1 Guidance title

Tobacco: harm-reduction approaches to smoking

1.1 Short title

Tobacco: harm reduction

2 Background

a) The National Institute for Health and Clinical Excellence (NICE) has been asked by the Department of Health (DH) to develop public health guidance on the use of harm-reduction approaches to smoking.

b) This guidance will support a number of related policy documents including:

- ‘Cancer reform strategy’ (DH 2007a).
- ‘Equity and excellence: liberating the NHS’ (DH 2010a).
- ‘Health inequalities: progress and next steps' (DH 2008).
- 'Improving outcomes: a strategy for cancer' (DH 2011b).
- ‘National stroke strategy’ (DH 2007b).
• ‘No health without mental health: a cross-government mental health strategy for people of all ages’ (DH 2011c).

• ‘Securing good health for the whole population’ (Wanless 2004).

• ‘The NHS outcomes framework 2011/12’ (DH 2010c).

• ‘The operating framework for the NHS in England 2011/12’ (DH 2011d).

c) This guidance will support a range of UK international agreements including: the ‘EU Directive on tobacco products’ (European Union 2001) and the ‘WHO framework convention on tobacco control’ (World Health Organization 2003).

d) This guidance will provide recommendations for good practice based on the best available evidence of effectiveness, including cost effectiveness. It is aimed at professionals, commissioners and managers with public health as part of their remit. It is especially aimed at those involved in smoking cessation services within the NHS, local authorities and the wider public, private, voluntary and community sectors. It will also be of interest to members of the public, especially people who want to stop or cut down the amount they smoke.

e) In this guidance, ‘tobacco harm reduction’ means reducing the illnesses and deaths caused by smoking tobacco – among people who smoke and those around them. People who smoke can do this by:

- stopping smoking altogether
- cutting down prior to quitting
- smoking less
- abstaining from smoking temporarily.
These changes in behaviour might involve completely or partially substituting the nicotine from smoking with nicotine from less hazardous sources that do not contain tobacco. (Examples include pharmaceutical nicotine and ‘electronic cigarettes’.) These nicotine sources could be used either temporarily or indefinitely. Although some definitions of harm reduction include the use of ‘reduced exposure cigarettes’ and ‘oral tobacco’ products, products containing tobacco will not be covered by this guidance.

f) The guidance will complement other NICE guidance on stopping smoking. For further details, see section 6.

This guidance will be developed using the NICE public health programme process.

3 The need for guidance

a) Tobacco smoking remains the single greatest cause of preventable illness and early death in England, accounting for 81,400 deaths in 2009 (NHS Information Centre 2010). Treating smoking-related illnesses was estimated to cost the NHS £2.7 billion in 2006/07 (Callum et al. 2010). The overall financial burden to society has been estimated at £13.74 billion a year. This includes both NHS costs and loss of productivity due to illness and early death (Nash and Featherstone 2010).

b) Although smoking rates have declined sharply in the last 30 years, more than one in five adults in England (21%) smoked cigarettes in 2008. Those from routine and manual backgrounds were about twice as likely to smoke as those from managerial or professional backgrounds (29% versus 14%) (NHS Information Centre 2010). Smoking is responsible for at least half of the excess risk of premature death faced by middle-aged men in manual occupations, compared to those in professional groups (Jha et al. 2006). The health of babies born into lower-income households is
also disproportionately affected by second-hand smoke (see below). In addition, as they are growing up in an environment where smoking is the norm, they are more likely to take up tobacco use in adolescence (British Medical Association 2007; Royal College of Physicians 2010).

c) Exposure to secondhand smoke in the home causes an estimated 11,000 deaths a year in the UK from lung cancer, stroke and ischaemic heart disease (Jamrozik 2005). It is estimated that 5 million children under the age of 16 are exposed to secondhand smoke at home (British Medical Association 2007). Children’s vulnerability to tobacco smoke has been well documented. A recent UK report estimated that passive smoking caused 22,600 new cases of wheeze and asthma, 121,400 new cases of middle ear infection and 40 sudden infant deaths (Royal College of Physicians 2010).

d) About two thirds (67%) of people who smoke say they would like to quit and three quarters of current smokers say they have tried to stop in the past. In 2008, about a quarter (26%) had tried in the past year (Lader 2009). This may indicate how difficult it is to quit. It is estimated that 4% of people who quit without using behavioural or pharmacological therapy are successful for a year or longer (Hughes et al. 2004). About 15% of people who quit using the NHS Stop Smoking Service are still not smoking a year later (Ferguson et al. 2005).

e) Those from routine and manual groups take in more nicotine from cigarettes than more affluent people (Jarvis 2010). This increases their exposure to the other toxins in tobacco smoke and, thus, increases their risk of smoking-related disease. Higher nicotine exposure can also make it harder for them to quit – and they are more likely to cut down first rather than quit smoking ‘abruptly’
(Siahpush et al. 2010). As a result, people on a low income may need additional support to quit (The Marmot Review Team 2010).

f) The harm associated with cigarette smoking is almost entirely caused by the toxins and carcinogens found in tobacco smoke – and not the nicotine (Royal College of Physicians 2007). However, although smokeless tobacco is less harmful, the risks vary between products and are not inconsequential (Royal College of Physicians 2007).

g) Nicotine is the addictive chemical that makes it difficult to quit tobacco. The UK’s Medicines and Healthcare Products Regulatory Agency (MHRA) has given marketing authorisation for medicinal products containing nicotine that are used for cutting down, temporary abstinence or harm reduction from smoking. These products are known as nicotine replacement therapy. A number of other, non-tobacco-based nicotine products, available in the UK, are not regulated. These products, which include ‘electronic cigarettes’, are currently being considered by the MHRA.

4 The guidance

Public health guidance will be developed according to NICE processes and methods. For details see section 5.

This document defines exactly what this guidance will (and will not) examine, and what the guidance developers will consider. The scope is based on a referral from the DH (see appendix A).

1 The Medicines and Healthcare Products Regulatory Agency is currently overseeing a programme of research and information gathering on the regulation of nicotine-containing products. The results of the programme will be announced in Spring 2013 (For further information, visit www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON065617)
4.1 **Who is the focus?**

4.1.1 **Groups that will be covered**

The guidance will cover people of all ages who:

- want to quit smoking but feel unable to do so ‘abruptly’ (that is, they want to cut down before quitting)
- are not willing or able to quit, but want to reduce the harm that smoking is doing to their health (or to the health of those around them)
- want to quit smoking but are not willing or able to stop using nicotine
- want to stop smoking temporarily, for example, while at work.

The guidance will focus, in particular, on groups who are more likely to smoke (this includes those in routine and manual occupations).

4.1.2 **Groups that will not be covered**

The guidance will not cover pregnant women.

4.2 **Approaches**

4.2.1 **Approaches that will be covered**

The guidance will cover the following tobacco harm-reduction approaches (see section 2[d] for a definition):

a) Pharmacotherapies that are (or will be) licensed for cutting down, temporary abstinence or harm reduction.\(^2\)

b) Other non-tobacco ‘nicotine-containing products’\(^3\), such as ‘electronic nicotine delivery systems’ (sometimes known as ‘electronic cigarettes’ or ‘e-cigarettes’) and topical gels.

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\(^2\) Nicotine replacement therapy (NRT) products are the only pharmacotherapy currently with UK marketing authorisation (that is, they are ‘licensed’) for cutting down, temporary abstinence or harm reduction. For further details, see [www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON065626](http://www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON065626). It is possible that other products may be licensed before consultation begins on the draft NICE guidance, in which case these will be considered.
c) Behavioural support, counselling or advice for individuals or groups.

d) Self-help.

4.2.2 Approaches that will not be covered

The guidance will not include:

- Any products containing tobacco. This includes products which are claimed to deliver reduced levels of toxicity (such as 'low tar' cigarettes) or which reduce exposure to tobacco smoke, for example, by warming instead of burning it.

- Products that are smoked that do not contain tobacco, such as herbal cigarettes.

- Smokeless tobacco products⁴ such as gutka, or paan. (These products are associated with a number of health problems and are the focus of NICE guidance in development – see section 6.)


- Alternative or complementary therapies, such as hypnotherapy or acupuncture. (Note: non-NHS services, including complementary therapies, were reviewed for NICE public health guidance 10 on ‘Smoking cessation services’.)

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³ The Medicines and Healthcare Products Regulatory Agency is currently overseeing a programme of research and information gathering on the regulation of nicotine-containing products. The results of the programme will be announced in Spring 2013 (For further information, visit www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON065617)

⁴ Smokeless tobacco is any product containing tobacco that is placed in the mouth or nose and not burned.
4.3 Key questions and outcomes

Below are the overarching questions that will be addressed, along with some of the outcomes that would be considered as evidence of effectiveness:

**Question 1:** How effective and cost effective are pharmacotherapies in helping people to:
- cut down smoking before quitting
- cut down or abstain from smoking, temporarily or indefinitely?

How effective and cost effective are different combinations of NRT products?

**Question 2:** How effective and cost effective are ‘nicotine-containing products’ in helping people to:
- cut down smoking before quitting
- cut down or abstain from smoking, temporarily or indefinitely?

**Question 3:** Which kinds of behavioural support, counselling, advice or self-help (with or without pharmacotherapy) are effective and cost effective in helping people to:
- cut down smoking before quitting
- cut down or abstain from smoking, temporarily or indefinitely.

**Question 4:** Do some tobacco harm-reduction approaches have a differential impact on different groups (for example, people of different ages, gender, socioeconomic status or ethnicity)?

**Question 5:** Are there any unintended consequences from adopting a tobacco harm-reduction approach, for example, does it deter people from trying to stop smoking?

**Question 6:** How can practitioners deliver messages about tobacco harm reduction without weakening the impact of advice about the benefits of stopping smoking?
Question 7: What factors might act as barriers or facilitators to tobacco harm-reduction approaches?

Question 8: Does long-term use of pharmacotherapies or ‘nicotine-containing products’ have any ill-effects on health?

Expected outcomes:
- Continuous abstinence for 6 or 12 months or longer (biochemically validated or self-reported).
- Abstinence at 6 or 12 months or later (biochemically validated or self-reported).
- A sustained reduction for 6 or 12 months or longer (biochemically validated or self-reported)\(^5\).

4.4 Status of this document

This is the final scope, incorporating comments from a 4-week consultation.

5 Further information


6 Related NICE guidance

Published


\(^5\) Please note: these tests only provide limited information, particularly when used to assess abstinence over differing lengths of time.


**Under development**

Smokeless tobacco: South Asians. NICE public health guidance (publication expected September 2012).

Smoking cessation in secondary care. NICE public health guidance (publication expected Summer 2013).
Appendix A Referral from the Department of Health

In February 2010 the Department of Health asked NICE:

'To produce public health guidance for PCTs and NHS smoking cessation services on the use of harm-reduction approaches to smoking cessation.'
Appendix B Potential considerations

It is anticipated that the Programme Development Group (PDG) will consider the following issues in relation to the approaches considered:

- Whether the approach is based on an underlying theory or conceptual model.
- The relative effectiveness and cost effectiveness of different approaches.
- Critical elements. For example, whether effectiveness and cost effectiveness varies according to:
  - the diversity of the population (for example, in terms of the person’s age, gender or ethnicity)
  - the status of the person delivering it and the way it is delivered
  - its frequency, length and duration, where it takes place and whether it is transferable to other settings
  - its intensity.
- Any trade-offs between equity and efficiency.
- Any techniques that may be more (or less) effective, for example, drawing up a schedule to help someone reduce the amount they smoke.
- Any factors that prevent – or support – effective implementation.
- Any adverse or unintended effects, such as encouraging people only to cut down smoking instead of stopping completely.
- Current practice.
- Availability and accessibility for different groups.
Appendix C References


Department of Health (2010a) Equity and excellence: liberating the NHS. London: Department of Health


Department of Health (2011c) No health without mental health: a cross-government mental health strategy for people of all ages. London: Department of Health


