantial changes to their regulation of NRT products in response to a review and recommendations by the Committee on Safety of Medicines, an advisory committee to the MHRA.11 These included the adoption of smoking rather than placebo as the comparator for NRT, which allowed some contraindications (eg stable cardiovascular disease) that inhibited use of NRT by smokers to be removed, extending the licence for NRT to include pregnant smokers, and smokers aged 12 and over, and allowing some NRT products to be used for cutting down in order to quit, as well as for abrupt quitting. There has also been a progressive relaxation of restrictions on the availability of NRT over recent years, starting in 2001 when prescriptions of NRT products became reimbursable through the NHS, and subsequently through extensions to retail availability by allowing NRT products to be sold by general retailers as well as pharmacies. Direct advertising of NRT to the public is permitted subject to regulations12 requiring the following from promotions: they are not misleading and do not imply that products are ‘safe’; they are compliant with the details listed in the summary of product characteristics; they are presented objectively to encourage rational use of...
the product; and they are not directed exclusively or principally at people aged under 16. Provision of free samples of NRT for promotional purposes remains prohibited. Since 2007, NRT sold over the counter has been subject to VAT at a reduced rate of 5% to help make products more affordable.13

In 2010, the MHRA expanded the indication for NRT to allow long-term use as a harm-reduction alternative to smoking for those who were unwilling or unable to quit.14 The question of whether e-cigarettes should be regulated as medicines was considered by the MHRA at this time, which proposed that nicotine be deemed a medicine by function, thereby requiring that e-cigarettes should either be licensed as medicines or removed from the market. However, as immediate classification as medicines would have caused all e-cigarettes on the market at the time to be withdrawn, and hence potentially cause the many smokers who had already switched from using tobacco cigarettes to e-cigarettes to go back to tobacco smoking, the MHRA consulted on options15 that included implementing medicines regulation immediately, or after a delay allowing e-cigarette manufacturers and importers to comply, or else imposing no additional regulation. The proposed licensing option was described by the MHRA as ‘light touch’ and presented as a simplified, and hence quicker and less costly, route to medicines licensing. In particular, the proposed ‘light touch’ approach assumed that any product that delivered nicotine to a degree comparable with existing licensed nicotine products was clinically effective, thus removing the requirement for manufacturers or importers of e-cigarettes or other nicotine-containing products to carry out clinical trials to demonstrate efficacy.

The consultation received over 1,000 responses, most of which came from e-cigarette users opposed to any regulation, or else supporting regulation introduced in a way that allowed e-cigarettes to remain available to them. Responses from public health organisations, including the RCP, were generally supportive of ‘light touch’ regulation, but most recommended a delay to allow time for manufacturers to comply. Support for immediate regulation, with removal of unlicensed products from the market within 21 days, came from organisations including pharmaceutical companies, pharmacist and trading standards groups, and Imperial Tobacco.15 The MHRA responded by allowing e-cigarettes to remain on the market pending further consideration, and in 2013 announced that it would require all nicotine products to be licensed as medicines from the date of implementation of a revision of the TPD (see Section 10.3 below). The TPD version under consideration at that time required medicines regulation for all but very-low-dose products. The MHRA later rebadged the medicines licensing process for nicotine products as ‘right touch’ regulation.

In 2014, a revised version of the TPD, which superseded the MHRA proposal by providing an alternative route to market for e-cigarettes without a medicines licence, was negotiated and agreed.3,16 Medicines regulation remained an option
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for manufacturers and importers of e-cigarettes, and the MHRA continues to encourage companies to apply voluntarily for licences. However, licensing is no longer mandatory and, at the time of going to press in early 2016, only one e-cigarette, owned by British American Tobacco (BAT), had been awarded a medicines licence by the MHRA and was not yet commercially available. It is not known whether medicines licence applications have been made for other e-cigarette products. A medicines licence has, however, been awarded to a nicotine inhaler (not an e-cigarette) called Voke, developed by Kind Consumer and licensed to BAT, but at the time of going to press this product had not been marketed.

10.3 The 2014 EU TPD

The 2014 revision of the EU TPD, which comes into effect from May 2016, imposes significant new regulations on nicotine products, including e-cigarettes and refill containers that do not have a medicines licence. Although limited areas of flexibility in implementation for member states remain, the main provisions of the TPD in relation to e-cigarettes are as follows:

1. Manufacturers and importers of e-cigarettes must provide a detailed notification to the government-appointed ‘competent authority’ of a range of details relating to each product, and make this information publicly available. Non-compliant products can be manufactured until 20 November 2016 and sold until 20 May 2017. Products already on the market by 20 May 2016 must be notified by 20 November 2016. New products or substantial modifications introduced into the market between 20 May and 19 November 2016 must be notified at least 1 day in advance of going on sale. From 20 November 2016 all new products or substantial modifications must be notified 6 months in advance of going on sale.

2. Required details include: quantification and toxicological data for all ingredients and emissions, including when heated, and their potential health and addictive effects; nicotine delivery and uptake; a description of the product components and production process; and a declaration of responsibility for the quality and safety of the product when used under normal or reasonable foreseeable conditions.

3. There will be a limit on total nicotine content in e-cigarettes, which will be allowed to contain a maximum of 2 mL nicotine solution at a maximum nicotine concentration of 20 mg/mL. Refill containers will be subject to a maximum volume of 10 mL. Nicotine and all other ingredients used in manufacture must be of high purity and not pose a risk before or after heating, and substances other than those declared should be present only in trace quantities, which are unavoidable during manufacture. Products must be child and tamper proof, and protected against breakage and leakage.
4 Nicotine doses are required to be delivered at consistent levels under normal conditions of use.

5 Products should include a leaflet, which, among other things, contains instructions, warnings, and information on contraindications, possible adverse effects, addictiveness and toxicity. Outside packaging must list ingredients, nicotine content and delivery per dose, carry a batch number, and a health warning stating ‘This product contains nicotine which is a highly addictive substance’. Outside packaging must not include any promotional element or feature to suggest that the product is less harmful or has other health or lifestyle benefits.

6 Cross-border advertising, sponsorship and promotion in the press and broadcast and internet media are prohibited, as are cross-border sales unless subject to a registration scheme. Domestic advertising through billboards, at point of sale, on public transport or other local media is permitted unless prohibited by domestic legislation, as is under consideration in Scotland. Provision of information about products online is still legal.

7 Manufacturers and importers must deliver an annual submission on their products to governments, which should include comprehensive data on sales volumes, consumer preferences, mode of sale and market developments. These submissions should be made publicly available unless classified as trade secrets.

8 Manufacturers, importers and distributors of products are required to establish and maintain a system for collecting information about all the suspected adverse effects on human health. Corrective action is required if there are reasons to believe that products are not safe or of good quality, or not conforming to the directive.

9 Regulation of flavours, and age of sale, remains the responsibility of member states.

At the time of going to press, the UK government’s intention to transpose the TPD into UK law was still the subject of a legal challenge by an e-cigarette company, Totally Wicked. However, in December 2015 the advocate general dismissed this and other challenges to the TPD20 and, although a final court ruling is not due until 4 May, it now seems likely that the TPD will be implemented as originally proposed on 20 May 2016. The UK competent authority for e-cigarettes under the EU TPD will be the MHRA.21 From 20 May 2016, therefore, all e-cigarettes sold in the UK will be regulated by the MHRA either under the provisions of the TPD or as medicines, or both.
10.4 Advantages and disadvantages of medicines and TPD regulation of non-tobacco nicotine

The impending need for e-cigarettes and other non-tobacco nicotine products, either currently on the market or in development, to comply with one of the above regulatory options has significant implications for suppliers of these devices, and for wider public health. Both approaches have significant advantages and disadvantages, which suppliers will have to balance in their decision on which route or routes to pursue. These are as follows.

10.4.1 Medicines licensing

Key advantages to manufacturers who pursue medicines licensing include:

- higher consumer confidence in product quality and safety
- relief from TPD limits on nicotine solution concentration and volume
- freedom to advertise on TV, radio and in printed media, in line with MHRA rules
- freedom to make justified health claims in relation to quitting and harm reduction
- no obligation to carry health warnings informing consumers that nicotine is addictive
- eligibility for use in, and for subsidised prescription through, the NHS
- potentially subject to 5% rather than 20% VAT in the UK.

The main disadvantage of medicines licensing is the cost in time and money of the application process itself, and of the much higher manufacturing standards required of medicines. It is understood that the MHRA estimates first application costs at between £252,000 and £390,000, and annual recurring costs at between £65,000 and £249,000 for each product. In practice, however, it is likely that application costs incurred by companies inexperienced in negotiating this regulatory system may be significantly higher, whereas the additional cost of manufacturing to the medicines standard is estimated at several million pounds. These financial and related opportunity costs inevitably represent a significant barrier to innovation and market entry for new licensed nicotine products, and favour larger, better resourced entities such as pharmaceutical and transnational tobacco companies. Licensing and presentation of products as medicines may also undermine the perception of e-cigarettes as a consumer rather than a medical product, and hence inhibit experimentation and use.

That only one licence has been awarded to an e-cigarette product in the 5 years since the MHRA announced its ‘light touch’ licensing option, despite the rapid growth and hence evident value of the e-cigarette market and verbal reports from
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the MHRA that ‘several’ e-cigarette companies had enquired about licensing, indicates that mandatory medicines regulation, had it been imposed as originally intended by the MHRA, would indeed have resulted in a period of several years in which no e-cigarettes were available for sale in the UK. Mandatory medicines licensing, as originally proposed, would therefore have been counterproductive to public health. Given the high product quality and safety standards that medicines licensing guarantees, as well as the option of providing products on prescription to those on low incomes, it is clearly desirable that the range of e-cigarette products available to consumers and health professionals includes some that are licensed as medicines. As recommended elsewhere, a review of the MHRA licensing process for e-cigarettes, to minimise the extent to which licensing procedures and demands unnecessarily obstruct the progress of new medicinal products to market, is clearly needed.

10.4.2 TPD regulation

At the time of writing, the exact detail of how the proposed TPD regulation will operate has not been published. It appears likely, however, that regulation under the TPD will offer e-cigarettes and other non-tobacco nicotine products a route to market that is less onerous, and hence quicker and less expensive, than medicines regulation.

The principal benefits of TPD regulation to consumers are that they will ensure that products that claim to deliver nicotine actually do so, and therefore that consumers are likely to find them effective, and provide reassurance that toxins and other by-products in vapour are at known and pragmatically low levels, thus protecting consumers from easily avoidable harm. Although it is inevitable that these reporting and performance requirements will impose costs on manufacturers and importers, these TPD measures appear to be congruent with the basic regulatory objective of ensuring that products are fit for purpose, and reasonably safe.

Other measures imposed by the TPD on e-cigarettes are less overtly constructive, however. The cap on nicotine concentrations may limit the effectiveness of e-cigarettes as a smoking substitute, particularly for heavier smokers. The derogation to member states of limits on the use of flavours, which may be a significant source of oxidant activity in e-cigarette vapour (see Chapter 5), may result in marked differences in relative potential harm of e-cigarettes available in different member states. Restrictions may also result in non-compliance. The restrictions on e-cigarette marketing, in effect limiting these to the point of sale, billboards, bus stops and other advertising that does not cross borders, limits opportunities for inappropriate promotion of e-cigarettes to non-smokers, including children, but also inevitably inhibits promotion to smokers. However,
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as most smokers are aware of e-cigarettes, and word of mouth and social media appear to have been the main drivers of use to date, it remains to be seen whether these advertising restrictions will reduce uptake by smokers. The Scottish Parliament is currently considering going further than the TPD to prohibit all advertising of e-cigarettes in Scotland other than at the point of sale.24

The requirement for nicotine products covered by the TPD to carry a health warning emphasising the risks of nicotine, when licensed nicotine products do not, appears illogical, as does the restriction on statements comparing the relative risks of e-cigarettes and tobacco cigarettes. The health warning required under the TPD provisions may also reinforce misperceptions about nicotine (see Section 10.7 below).

A further concern about TPD regulation is that, although a facility to recall products from the market is written into the legislation, there are no powers to relax regulations if usage and innovation are unnecessarily or inappropriately constrained by them. Despite requiring a review 3.5 years after implementation and at 2-yearly intervals thereafter, the previous EU TPD was not revised for 13 years, which is of great concern because much quicker mechanisms of feedback and revision will be required to maximise the benefits as well as minimise the risks of e-cigarettes. For these reasons, it is clearly important that TPD implementation be closely monitored to assess the extent of unintended, as well as intended, effects on the availability and use of non-tobacco nicotine products and, in particular, the consequences of these effects on tobacco smoking rates; it should also ensure that prompt action be taken if TPD regulation proves to work against, rather than for, the benefit of public health. We therefore recommend annual review in the UK.

10.5 The future of nicotine regulation

The UK is currently ahead of most countries in having an agreed set of principles on what nicotine regulation should be designed to achieve, which, as stated in our last report, is that ‘The current nicotine regulatory framework needs to be changed so that it encourages as many smokers as possible to quit smoking and all nicotine use completely, and encourages those who cannot quit to switch to a safer source of nicotine, while minimising use by people who would not otherwise have used nicotine products’. The UK government has reinforced the need for harm reduction alongside abrupt cessation and preventive approaches to tobacco control by introducing ‘new routes to quitting’,25,26 which involve encouraging smokers to reduce their cigarette consumption as a precursor to complete quitting, manage their nicotine addiction by using a safer alternative product when unable to smoke, and dramatically reduce harm to themselves and
others by using a safer alternative to smoking whenever possible at other times. The UK government also encouraged innovation in the design and marketing of nicotine delivery medicines.\(^{25,27}\) The MHRA, by relaxing its regulation of nicotine-containing products, is following the same path. In 2013, the National Institute for Health and Care Excellence (NICE) produced public health guidance on harm-reduction approaches to smoking,\(^{28}\) recommending the integration of harm reduction into NHS and other care pathways. Public Health England\(^{29}\) has also recently endorsed the principles of the approach set out in the RCP’s 2007 report,\(^1\) as has civil society, through the more than 120 health-related organisations that endorsed the recent *Smoking still kills* policy document published by Action on Smoking and Health in 2015.\(^{30}\)

However, there is still some disagreement about the appropriate level of regulation to meet these principles. Some argue that medicines regulation is the best guarantee of safety, although experience to date suggests that it is too restrictive; some argue that the TPD regulatory framework about to be introduced is too stringent and will undermine the growing market for less harmful alternative nicotine products and restrict innovation; some believe that proposed TPD regulation does not sufficiently address the potential short- and long-term hazards of e-cigarette use which, although likely to be far less than those of smoking (see Chapter 5), could be minimised by medicinal quality and safety standards.

In 2007, the RCP argued for the creation of a regulatory authority specifically designed to cover all nicotine products, and to rationalise regulatory controls by making them proportionate to product hazards.\(^1\) However, experience elsewhere of giving powers to regulatory bodies to cover all nicotine products, eg in the USA and Canada, has not been encouraging (see Chapter 11), although in any case the current aversion to new regulation in the UK does not make a new regulatory body a feasible option at present.\(^{31}\) Some countries have regulated e-cigarettes in the same way as tobacco products, which we believe to be entirely inappropriate because e-cigarettes do not contain tobacco, and have a very different profile of risk. The political reality is therefore that, for the coming years, unless the legal challenge to the TPD is successful (see below), non-tobacco nicotine products in the UK will be regulated either by the TPD or as a medicine, whereas tobacco products will continue to be limited by the TPD and other national restrictions on use and presentation. It remains to be seen whether this approach will benefit public health by encouraging widespread substitution of smoked tobacco by non-tobacco nicotine in current and future smokers, or will in effect sustain smoked tobacco as the most widely used nicotine product. Much will depend on the approach taken by the MHRA in its role as the competent authority for TPD implementation. It is, however, crucial that the UK takes care to implement the revised TPD in such a way as to minimise, as far as is consistent with the regulations, the burden to manufacturers and importers in
meeting the TPD requirements. It is also important to look again at the medicinal licensing route to market, to try to make compliance more attractive to producers.

10.6 If e-cigarettes are removed from the TPD, what are the alternatives?

Following the December advocate general’s legal opinion, it seems likely that regulation under the TPD will go ahead. However, starting from the counterfactual\textsuperscript{32} allows options for a more appropriate regulatory structure to be set out within a European context. If the legal challenge to e-cigarette regulation under the revised TPD succeeds, then the previous status will prevail, unless and until the EU develops a new regulatory framework. This could be in the form of a new revision to the TPD, but past experience indicates that this would be likely to take years to materialise. An alternative is the earlier MHRA proposal to regulate all nicotine products as medicines, which to date has proved to operate against public health interest and has, in any case, been subject to successful legal challenges in other EU member states.\textsuperscript{32} Another option is to develop harmonised EU-wide standards under the General Products Safety Directive process, which could be less costly for manufacturers and importers to comply with than if each member state developed its own.\textsuperscript{33} Such standards could build on those being developed under the European CEN/TC 437 process,\textsuperscript{34} which is one of the three European standardisation organisations officially recognised by the EU and the European Free Trade Association (EFTA) as responsible for developing and defining voluntary standards at the European level.

A balance is needed to make products attractive, palatable, satisfying and effective substitutes for tobacco smoking, but also as safe as is reasonably possible, and avoiding use by adolescents and never-smokers. A pragmatic approach would retain the reporting requirements on nicotine delivery and toxins in e-cigarette vapour proposed under the TPD (see Section 10.3 above), adhere to industry and product standards, incorporate obvious safety measures such as childproof and tamper-proof seals and design, and simple advice on how to charge e-cigarettes safely. Advertising should be permitted as per current codes of practice administered by the ASA (with regular reviews to ensure that they remain fit for purpose), with the facility to promote claims of reduced risk in relation to tobacco smoking. Limits on nicotine dose and the requirement for health warnings are probably not appropriate. Any voluntary approach would have to build on the current BSI PAS 54115 standard for product regulation and the compulsory advertising codes, which are currently under review. Alternatives to the above approaches have been suggested, such as regulation as food or cosmetics, but neither regulatory structure seems appropriate to a product that is...
inhaled. Whatever approach is taken, it will remain essential to monitor sales and uptake of non-tobacco nicotine products, so that early action can be taken to deal with any trends or patterns of use likely to be detrimental to public health interest.

10.7 Providing consistency in messages to smokers

Recent evidence indicates that smokers are confused about the relative risks of tobacco and e-cigarettes, with many coming to believe that the health hazards of e-cigarettes and tobacco cigarettes are similar. Health professionals are also uncertain about the role of unlicensed nicotine products in healthcare provision, with many feeling reluctant to recommend or endorse a product or product class that is relatively unregulated and has unknown long-term health effects. The introduction of a regulatory structure for unlicensed products, as, for example, proposed under the TPD, may help to overcome these reservations, but there is a need for clear guidance on the role of unlicensed nicotine products in clinical services. The National Centre for Smoking Cessation and Training has produced new guidance on integrating e-cigarette use into the provision of smoking cessation services*, but to date NICE, which has issued extensive guidance on smoking cessation and harm reduction to organisations responsible for public health and tackling tobacco use, health professionals and the general public, has not addressed this issue. Some stop smoking services are providing advice and behavioural support to smokers interested in using e-cigarettes with encouraging results (see Chapter 6), but health professionals have a wider role to play in providing support and reassurance to e-cigarette users in routine contacts. NICE guidance should, therefore, be updated to include pragmatic recommendations on the role of e-cigarettes in tobacco harm reduction.

10.8 Taxation and price

Price is a key driver of consumer behaviour and, if the potential for e-cigarettes and other non-tobacco nicotine products to act as a widespread substitute for smoked tobacco is to be fully realised, it is crucial that they are priced as advantageously as possible in relation to tobacco. It is for this reason that the VAT applied to NRT products in the UK was reduced from 20% to 5% in 2007. Adding to the tax burden of e-cigarettes by including them in the remit of the EU Tobacco Tax Directive, and hence requiring them to be taxed as tobacco products in addition to the current taxation through VAT, would therefore be counterproductive. A rational approach to nicotine taxation would be to apply

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*www.ncsct.co.uk/usr/pub/Electronic_cigarettes_A_briefing_for_stop_smoking_services.pdf
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tax in proportion to their hazard, in which case the tax on e-cigarettes and other non-tobacco nicotine products should be held stable or even reduced. The availability of these products as a viable alternative for people addicted to nicotine does, however, provide justification for further tax increases on tobacco.

10.9 Summary

> The ideal regulatory framework for nicotine products is one that minimises harm to society arising from nicotine use.
> At present, nicotine is in widespread use in UK society and the most popular source of nicotine, the cigarette, is by far the most hazardous of those available.
> Nicotine regulatory approaches should therefore be designed to encourage as many smokers as possible to either quit all nicotine use, or switch completely from smoking to an alternative source of nicotine.
> Products are regulated to ensure that they are safe and fit for purpose. Regulation of e-cigarettes and other similar products should therefore aim to minimise potential exposure to harmful vapour constituents, ensure that those that deliver nicotine do so in doses that smokers find satisfying, and encourage substitution for smoked tobacco.
> Regulatory restrictions should therefore be designed to safeguard against unnecessary hazard but should also be proportionate, so as not unnecessarily to inhibit the development, availability and use of viable alternatives to smoking.
> Attempts by the MHRA over the past 5 years to adapt medicines licensing to the rapidly developing e-cigarette market has resulted in the award of only two medicines licences for alternative nicotine products, and no licensed e-cigarette has come to market.
> Regulations for e-cigarettes proposed in the new revision of the EU TPD include quality controls that are more permissive and, in our view, more proportionate than medicines regulation, but include some measures that may inappropriately constrain the e-cigarette market and hence inhibit e-cigarette use.
> At the time of going to press, the TPD regulations for e-cigarettes are still the subject of a legal challenge, but are expected to come into effect from 20 May 2016.
> In the event that the legal challenge succeeds, then a replacement regulatory approach should retain the requirements on reporting of nicotine delivery and toxins in e-cigarette vapour proposed under the TPD, and adhere to industry and product standards.
> To encourage smokers to switch from tobacco to less hazardous sources of nicotine, it is vital that non-tobacco nicotine products be excluded from tobacco taxes.
It is essential that NICE and other health organisations give clear guidance on the role of e-cigarettes, licensed or unlicensed, in smoking cessation and tobacco harm reduction.

Effective regular surveillance, which we recommend should be annual, will be required to monitor intended and unintended impacts of regulation, and a rapid feedback mechanism to allow changes to be made to ensure that the potential benefits of e-cigarettes are maximised, while minimising the risks.

References

8 BBC News. A public health law which includes a ban on e-cigarette has been rejected. BBC News Wales politics, 16 March 2016. www.bbc.co.uk/news/live/uk-wales-politics-35803117 [Accessed 1 April 2016].
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1.1 Harm reduction and tobacco control policy implementation in the UK

Since the publication of the white paper *Smoking kills* in 1998, the UK has introduced an extensive and comprehensive range of tobacco control measures (see Chapter 3) and, having been at the forefront of the global smoking epidemic of the 20th century, is now a world leader in smoking prevention. As a result, UK smoking prevalence has declined substantially and at a rate similar to that observed in other countries that have also implemented comprehensive tobacco control programmes such as Australia, Canada, the USA (in California) and Uruguay. As discussed in Chapter 10, in addition to this comprehensive package of conventional tobacco control policies, England has also adopted a complementary harm-reduction policy strand that is embedded in national policy through government health and tobacco control strategies, guidance by the National Institute for Health and Care Excellence (NICE) and medicines regulation. To our knowledge the UK is the only country in the world to have developed, and to be in the process of implementing, a proactive tobacco harm-reduction approach to smoking prevention. This chapter describes the regulation of e-cigarettes and their use in other countries.

1.2 Approaches to regulation of e-cigarettes in other countries

There is a wide variation in approaches taken in different countries to the regulation of e-cigarettes and other unlicensed, non-tobacco nicotine products. The Institute for Global Tobacco Control (IGTC) summarises policy approaches in a total of 123 countries, including 90 from a World Health Organization (WHO) report on e-cigarette policies. Regulations are evolving rapidly, so the discussion here and in the following sections is based on data reported on the IGTC website* unless otherwise stated, and was accurate at the time of going to press. A discussion of whether published regulations have actually been enforced is beyond the scope of this chapter.

*http://globaltobaccocontrol.org
Also at the time of going to press, the use of e-cigarettes had been completely prohibited in three countries (Cambodia, Jordan and the United Arab Emirates), prohibited in enclosed public places in 15 countries and restricted in a further eight, prohibited on public transportation in 19 countries and restricted (or limited to non-nicotine-containing products) on certain public transportation vehicles in three. Restrictions on purchase or sale comprise: a minimum age for e-cigarette purchase which is usually the same as that for traditional cigarettes, and ranges from 18 to 21 years in 16 countries; prohibition (26 countries) or restrictions (21 countries) on the sale of all types of e-cigarette, including restriction or prohibition of sale or requirement for marketing authorisation for products that have nicotine. Of the 47 countries banning or restricting sale, 33 also prohibited or restricted advertising, promotion or sponsorship of e-cigarettes in their policies. Twelve other countries had explicit promotion bans/restrictions. Two countries (Togo and the Republic of Korea) impose taxes on e-cigarettes in addition to general sales taxes. Similar to the UK, some countries, including the USA, allow e-cigarettes to be sold under general consumer product regulations.

The experience of regulating e-cigarettes along with other nicotine products in a single regulatory structure, as proposed by the RCP in 2007, has since proved less encouraging than hoped. The US Food and Drug Administration (FDA), already responsible for regulating medicinal nicotine, was given responsibility for regulating tobacco products in 2009 and, after a legal decision, announced in 2011 that e-cigarettes would be brought within the remit of tobacco product regulation. At the time of writing the FDA still has more stringent regulations on the sale of medicinal nicotine than the UK, and has not yet put a regulatory process for e-cigarettes in place. Similar to the US experience with FDA regulation, Health Canada’s jurisdiction over all tobacco and nicotine products, which regulates nicotine under the Food and Drug Act, requires a marketing authorisation for e-cigarettes containing nicotine, and none has yet been awarded. The effect of this is therefore an actual prohibition of sale. In practice, however, this is not being observed, because a recent Canadian House of Commons’ report concluded that e-cigarettes with nicotine were still available in Canada. The report put forward recommendations to develop a new legislative framework for e-cigarettes that would probably allow their sale with nicotine, but with strict controls on marketing in line with those for tobacco. In the absence of a clear regulatory approach by Health Canada at the federal level, a number of provinces have already moved to impose strict regulations on e-cigarettes, including prohibition of use in public places, and of advertising and display.

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Thus, the experience of a single regulatory authority in both the USA and Canada is that, in both cases, the authority has been unable to use its powers effectively to regulate nicotine products in relation to their hazard. Indeed, in both cases, single-body regulation of all nicotine products has probably hindered, rather than enabled, access to reduced-hazard nicotine products.

11.3 Awareness and use of e-cigarettes in different countries

Although there is a rapidly growing body of research on the prevalence of e-cigarette use in adults and adolescents internationally, methodological differences in the definition and measurement of ever, past or current use, particularly in adolescent research, make direct comparisons between studies difficult. This section therefore describes trends internationally drawing predominantly on between-country surveys; Section 11.4 analyses the relationship between regulatory frameworks and use where the evidence enables such comparisons to be made.

11.3.1 Awareness and use of e-cigarettes in adults

Significant variability in the prevalence of use of e-cigarettes has been observed between countries over time, but international surveys demonstrate rapid global increases in e-cigarette use across high-, middle- and low-income countries. The earliest between-country study\(^\text{18}\) assessed e-cigarette awareness and use among nationally representative samples of smokers and recent ex-smokers based on 2010–11 data from the International Tobacco Control policy evaluation project (ITC) in the UK, the USA, Australia and Canada. In the UK and the USA, e-cigarettes are regulated as consumer products; in Canada, e-cigarettes containing nicotine require authorisation, but none has been authorised; in Australia there is a ban on the sale and importation of e-cigarettes with nicotine, although there is a mechanism for legal import as an unapproved medicine with a doctor’s prescription. Awareness and current use were higher in the two countries where there were fewer restrictions (the USA and the UK).

The Canadian Tobacco, Alcohol and Drugs Survey (CTADS) also found, in 2013, much lower levels of e-cigarette use among adults in Canada than in the UK.\(^\text{19}\) Another ITC study compared trends in awareness, trial and use of e-cigarettes among nationally representative samples of smokers and ex-smokers in the UK and Australia.\(^\text{20}\) Use (defined as less than monthly or more often) of e-cigarettes was 18.8% in the UK and 6.6% in Australia in 2013; however, use increased at the same rate in both countries between 2010 and 2013.\(^\text{20}\) It therefore appears that prohibition may have delayed the uptake of e-cigarettes in Australia, but has not prevented a subsequent rapid increase in use.
A further ITC study presented data from 10 countries (the USA, the UK, Australia, Canada, the Netherlands, South Korea, Malaysia, Brazil, Mexico and China) surveyed at different time points between 2009 and 2013. Again, there was considerable variation in e-cigarette awareness and use among them: awareness varied from 88% in the Netherlands (where e-cigarettes are regulated as a consumer product with some restrictions) to 31% in China (where sale and purchase are legal at the national level, although may be restricted in some regions); self-reported trials varied from 20% in Australia to 2% in China; and current use from 14% in Malaysia (where sale, distribution or importation of unlicensed nicotine-containing e-cigarettes is prohibited; nicotine-containing e-cigarettes can be sold only by licensed pharmacies or registered medical practitioners) to 0.05% in China. These differences are likely to be due in part to differences in survey dates, but also to differences in regulations, market forces and enforcement. However, Malaysia had the highest prevalence of e-cigarette use despite tight restrictions on their sale.

The Global Adult Tobacco Survey has also published data on e-cigarette use among smokers and non-smokers from four middle- and low-income countries: Indonesia (in 2011), Malaysia (2011), Qatar (2013) and Greece (2013). At the time of the surveys, all these countries prohibited the sale of e-cigarettes apart from Malaysia, where only nicotine-containing e-cigarettes were restricted. E-cigarette awareness was highest in Greece (88.5%), followed by Qatar (49%), Malaysia (21%) and Indonesia (10.9%). Current use (daily and non-daily) of e-cigarettes among smokers was again highest in Malaysia (in this survey prevalence of use was 10.4%), followed by Qatar (7.6%), Indonesia (4.2%) and Greece (3.4%). Use of e-cigarettes among non-smokers was highest in Greece (1.3%), followed by 0.4% in each of the other three countries. Again, these data demonstrate little evidence that more restrictive national policies on e-cigarettes result in lower levels of use.

The most recent Eurobarometer survey, carried out in November and December 2014, enabled an assessment of use of both tobacco cigarettes and e-cigarettes (defined as e-cigarettes or other similar electronic device) among people aged 15 years and over in the 28 European Union member states. France, Cyprus and Estonia (where e-cigarettes are regulated as either consumer or medicinal products according to nicotine content) had the highest proportions of respondents stating that they had ever tried e-cigarettes (17% or higher); France and the UK had the highest prevalence of current e-cigarette use (both 4%) and the UK had the highest proportion of current smokers who also used e-cigarettes (11%). Fewer than 1% of never-smokers currently used e-cigarettes in every country surveyed. The most common reason given for using e-cigarettes was to stop or reduce smoking. Across the EU, 14% of smokers or ex-smokers who had tried e-cigarettes reported that they had helped them to stop smoking completely, 13% that they had helped them to stop for a while before
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relapsing, 45% that they had not reduced their tobacco smoking and 21% that they helped them to reduce, but not stop, tobacco use. Ireland (24%) and the UK (21%) had the highest proportions of respondents who reported successfully stopping smoking with the help of e-cigarettes. The proportion of smokers using e-cigarettes in their quit attempts was highest in countries regulating them as consumer products: the UK and Ireland (19%), France (18%) and Cyprus (16%). The Eurobarometer noted that there were continuing declines in smoking across the EU at a time when e-cigarette use was increasing, as has been observed in UK surveys (see Chapters 2 and 7) and in the USA.26

11.3.2 Awareness and use of e-cigarettes by adolescents

We have been unable to find any survey using a consistent methodology to compare awareness and use of e-cigarettes among adolescents in different countries. Data on people aged 15 and over are included in the 2014 Eurobarometer study referred to above,24 which reported the prevalence of current use of e-cigarettes among people who had never smoked at 0%, suggesting that there were few such users among young or older people.

Survey data on the prevalence of e-cigarette use in young people at the country level are more extensive, but methodological differences, including the use of different definitions or terms to describe the different stages of e-cigarette use (ever, trial, current use), and differences in age ranges studied, limit the comparability of these findings. A recent review concluded that the common pattern emerging in countries where data were available was of very high awareness and increasing trial of e-cigarettes among young people, but very low levels (3% or less) of regular use.27 However, there were two countries where current use was substantially higher: Poland (where e-cigarettes are classified as consumer products, but with cartridges subject to regulations on chemical mixtures) at around 30%,28 and Hawaii (where e-cigarettes are classified as consumer products), where 29% of the sample of young people had tried e-cigarettes and 18% had used them in the past month.29

Serial surveys of young people in the USA have documented a rising prevalence of ever use of e-cigarettes30–32 and demonstrated that, as in the UK (see Chapter 7), those who use e-cigarettes are more likely also to smoke tobacco.31 A cohort study from California35 found that secondary school pupils who had not smoked, but reported having ever tried an e-cigarette, were more likely at 6- or 12-month follow-up to have ever tried a tobacco cigarette. A cohort study of a national US sample of 694 never-smokers who were classified as non-susceptible to tobacco smoking at baseline in 2013–14, and restudied in 2015,34 found that the 16 participants who reported ever
having used an e-cigarette at baseline were significantly more likely, after controlling for other covariates, to have become susceptible to cigarette smoking or have smoked at least one puff of a cigarette at follow-up. However, claims that these findings indicate that e-cigarette use may cause uptake of tobacco smoking have been challenged on the grounds of common liability (see Chapter 8), lack of measures of more regular use of either e-cigarettes or tobacco cigarettes, and that, during the time that these studies have been carried out, the prevalence of tobacco smoking among young people in the USA fell to a 22-year low.\textsuperscript{35–37}

There is evidence from the USA that adolescent smokers using e-cigarettes are also more likely to use products such as tobacco hookahs or shisha and blunts (marijuana and tobacco).\textsuperscript{38}

### 11.4 Patterns of use across countries with different regulatory regimens

Although standardised between-country data on e-cigarette use over time are generally lacking, it is clear from the evidence presented above that, whereas countries with more liberal policies (which typically involve regulating e-cigarettes as consumer products) have higher levels of adult e-cigarette use, prohibition and tight restrictions have not prevented increasing uptake of e-cigarette use among adults in other countries. For adolescents the data are less clear but, as an example, the 2013 CTADS of Canadians aged 15 years and older found that 9% had ever tried an e-cigarette, with trials being higher among young people aged 15–19 years at 20%.\textsuperscript{19} This latter percentage is not dissimilar from the percentage who had tried e-cigarettes in the UK in 2015 (12.7% of 11- to 18-year-olds). Again, therefore, it appears that prohibition of sale has had little effect on experimentation with e-cigarettes in Canada, at least not in the younger age groups in these studies. A recent US study assessed the impact of state bans on sales of e-cigarettes on smoking rates among 12- to 17-year-olds across the USA,\textsuperscript{39} and found that reducing access through age-of-sale laws increased smoking among 12- to 17-year-olds, suggesting that restrictive regulations on e-cigarettes may be counterproductive.

In the EU, as set out in Chapter 10, the introduction of the Tobacco Products Directive\textsuperscript{40} will lead to a common regulatory platform from May 2016, although individual member states will be able to go further in prohibiting all advertising (as is under consideration in Scotland), restricting or prohibiting their use in public places (recently under consideration in Wales), legislating for an age of sale (set at 18 in England), restricting or prohibiting flavours, and implementing additional taxation. Monitoring the impact of these regulatory changes, and of their variations across the EU, will provide a useful indicator of the impact of different regulatory approaches.
**11.5 Harm reduction and the WHO Framework Convention on Tobacco Control**

E-cigarettes were not available when the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) was first negotiated. However, the FCTC\(^41\) alludes to harm reduction in Article 1, where tobacco control is defined as including ‘harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke’. This is further considered in Article 5.2(b), which states that ‘each Party shall, in accordance with its capabilities … adopt and implement effective legislative, executive, administrative and/or other measures and cooperate, as appropriate, with other Parties in developing appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke’. The FCTC does not have a remit for the regulation of medicinal nicotine, although it has produced guidelines on tobacco dependence and cessation (Article 14 of the FCTC).\(^42\)

The growing popularity of e-cigarettes led to discussions on their role at the biennial FCTC Conference of the Parties (COP), the governing body of the treaty, in 2010 and 2012. At the 2012 COP5, the WHO was asked to produce a report on ‘options for prevention and control’ of e-cigarettes (referred to as electronic nicotine delivery systems or ENDSs) for consideration at the next COP.\(^43\) The WHO report to COP6\(^14\) focused on three areas of concern: health risks to users and non-users; efficacy in helping smokers to quit smoking and (ultimately) nicotine use; and interference with existing tobacco control efforts and implementation of the FCTC. The main focus of the report was on the latter issues, but, in terms of health risks, the report concluded that ‘well-regulated ENDS’ would be likely to be less toxic than tobacco cigarette smoking for established adult smokers. In relation to smoking and nicotine cessation, the report concluded that e-cigarettes might have a role in supporting attempts to quit for individuals who had failed treatment, or who were intolerant of or refused conventional treatments. The report discussed and recommended parties to regulate e-cigarettes as either medicines or tobacco products, in accordance with the FCTC.

In response, the Framework Convention Alliance (FCA, a coalition of over 350 non-governmental organisations from over 100 countries) developed a consensus position.\(^44\) The FCA concluded that, because of differences in regulatory systems and national circumstances, it would be difficult to reach consensus at COP6 on specific regulatory approaches to ENDSs. Instead, the FCA position paper set out the following principles as a starting point for reaching agreement on the role and regulation of e-cigarettes, for consideration by the COP:
1 The global burden of death and disease from tobacco is primarily caused by smoking.

2 Although quitting tobacco use is paramount, quitting nicotine use altogether is the best option.

3 For those unable to quit, switching to alternative sources of nicotine that are less harmful than tobacco can reduce, often very substantially, the harm that smoking causes to the individual.

4 The benefits of such an approach would be maximised if uptake were limited to existing smokers who are unable to quit.

5 The risks of such an approach would be minimised by limiting uptake by never-smokers, in particular among young people, and by taking measures to protect non-users and discourage long-term dual use.

6 There could be negative unintended consequences from over-regulation, just as there could be from under-regulation.

7 The involvement of tobacco companies in the production and marketing of e-cigarettes is a matter of particular concern, because there is an irreconcilable conflict of interest between those profiting from the sale of tobacco and public health.

After discussion by the COP, a decision was taken to ask parties to the FCTC to take note of the WHO report, and the WHO was asked to produce a further report with updated intelligence for consideration in time for COP7, which will be held in the last quarter of 2016. The decision also asked parties to the FCTC to consider ‘prohibiting or regulating’ e-cigarettes, suggesting that this could be as tobacco, or medicinal or consumer products, and to comprehensively monitor their use.45 E-cigarettes will therefore be discussed again at the next WHO FCTC COP in November 2016 in India.

In the case of tobacco, a range of comprehensive tobacco control measures has been found to be effective and been codified in the FCTC. E-cigarette regulation does not sit appropriately within the context of the FCTC, the explicit objective of which is control of the supply of and demand for a lethal product, tobacco, through the introduction of increasingly restrictive and prohibitive regulatory measures. Furthermore, there is as yet an insufficient evidence base or range of national experience that would enable the development of a detailed set of recommendations for the specific approaches to many of the complicated regulatory issues that these products raise at the global level.
11.6 Summary

- A variety of different approaches to tobacco harm reduction and regulation of e-cigarettes, including extension of regulations for alternative products to e-cigarettes and including complete prohibition, have been adopted in different countries around the world.
- The prevalence of use of e-cigarettes is rising or already significant in some countries that have attempted to prohibit use, suggesting that prohibition is not an effective approach to regulation.
- Surveillance data are limited in most countries, as are the use of consistent terminology and standardised measures of e-cigarette use, so between-country differences are difficult to assess.
- There is general recognition that comprehensive monitoring and surveillance of the evidence and national regulatory experience of e-cigarettes are essential.
- The WHO recognises a role for e-cigarettes as part of a harm-reduction strategy for smokers, but in the context of a recommendation by the FCTC COP that they be regulated to minimise any potential risks.
- However, currently there is no consensus about what this regulatory framework should be, and as yet an insufficient evidence base, or range of national experience, that would justify the development of a regulatory structure at a global level.

References


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12 Ethics and conclusions

12.1 Moral and ethical considerations of harm-reduction strategies

This report has made the case for applying harm-reduction principles to tobacco smoking, principally to prevent avoidable harm to smokers. There is, however, a strong ethical dimension to the use of harm-reduction strategies in tobacco control that were discussed in some detail in our earlier report; these strategies include a duty to ensure that options to reduce harm are made available to smokers, and provision of a substitute for tobacco to smokers, particularly those on low incomes, to protect them from the hardship that might otherwise arise from applying tax increases to provide a stronger fiscal disincentive to smoke. There are, however, wider considerations arising from concerns over the broader effects of applying harm-reduction strategies in society.

The central ethical concern is with harm, and whether the harm-reduction strategies identified and adopted will, in practice, reduce it. However, there are also wider questions relating to the ethos of harm reduction itself, over and above any examination of the effectiveness of particular strategies. In some areas of public health (particularly in drug control, alcohol control and sex work control, for example), there is a societal concern that the behaviour being targeted is inherently wrong. Drug addiction, prostitution and drunkenness, it is sometimes thought, are inherently bad, and the proper focus of public health should not be on making the use of drugs, or sex work, or excess alcohol consumption safer; it should be on eradicating these behaviours. In tobacco control, however, this argument is rarely made: few people acknowledge smoking as a behaviour that is immoral. Its harms are real and serious, and inflicting these on unwilling third parties is wrong, but these concerns fit quite naturally within the harm-reduction model.

A second concern is with the distribution of harm. A harm-reduction strategy could be considered to have failed if the net harm were reduced, but the distribution of harm changed in a way that was unjust, eg if, as a result of the harm-reduction strategy, some socially or economically vulnerable group
became more at risk of harm, or systematically less able to benefit from smoking cessation and prevention strategies. The benefit to existing smokers of switching to e-cigarettes is clear, but, if large numbers of never-smokers were to take up e-cigarette use, they would be exposing themselves to health risks that would otherwise be avoided, and financial costs, which are of particular detriment to poorer smokers, that they would not otherwise incur. At present this does not appear to be happening, but it could occur, for example, if the addictive potential of e-cigarettes and other non-tobacco nicotine products increases over time.

A third concern relates to social responsibility: if engaging in harm reduction involves working with corporate actors with a track record of deceit or other socially irresponsible business practices, and particularly of undermining public health, then there is a concern that doing so may have wider ramifications than the harm-reduction strategy itself. Such engagement might, for example, discredit other public health interventions or institutions that are focused on ending these bad practices. We can think of this as ‘reputational harm’. Conversely, it may be that such corporate actors acquire some perverse benefit from such engagement: by appearing to be responsible in one area (the provision of reduced-harm products) they might be able to reclaim a good reputation in other areas, however undeservedly. From a ‘harm-reduction’ point of view, these factors must be considered, but these harms may be inchoate and hard to measure, certainly compared with the real benefits accruing to harm-reduction products in terms of reductions in mortality and morbidity.

Setting aside these objections to harm reduction in principle, we turn instead to the objections that might be raised against particular harm-reduction strategies from within a focus on harm. Obviously, the most important consideration is whether the harm-reduction intervention actually does reduce harm, in terms of reduction of lives (and life years) lost, increase in numbers of smokers who successfully quit smoking tobacco, reductions in the numbers of new smokers, etc. However, as for any other medical or public health intervention, we need to consider any particular strategy in the light of available alternatives: in particular, if we focus on regulation of a tobacco harm-reduction product, we need to ask whether the regulatory mechanism is the most effective in reducing harm, or whether some other approach would be more effective. We need to ask whether adoption of a particular regulatory approach makes the production of some products more likely than others, and whether the products favoured by this approach are, in fact, better from a harm-reduction and public health point of view than those disfavoured. As within the harm-reduction model, the least harmful intervention is the most ethical intervention, we need always to keep in mind that choice of regulatory approach must be seen in ethical terms. The evidence summarised in this report goes some way towards addressing these questions.
12.2 Smoking and public health

Tobacco smoking is the biggest avoidable cause of death and disability in the UK. In 2014, 21% of men and 16% of women were smokers, which in absolute terms represents almost 9 million people. Half these smokers, or 4.5 million people, alive in the UK today will have their lives cut short by smoking and, if their smoking continues unabated, their total loss of life will amount to nearly 90 million years. Their smoking will also cause thousands of fetal deaths and cases of childhood illness, and deaths in non-smoking adults, and cost our health services and wider society billions of pounds. This massive burden of death, disability and lost opportunity has been entirely avoidable, and much of it can still be prevented by measures that encourage as many smokers as possible, as soon as possible, to stop smoking. As the biggest beneficiaries of preventing smoking are individuals who are disadvantaged, marginalised or have mental health problems, prevention of smoking will make society both healthier and more equal. Smoking may be less prevalent today than when the RCP published its first report on smoking and health in 1962, but it is still our biggest health problem. All measures that can be deployed to prevent smoking should therefore be applied, as quickly as possible, and to their maximum effect.

12.3 The effect of conventional tobacco control approaches

The UK is a world leader in tobacco control policy. Since the late 1990s, a comprehensive package of policies, including an advertising ban, smoke-free legislation, high taxes, minimum purchase age, mass media campaigns, a point-of-sale display ban and clinical services to help smokers to quit, has been introduced, and will be enhanced in 2016 by standardised packaging legislation. The result in the UK has been the same as in other countries that have followed this approach: smoking prevalence has fallen steadily, but slowly. However, the decline in smoking prevalence that has occurred over recent decades appears to owe more to success in preventing the uptake of smoking: quit rates among established smokers have changed relatively little. However, it is the adults smoking today, particularly those in middle and older age, who will generate most of the burden of death and disability caused by smoking in the short- and near-term future, and it is these adults whom tobacco control policies need to target in particular if this burden of harm is to be reduced. All existing and new policies with the potential to promote smoking cessation, particularly among disadvantaged groups, should therefore be applied to their fullest extent.
12.4 Priorities for conventional tobacco control policy implementation

Of the range of policies available, the UK has already achieved a relatively high level of prohibition of tobacco advertising and smoke-free policy. Opportunities to promote tobacco brands will be further reduced by the introduction of mandatory standardised packaging in May 2016, although a great deal more could be done to reduce exposure of children and young people to the normalising effect of smoking imagery in the media, including films, television programmes, music videos and computer games. Children may also be less likely to grow up thinking that smoking is a normal or aspirational adult behaviour if they were exposed less to smoking behaviour among adults in their everyday lives, which could be achieved by extending smoke-free policies to outdoor areas, eg at school gates, play areas, town centres and other areas where smokers congregate in view of children. Making hospital premises completely smoke free generates an opportunity to initiate and support cessation among the many smokers, and their visitors, who use hospital services. Similarly, making prisons smoke free will provide an opportunity to reduce the very high prevalence of smoking among prisoners. More could also be done to reduce retail availability of tobacco to children, particularly in areas close to schools, and the requirement that tobacco retailers be licensed would be a useful step towards making enforcement of regulations easier. Mass media campaigns are effective in motivating smokers to try to quit, but require funding to achieve and sustain the necessary intensity and salience for success. Cessation services also need to be adequately funded, and in clinical settings integrated much more systematically into routine health service delivery. Large increases in tobacco prices, particularly in the lower cost range of products preferred by low-income smokers, have a particular potential to reduce smoking among disadvantaged groups. Proper funding of enforcement measures against illicit tobacco and measures to curtail the tobacco industries’ own involvement in this trade are crucial. All these measures would be likely to help to achieve further reductions in smoking prevalence. However, almost all would be complemented by promoting harm-reduction approaches that encourage smokers, who otherwise prove unwilling or unable to quit smoking, to switch to an alternative, low-hazard source of nicotine.

12.5 Nicotine addiction and its effects

Nicotine is the main addictive component of tobacco smoke. Although other tobacco smoke components probably contribute to the development of nicotine addiction, it is the capacity to achieve rapid increases in systemic arterial levels through pulmonary absorption that makes tobacco smoking particularly addictive, as well as lethal, although factors such as the taste and smell of
cigarette smoke, and the behavioural action of smoking, can reinforce nicotine use and hence themselves become important drivers of continued smoking. At low doses, nicotine is a stimulant, which in the short term increases heart rate and may improve attention, memory and fine motor skills. Although potentially lethal at very high doses, at the blood levels typically achieved by smoking nicotine does not result in clinically significant short- or long-term harms. Nicotine is not a carcinogen; there is no evidence that sustained human use of nicotine alone increases the risk of cancer. It is possible that nicotine exposure during the fetal and/or adolescent periods causes cognitive impairment, but in all other respects, and certainly in relation to tobacco smoke, the real and potential hazards of sustained nicotine use are negligible. The harm of smoking is therefore caused not by nicotine, but by other constituents of tobacco smoke. Non-tobacco nicotine products that reproduce the nicotine delivery and behavioural characteristics of smoking, without the many other toxins in tobacco smoke, therefore have the potential to allow smokers to continue to use nicotine and avoid the significant harm to themselves and others that smoking causes.

12.6 Non-tobacco nicotine products

A wide range of nicotine replacement therapy (NRT) products, licensed as medicines to reduce symptoms of nicotine withdrawal among people trying to quit smoking, is available. In clinical trials, NRT has been shown consistently to be effective in helping smokers to quit smoking. Although initially developed to help people give up all smoking and nicotine use, NRT licences have been extended to include short-term use to relieve withdrawal symptoms during temporary abstinence from smoking, and long-term use as a partial or complete substitute for smoking (harm reduction). These licensed applications of NRT, which are endorsed by the National Institute for Health and Care Excellence (NICE), promote dual use of NRT and tobacco on the grounds that smokers who learn to use NRT in this way are more likely to quit smoking completely. NRT products have to date been produced by pharmaceutical companies and offer high levels of purity and hence safety, such that a smoker who switches from tobacco to NRT use, but continues to use NRT in the long term, probably achieves much the same in health terms as a smoker who quits all tobacco and nicotine use.

The choice of non-tobacco nicotine products in the UK has been substantially extended by the emergence of e-cigarettes, which have to date been marketed as consumer alternatives to smoking. E-cigarettes offer a behavioural experience that is much closer to smoking than is the case with NRT products, and later-generation e-cigarettes appear able to achieve venous nicotine levels similar to those of tobacco smoking. The extent to which inhalation of e-cigarette vapour results in rapid pulmonary absorption remains uncertain, but it seems likely that,
as the technology improves, the degree of pulmonary absorption will increase, making the products more effective as smoking substitutes, but also increasing addictiveness, and hence posing the new ethical problems highlighted above. E-cigarettes generate vapour from a solution that typically contains nicotine, propylene glycol and glycerine, but, in addition to these constituents, e-cigarette vapour contains a variable range of compounds arising from impurities in the solutions or generated by the heating process that produces vapour. There appear to be few, if any, significant short-term adverse effects of e-cigarette use, but adverse health effects from long-term exposure to constituents of vapour cannot be ruled out. Although unknown, the hazard to health arising from long-term vapour inhalation is unlikely to exceed 5% of the harm from tobacco smoke. Switching from tobacco to e-cigarettes is therefore likely to be almost as effective in preventing harm as switching to NRT. However, the recent award of a medicines licence to an e-cigarette product raises the prospect of e-cigarettes with safety profiles similar to NRT becoming available in the near future.

12.7 How smokers in the UK try to quit, and their chances of success

Around one in three smokers in the UK tries to quit each year, but only around one in every six of those who try to quit is successful. Those who try are slightly more likely to be younger and female, and to be in non-manual occupations; those in non-manual occupations are also more likely to succeed. Most of those who try to quit do so without help, or until recently by using NRT bought over the counter. Over the past 3 years, however, e-cigarettes have become the most widely used aid to quitting.

The observational data on quitting used in this report suggest that those who use prescribed medication and behavioural support from a qualified stop smoking adviser (typically through NHS Stop Smoking Services (SSSs)) are two to three times more likely to succeed than those using no help. However, the use of NHS SSSs has declined significantly in recent years, such that they are now accessed by only a small minority of smokers. For reasons that are not clear, those who use over-the-counter NRT appear to be no more likely to succeed in quitting smoking than those using no help, whereas those who use e-cigarettes, or NRT or other pharmacotherapy provided by a healthcare professional, are around 50% more likely to succeed than those using no help at all.

The popularity of e-cigarettes has thus resulted in a substantial increase in the proportion of smokers using effective help to quit. It is probable that adding behavioural support would increase the likelihood of quitting with e-cigarettes still further, and this is an important area for new research. Possible explanations for the popularity of e-cigarettes, and their effectiveness relative to NRT, include...
their ability to replace some of the behavioural components of smoking, their relatively high nicotine delivery, the fact that smokers tend to try them for longer and with more frequent dosing than NRT, and their cultural acceptability.

Smokers are motivated to make a quit attempt in particular by cost and health concerns. Price rises, media campaigns and health professional advice are therefore likely to increase the numbers of smokers trying to quit.

12.8 Use of e-cigarettes by smokers and non-smokers

E-cigarettes are used almost exclusively by smokers who are trying to cut down or quit smoking, or who have quit smoking. Among adults, use by non-smokers is extremely rare. A higher proportion of non-smoking children than adults have experimented with e-cigarettes, but most of those who do have smoked in the past, or are current smokers. More than experimental use among children who are not also experimenting with tobacco is rare. Among regular users, whether children or adults, second- and third-generation devices are now much more widely used than first-generation ‘cigalike’ devices. Fruit flavours are popular among e-cigarette users, whether adults or children.

12.9 Harm reduction and population health

The emergence and consumer success of e-cigarettes, as a partial or complete substitute for smoking, reflects significant potential to reduce the harm caused by smoking to society by encouraging as many smokers as possible to use e-cigarettes, or indeed other non-tobacco nicotine products, rather than tobacco cigarettes. There are many, however, who retain significant concerns over the potential risks and adverse effects of this approach, for both individuals and wider society.

Concerns that e-cigarettes are not hazard free are justified, but this hazard could be minimised by a combination of technological development and appropriate regulation. Concerns that e-cigarettes will be used dually by smokers are inconsistent with current guidance and licence indications for NRT, which encourage dual use as a step towards quitting smoking and of protecting those around the smoker from the harmful effects of second-hand smoke. All the UK evidence, and almost all the international evidence, on the use of e-cigarettes by children and young people to date indicates that concerns about e-cigarettes helping to recruit a new generation of tobacco smokers through a gateway effect are, at least to date, unfounded, although vigilant surveillance is required to ensure that the emergence of any such effect is detected and reversed promptly. Renormalisation concerns, based on the premise that e-cigarette use encourages
tobacco smoking among others, also have no basis in experience to date. Exploitation of e-cigarette advertising as a means of promoting tobacco smoking by tobacco companies is perhaps a more real concern, but will largely be prevented by impending controls on advertising in the EU Tobacco Products Directive (TPD). 8

12.10 Regulation and harm reduction

It is difficult to determine, and more difficult still to apply, the right level of regulation for reduced-harm products. The wide range of different regulatory approaches adopted in different countries in relation to e-cigarettes, which spans a spectrum from freedom to market as a consumer product to complete prohibition, reflects a desire, on the one hand, to encourage as many smokers as possible to switch from tobacco to e-cigarettes and, on the other, to prevent harm to users or others from e-cigarette use. A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, eg exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks. However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult.

In the UK, consumer product regulation supported by advertising codes of practice has worked well to date, but does not guarantee that products actually deliver nicotine to a degree that smokers will find satisfying or, more importantly, that vapour is as toxin free as is reasonably possible. Medicines regulation guarantees efficacy and safety, but imposes high manufacturing, compliance and opportunity costs. That even the streamlined Medicines and Healthcare products Regulatory Agency (MHRA) ‘right touch’ medicines regulation has to date awarded a licence to only one e-cigarette, and none that has come to market, indicates that mandatory medicines regulation of e-cigarettes, although valuable as a complement to other regulatory approaches, is not ideal as a single regulatory approach. EU TPD regulation, if implemented as planned, offers a compromise between these two approaches by requiring emission reporting that will enable consumers to identify the best and cleanest nicotine delivery systems, but includes much, such as health warnings and nicotine content limits (see Chapter 10), that is potentially counterproductive. None of these approaches is therefore ideal, and experience in other countries does not offer better alternatives. The UK needs a nicotine regulatory system that applies controls on products in proportion to their potential harm, to promote innovation and diversity, ensure reasonable levels of protection for consumers and, above all, discourage tobacco use.
The use of reduced-harm products, and hence the health gains that they generate, is also influenced by other regulatory policies. Applying low levels of tax to non-tobacco nicotine products, as, for example, the 5% VAT rate levied on NRT, helps to make reduced-harm products attractive to smokers and offset the potentially regressive effect of tobacco tax increases. Allowing messages on harm relative to smoking in commercial and government media campaigns could help to reverse the growing misconception that e-cigarettes and tobacco cigarettes are similarly harmful (see Chapter 10). Prohibition of use of e-cigarettes where smoking is also prohibited may discourage smokers from trying e-cigarettes, and may also contribute to a false impression that they are similarly harmful. The inclusion of recommendations on use of unlicensed (and, in due course, licensed) e-cigarettes in NICE guidance is another example of an area where policies can change to encourage more smokers to switch from smoking to a non-tobacco nicotine product.

12.11 The tobacco industry and e-cigarettes

Tobacco companies make their money by selling tobacco, and the industry’s recent programme of investment and acquisitions in e-cigarettes perhaps indicates recognition that these products represent a disruptive technology that should be harnessed to protect the core business of selling tobacco, exploited to expand tobacco markets or developed as an opportunity to make nicotine products attractive to non-smokers. There is little likelihood that the industry sees e-cigarettes as a route out of the tobacco business, but it is highly likely that e-cigarettes will be exploited to enhance claims of corporate social responsibility, and to undermine implementation of Article 5.3 of the World Health Organization Framework Convention on Tobacco Control. There is no firewall between a ‘good’ tobacco industry that is marketing harm-reduction products in the UK and a ‘bad’ one that promotes smoking, or undermines tobacco control activities, in low- and middle-income countries.

12.12 Conclusions

Harm reduction was proposed by the RCP in 20071 as a means of reducing still further the vast burden of death and disability that tobacco smoking causes in our society. The evidence summarised in this report demonstrates that the emergence of e-cigarettes has generated a massive opportunity for a consumer-as well as a healthcare-led revolution in the way that nicotine is used in society. As the technology of these and other non-tobacco nicotine products improves, so the vision of a society that is free from tobacco smoking, and the harm that smoking causes, becomes more realistic. Experience to date suggests that, as predicted in principle in the 2007 report,1 the availability of e-cigarettes has been beneficial to UK public health. There is, however, no room for complacency and
it is particularly important that patterns of use of tobacco and non-tobacco nicotine continue to be monitored closely, and prompt remedial measures applied to deal with changes that are counterproductive to health. The potential for the tobacco industry to exploit and appropriate harm reduction, to undermine public health and bolster sales of tobacco, is a real problem that is likely to become more acute as tobacco companies move into the licensed, as well as unlicensed, nicotine market, but that problem can be managed with vigilance and care. Large-scale substitution of e-cigarettes, or other non-tobacco nicotine products, for tobacco smoking has the potential to prevent almost all the harm from smoking in society. Promoting e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible, as a substitute for smoking, is therefore likely to generate significant health gains in the UK.

12.13 Summary

> Smoking is the biggest avoidable cause of death and disability, and social inequality in health, in the UK.
> Most of the harm to society and to individuals caused by smoking in the near-term future will occur in people who are smoking today.
> Vigorous pursuit of conventional tobacco control policies encourages more smokers to quit smoking.
> Quitting smoking is very difficult and most adults who smoke today will continue to smoke for many years.
> People smoke because they are addicted to nicotine, but are harmed by other constituents of tobacco smoke.
> Provision of the nicotine that smokers are addicted to without the harmful components of tobacco smoke can prevent most of the harm from smoking.
> Until recently, nicotine products have been marketed as medicines to help people to quit.
> NRT is most effective in helping people to stop smoking when used together with health professional input and support, but much less so when used on its own.
> E-cigarettes are marketed as consumer products and are proving much more popular than NRT as a substitute and competitor for tobacco cigarettes.
> E-cigarettes appear to be effective when used by smokers as an aid to quitting smoking.
> E-cigarettes are not currently made to medicines standards and are probably more hazardous than NRT.
> However, the hazard to health arising from long-term vapour inhalation from the e-cigarettes available today is unlikely to exceed 5% of the harm from smoking tobacco.
> Technological developments and improved production standards could reduce the long-term hazard of e-cigarettes.
Tobacco harm reduction

> There are concerns that e-cigarettes will increase tobacco smoking by renormalising the act of smoking, acting as a gateway to smoking in young people, and being used for temporary, not permanent, abstinence from smoking.
> To date, there is no evidence that any of these processes is occurring to any significant degree in the UK.
> Rather, the available evidence to date indicates that e-cigarettes are being used almost exclusively as safer alternatives to smoked tobacco, by confirmed smokers who are trying to reduce harm to themselves or others from smoking, or to quit smoking completely.
> There is a need for regulation to reduce direct and indirect adverse effects of e-cigarette use, but this regulation should not be allowed significantly to inhibit the development and use of harm-reduction products by smokers.
> A regulatory strategy should, therefore, take a balanced approach in seeking to ensure product safety, enable and encourage smokers to use the product instead of tobacco, and detect and prevent effects that counter the overall goals of tobacco control policy.
> The tobacco industry has become involved in the e-cigarette market and can be expected to try to exploit these products to market tobacco cigarettes, and to undermine wider tobacco control work.
> However, in the interests of public health it is important to promote the use of e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible as a substitute for smoking in the UK.

References


Nicotine without smoke
Tobacco harm reduction
A report by the Tobacco Advisory Group
of the Royal College of Physicians

April 2016
Liberating Nicotine from Smoke to Save Lives Now:

Facing and Answering 7 Core Questions*  
to Guide Regulation, Policy, and Communications.

The E-Cigarette Summit - Science, Regulation & Public Health  

* The 7 core questions were originally put forth by Mitch Zeller, Director, Center for Tobacco Products,  
U.S. Food and Drug Administration.
Background

E-cigarettes and vaping are a contentious and complicated issue, and they also raise critical questions about society’s acceptance of the use of nicotine in any form. Seven core issues† are raised by the emergence of a class of innovative products (like e-cigarettes) as alternative modes of nicotine delivery without combustion of tobacco. Emerging products are fundamentally changing the way nicotine is delivered and may disrupt the 120+ year reign of the cigarette as the dominant mode of delivering a deadly inhaled mix of toxic smoke along with nicotine.

The 50th Anniversary Surgeon General’s Report bluntly concluded: “The burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products; rapid elimination of their use will dramatically reduce this burden” p.7 and “The current rate of progress in tobacco control is not fast enough. More needs to be done.” p. 875.1

Going forward, to minimize preventable premature death and suffering as quickly as possible, we present these responses to the seven issues, integrating both current science and values-based policy analysis to the critical questions that underpin regulations and communications on nicotine. Our focus is on the core issues raised by nicotine; at times, we mention vaping as a topical and clearly popular example, but vaping is merely an example, not the central issue. The central focus is more generally about reframing nicotine use2 to complement and enrich existing tobacco control strategies in the context of the very different modes of nicotine delivery when decoupled from the toxins in the inhaled smoke from combusted tobacco.

Can longer-term use of nicotine for those who need it be accepted?

As an alternative to the high probability of premature death from smoking, long-term use of nicotine delivered by relatively less harmful, non-combusted means is acceptable. The smoke inhaled from burning tobacco (combustibles like cigarettes) is deadly from the carbon monoxide and cancer-causing chemicals in the tar and not from the nicotine itself.1,3 For every two people who continue a lifetime of smoking, one life will be lost prematurely.4 People smoke for the nicotine but they die from the tar.5 Providing smokers with acceptable less harmful nicotine alternatives can yield massive health benefits. As an example, e-cigarette use (called vaping) is dramatically less harmful than combustibles. The United Kingdom Royal College of Physicians says: “Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure” (p. 87).6 Expert reviews of toxicological, clinical, and epidemiological evidence indicate that nicotine does not cause cancer and that the chemicals released during vaping are far fewer and well below the harm from inhaled smoke.3,6-10 New data should always be considered and added to the available evidence, but the public deserves our best judgment based on what we now know.

The dramatic difference in risk and in product characteristics between non-combusted modes of nicotine delivery and the toxic inhaled smoke from combustion should drive both personal decisions and the policy discourse about nicotine. The alternative classes of emerging products are vastly different from cigarettes. Thus, harms from nicotine also vary dramatically by different modes of delivery, including FDA-approved nicotine replacement medicinal products, non-combusted products like e-cigarettes and low-nitrosamine Swedish snus, all of which likely (or almost certainly) can be used long-term by most smokers with little evidence of harm from the long-term use of nicotine itself.3,6,11

What about recreational nicotine use for adults who may want it?

Users of noncombustible nicotine should know there may be some risks, although dramatically smaller than the risk of cigarettes and other combustibles6-8,12 and should be able to choose based on accurate

† The 7 core questions were originally put forth by Mitch Zeller, Director, Center for Tobacco Products, U.S. Food and Drug Administration
relative risk information. In terms of impacts on health, recreational use of noncombustible nicotine by adults is vastly different from combustible smoking; the two should not be equated and such misperceptions should be corrected. Consumers must have full accurate and up-to-date information about relative harms of the different classes of nicotine products to make informed decisions.13

Can a short transitional period of dual use be ok? Or a longer period?

Using both noncombustible nicotine products and cigarettes (dual use) is common among those attempting to quit smoking.14-16 Most smokers quitting with FDA-approved nicotine replacement therapy (NRT) still smoke and such use is permitted by labeling.17 Basically, dual use is a transition where a smoker tries out alternative products and methods until they find one that helps them stop smoking. This process can take time and should not be discouraged as a pathway towards eventual quitting or exclusive use of less harmful products. The goal must remain stopping use of combustibles completely and as soon as possible, but some smokers may need longer transition periods to achieve this goal. There is increasing scientific evidence that those who persist in finding an alternative nicotine product that is appealing and satisfying to them and then use it daily over an extended period (e.g. a month or more, rather than only a few times) are much more likely to quit smoking cigarettes or become exclusive e-cigarette users during the year following cessation of cigarettes.8,16,18-22

How much youth initiation can we tolerate?

We should strive to prevent all youth initiation of nicotine. We should prohibit the sale of all nicotine-containing products to those under legal purchase age, something we are now doing in all 50 states. But this goal must be tempered by the realities of adolescent behavior despite our best prevention efforts.

Even with sales prohibitions, some youth will at least experiment with novel products, via “leakage” of products sold to adults into the underage market as youth do with many products, especially those predisposed to risk taking. On the one hand, if the leakage is to teenagers who otherwise would never have used nicotine in any form it is a potential concern from a health perspective if use persists beyond experimentation. A more substantial concern would accrue if some of those who would otherwise have been non-users of nicotine subsequently transition to becoming lifetime cigarette smokers. But the extent, or even the existence, of that behavior pattern remains unknown. On the other hand, use of e-cigarettes by those who otherwise would have started smoking anyway – or those who are already smoking and trying to quit – likely might represent a net health gain if e-cigarette use indeed displaced or prevented further progression to cigarette use.

Kozlowski and Warner (2017) carefully reviewed the evidence to date concerning the actual patterns of e-cigarette and tobacco use as well as the concerns of excessive harms to youth of having alternative less harmful forms of nicotine delivery on the marketplace.23 After a steep rise from 2011-2014, e-cigarette use among youth dropped significantly in 2016 and use remains largely experimental and among those already using tobacco.24-27 Kozlowski and Warner (2017) concluded that while society must be vigilant in tracking trends, the fears of harms seem to be exaggerated and are unlikely to undermine the larger potential benefits of alternative nicotine delivery systems being on the market (see also: Levy et al, 2016; Villanti et al 2016; Warner, 2015; 2016; Glasser et al, 2017).8,25-28 Such modes of delivery ideally should eventually make the use of smoked tobacco obsolete, protecting youth and adults alike from the most deadly form of nicotine delivery via combustion.29 Moreover, for adults and society in general, misleading youth or keeping from them truthful information to get them to do what we want is always a failed strategy.13

How much weight should diminished interest in quitting play?

There is no evidence to suggest that meaningful numbers of people who have tried e-cigarettes or initiated dual use will stop there and lose all interest in achieving full cessation of combustibles. In fact, in the
years when e-cigarette use has increased most sharply, we have seen a faster drop in cigarette use among both adolescents and adults, leading to record low rates - and we also have seen a greater number of quit attempts in adults over that same time period.\textsuperscript{16,23,26,27,30,31} Until and unless evidence emerges that vaping substitutes for quitting, the possibility that it might deserves little weight in decision-making. What’s more, increasing evidence from recent and more scientifically robust studies indicates that alternative nicotine delivery systems, such as e-cigarettes, have surpassed nicotine replacement therapies as the leading method smokers are using to quit smoking.\textsuperscript{16} E-cigarette use is also associated with greater numbers of quit attempts and cessation success when used on a regular basis and with the availability of newer devices that deliver nicotine more effectively.\textsuperscript{8}

\textbf{Can we revise labeling and indications for medical nicotine to increase quitting?}

Quitting smoking is hard. Information that improves quit rates is therefore valuable. Many smokers wrongly believe any use of nicotine is as harmful as the use of combustibles,\textsuperscript{32-34} to some extent, that belief stems from misguided public health efforts. Smokers should know that nicotine without smoke is much less damaging to their health than nicotine in combustibles. Non-combustible nicotine products can be useful for smoking cessation.\textsuperscript{8,16,19,22,35,36} Alternative nicotine delivery can help smokers cut down and eventually quit by reducing the urge to smoke or preventing relapse.\textsuperscript{17} Sound public education must fully communicate the relative safety of different modes of nicotine delivery and especially when nicotine is decoupled from combusted tobacco smoke.\textsuperscript{13}

\textbf{Where does the principle of harm reduction come in?}

Harm reduction, like in many other areas of public health, should be embraced in tobacco control. It is a pragmatic approach that complements and enriches our proven current tobacco control efforts. Harm reduction is often misunderstood in the tobacco control community. Contrary to some skeptics’ characterizations, harm reduction acknowledges that no use of nicotine is preferred to any use of nicotine; thus, both prevention of any use of nicotine by underage youth and cessation of smoking by adults is desirable. However, for those who continue to smoke, it is pragmatic to recommend using lower-harm alternatives to combustibles to save many more lives that would otherwise be lost prematurely. This harm reduction strategy is consistent with the 50\textsuperscript{th} anniversary Surgeon General’s admonition that more must be done now to eliminate the preventable deaths overwhelmingly caused by cigarettes and other smoked tobacco use.\textsuperscript{1}
References


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Daniel Wikler, Ph.D. Mary B. Saltonstall, Professor of Ethics and Population Health Department of Global Health & Population
Dear Mayor Slavik and Council Members,

At your September 26, 2017 meeting, the topic of raising the minimum legal age for the purchase of tobacco and e-cigarette products in Plymouth from 18 to 21 years was discussed.

The League of Women Voters Wayzata Plymouth Area strongly supports this recommendation.

The League of Women Voters Minnesota, a nonpartisan, educational and political organization has a 98-year history of advocating on behalf of children. Back in 1999, our members supported the following position on smoking:

LWV Minnesota supports:
* Ongoing anti-smoking programs, starting in the elementary school and continuing in the middle and high school

* Regular continuing education for adult educators, coaches and school administrators

* Alternatives to suspension for alcohol, tobacco, other drugs and e-cigarette violations in the schools

* Youth-led and peer-to-peer education and programs. Allocation of public funds for community initiatives to prevent illegal alcohol, tobacco, other drugs and e-cigarette use

* Consistent city and school guidelines for adults who chaperone youth activities

* City ordinances and law enforcement efforts designed to reduce underage alcohol, tobacco, other drugs and e-cigarette use

As the Plymouth City Council addresses the public health problem of smoking, the League of Women Voters Wayzata Plymouth Area strongly encourages the Council to be a leader among municipalities by enacting strict ordinances to protect the long-term health of our youth.

Sincerely,

Deborah Price

President

League of Women Voters Wayzata Plymouth Area
Coalition of Neighborhood Retailers

DATE: October 23, 2017

TO: Plymouth City Council

The five retail trade associations that make up the Coalition of Neighborhood Retailers are writing to you to share important updated information and additional concerns on raising the legal age to purchase tobacco to 21 in the city of Plymouth.

Please review the letter that highlights three main points to be discussed in your upcoming work session.

"Cities Deciding Not to Move Forward on Raising Legal Age for Tobacco Purchases"
Several cities around the state have considered the Tobacco 21 agenda and made the decision not to move forward at this time. These cities include: Detroit Lakes, Elk River, Sartell, Waite Park, Sauk Rapids, St. Joseph, and St. Augusta. Also, Mankato and North Mankato have sent their proposal back to an intergovernmental committee for further review. Further, the Mayor in St. Cloud has voiced direct opposition to this policy under consideration. As of the date of this letter, only two cities have passed age increases, Edina and St. Louis Park.
We appreciate you taking the time to read our letter and consider our additional concerns.
Coalition of Neighborhood Retailers

October 23, 2017

Mayor Kelli Slavik
Council Member Judy Johnson
Council Member Jeffry Wosje
Council Member Jim Davis
Council Member Jim Prom
Council Member Ned Carroll
Council Member Jim Willis
3400 Plymouth Boulevard
Plymouth, MN 55441-1482

Re: The Issue of Raising the Legal Age to Purchase Tobacco

Dear Mayor Slavik and City Council Members:

The retail trade associations that comprise the Coalition of Neighborhood Retailers and our respective retail store members located in Plymouth appreciate the opportunity to share updated information and further concerns about the city council potentially raising the legal age to purchase tobacco products.

This letter will focus on three main points. First, on Food and Drug Administration (FDA) tobacco sales sting operations carried out by the Minnesota Department of Health using minors to buy tobacco, Plymouth retailers have achieved a 97% compliance rate of never selling to youth. Second, passing this ordinance in Plymouth creates an island of regulation and is unnecessary, especially when legislation for raising the purchase age to 21 is currently pending at the state legislature. Finally, increasing the purchase age to 21 without also including a consumption and possession ban for individuals 18, 19, or 20 years of age achieves nothing, except to harm lawful retail businesses while exacerbating the social sources problem.

Plymouth Retailers Achieve a 97% Compliance Rate on FDA Retail Tobacco Checks

Over the past three and a half years, Plymouth retailers have undergone 82 tobacco inspection compliance checks by the FDA and Minnesota Department of Human Services which utilize minors trying to buy tobacco products. 80 out of 82 times tobacco was not sold to minors. The data sheet accompanying this letter directly from the FDA reflects these results and can be accessed at [www.FDA.gov](http://www.FDA.gov). This information shows that retailers are not the problem with youth access. We encourage this council to closely consider the justification for punishing lawful retailers in Plymouth by removing their ability to sell a legal product to 18, 19 and 20-year old adults.
Cities Deciding Not to Move Forward on Raising Legal Age for Tobacco Purchases

Several cities around the state have considered the Tobacco 21 agenda and made the decision not to move forward at this time. These cities include: Detroit Lakes, Elk River, Sartell, Waite Park, Sauk Rapids, St. Joseph, and St. Augusta. Also, Mankato and North Mankato have sent their proposal back to an intergovernmental committee for further review. Further, the Mayor in St. Cloud has voiced direct opposition to this policy. As of the date of this letter, only two cities have passed age increases, Edina and St. Louis Park.

Please carefully examine whether the right choice for Plymouth residents is an Age 21 ordinance that would prohibit 18, 19 and 20-year old adults from purchasing legal tobacco products. This is even more significant when you take into account the importance of allowing young adults to purchase tobacco products that fall in the “harm reduction” category such as electronic cigarettes that can help many adults transition away from combustible tobacco products. Every adult should be allowed to have the option of purchasing less harmful tobacco products.

Don’t Make Plymouth an Island of Unnecessary Regulation, Legislation Already Introduced at State Level

A uniform law applied to the entire state should be preferred instead of making Plymouth an uncompetitive island for its lawful businesses. To that end, a bill at the legislature addressing increasing the age to purchase tobacco products to 21 has already been introduced. Senate File 2370 was introduced on May 4th with bipartisan support. I have attached a copy of that legislation for your review. We urge this council to not jump in front of statewide legislation.

Passing Tobacco 21 without Consumption and Possession Bans Changes Nothing, Except Harming Lawful Retail Businesses in Plymouth

The dialogue around raising the legal age to 21 centers on whether to make it illegal for 18, 19 and 20 year olds to possess and consume tobacco products in addition to prohibiting the sale to these adults. The advocates who are proposing to raise the legal purchase age to 21 claim that there will be a health benefit because 18, 19 and 20 year olds would then not use tobacco products nor serve as a social source for underage youth.

However, if 18, 19 and 20-year-old adults are not prohibited from possessing and using tobacco products, these adults will simply drive to a neighboring or nearby city or town, purchase their preferred tobacco products, and then legally possess and use them in their hometown. This also means that these adults can continue to be a social source of tobacco for minors. In other words, the public health benefit claimed will be marginal to non-existent, but your local retailers would suffer the financial loss of tobacco sales to legal age adults along with reduced gasoline, snack and beverage sales when these adults drive to nearby towns to patronize other retailers.

If your city council decides to proceed with an age 21 ordinance that would also ban the possession and use of tobacco products, then your local police department may oppose an ordinance because the police would be tasked with enforcing the ordinance by citing and/or arresting 18, 19 and 20-year-old adults for possessing and/or using legal tobacco products. At a Bloomington City Council workshop session held on August 14, 2017, a representative of ClearWay Minnesota (the anti-
tobacco organization formed as a result of the 1998 tobacco litigation settlement in Minnesota), informed the Bloomington City Council that if an age 21 ordinance included a prohibition on the possession and use of tobacco by 18, 19 and 20 year olds, then the organizations that make up the Tobacco 21 movement would likely withdraw their support for the ordinance.

This opposition to prohibiting the possession and use of tobacco, while at the same time raising the legal age to 21 to purchase tobacco, creates a conflicting double standard. Minnesota Statutes Section 340A.503 makes it illegal for anyone under the age of 21 to buy, possess or use alcohol. However, these advocate groups apparently oppose uniformity with the state liquor laws and, instead, want to allow 18, 19, and 20-year-old adults to be able to possess and use tobacco.

Here is the Catch 22: On the one hand, the supporters of an age 21 ordinance claim a health benefit if the age to purchase tobacco is raised, but fail to acknowledge that there will little if any health benefit because 18, 19 and 20 year olds could still possess and use tobacco and that social sources will remain the leading access point to tobacco for underage youth. On the other hand, when the possibility of also prohibiting possession and use of tobacco is raised to be in line with the state liquor possession and use law, the advocates publicly state that support for raising the legal age will likely be withdrawn. These positions are contradictory and demonstrate the difficulty presented by considering a policy that changes the legal of adulthood.

If the goal is to benefit the public health, then an age 21 ordinance that does not ban possession and use will not reach that goal. If possession and use of tobacco by 18, 19 and 20-year-olds are prohibited, then proponents of idea of raising the legal age to 21 may no longer support the ordinance.

We appreciate you considering our concerns and urge you to not consider an ordinance that would raise the legal age to 21 to purchase tobacco products.

Sincerely,

Lance Klatt, Executive Director
Minnesota Service Station Association

Jamie Pfuhl, President
Minnesota Grocers Association

Kevin Thoma, Executive Director
Minnesota Petroleum Marketers Association

Brian Carr, Deputy Executive Director
National Association of Tobacco Outlets

Bruce Nustad, President
Minnesota Retailers Association
You searched for:

City contains: Plymouth

State is MN

Decision Date: 01/01/2014 through 10/23/2017

Minor Involved: Yes

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WALGREENS #2767 4005 VINEWOOD LANE PLYMOUTH MN
SMOKIES SUPERETTE 17405 COUNTY ROAD 6 PLYMOUTH MN
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PLYMOUTH BP 3855 PLYMOUTH BLVD. PLYMOUTH MN
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HOLIDAY 16825 CO. RD. 24 PLYMOUTH MN
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Response to Tobacco Age 21 Proposals
Youth Smoking Declining Sharply Without Restrictions

- MN Smoking Rates on Sharp Decline
  - 9th Graders: 80% Decline from 19.6% in 2001 to 4.3% in 2016
  - 11th Graders: 75% Decline from 35.4% in 2001 to 8.4% in 2016
- Smoking Rates Drop in Absence of Age 21 Ordinance
Retailers Are Not the Source

➢ Retail Compliance Rates

99% Compliance Rate (MN Department of Human Services)

➢ Social Sources Are Acknowledged as the Real Problem
YOUTH ACCESS TO TOBACCO PRODUCTS AMONG PAST 30-DAY USERS: WHERE DO YOUTH GET TOBACCO?

Source of access to tobacco product among 15-17 year old current users

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<th>Product Type</th>
<th>Bought myself</th>
<th>Gave someone else money to buy</th>
<th>Bought from someone/took from store or another person</th>
<th>Asked for or someone offered</th>
<th>Other/missing/don't know/refused</th>
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<td>Cigarettes (n=533)</td>
<td>13.8%</td>
<td>32.0%</td>
<td>6.6%</td>
<td>42.5%</td>
<td>5.0%</td>
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<tr>
<td>E-cigarettes (n=342)</td>
<td>10.5%</td>
<td>17.3%</td>
<td>5.8%</td>
<td>56.7%</td>
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<tr>
<td>Cigarillos (n=257)</td>
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<td>34.2%</td>
<td>4.1%</td>
<td>37.3%</td>
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<td>Hookah (n=189)</td>
<td>12.0%</td>
<td>17.3%</td>
<td>4.8%</td>
<td>56.9%</td>
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<td>Smokeless (n=154)</td>
<td>23.2%</td>
<td>37.0%</td>
<td>4.9%</td>
<td>31.2%</td>
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# Estimate suppressed because it is statistically unreliable; it is based on a sample size of less than 50, or the coefficient of variation of the estimate is larger than 30 percent.
Age 21 is Not the Solution

- Older Adults Will Still Be a Social Source
- No Empirical, Broad-Based Longitudinal Study Exists on Impact of Higher Age
- Needham, MA (50% Drop in Youth Smoking After Age 21)
- Minnesota: 75% to 80% Drop in Youth Smoking Without Higher Age 21
Age 21 Catch 22

- Age 21 Ordinance That Allows Possession and Use Has Minimal Health Benefits
- Allowing Possession and Use Allows Social Sources to Continue
- Prohibiting Possession and Use Aligns Tobacco Laws with Alcohol Laws
- If Possession and Use Prohibited, then Advocates Withdraw Support
Retailers Will Be Impacted

- Claim of “Little short-term effect” is Not Accurate
- Reduction in Sales of Gasoline and Other Products Will Exacerbate Sales Declines
- Your City Will Be an Island
- Hospitality Industry Could be Impacted
- Retailers Should Not Be Penalized for Complying with Current Laws
A bill for an act
relating to health; adding charter schools to the prohibition of tobacco in schools; increasing the tobacco sale age; increasing administrative penalties; allowing alternative penalties; amending Minnesota Statutes 2016, sections 144.4165; 144.4167, subdivision 4; 171.171; 461.12, subdivisions 2, 3, 4, 5, 6; 461.18; 609.685; 609.6855; proposing coding for new law in Minnesota Statutes, chapter 461.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2016, section 144.4165, is amended to read:

144.4165 TOBACCO PRODUCTS PROHIBITED IN PUBLIC SCHOOLS.

No person shall at any time smoke, chew, or otherwise ingest tobacco or a tobacco product, or inhale or exhale vapor from an electronic delivery device as defined in section 609.685, subdivision 1, in a public school, as defined in section 120A.05, subdivisions 9, 11, and 13, and no person under the age of 18 shall possess any of these items or in a charter school, as defined in section 124E.03, subdivision 2. This prohibition extends to all facilities, whether owned, rented, or leased, and all vehicles that a school district owns, leases, rents, contracts for, or controls. Nothing in this section shall prohibit the lighting of tobacco by an adult as a part of a traditional Indian spiritual or cultural ceremony. For purposes of this section, an Indian is a person who is a member of an Indian tribe as defined in section 260.755, subdivision 12.

Sec. 2. Minnesota Statutes 2016, section 144.4167, subdivision 4, is amended to read:

Subd. 4. Tobacco products shop. Sections 144.414 to 144.417 do not prohibit the lighting of tobacco in a tobacco products shop by a customer or potential customer for the

Sec. 2.
specific purpose of sampling tobacco products. For the purposes of this subdivision, a tobacco products shop is a retail establishment with an entrance door opening directly to the outside, and that derives more than 90 percent of its gross revenue from the sale of loose tobacco, plants, or herbs and cigars, cigarettes, pipes, and other smoking devices for burning tobacco and related smoking accessories, tobacco-related devices, and electronic delivery devices, as defined in section 609.685, and in which the sale of other products is merely incidental. "Tobacco products shop" does not include a tobacco department or section of any individual business establishment with any type of liquor, food, or restaurant license.

Sec. 3. Minnesota Statutes 2016, section 171.171, is amended to read:

171.171 SUSPENSION; ILLEGAL PURCHASE OF ALCOHOL OR TOBACCO.

The commissioner shall suspend for a period of 90 days the license of a person who:

(1) is under the age of 21 years and is convicted of purchasing or attempting to purchase an alcoholic beverage in violation of section 340A.503 if the person used a license, Minnesota identification card, or any type of false identification to purchase or attempt to purchase the alcoholic beverage;

(2) is convicted under section 171.22, subdivision 1, clause (2), or 340A.503, subdivision 2, clause (3), of lending or knowingly permitting a person under the age of 21 years to use the person's license, Minnesota identification card, or other type of identification to purchase or attempt to purchase an alcoholic beverage; or

(3) is under the age of 18 years and is found by a court to have committed a petty misdemeanor under section 609.685, subdivision 1, if the person used a license, Minnesota identification card, or any type of false identification to purchase or attempt to purchase a tobacco product; or

(4) is convicted under section 171.22, subdivision 1, clause (2), of lending or knowingly permitting a person under the age of 18 years to use the person's license, Minnesota identification card, or other type of identification to purchase or attempt to purchase a tobacco product, a tobacco-related device, an electronic delivery device, as defined in section 609.685, subdivision 1; or a nicotine or lobelia delivery product, as described in section 609.6855, subdivision 1.
Sec. 4. Minnesota Statutes 2016, section 461.12, subdivision 2, is amended to read:

Subd. 2. **Administrative penalties; licensees.** If a licensee or employee of a licensee sells, gives, or otherwise furnishes tobacco, tobacco-related devices, electronic delivery devices, or nicotine or lobelia delivery products to a person under the age of 18 or violates any other provision of this chapter, the licensee shall be charged an administrative penalty of $75. An administrative penalty of $200 must be imposed for a second violation at the same location within 24 months after the initial violation. For a third or any subsequent violation at the same location within 24 months after the initial violation, an administrative penalty of $250 must be imposed, and the licensee's authority to sell tobacco, tobacco-related devices, electronic delivery devices, or nicotine or lobelia delivery products at that location must be suspended for not less than seven days and may be revoked.

No suspension, revocation, or other penalty may take effect until the licensee has received notice, served personally or by mail, of the alleged violation and an opportunity for a hearing before a person authorized by the licensing authority to conduct the hearing. A decision that a violation has occurred must be in writing.

Sec. 5. Minnesota Statutes 2016, section 461.12, subdivision 3, is amended to read:

Subd. 3. **Administrative penalty; individuals.** An individual who sells, gives, or otherwise furnishes tobacco, tobacco-related devices, electronic delivery devices, or nicotine or lobelia delivery products to a person under the age of 18 years must be charged an administrative penalty of $50. No penalty may be imposed until the individual has received notice, served personally or by mail, of the alleged violation and an opportunity for a hearing before a person authorized by the licensing authority to conduct the hearing. A decision that a violation has occurred must be in writing.

Sec. 6. Minnesota Statutes 2016, section 461.12, subdivision 4, is amended to read:

Subd. 4. **Minors Persons under age 21.** The licensing authority shall consult with interested educators, parents, children persons under the age of 21 years, and representatives of the court system to develop alternative penalties for minors persons under the age of 21 years who purchase, possess, and consume or attempt to purchase, tobacco, tobacco-related devices, electronic delivery devices, or nicotine or lobelia delivery products using a driver's license, permit, Minnesota identification card, or any other type of false identification to misrepresent the person's age, in violation of section 609.685 or 609.6855. The licensing authority and the interested persons shall consider a variety of options, including, but not
limited to, tobacco-free education, tobacco cessation programs, notice to schools, parents, community service, and other court diversion programs.

Sec. 7. Minnesota Statutes 2016, section 461.12, subdivision 5, is amended to read:

**Subd. 5. Compliance checks.** A licensing authority shall conduct unannounced compliance checks at least once each calendar year at each location where tobacco, tobacco-related devices, electronic delivery devices, or nicotine or lobelia delivery products are sold to test compliance with sections 609.685 and 609.6855. Compliance checks must involve minor persons over the age of 15, but under the age of 21, who, with the prior written consent of a parent or guardian if under the age of 18, attempt to purchase tobacco, tobacco-related devices, electronic delivery devices, or nicotine or lobelia delivery products under the direct supervision of a law enforcement officer or an employee of the licensing authority.

Sec. 8. Minnesota Statutes 2016, section 461.12, subdivision 6, is amended to read:

**Subd. 6. Defense.** It is an affirmative defense to the charge of selling tobacco, tobacco-related devices, electronic delivery devices, or nicotine or lobelia delivery products to a person under the age of 21 years in violation of subdivision 2 or 3 that the licensee or individual making the sale relied in good faith upon proof of age as described in section 340A.503, subdivision 6.

Sec. 9. Minnesota Statutes 2016, section 461.18, is amended to read:

**461.18 BAN ON SELF-SERVICE SALE OF PACKS SALES; EXCEPTIONS.**

Subdivision 1. **Except in adult-only age 21 and older facilities.** (a) No person shall offer for sale tobacco or tobacco-related devices, or electronic delivery devices as defined in section 609.685, subdivision 1, or nicotine or lobelia delivery products as described in section 609.6855, in open displays which are accessible to the public without the intervention of a store employee.

(b) [Expired August 28, 1997]

c) [Expired]

(d) [b) This subdivision shall not apply to retail stores which that have an entrance door opening directly to the outside and that derive at least 90 percent of their gross revenue from tobacco and tobacco-related devices, and electronic delivery devices as defined in section...
5.1 Subd. 1. Retail sales prohibited. No person shall sell tobacco products, electronic delivery devices, or nicotine or lobelia delivery products to any person under the age of 21 years of age.

5.2 Subd. 2. Vending machine sales prohibited. No person shall sell tobacco products, electronic delivery devices, or nicotine or lobelia delivery products from vending machines. This subdivision does not apply to vending machines in facilities that cannot be entered at any time by persons younger than 21 years of age.

5.3 Subd. 3. Federal regulations for cartons, multipacks. Code of Federal Regulations, title 21, part 897.16(c) 1140.16(c), as amended by Code of Federal Regulations, volume 81, number 90 (May 10, 2016), and as otherwise amended from time to time, is incorporated by reference with respect to cartons and other multipack units.

5.4 Sec. 10. [461.22] SIGNAGE REQUIRED. At each location where tobacco, tobacco-related devices, electronic delivery devices, or nicotine or lobelia delivery products are sold, the licensee shall display a sign in plain view to provide public notice that selling any of these products to any person under the age of 21 is illegal and subject to penalties. The notice shall be placed in a conspicuous location in the licensed establishment and shall be readily visible to any person who is purchasing or considering a purchase of such products. The sign must provide notice that all persons responsible for selling such products shall verify, by means of photographic identification containing the bearer's date of birth, the age of any person under 30 years of age.

5.5 Sec. 11. Minnesota Statutes 2016, section 609.685, is amended to read:

609.685 SALE OF TOBACCO TO CHILDREN PERSONS UNDER AGE 21.

Subdivision 1. Definitions. For the purposes of this section, the following terms shall have the meanings respectively ascribed to them in this section.

(a) "Tobacco" means cigarettes and any product containing, made, or derived from tobacco that is intended for human consumption, whether chewed, smoked, absorbed, dissolved, inhaled, snorted, sniffed, or ingested by any other means, or any component, part, or accessory of a tobacco product including but not limited to cigars; cheroots; stogies; perique; granulated, plug cut, crimp cut, ready rubbed, and other smoking tobacco; snuff; snuff flour; cavendish; plug and twist tobacco; fine cut and other chewing tobaccos; shorts; refuse scraps, clippings, cuttings and sweepings of tobacco; and other kinds and forms of tobacco. Tobacco excludes any tobacco product that has been approved by the United States Food and Drug Administration for sale as a tobacco-cessation product, as a
tobacco-dependence product, or for other medical purposes, and is being marketed and sold
solely for such an approved purpose.

(b) "Tobacco-related devices" means cigarette papers or pipes for smoking or other
devices intentionally designed or intended to be used in a manner which enables the chewing,
sniffing, smoking, or inhalation of vapors of tobacco or tobacco products. Tobacco-related
devices include components of tobacco-related devices which may be marketed or sold
separately.

c) "Electronic delivery device" means any product containing or delivering nicotine,
lobelia, or any other substance intended for human consumption that can be used by a person
to simulate smoking in the delivery of nicotine or any other substance through inhalation
of vapor from the product. Electronic delivery device includes any component part of a
product, whether or not marketed or sold separately. Electronic delivery device does not
include any product that has been approved or certified by the United States Food and Drug
Administration for sale as a tobacco-cessation product, as a tobacco-dependence product,
or for other medical purposes, and is marketed and sold for such an approved purpose.

Subd. 1a. **Penalty to sell or furnish.** (a) Whoever sells, gives, or otherwise furnishes
tobacco, tobacco-related devices, or electronic delivery devices to a person under the age
of 18 21 years is guilty of a misdemeanor for the first violation. Whoever violates this
subdivision a subsequent time within five years of a previous conviction under this
subdivision is guilty of a gross misdemeanor.

(b) It is an affirmative defense to a charge under this subdivision if the defendant proves
by a preponderance of the evidence that the defendant reasonably and in good faith relied
on proof of age as described in section 340A.503, subdivision 6.

Subd. 2. **Other offenses Use of false identification.** (a) Whoever furnishes tobacco,
tobacco-related devices, or electronic delivery devices to a person under the age of 18 years
is guilty of a misdemeanor for the first violation. Whoever violates this paragraph a
subsequent time is guilty of a gross misdemeanor.

(b) A person under the age of 18 21 years who purchases or attempts to purchase tobacco,
tobacco-related devices, or electronic delivery devices and who uses a driver's license,
permit, Minnesota identification card, or any type of false identification to misrepresent the
person's age, is guilty of a petty misdemeanor.

Subd. 2a. **Alternative penalties.** Law enforcement and court system representatives
shall consult with interested parents, persons under the age of 21 years, educators, and others
to develop alternative penalties for persons under the age of 21 years who violate any

Sec. 11.
subdivision of this section. Law enforcement, court system representatives, and all interested persons shall consider a variety of options including, but not limited to, tobacco-free education programs, notice to schools and parents, community service, tobacco cessation programs, and court diversion programs.

Subd. 3. Petty misdemeanor. Except as otherwise provided in subdivision 2, whoever possesses, smokes, chews, or otherwise ingests, purchases, or attempts to purchase tobacco, tobacco-related devices, or electronic delivery devices and is under the age of 18 years is guilty of a petty misdemeanor.

Subd. 4. Effect on local ordinances. Nothing in subdivisions 1 to 3 2a shall supersede or preclude the continuation or adoption of any local ordinance which provides for more stringent regulation of the subject matter in subdivisions 1 to 3 2a.

Subd. 5. Exceptions. (a) Notwithstanding subdivision 2, an Indian may furnish tobacco to an Indian under the age of 18 21 years if the tobacco is furnished as part of a traditional Indian spiritual or cultural ceremony. For purposes of this paragraph, an Indian is a person who is a member of an Indian tribe as defined in section 260.755, subdivision 12.

(b) The penalties in this section do not apply to a person under the age of 18 21 years who purchases or attempts to purchase tobacco, tobacco-related devices, or electronic delivery devices while under the direct supervision of a responsible adult for training, education, research, or enforcement purposes.

Subd. 6. Seizure of false identification. A retailer may seize a form of identification listed in section 340A.503, subdivision 6, if the retailer has reasonable grounds to believe that the form of identification has been altered or falsified or is being used to violate any law. A retailer that seizes a form of identification as authorized under this subdivision shall deliver it to a law enforcement agency within 24 hours of seizing it.

Sec. 12. Minnesota Statutes 2016, section 609.6855, is amended to read:

609.6855 SALE OF NICOTINE DELIVERY PRODUCTS TO CHILDREN PERSONS UNDER AGE 21.

Subdivision 1. Penalty to sell or furnish. (a) Whoever sells, gives, or otherwise furnishes to a person under the age of 18 21 years a product containing or delivering nicotine or lobelia intended for human consumption, or any part of such a product, that is not tobacco or an electronic delivery device as defined by section 609.685, is guilty of a misdemeanor for the first violation. Whoever violates this subdivision a subsequent time within five years of a previous conviction under this subdivision is guilty of a gross misdemeanor.
(b) It is an affirmative defense to a charge under this subdivision if the defendant proves
by a preponderance of the evidence that the defendant reasonably and in good faith relied
on proof of age as described in section 340A.503, subdivision 6.

(c) Notwithstanding paragraph (a), a product containing or delivering nicotine or lobelia
intended for human consumption, or any part of such a product, that is not tobacco or an
electronic delivery device as defined by section 609.685, may be sold to persons under the
age of 18 if the product has been approved or otherwise certified for legal sale by the
United States Food and Drug Administration for tobacco use cessation, harm reduction, or
for other medical purposes, and is being marketed and sold solely for that approved purpose
is a drug, device, or combination product authorized for sale by the United States Food and
Drug Administration, as those terms are defined in the Federal Food, Drug, and Cosmetic
Act.

Subd. 2. Other offense. Use of false identification. A person under the age of 18 years who purchases or attempts to purchase a product containing or delivering nicotine or
lobelia intended for human consumption, or any part of such a product, that is not tobacco
or an electronic delivery device as defined by section 609.685, and who uses a driver's
license, permit, Minnesota identification card, or any type of false identification to
misrepresent the person's age, is guilty of a petty misdemeanor. This penalty does not apply
to a person under the age of 21 years who purchases or attempts to purchase such a product
while under the direct supervision of a responsible adult for training, education, research,
or enforcement purposes.

Subd. 3. Petty misdemeanor. Alternative penalties. Except as otherwise provided in
subdivisions 1 and 2, whoever is under the age of 18 years and possesses, purchases, or
attempts to purchase a product containing or delivering nicotine or lobelia intended for
human consumption, or any part of such a product, that is not tobacco or an electronic
delivery device as defined by section 609.685, is guilty of a petty misdemeanor. Law
enforcement and court system representatives shall consult with interested parents, persons
under the age of 21 years, educators, and others to develop alternative penalties for persons
under the age of 21 years who violate any subdivision of this section. Law enforcement,
court system representatives, and all interested persons shall consider a variety of options
including, but not limited to, tobacco-free education programs, notice to schools and parents,
community service, tobacco cessation programs, and court diversion programs.
Dear Mayor Slavik and Members of the City Council,

You have probably already reviewed the Plymouth Draft Ordinance but I am concerned that Penalties for Possession, Use and Purchase of tobacco products are still included (1150.05 – Other Illegal Acts. Subds 2, 3 and 5 need to be removed in order to remove PUP penalties).

Best practices are to remove those penalties and provide the background evidence to support that:

a. Penalties related to purchasing, using and possession (PUP) tobacco products by underage tobacco users have not been proven to reduce youth tobacco use.

b. PUP penalties also divert focus from addressing irresponsible retailers and the tobacco industry which has a long history of targeting youth.

c. PUP penalties open the door to selective enforcement against young persons of color.

There is consensus from national health organizations like Campaign for Tobacco Free Kids, the American Cancer Society and the American Heart Association that Tobacco 21 policies should eliminate PUP penalties. Local organizations, including the Minnesotans for a Smoke-free Generation Coalition, also oppose Tobacco 21 ordinances that include PUP penalties.

Thanks for your consideration of these changes!

Best Regards!

Laurie Lafontaine
11400 5th Ave. N.
Plymouth, MN  55441
From: Luke Fischer
Sent: Tuesday, October 24, 2017 11:07 AM
To: Amy Gottschalk <agottschalk@plymouthmn.gov>; Sandy Engdahl <SEngdahl@plymouthmn.gov>
Subject: FW: Tobacco 21 ordinance advocacy

From: Emily Borman-Shoap [mailto:borm0029@umn.edu]
Sent: Monday, October 23, 2017 3:42 PM
To: Kelli Slavik <KSlavik@plymouthmn.gov>; Council Members <Council@plymouthmn.gov>; Jeffry Wosje <jwosje@plymouthmn.gov>
Cc: Caitlin DeVos <caitlin.devos@gmail.com>; Amanda Jansen <AJansen@clearwaymn.org>; Emily Myatt <emily.myatt@cancer.org>; Grace Higgins <ghiggins@metrodoctors.com>
Subject: Tobacco 21 ordinance advocacy

Dear Mayor Slavik and Members of the City Council,

I am a Plymouth resident, parent of two boys ages 10 and 8, and a pediatrician. I am so glad to see that the Plymouth City Council is considering a tobacco 21 ordinance and I understand that you will be discussing this policy at your study session tomorrow night (Tuesday). Councilman Wosje and I had a brief e-mail exchange earlier this summer, but I thought I would follow up with the full council since the meeting is tomorrow.

I am very grateful to my colleagues at the Twin Cities Medical Society and the Minnesotans for a Smoke-Free Generation group for bringing me up to speed on some of the specific benefits of limiting youth access to tobacco.

I'm sure you will be reviewing many materials, but I wanted to draw your attention to two quick documents. The first is a fact sheet that clearly outlines the expected benefits of raising the tobacco age to age 21 (attached).

The second is important information on the potential impact of having penalties for youth who are found to be in possession of tobacco products. I believe the current draft of the ordinance includes language about having penalties for youth. Although I can certainly understand the intention behind having these penalties, experience in other states and municipalities has shown that these penalties do not have the desired impact of limiting youth smoking. (fact sheet attached).

Additionally, I am concerned that the penalties for youth detract from the real message which is that we should be limiting the marketing and sales of a harmful product to people under age 21. Focusing on a more streamlined ordinance without the penalties is what I would recommend.
I’m sure you don’t need me to reiterate for you all of the negative health consequences of tobacco use including early death, heart disease, strokes, multiple types of cancer, etc.

One piece of information that may help to inform your decisions is to remember that the biology of decision making is controlled by a part of the brain called the frontal lobe. We know that this part of the brain is not fully mature until age 25. It is, therefore, incredibly important to protect our vulnerable young people ages 18 to 21 and limit access to tobacco products during this time of ongoing maturation.

Most late adolescents simply aren’t thinking ahead about the long-term risks of heart attacks, strokes and lung cancer. I have attached an info graphic about teenage decision-making that you might find useful as you consider this topic.

I am not able to attend the study session tomorrow night, but would be happy to serve as a local resource with expertise in child and adolescent health.

I am excited to see my city taking important steps to promote the health and well-being of young people and would love for us to catch up with the pioneering efforts already being made in Edina and St. Louis Park

Please feel free to contact me if you have any questions and I’ll be very interested to see the outcome of tomorrow’s meeting.

Sincerely,

Emily Borman-Shoap, MD
720 Niagara Lane North, Plymouth, MN
borm0029@umn.edu, cell phone 612-802-8686

Emily Borman-Shoap, MD
Director
Pediatric Residency Program
Medical Student Faculty Advisor
Assistant Professor
University of Minnesota
612-624-4477
Research shows that youth access laws successfully reduce youth tobacco use when they are well enforced and disrupt the sale of tobacco products to minors. Today, all 50 states and the District of Columbia have laws that restrict the sale of tobacco products to minors. But in addition to restricting the sale, 45 states and the District of Columbia have laws that also prohibit the purchase, use, and/or possession (PUP) of tobacco products by underage persons. Penalties for youth who violate a PUP law typically include a fine but may also include other penalties like community service, attending mandatory smoking education or cessation programs, or the suspension of a driver’s license or permit. Only five states—Maryland, Massachusetts, Nevada, New Jersey, and New York—do not have PUP laws.

Some states passed PUP laws with the intention of reducing youth smoking by making kids more personally responsible for buying and using tobacco products. Penalizing children, however, has not been proven to be an effective strategy for reducing youth smoking; and some experts argue that PUP laws could actually detract from more effective enforcement measures and tobacco control efforts.

PUP laws also unfairly punish and stigmatize children, many of whom became addicted at a young age as a result of the tobacco industry’s aggressive marketing to kids. In this way, PUP laws shift the blame away from the industry’s irresponsible marketing and retailers’ irresponsible sales, to its victims. Penalties against youth become even more unreasonable when little is done to counter the tobacco industry’s targeted marketing to kids. Rather than treat children as the wrongdoers, youth access laws should focus on limiting access to tobacco products by conducting ongoing retailer compliance checks with strong penalties for sales to underage persons.

Additional Concerns about PUP Laws

- Penalizing youth can divert enforcement officials’ attention from stopping retailers from illegally selling tobacco to kids in the first place. PUP laws are more difficult to systematically enforce than sanctions against retailers, especially since PUP laws rarely provide additional enforcement resources. It is easier and more effective to conduct compliance checks for retailers, who are fewer in number compared to youth and whose locations are both known and constant.

- The ease of discretely possessing and using some tobacco products makes PUP laws more challenging to enforce than laws restricting sales to minors. Similarly, the perceived risk among youth of getting caught and punished is likely too low to have a meaningful impact on deterring tobacco use. In fact, there is little evidence showing that PUP laws have been enforced well enough to reduce youth smoking.

- Tobacco companies and their allies have a history of supporting PUP laws as alternatives to other laws that would produce greater declines in youth smoking, such as increasing the price of cigarettes. Tobacco companies have also promoted the passage of PUP laws in order to get additional provisions enacted that make implementing or enforcing additional tobacco control measures more difficult (e.g., preemption of strong local laws/ordinances).

- Despite the fact that many youth smokers are addicted, making it difficult for them to quit, few PUP laws include provisions ensuring that quit smoking resources are made available to them. Some research even suggests that penalizing youth could deter them from seeking support for cessation. Promoting interventions that provide cessation resources for youth interested in quitting could be a more beneficial alternative.

Youth Access Laws Should Emphasize Restricting Sales to Minors

Youth access laws that restrict sales to minors are better supported by research as a way to reduce youth smoking than laws that focus primarily on penalizing youth for purchase or possession of tobacco.
PUP laws may have some potential if combined with laws banning sales to minors, evidence of their effectiveness still is lacking, and many concerns about how to effectively implement them remain.

Regardless of whether a state chooses to implement PUP provisions as part of its youth access law, rigorous enforcement of restrictions against sales to minors is critical to minimizing the accessibility of tobacco products and, ultimately, reducing youth tobacco use. The most successful youth access programs incorporate routine retailer compliance checks which use minors to attempt tobacco purchases.\(^\text{11}\)

\[\text{Campaign for Tobacco-Free Kids, March 28, 2016/ Becca Knox}\]

\begin{flushleft}
\footnotesize
1 DiFranza, JR, “Which interventions against the sale of tobacco to minors can be expected to reduce smoking?” Tobacco Control, doi:10.1136/tobaccocontrol-2011-050145, published online first October 12, 2011.

2 Most states set the age for sale of tobacco products at 18. As of 3/28/16, Alabama, Alaska, New Jersey, and Utah set the age at 19, and Hawaii sets it at 21.


11 DiFranza, JR, “Which interventions against the sale of tobacco to minors can be expected to reduce smoking?” Tobacco Control, doi:10.1136/tobaccocontrol-2011-050145, published online first October 12, 2011.
\end{flushleft}
INCREASE THE TOBACCO AGE TO 21

Minnesotans agree: We can do more to prevent kids from becoming addicted. A national consensus is growing to prevent addictions and future health problems by ensuring that those who sell tobacco products do so to adults who are 21 and older. Minnesotans for a Smoke-Free Generation supports this movement.

RAISING THE TOBACCO AGE TO 21 WILL PREVENT YOUTH TOBACCO USE AND SAVE LIVES.

Almost 95 percent of addicted adult smokers started smoking by age 21.2

- Increasing the age gap between kids and those who can legally buy tobacco will help remove access to tobacco products from the high-school environment.

BIG TOBACCO ACTIVELY RECRUITS REPLACEMENT SMOKERS TO GUARANTEE PROFITS.

- The tobacco industry heavily targets 18-to-21-year-olds with menthol and candy flavoring, magazine advertisements, product design and packaging, and event sponsorships and promotions.3,4

ADULTS SUPPORT RAISING THE TOBACCO AGE TO 21.

- A national survey shows that 75 percent of adults favor increasing the minimum sale age for tobacco to 21.3
- 70 percent of smokers are in support of raising the minimum legal age.3

Research shows a 25 percent reduction in smoking initiation among 15-to-17-year-olds following such an increase.1
STATE AND LOCAL GOVERNMENTS ARE TAKING ACTION TO PROTECT YOUTH.

- California, Hawaii and more than 200 localities in the United States have raised the sale age of tobacco to 21, including New York City, Boston and Kansas City.
- Needham Massachusetts found that tobacco use among high-school students fell by nearly half after raising the age to 21.5

NICOTINE CAN CAUSE ADDICTION AND DISRUPT ATTENTION AND LEARNING IN ADOLESCENTS? 7

- Nicotine is addictive, and adolescents are especially vulnerable to the health impacts of tobacco use.6
- The adolescent brain is negatively impacted by nicotine, and its long-term effects are a significant public health concern.7

Minnesotans for a Smoke-Free Generation is a coalition of Minnesota organizations that share a common goal of saving Minnesota youth from a lifetime of addiction to tobacco. The coalition supports policies that reduce youth smoking, including keeping tobacco prices high, raising the tobacco sale age to 21, limiting access to candy-, fruit- and menthol-flavored tobacco and funding future tobacco control programs. Find out more at www.smokefreegenmn.org.

Approximately 95% of current adult smokers started before they were 21. If youth don’t smoke by the time they are 21, they likely never will.
Dear Kelly Slavik

Tobacco use is still the number one cause of preventable death and disease in Minnesota. Increasing the age gap between young people and those who can legally buy tobacco will reduce youth access to tobacco and ensure our youth don't suffer from a lifetime of tobacco addiction.

By increasing the tobacco sale age to 21, you can help prevent addiction and tobacco-related diseases. Please act now to protect our community and our youth.

Sincerely,

Jackie Holmbeck

Address: 17620 25th Ave. No.

City: Plymouth Zip: 55447

I am against PUP penalties.

Kelli Slavik
Plymouth Mayor
City Hall
Plymouth, MN.
To: Mayor and Council

Prepared by: Dave Callister, City Manager

Reviewed by:

Item: Set Future Study Sessions

Pending Study Session Topics (at least three Council members have approved the following study items on the list):

None at this time.

Other Council requests for Study Session Topics:

None at this time.

Staff’s requests for Study Sessions:

None at this time.
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1. **November 2017**

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<td>7:00 PM</td>
<td>Planning Commission Meeting</td>
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<td>7:00 PM</td>
<td>Environmental Quality Committee (EQC) Meeting</td>
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<td>5:30 PM</td>
<td>Special Council Meeting: Budget Medicine Lake Room 7:00 PM Regular Council Meeting Council Chambers</td>
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<td>Housing and Redevelopment Authority (HRA) Meeting Medicine Lake Room</td>
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<td>Thanksgiving City Offices Closed</td>
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<td>5:30 PM</td>
<td>Special Council Meeting: Median/Beautification Projects Medicine Lake Room 7:00 PM Regular Council Meeting Council Chambers</td>
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**City Offices Closed**

**Veterans Day Observed**

**Plymouth Arts Fair**

**City of Plymouth**

**Adding Quality to Life**

**OFFICIAL CITY CALENDAR**

3400 Plymouth Boulevard

Plymouth, MN 55447

Phone: 763-509-5000

Fax: 763-509-5060

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<td>7:00 PM ENVIRONMENTAL QUALITY COMMITTEE (EQC) MEETING</td>
<td>7:00 PM CHARTER COMMISSION MEETING</td>
<td>7:00 PM PARK &amp; REC ADVISORY COMMISSION (PRAC) MEETING</td>
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<td>7:00 PM HOUSING AND REDEVELOPMENT AUTHORITY (HRA) MEETING</td>
<td>Medicine Lake Room</td>
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December 2017

3400 Plymouth Boulevard
Plymouth, MN  55447

OFFICIAL CITY CALENDAR

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<td><strong>NEW YEAR’S DAY</strong>&lt;br&gt;<strong>CITY OFFICES CLOSED</strong></td>
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<td><strong>5:30 PM</strong>&lt;br&gt;<strong>SPECIAL COUNCIL MEETING</strong>&lt;br&gt;Goals/Legislative Priorities&lt;br&gt;<strong>Medicine Lake Room</strong>&lt;br&gt;<strong>7:00 PM</strong>&lt;br&gt;<strong>REGULAR COUNCIL MEETING</strong>&lt;br&gt;Council Chambers</td>
<td><strong>7:00 PM</strong>&lt;br&gt;<strong>ENVIRONMENTAL QUALITY COMMITTEE MEETING</strong>&lt;br&gt;<strong>Medicine Lake Room</strong></td>
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## February 2018

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