

# Smoking: harm reduction

Public health guideline

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[www.nice.org.uk/guidance/ph45](http://www.nice.org.uk/guidance/ph45)

## Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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This guideline partially replaces PH10.

This guideline is the basis of QS92.

## Overview

This guideline covers reducing harm from smoking. It aims to help people, particularly those who are highly dependent on nicotine, who:

- may not be able (or do not want) to stop smoking in one step
- may want to stop smoking, without necessarily giving up nicotine
- may not be ready to stop smoking, but want to reduce the amount they smoke.

It recommends harm-reduction approaches which may or may not include temporary or long-term use of licensed nicotine-containing products.

NICE has also produced guidelines on [stop smoking services](#) and [smoking: brief interventions and referrals](#).

In July 2013, changes were made to reflect the MHRA decision that all nicotine-containing products should be regulated. For further details, see the [MHRA website](#).

## Who is it for?

- Commissioners, managers and practitioners in public health, especially those involved in advice about smoking cessation
- Organisations providing education and training
- Manufacturers and retailers of licensed nicotine-containing products

# Introduction: scope and purpose of this guidance

## What is this guidance about?

Nicotine inhaled from smoking tobacco is highly addictive. But it is primarily the toxins and carcinogens in tobacco smoke – not the nicotine – that cause illness and death. The best way to reduce these illnesses and deaths is to stop smoking. In general, [stopping in one step](#) (sometimes called 'abrupt quitting') offers the best chance of lasting success (see NICE guidance on [smoking cessation](#)). However, there are other ways of reducing the harm from smoking, even though this may involve continued use of nicotine.

This guidance is about helping people, particularly those who are highly dependent on nicotine, who:

- may not be able (or do not want) to [stop smoking in one step](#)
- may want to stop smoking, without necessarily giving up nicotine
- may not be ready to stop smoking, but want to reduce the amount they smoke.

This guidance recommends harm-reduction approaches which may or may not include temporary or long-term use of [licensed nicotine-containing products](#). (See [box 1](#) for details.)

The recommendations cover:

- Raising awareness of licensed nicotine-containing products.
- [Self-help materials](#).
- Choosing a harm-reduction approach.
- [Behavioural support](#).
- Advising on licensed nicotine-containing products.
- Supplying licensed nicotine-containing products.
- Follow-up appointments.
- Supporting [temporary abstinence](#).

- People in [closed institutions](#).
- Staff working in closed institutions.
- Commissioning [stop smoking services](#).
- Education and training for practitioners.
- [Point-of-sale](#) promotion of licensed nicotine-containing products.
- Manufacturer information on licensed nicotine-containing products.

This guidance does not cover pregnant women or maternity services. (See [Related NICE guidance](#) for other recommendations that may be relevant to tobacco harm-reduction among this group.)

In addition, this guidance does not cover 'reduced exposure cigarettes', 'smokeless tobacco' or any other products containing tobacco that may be used as a means of 'harm reduction'.

The guidance complements but does not replace NICE guidance on smoking cessation. (For further details see [Related NICE guidance](#).)

See [About this guidance](#) for details of how the guidance was developed and its current status.

## Who is this guidance for?

The guidance is for: commissioners, managers and practitioners with public health as part of their remit, organisations that provide education and training, manufacturers and retailers of licensed nicotine-containing products. It is especially aimed at those involved in providing advice about stopping smoking, smoking cessation services within the NHS, local authorities and the wider public, private, voluntary and community sectors. The guidance may also be of interest to members of the public, especially people who want to stop or reduce the amount they smoke.



# 1 Recommendations

The Programme Development Group (PDG) considers that the recommended approaches are cost effective.

The evidence underpinning the recommendations is listed in [The evidence](#).

See also [What evidence is the guidance based on?](#) for the evidence reviews, economic modelling report and expert papers.

For the research recommendations and gaps in research see [Recommendations for research and Gaps in the evidence](#).

## Context

[Stop smoking services](#) provide highly cost-effective interventions to help people stop smoking<sup>[1]</sup> and any investment in the harm-reduction approaches covered by this guidance should not detract from their provision. Rather, the recommendations in this guidance are intended to support and extend the reach and impact of existing services.

Although existing evidence is not clear about the health benefits of [smoking reduction](#), those who reduce the amount they smoke are more likely to stop smoking eventually, particularly if they are using [licensed nicotine-containing products](#).

## Definitions

The recommendations use the phrase 'licensed nicotine-containing products' to cover products containing nicotine that have 'marketing authorisation' for use as a smoking cessation aid and for tobacco harm-reduction<sup>[2]</sup> from the Medicines and Healthcare products Regulatory Agency (MHRA). Authorisation by the MHRA ensures they are effective, deliver nicotine [safely](#) and are manufactured to a consistent [quality](#).

Using these products can make it easier for people to [cut down before stopping](#), [reduce their smoking](#) or [abstain](#). They can also help reduce compensatory smoking behaviour, such as inhaling smoke more deeply to compensate for smoking fewer cigarettes.

## Box 1 Harm reduction approaches covered by the guidance

- **Stoppingsmoking**, but using one or more licensed nicotine-containing products as long as needed to prevent relapse
- **Cutting down prior to stopping smoking** (cutting down to quit)
  - with the help of one or more licensed nicotine-containing products (the products may be used as long as needed to prevent relapse)
  - without using licensed nicotine-containing products.
- **Smokingreduction**
  - with the help of one or more licensed nicotine-containing products (the products may be used as long as needed to prevent relapse)
  - without using licensed nicotine-containing products.
- Temporary abstinencefromsmoking
  - with the help of one or more licensed nicotine-containing products
  - without using licensed nicotine-containing products.

## Whose health will benefit?

The approaches covered by this guidance are aimed at people who:

- may not be able (or do not want) to stop smoking in one step
- may want to stop smoking, without necessarily giving up nicotine
- may not be ready to stop smoking, but want to reduce the amount they smoke.

The recommendations are particularly relevant to people who are highly dependent on nicotine and groups where smoking prevalence is higher than average. Examples include: people with mental illness, people from lower socioeconomic groups and people from lesbian, gay and bisexual and trans-gendered groups. They are also relevant to people who are less likely to use services focusing on abrupt cessation.

## Recommendation 1 Raising awareness of licensed nicotine-containing products

### Who should take action?

- National, subnational and local organisations responsible for public health and tackling tobacco use. This includes:
  - professional bodies with a healthcare or public health responsibility
  - subnational tobacco control organisations
  - stop smoking services
  - statutory agencies such as health and wellbeing boards and local authorities
  - voluntary and community sector organisations.

### What action should they take?

- Raise public awareness of the harm caused by smoking and secondhand smoke. Provide information on how people who smoke can reduce the risk of illness and death (to themselves and others) by using one or more licensed nicotine-containing products. Explain that they could be used as a partial or complete substitute for tobacco, either temporarily or in the long-term.
- Provide this information in a range of formats and languages for different target groups.

- Ensure it includes the following information:
  - smoking causes a range of diseases and conditions including cancer, chronic obstructive pulmonary disease (COPD) and cardiovascular disease (CVD)
  - most health problems are caused by other components in tobacco smoke, **not** by the nicotine
  - smoking is highly addictive largely because it delivers nicotine very quickly to the brain and this makes stopping smoking difficult
  - nicotine levels in licensed nicotine-containing products are much lower than in tobacco, and the way these products deliver nicotine makes them less addictive than smoking tobacco
  - licensed nicotine-containing products are an effective way of reducing the harm from tobacco for both the person smoking and those around them
  - it is safer to use licensed nicotine-containing products than to smoke
  - nicotine replacement therapy (NRT) products<sup>[3]</sup> have been demonstrated in trials to be safe to use for at least 5 years
  - there is reason to believe that lifetime use of licensed nicotine-containing products will be considerably less harmful than smoking
  - little direct evidence is available on the effectiveness, quality and safety of nicotine-containing products that are not regulated by the MHRA<sup>[3]</sup>. However, they are expected to be less harmful than tobacco.
- Provide information on how to obtain and use licensed nicotine-containing products including:
  - what forms they take
  - how to use them effectively when trying to stop or reduce smoking (either as a partial or complete substitute for smoking)
  - long-term use to reduce the risk of relapsing
  - where to obtain them (including from GPs)
  - the cost compared with smoking.

## Recommendation 2 Self-help materials

### Who should take action?

- National, subnational and local organisations responsible for public health and tackling tobacco use. This includes:
  - professional bodies with a public health responsibility
  - subnational tobacco control organisations
  - stop smoking services
  - statutory agencies such as health and wellbeing boards and local authorities
  - voluntary and community sector organisations.
- Organisations providing practitioners with training in reducing the harm caused by smoking, such as the [National Centre for Smoking Cessation and Training \(NCSCT\)](#).
- Telephone helplines and Internet support sites aimed at helping people to stop smoking.
- Manufacturers of licensed nicotine-containing products.
- Retailers.

### What action should they take?

- Provide [self-help materials](#) in a range of formats and languages, tailored to meet the needs of groups where smoking prevalence and tobacco dependency is high. For example, these may include people with a mental illness, people from lower socioeconomic groups and people from lesbian, gay and bisexual and trans-gendered groups. Also target groups that are less likely to access services focusing on abrupt cessation.

- Self-help materials should include:
  - details about the harm-reduction approaches outlined in [box 1](#)
  - an emphasis on the fact that stopping smoking will improve health far more than continuing to smoke, even at a reduced rate
  - advice on how to plan a schedule (see [recommendation 4](#))
  - advice on strategies to cut down and gradually stop or reduce the amount they smoke (see [recommendation 4](#))
  - benefits of using licensed nicotine-containing products to reduce the harm from smoking (see [recommendation 1](#))
  - type of licensed nicotine-containing products available (the [MHRA website](#) is the most up-to-date source)
  - how to use licensed nicotine-containing products effectively to manage the cravings, mood swings and other effects of nicotine dependency and to prevent relapse
  - where licensed nicotine-containing products can be purchased and who is able to supply or prescribe them
  - where to get further help and support.
- Use social media websites as a means of promoting self-help materials.

## Recommendation 3 Choosing a harm-reduction approach

### Who should take action?

- Stop smoking advisers.

- Health and social care practitioners and others with a public health responsibility, in particular those working in:
  - primary and secondary healthcare
  - pharmacies
  - local authorities
  - residential and domiciliary care.
- Community and voluntary organisations.
- Telephone helplines and Internet support sites aimed at helping people to stop smoking.

## What action should they take?

- Identify people who smoke and advise them to stop smoking in one step as the best approach. See NICE guidance on [smoking cessation services](#) and [brief interventions and referral for smoking cessation](#) and the Department of Health's [Stop smoking service delivery and monitoring guidance 2011/12](#).
- If someone does not want, is not ready or is unable to stop smoking in one step, ask if they would like to consider a harm-reduction approach. If they agree, help them to identify why they smoke, their smoking triggers and their smoking behaviour. Use this information to work through the harm-reduction approaches outlined in [box 1](#).
- Use professional judgement to suggest which approach(es) might be most suitable, based on the person's smoking behaviour, experience of previous quit attempts and their health and social circumstances. Briefly discuss the merits of each approach to help them choose.
- Ensure people know that licensed nicotine-containing products (such as nicotine patches, gum, or spray) make it easier to cut down prior to stopping, or to reduce the amount they smoke. Explain that using these products also helps avoid [compensatory smoking](#) and increases the chances of stopping in the longer term.
- Recommend one or more licensed nicotine-containing products. If possible, supply or prescribe these products. Otherwise, encourage people to ask their GP or pharmacist for them, or tell them where they can buy the products themselves (see [recommendation 6](#)).
- Advise people that they can continue to use licensed nicotine-containing products in the long term, rather than risk relapsing after they have stopped, or reduced their smoking.

- If more intensive support is required, offer a referral to stop smoking services. These services provide [pharmacotherapies](#) and more comprehensive support and advice about harm reduction and stopping smoking in the longer term (see recommendations 4–7).

## Recommendation 4 Behavioural support

### Who should take action?

- Stop smoking advisers.
- Health and social care practitioners and others with a public health responsibility who are trained to provide [behavioural support](#) to help people stop smoking.
- Telephone helplines and Internet support sites aimed at helping people to stop smoking.

### What action should they take?

- Find out about the person's smoking behaviour and level of nicotine dependence by asking how many cigarettes they smoke – and how soon after waking. (See the Department of Health's [Stop smoking service delivery and monitoring guidance 2011/12.](#))
- Use the information gathered to help people set goals and discuss reduction strategies. This may include increasing the time interval between cigarettes, delaying the first cigarette of the day or choosing periods during the day, or specific occasions, when they will not smoke.
- Help people who are cutting down prior to stopping smoking to set a specific quit date. The quit date should normally be within 6 weeks from the start of receiving behavioural support, although the sooner the better. Help them to develop a schedule detailing how much they aim to cut down (and when) in the lead up to that date.
- Help people who are aiming to reduce the amount they smoke (but not intending to stop) to set a date when they will have achieved their goal. Help them to develop a schedule for this or to identify specific periods of time (or specific events) when they will not smoke.
- Tell people who are not prepared to stop smoking that the health benefits from smoking reduction are unclear. However, advise them that if they reduce their smoking now they are more likely to stop smoking in the future. Explain that this is particularly true if they use licensed nicotine-containing products to help reduce the amount they smoke.
- Where necessary, advise people how to use licensed nicotine-containing products effectively.



- Offer follow-up appointments to review progress and support people who have adopted a harm-reduction approach (see [recommendation 7](#)).

## Recommendation 5 Advising on licensed nicotine-containing products

### Who should take action?

- Stop smoking advisers.
- Health and social care practitioners and others with a public health responsibility, in particular those working in:
  - primary and secondary healthcare
  - pharmacies
  - local authorities
  - residential and domiciliary care.
- Community and voluntary organisations.
- Telephone helplines and Internet support sites aimed at helping people to stop smoking.

### What action should they take?

- Reassure people who smoke that licensed nicotine-containing products are a safe and effective way of reducing the amount they smoke. Advise that they can be used as a complete or partial substitute for tobacco, either in the short or long term. Reassure them that it is better to use these products and reduce the amount they smoke than to continue smoking at their current level.
- Explain how to use licensed nicotine-containing products correctly. This includes ensuring people know how to achieve a sufficiently high dose to control cravings, prevent compensatory smoking and achieve their goals on stopping or reducing the amount they smoke.
- Explain that people can use one product on its own or a combination of different ones. Advise them that using more than one product is more likely to be successful, particularly for more dependent smokers. (Some products are fast acting and deal better with immediate cravings, whereas others are long acting and provide a steadier supply of nicotine.)

- Advise people to replace each cigarette with a licensed nicotine-containing product, for example, a lozenge or piece of gum. Ideally they should use this **before** the usual time they would have had the cigarette, to allow for the slower nicotine release from these products.
- Advise people that licensed nicotine-containing products can be used for as long as they help reduce the desire to smoke – and for the long term, if necessary, to prevent relapse.
- Tell people that some nicotine-containing products are not regulated by the MHRA<sup>[4]</sup> and, therefore, their effectiveness, safety and quality cannot be assured. Also advise them that these products are likely to be less harmful than cigarettes.

## Recommendation 6 Supplying licensed nicotine-containing products

### Who should take action?

- Stop smoking advisers.
- GPs and other healthcare professionals with prescribing rights.
- Practitioners named by patient group directives.
- Prison health service staff.
- Custody officers, police force medical examiners and related healthcare professionals.

### What action should they take?

- Offer all types of licensed nicotine-containing products to people who smoke, as part of a harm-reduction strategy (either singly or in combination). Take into account their preference and level of dependence. As an example, patches could be offered with gum or lozenges.
- Offer licensed nicotine-containing products, as necessary, to help prevent a relapse among people who have stopped smoking or reduced the amount they smoke. (This includes people who have stopped smoking in one step or by cutting down prior to stopping.)

## Recommendation 7 Follow-up appointments

### Who should take action?

- Stop smoking advisers.

- Health and social care practitioners who are trained to provide behavioural support to help people stop smoking.

## What action should they take?

- Follow people up to see whether they have achieved their goal(s). If those who set out to reduce the amount they smoke (or to abstain temporarily) have been successful, assess their motivation to maintain that level, to further reduce the amount they smoke or to stop smoking.
- Use professional judgement about the number, timing and frequency of appointments offered.
- At appropriate intervals, measure exhaled carbon monoxide level to gauge people's progress and help motivate them. Ask them whether daily activities, for example climbing the stairs or walking uphill, have become easier. Use this feedback to prompt discussion about the benefits of reducing their smoking and, where appropriate, to encourage a further reduction or stopping completely.
- Encourage people who have not achieved their goals to try again. Also discuss whether they would like to continue using the same licensed nicotine-containing product or try a different one (or a different combination of products).

## Recommendation 8 Supporting temporary abstinence

### Who should take action?

- Stop smoking advisers.
- Health and social care practitioners and others with a public health responsibility, in particular those working in:
  - primary and secondary healthcare
  - pharmacies
  - local authorities
  - residential and domiciliary care.
- Community and voluntary organisations.
- Telephone helplines and Internet support sites that help people to stop smoking.

## What action should they take?

- Offer people who want (or need) to abstain temporarily on a short-, medium- or longer-term basis advice on how to do this<sup>[5]</sup>. Include information about the different types of licensed nicotine-containing products and how to use them (see [recommendation 5](#)). Where possible, prescribe them (see [recommendation 6](#)).
- Offer behavioural support to people who want (or need) to abstain temporarily. Support may be provided in one-to-one or group sessions by specialist services (see [recommendation 4](#)). It could include discussing why it is important to reduce the harm caused by smoking (to others as well as themselves). It could also include encouraging people to consider other times or situations when they could abstain.
- Offer follow-up appointments (see [recommendation 7](#)).

## Recommendation 9 People in closed institutions

### Who should take action?

Managers of services where smoking is not permitted such as:

- secure mental health units
- immigration retention centres
- custodial sites such as prisons and police stations.

### What action should they take?

- Incorporate management of smoking in the care plan of people in [closed institutions](#) who smoke.
- Ensure those giving harm-reduction advice in situations where smoking is not permitted are trained to the same standard as the level required for the [National Centre for Smoking Cessation and Training](#) stage 2 assessment (or the equivalent). This includes people working in mental health and prison health services.
- Ensure staff recognise that some people perceive smoking as an integral part of their lives. Also ensure staff recognise the issues arising from enforced, as opposed to voluntary, abstinence.

- Ensure staff recognise how the closed environment may restrict the techniques and coping mechanisms that people would normally use to stop smoking or reduce the amount they smoke. Provide the support required for their circumstances (see recommendations 3–7). This includes prescribing or supplying licensed nicotine-containing products.
- Ensure staff understand that, if someone reduces the amount they smoke (or stops completely), this can impact on their need for psychotropic and some other medications (see UK [Medicines information](#) for further details). Ensure arrangements are in place to adjust their medication accordingly.

## Recommendation 10 Staff working in closed institutions

### Who should take action?

Managers of services where smoking is not permitted such as:

- secure mental health units
- immigration retention centres
- custodial sites such as prisons and police stations.

### What action should they take?

- Ensure staff with health and social care or custodial responsibilities do not smoke during working hours in locations where the people in their care are not allowed to smoke.
- Ensure systems are in place for staff who smoke to receive advice and guidance on how to stop smoking in one step (see [recommendation 3](#), also see NICE guidance on [workplace interventions to promote smoking cessation](#)). If, after discussion, the person does not want (or does not feel able) to do this, ask them if they would like to consider a harm-reduction approach, as outlined in [box 1](#).
- Encourage staff to use stop smoking services to stop or reduce the amount they smoke.
- Encourage staff who do not want to stop smoking to use licensed nicotine-containing products to help them abstain immediately before and while on duty.

## Recommendation 11 Commissioning stop smoking services

### Who should take action?

Commissioners of stop smoking services.

### What action should they take?

- Ensure investment in harm-reduction approaches does not detract from, but supports and extends the reach and impact of, existing stop smoking services. (The latter provide highly cost-effective interventions to help people stop smoking in one step<sup>[1]</sup>.)
- Develop smoking cessation referral and treatment pathways to ensure a range of approaches and interventions are available to support people who opt for a harm-reduction approach (see [box 1](#)).
- Ensure the providers of stop smoking and other behaviour-change services offer people who smoke the harm-reduction approaches outlined in [box 1](#). Ensure services are available in the community, as part of primary and secondary healthcare and on offer from local authorities.
- Develop activity and outcome measures to assess the performance of service providers involved in supporting people who are using harm-reduction approaches. Measures of activity could include:
  - numbers attending the services (to allow comparison with the numbers attending before harm-reductions options were offered)
  - classifying the harm-reduction approaches used (see [box 1](#))
  - client characteristics (such as demographic data, cigarette usage, level of dependency and previous quit attempts)
  - type and amount of licensed nicotine-containing products supplied or prescribed, and over-the-counter sales of these products
  - number of people setting a quit date.

- Ensure service specifications include a requirement that providers of stop smoking services offer licensed nicotine-containing products on a long-term basis to help prevent a relapse among people who have stopped smoking. Long-term use should also be available to help people maintain a lower level of consumption.
- Ensure service specifications include a requirement that staff working in stop smoking services are trained to the National Centre for Smoking Cessation and Training stage 2 assessment level (or the equivalent).

## Recommendation 12 Education and training for practitioners

### Who should take action?

- Health Education England and local education and training boards.
- Royal medical and nursing colleges and other professional bodies.
- Organisations providing training on the harm caused by smoking, such as the National Centre for Smoking Cessation and Training.
- Commissioners, providers and managers of stop smoking services.

### What action should they take?

- Include the principles and practice of tobacco harm reduction, as outlined in this guidance, within all relevant curricula.
- Ensure service specifications and service-level agreements state that staff are trained to National Centre for Smoking Cessation and Training stage 2 assessment level (or the equivalent). Staff should also undertake continuing professional development on a regular basis.

## Recommendation 13 Point-of-sale promotion of licensed nicotine-containing products

### Who should take action?

Manufacturers and retailers of licensed nicotine-containing products, including tobacco retailers.

## What action should they take?

- Encourage people who smoke to consider the harm-reduction approaches outlined in [box 1](#).
- Display licensed nicotine-containing products in shops and supermarkets, and on websites selling cigarettes and tobacco products.

## Recommendation 14 Manufacturer information on licensed nicotine-containing products

### Who should take action?

Manufacturers of licensed nicotine-containing products.

### What action should they take?

- Provide clear, unambiguous and accurate information to the consumer on the health risks of any licensed nicotine-containing product, as compared to continuing to smoke and not smoking. This should include details on long-term use.
- Provide simple, clear instructions on how to use licensed nicotine-containing products to support the harm-reduction approaches outlined in [box 1](#).
- Consider providing information on the outer packaging as well as in the enclosed leaflet.
- Package products in a way that makes it as easy as possible for people to take the recommended dose for the right amount of time.

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<sup>[1]</sup> See NICE guidance on [smoking cessation services](#).

<sup>[2]</sup> At the time of publication (June 2013), only [nicotine replacement therapy](#) (NRT) products were licensed by the Medicines and Healthcare products Regulatory Agency (MHRA). A decision from the MHRA on the regulation of other [nicotine-containing products](#) (for example, electronic cigarettes and topical gels) was pending. The MHRA has since issued a decision that all nicotine-containing products should be regulated once the European Commission's revised Tobacco Products Directive comes into effect in the UK (this is expected to be in 2016). In the meantime, the UK government will encourage applications for medicines licences for nicotine-containing products and will make best use of the flexibilities within the existing framework to enable licensed products to be available. For further details, see the [MHRA website](#).



<sup>[3]</sup> At the time of publication (June 2013), NRT products were the only licensed nicotine-containing products. The MHRA has since issued a decision that all nicotine-containing products should be regulated once the European Commission's revised Tobacco Products Directive comes into effect in the UK (this is expected to be in 2016). In the meantime, the UK government will encourage applications for medicines licences for nicotine-containing products and will make best use of the flexibilities within the existing framework to enable licensed products to be available. For further details, see the MHRA website.

<sup>[4]</sup> Unlicensed products that are currently being marketed, such as electronic cigarettes, and products new to the market will need a medicines licence once the European Commission's revised Tobacco Products Directive comes into effect in the UK (this is expected to be in 2016). In the meantime, the UK government will encourage applications for medicines licences for nicotine-containing products and will make best use of the flexibilities within the existing framework to enable licensed products to be available. For further details, see the MHRA website.

<sup>[5]</sup> People might temporarily abstain in the short-term to comply with smokefree policies, for example, at work. Medium-term temporary abstinence may occur when admitted to hospital. Long-term temporary abstinence might occur during a custodial sentence.

## 2 Public health need and practice

### Introduction

Tobacco smoking remains the single greatest cause of preventable illness and early death in England, accounting for 79,100 deaths among adults aged 35 and over in 2011 (NHS Information Centre 2012). The effects of smoking are not limited to the smoker, but also have implications for those around them. Secondhand smoke is a human carcinogen and no safe level of exposure has been identified (US Surgeon General 2006).

Treating smoking-related illnesses cost the NHS in England an estimated £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 NHS costs (based on the figure above) and loss of productivity due to illness and early death (Nash and Featherstone 2010).

Although smoking prevalence has fallen sharply in the past 30 years, there is some evidence that this decline is levelling off. In 2010, 1 in 5 adults in England (20%) smoked cigarettes, with prevalence highest among those aged 20–24 and 25–34 (28% and 26% respectively) (NHS Information Centre 2012).

People from routine and manual occupational backgrounds are almost twice as likely to smoke as those from managerial or professional backgrounds (27% versus 13%) (NHS Information Centre 2012). 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).

Smoking prevalence is particularly high among some groups. This includes: lesbian, gay, bisexual and transgendered people, those with mental health problems, people in prison and those who are homeless. For example, a recent survey of smoking prevalence among gay and bisexual men found that just over 35% smoked cigarettes, including 48% of those who were HIV-positive (Hickson et al. 2007).

There is less UK data available on lesbian women. But small surveys in the West Midlands indicate that 42% to 55% smoke – twice as many as the West Midlands average for women (Meads et al. 2007).

A third (33%) of people with mental health problems (McManus et al. 2010) and more than two-thirds (70%) of patients in psychiatric units smoke tobacco (Jochelson and Majrowski 2006). Recent studies show that people with mental health problems are just as likely to want to stop smoking as the general population – and are able to stop when offered evidence-based support. However, support is not always available (Jochelson and Majrowski 2006; Siru et al. 2009).

## Children and young people

Exposure to secondhand smoke in the home affects an estimated 5 million children under the age of 16 (British Medical Association 2007). Children's vulnerability to tobacco smoke has been well documented. A 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).

The health of babies born into lower income households is disproportionately affected by secondhand smoke. In addition, as they are growing up in an environment where smoking is the norm, they are more likely to start smoking in adolescence (British Medical Association 2007; Royal College of Physicians 2010).

In England, the number of children admitted to hospital with asthma symptoms had been increasing on an annual basis up to 2007, when smoke-free legislation was introduced. It has been calculated that, in the first 3 years following implementation of the legislation, there were 6802 fewer admissions for asthma (Millett et al. 2013). Following this there has been a continuing annual reduction.

Legislation requiring all large shops and supermarkets to remove cigarette displays at the point-of-sale came into force in April 2012. The aim is to reduce the impact of tobacco marketing on children and young people and so reduce the likelihood of them taking up smoking. Newsagents and small stores will be able to display cigarettes until 2015.

## Stopping smoking

About two-thirds (67%) of people who smoke say they would like to stop and three-quarters (75%) of them say they have tried to do so in the past. In 2008, about a quarter (26%) of all smokers had tried in the past year (Lader 2009). Most people attempt to stop without help, but only around 4% of those who stop without using behavioural or pharmacological therapy are successful for a year or longer (Hughes et al. 2004). This compares with about 15% at 1 year of those who stop with support from NHS stop smoking services (Ferguson et al. 2005).

People often try many times before they eventually succeed in stopping smoking. People who have recently tried and failed are more likely to try again – but they are also more likely to relapse than those who have not tried recently. Relapse is associated with:

- nicotine dependence
- exposure to smoking cues
- craving
- withdrawal symptoms
- lack of help to stop (the latter could include medication, behavioural support or support from family and friends)

(Zhou et al. 2009).

## Reducing cigarette consumption

In 2009, 57% of smokers in England reported that they would find it difficult to go without smoking for a day. People in routine and manual occupational groups were more likely to say they would find this difficult compared to those in managerial and professional occupations (61% and 50% respectively). This difference was less pronounced in people who smoked 20 or more a day (83% and 78%) (NHS Information Centre 2011).

People from routine and manual groups are more likely to cut down first, rather than stop 'abruptly' (Siahpush et al. 2010). They inhale more nicotine from cigarettes and are more dependent than more affluent people. To take in more nicotine they inhale more deeply and smoke more of the cigarette, which increases their exposure to the other toxins in tobacco smoke and, thus, increases their risk of smoking-related disease. As a result, they are likely to find it harder to stop smoking and so may need additional support (Jarvis 2010).

The harm associated with cigarette smoking is almost entirely caused by the toxins and carcinogens found in tobacco smoke – not the nicotine (Royal College of Physicians 2007). However, nicotine is the main addictive chemical that makes it difficult to stop smoking.

Medicinal products containing nicotine which aim to help people cut down, temporarily abstain or reduce the harm caused by smoking have been given marketing authorisation by the UK's Medicines and Healthcare products Regulatory Agency (MHRA). At the time of publication (June 2013), only nicotine replacement therapy (NRT) products were licensed by the MHRA. A

number of other nicotine-containing products that are not tobacco-based, including electronic cigarettes, were being considered for regulation by the MHRA when this guidance was published.

The MHRA has since issued a decision that all nicotine-containing products should be regulated. Unlicensed products that are currently being marketed, such as electronic cigarettes, and products new to the market will need a medicines licence once the European Commission's revised Tobacco Products Directive comes into effect in the UK (this is expected to be in 2016). In the meantime, the UK government will encourage applications for medicines licences for nicotine-containing products and will make best use of the flexibilities within the existing framework to enable licensed products to be available. For further information, visit the [MHRA website](#).

## 3 Considerations

The Programme Development Group (PDG) took account of a number of factors and issues when developing the recommendations, as follows. Please note: this section does not contain recommendations. (See [Recommendations](#).)

### Background

- 3.1 Stopping smoking leads to considerable health benefits – for smokers and those around them. These include: a reduction in the incidence and severity of chronic smoking-related conditions such as cardiovascular and peripheral vascular disease, stroke, certain cancers, chronic obstructive pulmonary disease and asthma. In addition, the need for medications (for example, neuroleptics, bronchodilators and antibiotics) is reduced, leading to subsequent cost savings.
- 3.2 Eliminating children and young people's exposure to cigarette smoking removes smoking role models and may, in turn, reduce the likelihood that they will smoke. This is in addition to the health benefits they will gain from reducing their exposure to secondhand smoke.
- 3.3 Harm-reduction strategies can be applied at both the individual and population level. However the PDG recognised that wider strategies, not included here, also have a contribution to make. These include: regulation (for example, to restrict where smoking can take place); community-led strategies (such as making it the norm not to smoke); and pricing (so people stop or reduce the amount they smoke because it becomes too expensive).
- 3.4 People may temporarily abstain from smoking for a variety of reasons. Some may do this as a way of protecting the health of those around them – and reducing the harm to themselves. Sometimes people use it as a way of working towards stopping smoking. Smoke-free legislation requires abstinence in the workplace and work vehicles, in public places and on public transport. For people in [closed institutions](#), such as secure mental health units and prisons, [temporary abstinence](#) may be imposed for lengthy periods, even years.
- 3.5 Trained health professionals and [stop smoking services](#) can provide advice on how to reduce the amount smoked, or how to stop smoking temporarily. They

can also supply licensed nicotine-containing products. In each case, contact with someone who smokes will also provide an opportunity to start people thinking about longer-term harm-reduction approaches or stopping smoking altogether.

## Stop smoking services

- 3.6 The PDG considered forthcoming changes in how stop smoking services will be commissioned as they move under local authority control in England.
- 3.7 The PDG was aware that stop smoking services would need service provision guidance on the range of support to offer people. This includes support for those who are trying to stop smoking, but are unable (or unwilling) to give up nicotine. For example, decisions would be needed on how long to provide support, funding of licensed nicotine-containing products and appropriate targets.

## Nicotine-containing products

- 3.8 Evidence is available from studies with up to 5 years follow-up which suggests that 'pure' nicotine, in the form available in nicotine replacement therapy (NRT) products, does not pose a significant health risk. This is the case whether it is used as a substitute for, or in combination with, cigarettes. Although there is a lack of data on using NRT products beyond 5 years, expert opinion is that lifetime use will be considerably less harmful than smoking.
- 3.9 The PDG recognised that electronic cigarettes and similar products could, without regulation, be marketed in a way that may ultimately promote smoking. They were concerned that steps be taken to ensure that such products would be promoted in a way that was compatible with promotion of current licensed nicotine-containing products. The PDG was concerned that people might be put off by the cost of some licensed nicotine-containing products. Of even more concern was the lower price of illicit tobacco. The Group believed some people may be at risk of a relapse after their prescriptions for licensed nicotine-containing products run out if they find cigarettes (legal or contraband) are cheaper.
- 3.10 In recommending licensed nicotine-containing products, the PDG weighed the cost of prescriptions and health professionals' time against the risk of people not using the products.

- 3.11 In reality, people trying to stop smoking often do not receive enough support and do not use enough of one or more licensed nicotine-containing product (or use it inappropriately). This may also be a problem for people who are cutting down to quit or are reducing the amount they smoke.
- 3.12 The technology of nicotine delivery systems is likely to develop further in the near future and the PDG took this into account in its research recommendations.

## The evidence

- 3.13 A range of evidence was considered. Some international evidence was not directly applicable to the UK but provided an indication of potential outcomes.
- 3.14 There is limited evidence on the effectiveness of some elements of strategies to reduce the harm from smoking (this includes a lack of evidence on any unintended consequences). There were few robust studies evaluating the impact at population and subpopulation level.
- 3.15 The PDG was aware of several benefits that could result from different harm-reduction approaches which are difficult to capture or quantify. They include: improved physical and mental wellbeing and reduced exposure to smoke for non-smokers. For smokers who are ill, stopping or reducing the amount they smoke can mean they have more time to participate in therapeutic activities.
- 3.16 It is not clear whether there are any long-term health benefits from adopting a smoking reduction approach (apart from the fact that someone who reduces may ultimately stop smoking). As a consequence, the PDG made a research recommendation.
- 3.17 There is mixed evidence on the effectiveness of behavioural support without also using NRT as part of a harm-reduction approach. A limited number of studies evaluated interventions where the primary outcome was to help people cut down prior to stopping smoking (mainly cognitive behavioural therapy and counselling). These studies showed a positive effect. There were more studies evaluating interventions where the primary outcome was smoking reduction (mainly motivational interviewing and counselling). The majority of these studies found no effect. The PDG therefore exercised caution when making



recommendations about behavioural interventions.

## Economics

- 3.18 An economic model was developed to assess a wide range of harm-reduction approaches. The PDG noted that all 21 interventions modelled (apart from temporary abstinence with no support) were highly cost effective compared with 'no intervention'. This included 3 that were cost saving. However, harm reduction approaches are not as cost effective as smoking cessation.
- 3.19 Many people who smoke may choose to replace smoking with licensed nicotine-containing products and may continue to use these products for very long periods of time. A two-way sensitivity analysis was used to vary the effectiveness and duration of use of a licensed nicotine-containing product. The PDG noted that providing NCPs for a period of up to 10 years would be considered a cost effective use of NHS resources for an intervention which achieves a quit rate of 6%. This would fall to 5 years for an intervention with a 4% quit rate. A supplementary analysis assumed there were no benefits from smoking reduction (in terms of quality-adjusted life years [QALYs] and comorbidities), other than an increased likelihood of stopping at 6 months. The analysis showed that, as the effectiveness of an intervention diminishes, so the time during which it is considered cost effective to provide NCPs reduces. For example, the costs potentially outweigh the benefits, when the reduction rate is 6% or less and someone uses a licensed nicotine-containing product for 12 months or longer. When a reduction of 20% or more is achieved, the cost of extending licensed nicotine-containing product use to 2 years may be outweighed by the benefits. (The 6% and 20% figures provide a useful benchmark for judging cost effectiveness in relation to duration of use of NCPs.)
- 3.20 A harm-reduction approach can lead to a range of economic benefits. These include savings for employers by reducing the number of staff cigarette breaks and the amount of sickness absence caused by chronic, smoking-related conditions. (Reducing the latter will also reduce social care costs for local authorities.) In addition, there will be a reduction in the number of house fires leading to savings for fire and rescue services and local authorities. (The latter will make savings on insurance for social housing.) For more details see NICE guidance on [workplace interventions to promote smoking cessation](#). Also see NICE's local government briefing on [tobacco](#).

- 3.21 People who use NRT to stop smoking, but fail in their attempt, are more likely to use it again – should they try again. Modelling the cost effectiveness of using NRT for a single attempt to stop smoking, or treating subsequent attempts as independent may, therefore, underestimate its cost effectiveness.
- 3.22 When the impact of secondhand smoke was included in the economic model, the cost per QALY was reduced for all the interventions modelled. The other potential benefits associated with tobacco harm-reduction (listed above) were not included. This may have resulted in an underestimation of the benefits of reducing and stopping smoking. If, for example, a smoker lost an average of 2 days productivity per year (relative to a former smoker), then this would amount to nearly £4000 in lost productivity over 30 years. (This estimate includes discounting at 3.5% per year.)
- 3.23 The PDG noted that offering a smoking reduction approach could potentially attract people who would otherwise have carried on smoking as usual. Moreover, some of those who choose to reduce the amount they smoke may go on to stop. Conversely, offering services to help people reduce their smoking may discourage others from stopping. For harm reduction approaches to be cost effective, at least 2 more 'reducers' would be needed to offset each person who decided to reduce the amount they smoke, instead of stopping. A supplementary analysis assumed there were no benefits from smoking reduction (in terms of QALYs and comorbidities), other than an increased likelihood of stopping at 6 months. This analysis showed that for each potential 'quitter' lost, 6 more 'reducers' would be needed to offset the lost benefits.
- 3.24 As with any economic evaluation, the model has limitations. These include a lack of data on how comorbidities varied with recent or long-term abstinence, and the assumption that smokers use only one type of intervention in any one attempt to stop smoking.

## 4 Recommendations for research

The Programme Development Group (PDG) recommends that the following research questions should be addressed. It notes that 'effectiveness' in this context relates not only to the size of the effect, but also to cost effectiveness and duration of effect. It also takes into account any harmful/negative side effects.

All the studies below should report on (and across) different subgroups including, for example: black and minority ethnic groups, lesbian, gay and bisexual and transgender groups, people with mental health problems, prisoners and those who are disadvantaged.

- 4.1 How effective are licensed nicotine-containing products when used for more than one year? What is the impact of different doses and duration of use? What is the effect on health of long-term use? What are smokers' and practitioners' views on long-term use?
- 4.2 What impact does stopping smoking but continued use of licensed nicotine-containing products for over a year have on the onset and progression of smoking-related health conditions?
- 4.3 How effective are interventions to help people reduce the amount they smoke (without the intention of stopping)? How great are the health benefits of smoking reduction (by substituting some cigarettes with licensed nicotine-containing products) compared to stopping smoking? What proportion of people who reduce the amount they smoke go on to stop smoking? How soon after starting to reduce the amount they smoke do they stop completely?
- 4.4 How effective are different behavioural strategies in helping people to cut down, either in order to stop smoking or to reduce the amount they smoke? This should include an evaluation of behavioural support used on its own and evaluations of specific components of such support (such as scheduling). It should also include evaluations of different types of behavioural support and follow-up, delivered within a clearly defined harm-reduction intervention.
- 4.5 What impact do different marketing strategies, including mass-media campaigns, have on the number of people who adopt a harm-reduction approach? For example, compare the prices, placements and promotions for

different types of licensed nicotine-containing product.

- 4.6 Which harm-reduction approaches are smokers using and how do these correlate with smoking rates at the population level and among particular groups? For example, how do young people respond to the wider adoption of harm-reduction approaches? Do these approaches contribute to a continued reduction in smoking prevalence among young people, or does it make stopping smoking appear less important?
- 4.7 What are the most effective methods of monitoring smoking status at the population level? This includes the development of biomarkers that can distinguish between nicotine use and smoking in order to validate these measures.

More detail identified during development of this guidance is provided in [Gaps in the evidence](#).

## 5 Related NICE guidance

### Published

[Smokeless tobacco cessation: South Asian communities](#). NICE public health guidance 39 (2012)

[Quitting smoking in pregnancy and following childbirth](#). NICE public health guidance 26 (2010)

[School-based interventions to prevent smoking](#). NICE public health guidance 23 (2010)

[Preventing the uptake of smoking by children and young people](#). NICE public health guidance 14 (2008)

[Smoking cessation services](#). NICE public health guidance 10 (2008)

[Workplace interventions to promote smoking cessation](#). NICE public health guidance 5 (2007)

[Varenicline for smoking cessation](#). NICE technology appraisal 123 (2007)

[Brief interventions and referral for smoking cessation](#). NICE public health guidance 1 (2006)

### Under development

[Smoking cessation: acute, maternity and mental health services](#). NICE public health guidance. Publication expected November 2013.

## 6 Glossary

### Behavioural support for tobacco harm reduction

Practical advice and discussion about goal-setting, self-monitoring and dealing with the barriers to reducing the amount someone smokes or stopping altogether.

### Closed institution

A secure environment where people are detained.

### Compensatory smoking

Inhaling more deeply or smoking more of each cigarette to compensate for smoking fewer cigarettes.

### Cutting down prior to stopping (cut down to quit)

Someone gradually reduces the amount of tobacco they smoke with a view to stopping smoking within the next few months.

### Licensed nicotine-containing products

Nicotine-containing products that are licensed have been given marketing authorisation by the Medicines and Healthcare products Regulatory Agency (MHRA). At the time of publication (June 2013), nicotine replacement therapy (NRT) products were the only type of licensed nicotine-containing product. Since publication the MHRA has issued a decision that all nicotine-containing products should be regulated and this is expected to come into effect in 2016. In the meantime, the UK government will encourage applications for medicines licences for nicotine-containing products and will make best use of the flexibilities within the existing framework to enable licensed products to be available. For further details, see the [MHRA website](#).

### Nicotine-containing products

Products that contain nicotine but do not contain tobacco and so deliver nicotine without the harmful toxins found in tobacco. Some, such as nicotine replacement therapy (NRT), are regulated

by the MHRA (see licensed nicotine-containing products). Unlicensed products that are currently being marketed, such as electronic cigarettes, and products new to the market will need a medicines licence once the European Commission's revised Tobacco Products Directive comes into effect in the UK (this is expected to be in 2016). In the meantime, the UK government will encourage applications for medicines licences for nicotine-containing products and will make best use of the flexibilities within the existing framework to enable licensed products to be available. For further details, see the [MHRA website](#).

## Nicotine replacement therapy (NRT) products

Nicotine replacement therapy products are licensed for use as a smoking cessation aid and for harm reduction, as outlined in the British National Formulary. They include: transdermal patches, gum, inhalation cartridges, sublingual tablets and a nasal spray.

## Pharmacotherapies

This includes medication such as varenicline or bupropion, as well as nicotine replacement therapy (NRT) products.

## Point-of-sale

Point-of-sale interventions take place at the point where tobacco could be sold. Primarily, they aim to deter shopkeepers from making illegal sales. In this guidance, they aim to raise smokers' awareness of [licensed nicotine-containing products](#) as a replacement for cigarettes.

## Quality

In this guidance, the quality of [nicotine-containing products](#) refers to the consistency of nicotine delivery, lack of defects and structural integrity of the product.

## Safety

In this guidance, safety in relation to [nicotine-containing products](#) refers to the incidence of minor and major side effects.

## Self-help materials

Any manual or structured programme, in written or electronic format, that someone can use to try

to quit smoking or reduce the amount they smoke. These materials can be used without the help of health professionals, stop smoking advisors or group support. They can be aimed at anyone who smokes, particular populations (for example, certain age or ethnic groups), or may be tailored to individual need.

## Smoking reduction

Smoking reduction generally involves the person smoking fewer cigarettes than they normally would without stopping, but it can involve smoking less of each cigarette. See also [compensatory smoking](#).

## Stopping in one step (abrupt quit)

Stopping in one step is the standard approach to smoking cessation currently adopted by the vast majority of NHS-commissioned [stop smoking services](#). The person makes a commitment to stop smoking on or before a particular date (the quit date). This may, or may not, involve the use of nicotine replacement therapy (NRT) products or medication (varenicline or bupropion) in the lead up to the quit date and for a limited period afterwards.

## Stop smoking services

Stop smoking services provide a combination of [behavioural support](#) and pharmacotherapy to aid smoking cessation. The behavioural support is free but pharmacotherapy may incur a standard prescription charge. The evidence-based treatment is based on the National Centre for Smoking Cessation and Training (NCSCT) standard programme and involves practitioners trained to its standards or the equivalent.

## Temporary abstinence

Abstaining from smoking. This could be for a particular event or series of events, in a particular location, for specific time periods (for example, while at work, during long-haul flights or during a hospital stay), or even for the foreseeable future. (The latter might include, for example, abstinence while serving a prison sentence or while detained in a secure mental health unit.)



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## 8 Summary of the methods used to develop this guidance

### Introduction

The reviews, primary research, commissioned reports and economic modelling report include full details of the methods used to select the evidence (including search strategies), assess its quality and summarise it.

The minutes of the Programme Development Group (PDG) meetings provide further detail about the Group's interpretation of the evidence and development of the recommendations.

All supporting documents are listed in [About this guidance](#).

### Guidance development

The stages involved in developing public health programme guidance are outlined in the box below.

1. Draft scope released for consultation
2. Stakeholder meeting about the draft scope
3. Stakeholder comments used to revise the scope
4. Final scope and responses to comments published on website
5. Evidence reviews and economic modelling undertaken and submitted to PDG
6. PDG produces draft recommendations
7. Draft guidance (and evidence) released for consultation and for field testing
8. PDG amends recommendations
9. Final guidance published on website
10. Responses to comments published on website

### Key questions

The key questions were established as part of the scope. They formed the starting point for the reviews of evidence and were used by the PDG to help develop the recommendations. The overarching questions were:

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?

These questions were made more specific for each review (see reviews for further details).

These questions were made more specific for each review (see reviews for further details).

# Reviewing the evidence

## Effectiveness reviews

Three reviews of effectiveness were conducted (reviews 2, 3 and 5). These covered:

- tobacco harm-reduction approaches with the intention of quitting with or without help
- long-term tobacco harm-reduction approaches without intending to quit and with or without help
- long-term use of non-tobacco nicotine-containing products among people who have quit smoking abruptly.

## Identifying the evidence

A number of databases were searched in August 2011 for: systematic reviews, guidelines, randomised controlled trials (RCTs), controlled trials, controlled and uncontrolled before-and-after studies and interrupted time series studies from January 1990.

A number of national and international websites were also searched.

In addition, a range of databases were searched for information on studies in progress, unpublished research or research reported in the grey literature.

A call for evidence from registered stakeholders was made in August 2011.

See each review for details of the databases and websites searched (and dates of any update searches).

## Selection criteria

Studies were included in the effectiveness reviews if: they covered the following people and at least 1 of the following interventions:

- people who want to quit smoking gradually, reduce their cigarette consumption or temporarily abstain from smoking
- people who have quit smoking abruptly and replaced cigarettes with nicotine replacement therapy or products containing nicotine

- pharmacotherapies licensed for cutting down, temporary abstinence or harm reduction
- other non-tobacco 'nicotine-containing products', such as 'electronic cigarettes' and topical gels
- behavioural support, counselling or advice for individuals or groups
- self-help.

Studies were excluded if they focused on pregnant women or were about:

- pharmacotherapies not licensed for cutting down, temporary abstinence or harm reduction
- products containing tobacco, including products that claim to deliver reduced levels of toxicity or that reduce exposure to tobacco smoke
- products that are smoked that do not contain tobacco.
- smokeless tobacco products
- alternative or complementary therapies.

See each review for details of the inclusion and exclusion criteria.

## Other reviews

### Review 1

#### Identifying the evidence

A range of databases and websites were searched in August 2011 for studies published from 1980 onwards. Studies were included if they were: RCTs, systematic reviews of RCTs, non-randomised trials and randomised and non-randomised pharmacokinetic studies.

This was supplemented by grey literature searches and a call for evidence.

See the review for details.

#### Selection criteria

Studies were included in review 1 if they:

- reported on the safety, risks and pharmacokinetic profiles of tobacco harm-reduction strategies
- addressed special pharmacokinetic or safety considerations that arise when using nicotine-containing products to help reduce the harm from smoking.

Studies were excluded if they focused on pregnant women.

## Review 4

### Identifying the evidence

A range of databases and websites were searched in August 2011 for: RCTs, systematic reviews of RCTs, non-randomised trials, qualitative and quantitative evidence of views and opinions, and process evaluations of intervention studies, from 1990 onwards.

This was supplemented by grey literature searches and 2 calls for evidence. Follow-up database searches were conducted in November 2011 and January 2012.

A call for evidence was also made.

See the review for details.

### Selection criteria

Studies were included if they focused on the following people or services and at least 1 of the following interventions:

- people (or the families of people) who want to quit smoking gradually, reduce their cigarette consumption or temporarily abstain from smoking
- service providers, healthcare personnel and policy makers who may deliver/commission/refer smokers to tobacco harm reduction interventions
- pharmacotherapies licensed for cutting down, temporary abstinence or harm reduction
- other non-tobacco products containing nicotine (electronic cigarettes and topical gels)
- behavioural support, counselling, advice or self-help.

Studies were excluded if they focused on pregnant women.

## Quality appraisal

Included papers were assessed for methodological rigour and quality using the NICE methodology checklist, as set out in [Methods for the development of NICE public health guidance](#). Each study was graded (++, +, -) to reflect the risk of potential bias arising from its design and execution.

### Study quality

++ All or most of the checklist criteria have been fulfilled. Where they have not been fulfilled, the conclusions are very unlikely to alter.

+ Some of the checklist criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are unlikely to alter the conclusions.

- Few or no checklist criteria have been fulfilled. The conclusions of the study are likely or very likely to alter.

The evidence was also assessed for its applicability to the areas (populations, settings, interventions) covered by the scope of the guidance. Each evidence statement concludes with a statement of applicability (directly applicable, partially applicable, not applicable).

## Summarising the evidence and making evidence statements

The review data was summarised in evidence tables (see full reviews).

The findings from the reviews were synthesised and used as the basis for a number of evidence statements relating to each key question. The evidence statements were prepared by the external contractors (see [About this guidance](#)). The statements reflect their judgement of the strength (quality, quantity and consistency) of evidence and its applicability to the populations and settings in the scope.

## Cost effectiveness

There was a review of economic evaluations and an economic modelling exercise.

## Review of economic evaluations

The databases searched included most of NICE's core databases. The search strategies from the effectiveness reviews were used with a filter designed to identify economic and costs studies.



Studies were included if they reported on a full economic evaluation with the same populations and interventions as in the effectiveness reviews (see above).

Two studies were identified that met the inclusion criteria but only 1 was applicable. The results are reported in [A rapid review of economic evidence on tobacco harm reduction strategies](#) on the NICE website.

## Economic modelling

An economic model was constructed to incorporate data from the reviews of effectiveness and cost effectiveness. The model covered quitting smoking using nicotine-containing products on a long-term basis. It also covered interventions to reduce smoking. Following a request from the Programme Development Group, a supplementary analysis was undertaken to explore additional scenarios.

The [results](#) are reported in: 'An economic evaluation of different interventions to promote tobacco harm reduction'; and the supplementary analysis entitled, 'An economic evaluation of different interventions to promote tobacco harm reduction: supplementary report'.

## Fieldwork

Fieldwork was carried out to evaluate how relevant and useful NICE's recommendations are for practitioners and how feasible it would be to put them into practice.

It was conducted with practitioners and commissioners who are involved in [stop smoking services](#) or who have a wider public health remit. This included those working in local authorities, the NHS and the voluntary and community sectors. It also included manufacturers and retailers of [licensed nicotine-containing products](#).

The fieldwork comprised: focus groups, telephone interviews and face-to-face interviews, carried out in the East Midlands, East of England, London, North West, North East, South West, West Midlands and Yorkshire by ICF GHK.

The main issues arising from the fieldwork are set out in [Fieldwork findings](#). The full fieldwork report is [Tobacco: harm-reduction approaches to smoking – final fieldwork report](#).

## How the PDG formulated the recommendations

At its meetings between October 2011 and June 2012, the Programme Development Group (PDG) considered the evidence, expert papers and cost effectiveness to determine:

- whether there was sufficient evidence (in terms of strength and applicability) to form a judgement
- where relevant, whether (on balance) the evidence demonstrates that the intervention or programme/activity can be effective or is inconclusive
- where relevant, the typical size of effect (where there is one)
- whether the evidence is applicable to the target groups and context covered by the guidance.

The PDG developed draft recommendations through informal consensus, based on the following criteria:

- Strength (type, quality, quantity and consistency) of the evidence.
- The applicability of the evidence to the populations/settings referred to in the scope.
- Effect size and potential impact on the target population's health.
- Impact on inequalities in health between different groups of the population.
- Equality and diversity legislation.
- Ethical issues and social value judgements.
- Cost effectiveness (for the NHS and other public sector organisations).
- Balance of harms and benefits.
- Ease of implementation and any anticipated changes in practice.

Where possible, recommendations were linked to an evidence statement(s) (see [The evidence](#) for details). Where a recommendation was inferred from the evidence, this was indicated by the reference 'IDE' (inference derived from the evidence).

## 9 The evidence

This section lists the evidence statements from 5 reviews provided by external contractors (see [What evidence is the guidance based on?](#)) and links them to the relevant recommendations. (See [Summary of the methods used to develop this guidance](#) for the key to quality assessments.)

This section also links the recommendations to the [expert papers](#) and sets out a brief summary of findings from the economic analysis and the fieldwork.

The evidence statements are short summaries of evidence, in a review, report or paper (provided by an expert in the topic area). Each statement has a short code indicating which document the evidence has come from. The letter(s) in the code refer to the type of document the statement is from, and the numbers refer to the document number, and the number of the evidence statement in the document.

**Evidencstatement 1.1a** indicates that the linked statement is numbered 1a in review 1 'Safety, risks and pharmacokinetics profiles of tobacco harm reduction technologies'. **Evidence statement 2.4.1** indicates that the linked statement is numbered 4.1 in review 2 'The effectiveness of tobacco harm reduction approaches with the intention of quitting (that is, [cutting down to quit](#) or reduction to stop smoking), with and without assistance'. **Evidence statement 3.1.5** indicates that the linked statement is numbered 1.5 in review 3 'The effectiveness of long-term harm reduction approaches without the prior intention of quitting'. **Evidence statement 4.1.37** indicates that the linked statement is numbered 1.37 in review 4 'Barriers and facilitators to implementing tobacco harm reduction approaches (including user and provider perspectives)'. **Evidence statement 5.1** indicates that the linked statement is numbered 1 in review 5 'Long term use of non-tobacco nicotine containing products in individuals who have quit smoking abruptly'.

The [reviews](#), [expert papers](#), [economic analysis](#) and [fieldwork report](#) are available online.

**Recommendation1:** evidence statements 1.1a, 1.1b, 1.1c, 1.2a, 1.2b, 1.3a, 1.3c, 1.4a, 1.4b, 1.4c, 1.5, 1.7, 1.8, 1.9, 2.3.1, 3.3.1, 3.8.3, 4.1.5, 4.1.17, 4.1.18, 4.1.37, 4.1.42, 5.4, 5.5, 5.6; expert papers 1, 2, 8a, 8b

**Recommendation2:** evidence statements 4.1.4, 4.1.10, 4.1.11, 4.1.15, 4.1.17, 4.1.18

**Recommendation3:** evidence statements 2.1, 2.1.1, 2.1.2, 3.1.1, 3.1.2, 3.1.3, 3.1.5, 5.1, 5.2, 5.3; expert paper 2

**Recommendation4:** evidence statements 2.4, 2.4.1, 2.4.2, 2.4.3, 2.5, 2.5.1, 2.5.2, 2.6, 2.6.1, 2.6.2, 3.4.1, 3.4.2, 3.4.3, 3.4.4, 3.4.5, 3.4.6, 3.4.7, 3.6.1, 3.6.2, 3.8.2, 4.1.15; IDE

**Recommendation5:** evidence statements 2.1, 2.1.1, 2.1.2, 3.1.1, 3.1.2, 3.1.3, 3.1.5, 3.1.6, 3.8.1, 3.8.2

**Recommendation6:** evidence statements 1.1a, 1.1b, 1.1c, 1.3a, 1.3c, 1.4b, 1.7, 2.1, 2.1.1, 2.1.2, 3.8.1, 3.8.2, 4.1.37, 4.1.42; expert paper 2

**Recommendation7:** IDE

**Recommendation8:** evidence statement 3.4.8; expert paper 2

**Recommendation9:** evidence statement 4.1.7; expert papers 5, 6

**Recommendation10:** evidence statements 4.1.7, 4.2.6; expert papers 5, 6

**Recommendation11:** evidence statements 5.1, 5.2, 5.3, 5.4, 5.5

**Recommendation12:** IDE

**Recommendation13:** IDE

**Recommendation14:** evidence statement 1.3c; IDE

## Evidence statements

Please note that the wording of some evidence statements has been altered slightly from those in the evidence review(s) to make them more consistent with each other and NICE's standard house style.

### **Evidence statement 1.1a Risks and adverse events associated with nicotine replacement and nicotine containing products: primary studies**

Evidence from 10 randomised controlled trials (4 [++]<sup>1-4</sup> and 6 [+]<sup>5-10</sup>) strongly suggests that adverse events are common when nicotine replacement therapy (NRT) is used for smoking harm reduction, but these tend to be mild or moderate and are rarely severe. No authors have attributed serious adverse events to NRT when used as part of smoking harm reduction. NRT is generally well

tolerated when used in this setting. Frequently reported adverse events depend on the route of administration but include throat irritation, coughing, nausea, vertigo/dizziness, vomiting or palpitations. One study<sup>7</sup> (+) reported no evidence of increased cardiac events in patients with existing cardiac disease treated with NRT for 18 months. The duration of use of NRT in these studies varied from 1–18 months. Follow up did not extend beyond 24 months, so the randomised trials do not provide safety data for longer-term use.

<sup>1</sup> Bolliger et al. 2000

<sup>2</sup> Carpenter et al. 2004

<sup>3</sup> Etter et al. 2002

<sup>4</sup> Rennard et al. 2006

<sup>5</sup> Batra et al. 2005

<sup>6</sup> Carpenter et al. 2003

<sup>7</sup> Haustein et al. 2004

<sup>8</sup> Joseph et al. 2008

<sup>9</sup> Kralikova et al. 2009

<sup>10</sup> Wennike et al. 2003

## **Evidence statement 1.1b Risks and adverse events associated with nicotine replacement and nicotine containing products: meta-analysis**

Evidence from a meta-analysis<sup>1</sup> (++) of 2767 participants drawn from several of the randomised trials cited above plus 2 unpublished sources corroborates the findings shown above. The unpublished trials used NRT for 9 months and 12 months. The results suggest that there is no difference between NRT (used for between 6 and 18 months) and placebo in terms of mortality, serious adverse events or discontinuation of therapy due to adverse events. But nausea occurs more frequently with active NRT (odds ratio [OR] 1.69, 95% confidence interval [CI] 1.21–2.36). Use of the meta-analysis has 2 caveats:

- the meta-analysis re-iterates a substantial body of the same data from 6 randomised trials (3 [++]<sup>2-4</sup> and 3 [+]<sup>5-7</sup>) cited above
- there was substantial heterogeneity of results in the meta-analysis of serious adverse events.

<sup>1</sup> Moore 2011

<sup>2</sup> Batra et al. 2005

<sup>3</sup> Bolliger et al. 2000

<sup>4</sup> Etter et al. 2002

<sup>5</sup> Haustein et al. 2004

<sup>6</sup> Rennard et al. 2006

<sup>7</sup> Wennike et al. 2003

## **Evidence statement 1.1c Risks and adverse events associated with nicotine replacement and nicotine containing products: cardiovascular risk markers**

Evidence from 5 randomised trials (2 [++]<sup>1,2</sup> and 3 [+]<sup>3-5</sup>) and 1 non-randomised, controlled study<sup>6</sup> (+) suggests that there are no substantial changes in risk markers for cardiac disease in people treated with NRT as part of smoking harm reduction. The randomised controlled trial evidence is cited from a Cochrane review [++]<sup>7</sup>. Risk markers studied included white blood cell count, fibrinogen, C-reactive protein (CRP), lipids, F2-isoprostanes, 4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanol (NNAL), 1-hydroxypyrene (1-HOP). One (++) study<sup>2</sup> found favourable changes in both NRT and placebo groups. No study reported increases in risk markers for cardiovascular disease arising from NRT. Follow up did not extend beyond 24 months.

<sup>1</sup> Bolliger et al. 2000

<sup>2</sup> Rennard et al. 2006

<sup>3</sup> Batra et al. 2005

<sup>4</sup> Joseph et al. 2008

<sup>5</sup> Kralikova et al. 2009

<sup>6</sup> Haustein et al. 2004

<sup>7</sup> Stead and Lancaster 2007

## **Evidence statement 1.2a Safety of long-term use of nicotine replacement therapy and nicotine containing products**

There are no studies available of the safety of NRT used in smoking harm reduction in the long term (maximum duration of NRT use is 5 years). The strongest evidence available for the long-term safety of NRT with concurrent smoking comes from a large subgroup of patients studied in the 5-year 'Lung health study'<sup>1,2</sup> (+) of NRT in smoking cessation, where a large patient group continued to smoke and continued to use NRT. The results of this multicentre randomised controlled trial suggest that long-term use of NRT is not associated with an increased incidence of harm, including cardiovascular events or cancer, with the latest analysis of outcome at 12.5 years from study outset.

<sup>1</sup> Murray et al. 1996

<sup>2</sup> Murray et al. 2009

## **Evidence statement 1.2b Safety of long-term use of nicotine replacement therapy and nicotine containing products: cardiac disease**

Six studies (4 [+]<sup>1-4</sup> and 1 [-]<sup>5</sup>) evaluated the safety of NRT in patients with cardiac disease and did not find any increased incidence of cardiovascular events or any other adverse events.

<sup>1</sup> Mahmarian et al. 1997

<sup>2</sup> Leja et al. 2007

<sup>3</sup> Joseph et al. 2008

<sup>4</sup> Joseph et al. 1996

<sup>5</sup> Paciullo et al. 2009

<sup>6</sup>Tzivoni et al. 1998

## Evidence statement 1.3a Risks associated with use of unlicensed nicotine containing products

All available evidence relates to electronic cigarettes (e-cigarettes). There is no evidence on the long-term safety of e-cigarettes, whether used alone or with concurrent cigarette smoking. There isn't a large volume of reliable evidence on the short-term safety of e-cigarettes. One (+) randomised crossover trial<sup>1</sup> found that the rate of acute adverse events arising from e-cigarette use (occurring on the first day of use) were intermediate between placebo e-cigarette and licensed nicotine inhalator. A non-randomised (+) study also found no acute effect on heart rate from the use of 2 models of e-cigarette<sup>2</sup>. There are no firm cases of harm that are directly attributable to e-cigarette use. One news article in the British press<sup>3</sup> (-) reported a death from lipoid pneumonia where e-cigarette use was implicated by a treating clinician. The inquest to the death recorded an open verdict.

<sup>1</sup> Bullen et al. 2010

<sup>2</sup> Vansickel et al. 2010

<sup>3</sup> BBC, 2011

## Evidence statement 1.3c Contents of e-cigarettes

There is evidence from 2 laboratory analyses (both [++])<sup>1,2</sup> that e-cigarettes can contain nicotine derived nitrosamine contaminants and diethylene glycol, a highly toxic substance. Most e-cigarettes include propylene glycol. This chemical is generally considered to be of low toxicity although there appears to be insufficient data concerning its inhalational toxicity. A physical evaluation of e-cigarettes (+)<sup>3</sup> found that e-cigarettes (including their constituent parts and instruction manuals) lack important information regarding contents, use and essential warnings. The same study<sup>3</sup> found that e-cigarettes frequently leak, presenting a hazard, and that there are currently no methods for proper disposal of e-cigarettes, including cartridges.

<sup>1</sup> Westenberger 2009

<sup>2</sup> Medicines and Healthcare Products Regulatory Agency 2011

<sup>3</sup> Trtchounian et al. 2011



## Evidence statement 1.4a Impact of nicotine replacement therapies and nicotine containing products on the concentration of nicotine in the blood

Evidence from 6 (all [+])<sup>1-6</sup> controlled studies suggests that nicotine concentrations with smoking alone are typically in the range 22–30 ng/ml. When NRT use is accompanied by smoking, nicotine concentrations can rise to higher levels. The highest value observed was 63.4 ng/ml when a 44 mg patch was used with ad libitum smoking (+)<sup>4</sup>. Some authors suggest that smoking behaviour self-regulates to maintain a constant nicotine concentration but evidence (particularly for patches) suggests that this is imprecise.

Despite increased nicotine concentration with concomitant use, the evidence from two studies (+)<sup>4,6</sup> suggests there are no increases in the incidence of side effects or significant changes in physiological parameters such as blood pressure and heart rate.

<sup>1</sup> Ebert et al. 1984

<sup>2</sup> Fagerstrom et al. 2002

<sup>3</sup> Foulds et al. 1992

<sup>4</sup> Pickworth et al. 1994

<sup>5</sup> Russell et al. 1976

<sup>6</sup> Zevin et al. 1998

## Evidence statement 1.4b Compensatory smoking

Compensatory smoking is a mechanism whereby smokers, who have reduced the number of cigarettes they smoke per day, modify their smoke intake, for example, by puffing more frequently or more intensely, and so titrate their nicotine intake<sup>1</sup> (+). Two studies<sup>1,2</sup> (1 [+] and 1 [-]) correlating reductions in expired carbon monoxide (CO) with reductions in the number of cigarettes per day have demonstrated that some compensation occurs, but that the reduction in CO is significant. A narrative review of studies [-]<sup>3</sup> suggests that for acute NRT forms (gum, lozenge, inhalator, nasal spray) a reduction in CO is accompanied by little change in plasma nicotine, suggesting close titration by subjects. In contrast, the same study found for nicotine patches, plasma nicotine increased, suggesting poor titration for the transdermal route.

Three studies<sup>4,5,6</sup> (all [+]) of snuff use and low yield cigarettes also indicate that users are able to manage their intake to achieve a plasma nicotine level of typically 35–37 ng/ml. One (+) study<sup>6</sup> showed that users of nasal snuff can generate similar plasma nicotine levels to those generated by smoking a cigarette, in approximately equal time (10 minutes).

<sup>1</sup> Hughes and Carpenter 2005

<sup>2</sup> Hughes 2000

<sup>3</sup> Fagerstrom and Hughes 2002

<sup>4</sup> Holm et al. 1992

<sup>5</sup> Jarvis et al. 2001

<sup>6</sup> Russell et al. 1981

## Evidence statement 1.4c Nicotine absorption routes from NRT and e-cigarettes

The routes of absorption of medicinal nicotine are buccal (lozenge, gum, microtab, inhalator), dermal (patches) and nasal mucosa (nasal spray). Notably nicotine is mainly absorbed from the inhalator via the oral mucosa, with minimal absorption via the lungs. The degree of absorption of nicotine from e-cigarettes is uncertain, 2 studies (both [-])<sup>1,2</sup> suggest the delivery of nicotine by these devices is via buccal absorption.

<sup>1</sup> Russell et al. 1987

<sup>2</sup> Vansickel and Eissenberg 2012

## Evidence statement 1.5 Pharmacokinetic data for each nicotine administration route

**Cigarettes** Evidence from a pharmacokinetic study (+) indicates that 10 minutes of cigarette smoking can generate an arterial blood C<sub>max</sub> of 38–40 ng/ml nicotine in T<sub>max</sub> 8 minutes and a venous blood C<sub>max</sub> of 17–19 ng/ml in a T<sub>max</sub> of 10–12 minutes<sup>1</sup>.

**Snus** Absorption of nicotine from snus is primarily through the oral mucosa and can produce a

venous blood C<sub>max</sub> of 14–15 ng/ml in a T<sub>max</sub> of 30–37 minutes (+)<sup>2-4</sup>.

**NRTlozenge/tablet** These products dissolve in the mouth (and are not intended to be swallowed) and absorption of nicotine is primarily through the oral mucosa. A single dose of between 1 and 6 mg nicotine that is allowed to dissolve in the mouth can generate a C<sub>max</sub> of 2–9 ng/ml in T<sub>max</sub> of 10–90 minutes (+)<sup>3,5-8</sup>. Multiple, sequential doses do not appear to result in a C<sub>max</sub> higher than 30 ng/ml (+)<sup>9-13</sup>.

**NRTgum** NRT gum is chewed in the mouth. Absorption of nicotine is primarily through the oral mucosa. When 2–4 mg nicotine or less is administered as gum and chewed for 20–30 minutes, a C<sub>max</sub> of 3–15 ng/ml is reached in T<sub>max</sub> of 20–56 minutes (+)<sup>2,3,5,8,11,14</sup>. Larger, sequential doses of 24–48 mg, chewed for 30 minutes each hour over 12 hours, result in a C<sub>max</sub> of 11–30 ng/ml in a T<sub>max</sub> of 28–30 minutes (+)<sup>9,10,13</sup>.

**NRTnasalspray** The absorption route for nasal spray is primarily through the nasal mucosa. A dose of 0.5–2.5 mg nicotine, given via nasal spray over 5 minutes or less, can result in C<sub>max</sub> of 5–23 (mean 11) ng/ml in T<sub>max</sub> of 5–30 (mean 12) minutes (+)<sup>15-19</sup>. Nasal spray, therefore, appears to offer potentially rapid absorption of nicotine, compared to the other NRT routes.

**NRTinhalator** The pharmacokinetic data on the NRT inhalator appear to support buccal absorption as the primary nicotine absorption route. 20 minutes of use appears to generate a variable C<sub>max</sub> of mean 23 ng/ml (range 2–34) in T<sub>max</sub> of 27 minutes (range 20–32 minutes) (+)<sup>20-21</sup>.

**NRTpatch** The absorption route for nicotine patches is transdermal. Patches appear to offer slow, but sustained absorption of nicotine. Doses of 15–40 mg, given over 16–24 hours, can result in a C<sub>max</sub> of 19 ng/ml (range 14–26 ng/ml) in T<sub>max</sub> of mean 9 hours (range 6–12 hours) (+)<sup>22-25</sup>.

**e-cigarettes** e-cigarettes are not licensed medicines in the UK and little is known about the extent to which they deliver nicotine to the circulation. A small volume of available data suggest that a 16 mg dose given over 5 minutes can result in a C<sub>max</sub> of 1.3 ng/ml in T<sub>max</sub> of 20 minutes (+)<sup>21</sup>. Data from one study (–)<sup>26</sup>, suggest that 10 consecutive puffs at 30-second intervals, followed by 60 minutes of ab libitum use, can generate a C<sub>max</sub> of 16.3 ng/ml in 75 minutes.

<sup>1</sup> Gourlay and Benowitz 1997

<sup>2</sup> Lunell and Curvall 2011

<sup>3</sup> Kotlyar et al. 2007

<sup>4</sup> Foulds 2003

<sup>5</sup> Dautzenberg 2007a

<sup>6</sup> Molander and Lunell 2000b

<sup>7</sup> Molander and Lunell 2000d

<sup>8</sup> Johnson and Johnson 2011a

<sup>9</sup> Dautzenberg 2007b

<sup>10</sup> Dautzenberg 2007c

<sup>11</sup> Molander and Lunell 2000a

<sup>12</sup> Molander and Lunell 2000c

<sup>13</sup> Johnson and Johnson 2011b

<sup>14</sup> Shiffman 2009

<sup>15</sup> Guthrie 1999

<sup>16</sup> Gourlay 1997b

<sup>17</sup> Perkins 1991

<sup>18</sup> Lunell 1995

<sup>19</sup> Sutherland 1992

<sup>20</sup> Molander 1996

<sup>21</sup> Bullen 2010

<sup>22</sup> Veagh-Geiss 2010

<sup>23</sup> Gourlay 1997a

<sup>24</sup> Lewis 2007

<sup>25</sup> Vanakoski 1996

<sup>26</sup> Vansickel and Eissenberg 2012

## Evidence statement 1.7 Snus and cancer risk

The evidence suggests that there is a statistically significantly increased risk of some types of cancer (pancreatic, oesophageal and possibly squamous cell head and neck cancer) associated with using Swedish snus after taking account of the risk arising from concurrent smoking<sup>1-5</sup>. However, these risks from snus are substantially lower than those associated with smoking. Nicotine itself is not regarded as a carcinogen.

Compared to non-smokers, smokers are at increased risk of cancers of the lung, oesophagus, oropharynx, stomach, rectum and anus<sup>5-10</sup>.

The risk of cancers (lung, pancreatic, oral, colon, rectum and anus) in dual smoker and snus users exceeds the risk of cancer attribute to using snus alone<sup>6, 10-12</sup>.

<sup>1</sup> Boffetta et al. 2008

<sup>2</sup> Broadstock 2007

<sup>3</sup> Lee and Hamling 2009a

<sup>4</sup> SCENIHR 2008

<sup>5</sup> Lewin et al. 1998 (cited by Broadstock et al. 2007)

<sup>6</sup> Luo et al. 2007 (cited by Broadstock et al. 2007)

<sup>7</sup> Lagergren et al. 2000 (cited by Broadstock et al. 2007)

<sup>8</sup> Ye et al. 1999 (cited by Broadstock et al. 2007)

<sup>9</sup> Roosaar et al. 2008 (cited by Broadstock et al. 2007)

<sup>10</sup> Zendejdel et al. 2008 (cited by Broadstock et al. 2007)

<sup>11</sup> Boffetta et al. 2005 (cited by Broadstock et al. 2007)

<sup>12</sup> Nordenvall et al. 2011

[NB: Although Swedish snus is excluded from the scope of this guidance, the evidence was used as a proxy measure of the effects of long-term nicotine use in the absence of long-term licensed nicotine-containing product data. For further details, see appendix 10 in evidence review 1.]

## Evidence statement 1.8 Snus and risk of myocardial infarction

The evidence suggests that use of Swedish snus is associated with greater likelihood of fatal myocardial infarction<sup>1-3</sup>. Duration of exposure is not consistently reported but 1 study suggested that duration of exposure was 15 years<sup>4</sup>. The evidence suggests that lengthy exposure is not associated with a change in resting blood pressure but there is experimental evidence that nicotine may affect lipid metabolism<sup>3</sup>.

Smokers are at substantially increased risk of myocardial infarction compared to non-smokers and also in comparison to non-smokers who use snus<sup>5</sup>. While former smokers currently using snus had an increased risk of acute myocardial infarction than never smokers<sup>6</sup>, the risk in current smokers who also use snus was larger<sup>5,6</sup>.

<sup>1</sup> Broadstock 2007

<sup>2</sup> Boffetta and Straif 2009

<sup>3</sup> SCENIHR 2008

<sup>4</sup> Bolinder et al. 1994 (cited by Broadstock et al. 2007)

<sup>5</sup> Huhtasaari et al. 1999 (cited by Broadstock 2007)

<sup>6</sup> Hergens et al. 2005 (cited by Broadstock 2007)

## Evidence statement 1.9 Snus in the context of years of life lost due

## to tobacco

One systematic review [1] reports that the precise magnitude of health gain arising from choosing less harmful alternatives to smoking is difficult to quantify. It cites data from a modelling study<sup>2</sup> which estimates the extent of harm (in years of life lost) in 4 different exposure-based groups: smokers who continue to smoke, smokers who switch to snus, smokers who quit smoking and snus users who never smoked. The model suggests that the health benefit gained (that is, by reducing the number of life years lost) for a smoker who switches to snus, but who would not otherwise have quit smoking, is substantially greater than the life years lost by a snus user who never smoked. The model suggests that the life years lost by a smoker who switches to snus are only marginally greater than the life years lost by a smoker who quits tobacco altogether. The systematic review authors conclude that the overall population effect of snus is likely to be beneficial.

NRT should be an intuitively safer option than Swedish snus because it does not contain the numerous potentially harmful constituents of snus for example, nitrosamines. In terms of NRT, a safety issue to overcome is whether through smoking with concurrent NRT, any harm is likely to result from the maximum blood concentrations of nicotine achieved and also the potentially long-term exposure to nicotine. Data from Swedish studies presented in this report appear to be based on long-term exposure (decades). The same studies do not accurately estimate the volume of nicotine taken over time from cigarettes and snus combined. Studies of efficacy may inform the PDG whether NRT use with concurrent smoking leads to a reduced volume of smoking expressed as cigarettes per day.

<sup>1</sup> Scientific Committee on Emerging and Newly Identified Health Risks 2008

<sup>2</sup> Gartner et al. 2007 (cited by SCENIHR 2008)

## Evidence statement 2.1 (including statements 2.1.1–2.1.2) How effective are pharmacotherapies in helping people cut down smoking before quitting?

2.1 Three RCTs examined the efficacy of NRT gum (1 [++]<sup>1</sup> and 1 [+]<sup>2</sup>) and lozenges (1 [++])<sup>3</sup>. In addition there was 1 (+) quasi-randomised controlled trial (quasi-RCT)<sup>4</sup> and 1 (–) uncontrolled before-and-after study (UBA)<sup>5</sup> with a combined intervention of behavioural therapy plus gum.

Two studies<sup>1,3</sup> were deemed to be studies at low risk of bias.

2.1.1 There is moderate evidence from 2 RCTs (1 [++]<sup>3</sup> and 1 [+])<sup>2</sup> of no significant difference in long-

term abstinence rates between gradual and abrupt cessation when using NRT (gum or lozenges) although the trend favours abrupt cessation. The CO and cotinine validated 4-week quit rate at 12 months was 16.5% for gradual compared to 24.0% for abrupt cessation,  $p=0.14$ <sup>2</sup>. The OR for CO validated abstinence at 6 months (gradual/abrupt) was 0.6 (95% CI 0.3, 1.2)<sup>3</sup>.

**2.1.2** There is moderate evidence from a large RCT ([++])<sup>1</sup> of a benefit from NRT versus placebo at 6 months; this was more marked in the 4 mg gum versus 2 mg dose rates with ORs of 6.0 (95%CI 2.9, 12.3) and 1.8 (95% CI 1.1, 2.9) respectively. Overall OR 2.86 (95% CI 1.93, 4.24).

The evidence from 2 much smaller studies, a quasi-RCT (+)<sup>4</sup> and an uncontrolled before-and-after study (-)<sup>5</sup>, is inconsistent. In the quasi-RCT mean quit rates for standard treatment versus behavioural counselling with NRT respectively at 6 months were 21% versus 27% (NS) and at 12 months 26% versus 27% (NS)<sup>4</sup>. In the UCBA study<sup>5</sup> 39% reported abstinence at 6 months and 68% reported a 50% or above reduction in cigarette consumption at the end of 8 weeks using a combination of gum and behavioural therapy. The difference in abstinence between participants who wanted to reduce to quit versus those who were refractory smokers was not significant (48% versus 32%,  $p=0.8$ )<sup>5</sup>.

**Applicability statement** The evidence from the RCTs<sup>1-3</sup> is partially applicable to people in the UK because, although there were no UK-based trials, the studies were community-based and are feasible within a UK setting. The Quasi-RCT relates specifically to recovering alcoholics<sup>4</sup>. The UBA was an intensive intervention which is unlikely to be feasible within the UK<sup>5</sup>.

<sup>1</sup> Shiffman et al. 2009

<sup>2</sup> Etter et al. 2009

<sup>3</sup> Hughes et al. 2010

<sup>4</sup> Martin et al. 1997

<sup>5</sup> Jiménez-Ruiz et al. 2009

## **Evidence Statement 2.3.1 How effective are 'nicotine-containing products' in helping people cut down smoking before quitting?**

For the purposes of this review 'nicotine containing products' were defined as 'electronic nicotine delivery systems' (sometimes known as 'electronic cigarettes' or 'e-cigarettes') and topical gels.



No studies were found that looked at the effectiveness of nicotine delivery systems (electronic cigarettes) for helping people to cut down before quitting.

## Evidence Statement 2.4 (including statements 2.4.1–2.4.2) How effective are behavioural support, counselling, advice or self-help (with or without pharmacotherapy) in helping people cut down smoking before quitting?

2.4 Nine studies incorporated behavioural support, including 3 RCTs (1 [++]<sup>1</sup>, 1 [+]<sup>2</sup>, and 1 [-]<sup>3</sup>), 4 quasi-RCTs (all [+])<sup>4-7</sup>, 1 trial with partial randomisation (-)<sup>8</sup> and 2 uncontrolled before-and-after studies (both [-])<sup>9,10</sup>.

Studies used behavioural intervention components in a variety of ways:

- Cognitive behavioural support (both [+])<sup>4,7</sup>
- Advice giving (+)<sup>2</sup>
- Investigating the feasibility of contingency management (providing tangible reinforcers contingent on abstinence or reduction of substance use to a target level". The tangible reinforcers in this study were gift certificates) (-)<sup>8</sup>
- Investigating the feasibility of computerised scheduled reduction (-)<sup>10</sup>.

In the other studies, all participants received a behavioural component (2 [+], 1 [++]<sup>1</sup>, 2 [-]<sup>3,5,6,9</sup>) and it is therefore not possible to infer the effectiveness of that component.

**2.4.1** There is moderate evidence for the effectiveness of cognitive behavioural therapy versus standard therapy from 2 quasi-RCTs (both [+])<sup>4,7</sup> both in reducing the number of cigarettes per day prior to quitting, and in quitting itself. At 12 months, 41% of the Cognitive Behavioural Therapy (CBT) group and 6% of the control group were abstinent,  $p < 0.01$ . Figures for 6 months were 53% and 6%,  $p < 0.01$ <sup>4</sup>. At 12 months 19.8% (95% CI 13.0, 28.3) of the contactable CBT group were abstinent compared to 5.8% (95% CI 2.1, 12.1,  $p < 0.0001$ )<sup>7</sup>. At the same time point 11.5% (95% CI 6.4, 18.5,  $p < 0.0001$ ) had reduced their cigarettes per day (CPD) by 25% or more compared to 0% in the control group<sup>7</sup>.

**2.4.2** There is moderate evidence from 2 RCTs (1 [++]<sup>1</sup> and 1 [-])<sup>3</sup> of a trend towards higher abstinence rates for abrupt cessation compared to gradual reduction when counselling is offered to both groups (in 1 study with nicotine<sup>1</sup>) but the findings are not significant. The OR for CO-verified

abstinence at 6 months for gradual versus abrupt cessation, was 0.6 (95% CI 0.3, 1.2)<sup>1</sup>. At 12 months follow-up there was a non-significant difference in self-reported abstinence between sudden and gradual withdrawal groups: 51.85% versus 38.71%<sup>3</sup>.

2.4.3 There is weak evidence from one quasi-randomised trial<sup>5</sup> (+) suggesting that cognitive behavioural therapy combined with advice to schedule and lengthen the time between cigarettes may enhance outcomes. Cotinine verified abstinence rates at 12 months were 44% (scheduled reduced), 18% (non-scheduled reduced), 32% (scheduled non-reduced) and 13% (non-scheduled non-reduced);  $p < 0.05$ .

### Applicability statement for evidence statements 2.4.1–2.4.7

This evidence is partially applicable to people in the UK. The use of rewards for response<sup>8</sup> is unlikely in this setting. However one study was based in the UK<sup>7</sup> and one was a web-based intervention<sup>2</sup>. All the other studies were community- or high school-based and feasible within a UK setting.

<sup>1</sup> Hughes et al. 2010

<sup>2</sup> Etter 2011

<sup>3</sup> Gunther et al. 1992

<sup>4</sup> Cinciripini et al. 1994

<sup>5</sup> Cinciripini et al. 1995

<sup>6</sup> Martin et al. 1997

<sup>7</sup> Marks 2002

<sup>8</sup> O'Leary Tevyaw 2007

<sup>9</sup> Jiménez-Ruiz 2009

<sup>10</sup> Riley 2002

## Evidence Statement 2.5 (including statements 2.5.1–2.5.2) Is

## there an optimal period for helping people cut down smoking with the aim of quitting?

2.5 Eleven studies reported reduction periods, including 5 RCTs (2 [++]<sup>1,2</sup> and 3[+]<sup>3-5</sup>), 3 quasi-RCTs (all [+])<sup>6-8</sup>, 2 uncontrolled before-and-after studies (both [-])<sup>9,10</sup> and 1 secondary analysis of RCT data (-)<sup>11</sup>.

Among the included studies, the reduction period varied from 7–10 days<sup>8</sup> through to 16 weeks<sup>9</sup>. Five studies employed reduction periods of between 2 and 5 weeks<sup>2,3,4,6,7</sup>. One<sup>10</sup> utilised a 7-week schedule and 2<sup>1,5</sup> an 8-week schedule.

One study<sup>5</sup> found no difference between 2 different reduction periods, although the interventions also differed. CO-verified quit rates at 12 months for the 3 groups (standard treatment with counselling over 4 weeks, counselling plus exercise and counselling plus NRT over 8 weeks) were 26%, 27% and 27% respectively.

None of the other included studies compared the effectiveness of different periods of cutting down prior to quitting. There was considerable variation in design between the studies and it is not possible to identify any relationship or trend between the length of the reduction period and the outcomes that is not subject to potential confounding by other aspects of the study designs.

However, 1 study<sup>11</sup> carried out a secondary analysis to examine whether delaying a quit attempt was associated with less success. This analysis was considered to be at high risk of bias.

2.5.1 There is weak evidence from a quasi-RCT<sup>5</sup> and a secondary analysis<sup>11</sup> to indicate that there is no relationship between time to planned or actual quit date and long-term abstinence rate among those cutting down prior to quitting.

2.5.2 There is no evidence concerning the optimum cutting-down period from 9 studies<sup>1-4,6-10</sup>. Reduction periods varied from 7 days to 16 weeks. None of the studies explored the effect of the reduction time on outcomes and, given the huge heterogeneity between studies, no relationship between reduction time and outcomes can be inferred.

### Applicability statement for evidence statements 2.5.1 and 2.5.2

This evidence is partially applicable to people in the UK who smoke, one study was a large community based study<sup>2</sup> that may be feasible in the UK, although a secondary analysis is a methodologically weak study. One study looked specifically at recovering alcoholics<sup>5</sup>.

<sup>1</sup> Shiffman 2009

<sup>2</sup> Hughes 2010

<sup>3</sup> Etter 2009

<sup>4</sup> Etter 2011

<sup>5</sup> Martin 1997

<sup>6</sup> Cinciripini 1994

<sup>7</sup> Cinciripini 1995

<sup>8</sup> Marks 2002

<sup>9</sup> Jiménez-Ruiz 2009

<sup>10</sup> Riley 2002

## **Evidence Statement 2.6 (including evidence statements 2.6.1–2.6.2) Is it more or less effective to draw up a schedule to help someone cut down smoking with the aim of quitting?**

2.6 One (+) quasi-RCT<sup>1</sup> compared scheduled versus non-scheduled reduction. One (++) RCT<sup>2</sup> and 1 (+) quasi-RCT<sup>3</sup> compared different types of schedule.

2.6.1 There is weak evidence from 1 quasi-RCT<sup>1</sup> for scheduled versus non-scheduled reduction that cognitive behavioural therapy combined with advice to schedule and lengthen the time between cigarettes enhanced outcomes. Cotinine-verified abstinence rates at 12 months: 44% (scheduled reduced), 18% (non-scheduled reduced), 32% (scheduled non-reduced) and 22% (non-scheduled non-reduced);  $p < 0.05$ .

2.6.2 There is weak evidence from 1 large RCT<sup>2</sup> and 1 quasi-RCT<sup>3</sup> that the type of smoking reduction schedule used does not make a difference. Reduction and abstinence rates did not appear to differ across the initially chosen methods (formal schedule, giving up 'easiest' cigarettes first, giving up 'hardest' cigarettes first) so the results were pooled across all the methods<sup>2</sup>. There was no difference between different intervention and scheduled reduction methods. CO-verified

quit rates at 12 months for the 3 groups (standard treatment with counselling over 4 weeks, counselling plus exercise and counselling plus NRT over 8 weeks) were 26%, 27% and 27% respectively<sup>3</sup>.

## Applicability statement for evidence statements 2.6.1 and 2.6.2

This evidence is partially applicable to people in the UK since the studies are community-based and feasible in UK settings. One study however, was in a specific population (recovering alcoholics)<sup>3</sup>.

<sup>1</sup> Cinciripini 1995

<sup>2</sup> Hughes 2010

<sup>3</sup> Martin 1997

## Evidence statements 3.1.1–3.1.3, 3.1.5, 3.1.6 How effective are pharmacotherapies in helping people cut down or abstain from smoking temporarily or indefinitely without the aim of quitting?

**3.1.1** There is strong to moderate evidence from 9 studies: 2 RCTs<sup>1,2</sup> (1 [++] and 1 [+]); 5 quasi-RCTs<sup>3–7</sup> (3 [+] and 2 [–]) and 2 UBAs<sup>8,9</sup> (both [–]) that NRT (gum or inhaler) versus placebo is effective in reducing cigarette consumption across multiple outcome measures and in eventual abstinence in smokers not looking to quit.

**3.1.2** There is strong to moderate evidence from a meta-analysis of 3 RCTs<sup>1,2,10</sup> (2 [++] and 1 [+]) and 1 (+) quasi-RCT<sup>4</sup> looking at 50% or more point prevalence reduction in CPD compared to baseline, that NRT, with or without a brief motivational interviewing (MI) component, is more effective than placebo with a relative risk (RR)=1.46 (95% CI 1.20, 1.78), with a number needed to treat (NNT) of 13 (95% CI 10, 20). A sensitivity analysis (excluding<sup>10</sup> which added a brief MI component to NRT) resulted in RR=1.35 (95% CI: 1.10, 1.65) and an NNT of 17 (95% CI 10, 50). Smoking reduction was verified by CO except in<sup>2</sup>.

**3.1.3** There is moderate evidence from a meta-analysis of 1 (++) RCT<sup>1</sup> and 2 quasi-RCTs (both [+])<sup>3,7</sup> that NRT is more effective than placebo in percentage reduction in cigarettes per day from baseline with a risk difference (RD) of –13.85 (95% CI: –25.5, –2.45).

**3.1.5** There is strong evidence from a meta-analysis of 9 studies: 3 RCTs (2 [++]<sup>1,10</sup> and 1 [+]<sup>2</sup>) and 6 quasi RCTs<sup>3,5,6,7,11,12</sup> (all [+]) investigating cessation in populations not looking to quit that NRT with

or without associated behavioural interventions has a statistically significant effect: RR=1.96 (95% CI 1.36, 2.80) with an NNT of 20 (95% CI 13, 34). A sensitivity analysis excluding studies with a behavioural component<sup>10,11,12</sup> found a similar result for NRT alone: RR=1.93 (95%CI 1.26, 2.96) and an NNT of 20 (95% CI 13, 34).

**3.1.6** There is moderate evidence from 1 (++) RCT<sup>13</sup> of patients undergoing elective surgery that nicotine patch versus placebo is effective in reducing post-operative smoking consumption, a statistically significant self-reported reduction was observed 30 days post-operation but this was not maintained at 6 months.

### **Applicability statement for evidence statements 3.1.1–3.1.6**

The majority of the evidence is applicable to the UK as the studies are community based and feasible in UK settings, although one study<sup>3</sup> involved participants making several clinic visits, while another<sup>14</sup> was in a laboratory setting. One study was conducted within a specific population (patients undergoing elective surgery)<sup>13</sup>.

<sup>1</sup> Bolliger 2000

<sup>2</sup> Etter 2007

<sup>3</sup> Batra 2005

<sup>4</sup> Hatsukami 2005

<sup>5</sup> Kralikova 2009

<sup>6</sup> Rennard 2006

<sup>7</sup> Wennike 2003

<sup>8</sup> Jiménez-Ruiz 2002

<sup>9</sup> Rennard 1990

<sup>10</sup> Chan

<sup>11</sup> Carpenter 2004

<sup>12</sup>Joseph 2008

<sup>13</sup>Warner 2005

<sup>14</sup>Foulds 1992

### **Evidence statement 3.3.1 How effective are 'nicotine-containing products' in helping people cut down or abstain from smoking, temporarily or indefinitely without the aim of quitting?**

Very weak evidence from 1 (-) UBA<sup>1</sup> suggests that e-cigarette availability can help smokers reduce. This evidence may be applicable to the UK as it is community based and feasible in a UK setting.

<sup>1</sup>Polosa 2011

### **Evidence statements 3.4.1–3.4.8 How effective are behavioural support, counselling, advice or self-help (with or without pharmacotherapy) in helping people to cut down or abstain from smoking, temporarily or indefinitely, without the aim of quitting?**

**3.4.1** There is consistent evidence from 7 studies: 2 RCTs<sup>1,2</sup> (both [+]), 4 quasi-RCTs<sup>3,4,5,6</sup> (all [+]) and 1 (-) CBA<sup>7</sup> that motivational interviewing – compared with other behavioural methods or with no support and whether provided in single or multiple sessions – is not effective in helping people to reduce smoking levels. This evidence applies to healthy adolescents and adults, with no statistically significant differences between groups reported across any of the studies reviewed. Weak evidence also exists for the lack of effectiveness of motivational interviewing for adolescent drug users<sup>2,7</sup> and military veterans with psychiatric problems<sup>6</sup>, with these studies again finding no significant differences between groups for the outcomes reported.

**3.4.2** There is strong evidence from a meta-analysis of 2 RCTs<sup>1,2</sup> (both [+]) and 3 quasi-RCTs<sup>3,4,5</sup> (all [+]) that motivational interviewing – compared with other behavioural methods or with no support and provided in single or multiple sessions – is not effective for smoking cessation in populations unable or unwilling to stop smoking: RR 1.34 (95% CI 0.75, 2.39; p=0.32). This is at variance with findings of a Cochrane systematic review of smoking cessation (Lai 2010). One (++) RCT<sup>6</sup> and 1 (+) quasi-RCT<sup>7</sup> suggest that the addition of NRT to a motivational component may improve the likelihood of abstinence: RR 3.09 (95% CI 1.06, 9.01; p=0.04).

**3.4.3** There is moderate evidence from a large well-conducted (++) RCT<sup>6</sup> that NRT combined with a

motivational component is effective, with a significant CO-validated 50% or more 7-day point prevalence reduction rate.

**3.4.4** There is strong to moderate evidence from 4 studies: 1 (+) RCT<sup>8</sup>, 1 (+) quasi-RCT<sup>9</sup>, 1 (+) non-RCT<sup>10</sup> and 1 (-) CBA<sup>11</sup> designed to reduce the impact of environmental tobacco smoke on children – of no effect for a variety of behavioural methods versus standard care in reducing parental smoking. This evidence applies to parents of children with asthma<sup>9,10</sup> as well as to parents of healthy children<sup>8,11</sup>.

**3.4.5** There is moderate evidence from 2 RCTs<sup>12,13</sup> (both [+]) and 1 (-) UBA<sup>14</sup> that counselling combined with nicotine replacement therapy is not effective in helping adolescents<sup>12</sup> or adults<sup>13,14</sup> to reduce their cigarette consumption or to ultimately quit. There were no differences at follow-up between intervention and control groups for any smoking-related outcomes.

**3.4.6** There is moderate evidence from 1 (++) RCT<sup>15</sup> that telephone counselling is an ineffective approach to reducing cigarette consumption. At the 12 month follow-up there were no significant differences between intervention and control groups in terms of numbers reducing their daily cigarette consumption by 50% or more or in carbon monoxide levels.

**3.4.7** There is moderate evidence from 1 (+) quasi-RCT<sup>16</sup> that computer-aided and manual-aided approaches to assist with reduction had similar effect sizes. Twelve months after the start of the study there were no differences between groups in smoking reduction, and although more participants in the computer-aided group had made a quit attempt than in the manual-aided group, this difference was not statistically significant.

**3.4.8** There is moderate evidence from 1 (+) systematic review of pre-operative smoking interventions<sup>17</sup> that counselling combined with NRT increases smoking cessation at the time of surgery for both brief and intensive interventions. However, only intensive interventions were effective at 12 month follow-up: RR 2.96 (95% CI 1.57, 5.55) for 2 trials.

## **Applicability statement for evidence statements 3.4.1–3.4.8**

The majority of evidence is applicable to the UK as the studies are feasible in UK settings. However 3 studies<sup>7,12,18</sup> are noted to have issues regarding applicability. Studies of specific populations included adolescents<sup>3,4,12,19</sup>; adolescent drug users<sup>2,7</sup>; mental health<sup>18,20,21</sup>; patients undergoing elective surgery<sup>17,22,23</sup>; and parents<sup>8,9,10,11</sup>.

<sup>1</sup> Horn 2007



<sup>2</sup> McCambridge 2005

<sup>3</sup> Kelly 2006

<sup>4</sup> Audrain-McGovern 2011

<sup>5</sup> Davis 2011

<sup>6</sup> Gulliver 2008

<sup>7</sup> Gray 2005

<sup>6</sup> Chan 2011

<sup>7</sup> Carpenter 2004

<sup>8</sup> Hovell 2000

<sup>9</sup> Irvine 1999

<sup>10</sup> Wakefield 2002

<sup>11</sup> Fossum 2004

<sup>12</sup> Hanson 2008

<sup>13</sup> Joseph 2008

<sup>14</sup> Hurt 2000

<sup>15</sup> Glasgow 2009

<sup>16</sup> Riley 2002

<sup>17</sup> Thomsen 2010

<sup>18</sup> Tidey 2002

<sup>19</sup>Horn 2007

<sup>20</sup>Griffiths 2010

<sup>21</sup>Schleicher 2010

<sup>22</sup>Munday 1993

<sup>23</sup>Walker 2009

## **Evidence statements 3.6.1–3.6.2 Is it more or less effective to draw up a schedule to help people cut down or abstain from smoking, temporarily or indefinitely, without the aim of quitting?**

**3.6.1** Weak evidence from 2 quasi-RCTs (1 [+]<sup>1</sup> and 1 [-]<sup>2</sup>) and 2 UBAs (both [-])<sup>3,4</sup> suggests using a schedule may assist in reducing smoking. Schedules included week-on-week reduction<sup>3,4</sup>, increased inter-cigarette interval or selective elimination<sup>1,2</sup>.

**3.6.2** There is limited evidence from 2 quasi-RCTs (1 [+]<sup>1</sup> and 1 [-]<sup>2</sup>) of no difference in effect between different types of schedule (increasing inter-cigarette intervals or selective elimination).

### **Applicability statement for evidence statements 3.6.1 and 3.6.2**

The evidence is partially applicable to people in the UK since all 4 studies were community-based (in the USA) and are feasible in UK settings.

<sup>1</sup> Riley 2002

<sup>2</sup> Riggs 2001

<sup>3</sup> Hatsukami 2005

<sup>4</sup> Hurt 2000

## **Evidence statements 3.8.1–3.8.3 Are there any unintended consequences from adopting a tobacco harm-reduction approach; for example, does it deter people from trying to cut down or abstain from smoking, temporarily or indefinitely?**

**3.8.1** There is strong evidence from 8 studies: 3 RCTs<sup>1,2,3</sup> (1[++]<sup>1</sup> and 2 [+]<sup>2,3</sup>), 3 quasi-RCTs<sup>4,5,6</sup> (all [+]) and 2 UBA(1 [+]<sup>7</sup> and 1 [-]<sup>8</sup>) reporting usage of NRT for periods between 6 months and 5 years – to suggest that NRT is generally well-tolerated long term with severe side effects being relatively rare.

**3.8.2** There is moderate evidence from 2 quasi-RCTs<sup>6,9</sup> (both [+]) that harm-reduction interventions do not deter smokers from wishing to quit.

**3.8.3** There is weak evidence from a single (-) UBA<sup>10</sup> that frequent adverse events are reported by e-cigarette users. This finding supports the conclusions from review 1 that more evidence is required concerning the safety of e-cigarettes.

### **Applicability statement for evidence statements 3.8.1–3.8.3**

Adverse event studies are likely to be applicable to the UK.

<sup>1</sup> Bollinger 2000

<sup>2</sup> Etter 2007

<sup>3</sup> Joseph 2008

<sup>4</sup> Batra 2005

<sup>5</sup> Kralikova 2009

<sup>6</sup> Wennike 2003

<sup>7</sup> Rennard 2006

<sup>8</sup> Jiménez-Ruiz 2002

<sup>9</sup> Carpenter 2004

<sup>10</sup> Polosa 2011

## **Evidence statement 4.1.4 Background environment factors described by smokers: social pressure to change smoking behaviour as a facilitator**

Social pressure from friends, family or society in general to reduce, quit or implement smokefree homes and cars was described as a facilitator in 8 studies (1 [++]<sup>1</sup>, 6 [+]<sup>2-7</sup>, and 1 [-]<sup>8</sup>). Smokers in 1 study were professionally supported to address their smoking behaviour<sup>7</sup>.

<sup>1</sup> Bottorff 2009

<sup>2</sup> Bolliger 2000

<sup>3</sup> Richter 2002

<sup>4</sup> Stewart 2011

<sup>5</sup> Abdullah 2011

<sup>6</sup> Herbert 2011

<sup>7</sup> Phillips 2007

<sup>8</sup> Green 2005

## **Evidence statement 4.1.5 Background environment factors described by smokers: social support from friends, family and professionals as a facilitator**

Social support from friends, family or professionals was perceived to be helpful in reducing smoking consumption in 3 (+) studies<sup>1-3</sup>. One study<sup>1</sup> involved surgery outpatients in receipt of a smoking telephone counselling intervention to reduce smoking consumption. Another study<sup>2</sup> involved low income women describing attitudes to smoking reduction or quitting and the third included adolescents describing ways in which they control smoking levels<sup>3</sup>.

<sup>1</sup> Estabrooks 2010

<sup>2</sup> Stewart 2011

<sup>3</sup> Johnson 2004

## **Evidence statement 4.1.7 Background environment factors described by smokers: smoking restrictions promote smoking reduction**

Eight studies (1 [++]<sup>1</sup>, 4 [+]<sup>2-5</sup> and 3 [-]<sup>6-8</sup>) included participants reporting that smoking restrictions helped them to reduce their smoking whether in: the home<sup>1,2,6</sup> at work<sup>7</sup> or in hospital<sup>8</sup>.

<sup>1</sup> Jones 2003

<sup>2</sup> Abdullah 2011

<sup>3</sup> Herbert 2011

<sup>4</sup> Phillips 2007

<sup>5</sup> Robinson 2010

<sup>6</sup> Blackburn 2003

<sup>7</sup> Amos 1995

<sup>8</sup> Keizer 2009

### **Applicability statement for evidence statements 4.1.1–4.1.7**

Just 7<sup>1-7</sup> of the 21 studies on background environment factors described by smokers were based in the UK and 2<sup>8-9</sup> from countries judged to have similar applicability to the UK.

<sup>1</sup> Amos 1995

<sup>2</sup> Beard 2011a

<sup>3</sup> Blackburn 2003

<sup>4</sup>Haddock 1997

<sup>5</sup>Jones 2011

<sup>6</sup>Phillips 2007

<sup>7</sup>Robinson 2010

<sup>8</sup>Hamilton 2000

<sup>9</sup>Thomsen 2009

### **Evidence statement 4.1.10 Smokers' attitudes, beliefs and experiences regarding THR efforts: smokers' perceived low ability in achieving smoking goals**

A common theme across 3 studies (2 [+]<sup>1,2</sup>, 1 ungraded<sup>3</sup>) was that participants' lack of confidence in their ability to achieve their smoking goals was a barrier to changing smoking behaviour. These studies were conducted in potentially more vulnerable groups: pre-surgical patients<sup>3</sup>; low income women<sup>1</sup> and adolescents<sup>2</sup>. One study included smokers that were receiving professional support to address their smoking behaviour<sup>3</sup>.

<sup>1</sup>Stewart 2011

<sup>2</sup>Johnson 2004

<sup>3</sup>Haddock 1997

### **Evidence statement 4.1.11 Smokers' attitudes, beliefs and experiences regarding THR efforts: perceived high nicotine dependence/smoking addiction**

The addictive effect of smoking and the difficulty of resisting subsequent cravings were described as barriers to reducing smoking or implementing smokefree homes in 3 studies (1 [++]<sup>1</sup>, 1 [+]<sup>2</sup> and 1 [-]<sup>3</sup>). However, in a further (+) study<sup>4</sup>, perceived dependence on smoking was not associated with quitting success among smokers who first cut down without professional support. The studies were conducted in general adult smokers<sup>4</sup>, psychiatric inpatients<sup>3</sup> and parents and/or new fathers with children living at home<sup>1,2</sup>. One study included smokers that were professionally supported to

address their smoking behaviour<sup>2</sup>.

<sup>1</sup> Bottorff 2009

<sup>2</sup> Herbert 2011

<sup>3</sup> Keizer 2009

<sup>4</sup> Cheong 2007

## **Evidence statement 4.1.15 Smokers' attitudes, beliefs and experiences regarding THR efforts: smokers' own structuring and scheduling of smoking**

Eight studies (1 [++]<sup>1</sup> and 7 [+])<sup>2-8</sup> identified that smokers use structuring or scheduling smoking techniques to limit or reduce their cigarette consumption or temporarily abstain was a facilitator to change. These included: half-butting or smoking part of the cigarette<sup>1-4</sup>; inhaling less or not at all<sup>2,4</sup>; carrying only a set number of cigarettes<sup>5</sup>; borrowing cigarettes instead of buying<sup>3</sup>; cutting out unnecessary cigarettes for example, not chain smoking<sup>2,3</sup>; restricting the number of cigarettes smoked, where or when smoked<sup>2,3,4,6</sup> or delaying time between cigarettes<sup>1,2,3,7,8</sup>. Three studies included smokers that were using NRT<sup>2,4</sup> or receiving behavioural interventions to achieve smoking goals<sup>5</sup>.

<sup>1</sup> Bottorff 2009

<sup>2</sup> Beard 2011a

<sup>3</sup> Johnson 2004

<sup>4</sup> Okuyemi 2001

<sup>5</sup> Estabrooks 2010

<sup>6</sup> Nguyen 2009

<sup>7</sup> Poland 2009

<sup>8</sup> Robinson 2010

## Evidence statement 4.1.17 Smokers' attitudes, beliefs and experiences regarding THR efforts: smokers' wish to protect children from smoke

Seven studies (2 [++]<sup>1,2</sup> and 5 [+]<sup>3-7</sup>) reported wishing to protect the health of their children as a facilitator to reducing their smoking<sup>3</sup> or in implementing smokefree homes<sup>1,2,4-6</sup>. Smokers in 1 study were receiving professional support to address their smoking behaviour<sup>4</sup>.

<sup>1</sup> Bottorff 2009

<sup>2</sup> Jones 2011

<sup>3</sup> Nichter 2008

<sup>4</sup> Abdullah 2011

<sup>5</sup> Herbert 2011

<sup>6</sup> Phillips 2007

<sup>7</sup> Poland 2009

## Evidence statement 4.1.18 Smokers' attitudes, beliefs and experiences regarding THR efforts: smokers' worries of harm to own health from smoking

Concern about the effect of tobacco on smokers' own health was a commonly reported facilitator across 13 studies (1 [++]<sup>1</sup>, 10 [+]<sup>2-11</sup>, 1 [-]<sup>12</sup> and 1 ungraded<sup>13</sup>) looking at reducing smoking or implementing smokefree homes. Smokers described both worries of harm to their own health<sup>2-7,13</sup> and perceived benefits to health from reduction of smoking<sup>1,8-10,12</sup>. However 1 study found that worries about damage to health and quality of life from smoking or perceived benefits to health from quitting, were not associated with quitting success among smokers who first cut down<sup>11</sup>. Smokers' in 2 studies were receiving professional support to address their smoking behaviour<sup>3,13</sup>.

<sup>1</sup> Bottorff 2009

<sup>2</sup> Bolliger 2000



<sup>3</sup>Estabrooks 2010

<sup>4</sup>Abdullah 2011

<sup>5</sup>Poland 2009

<sup>6</sup>Stewart 2011

<sup>7</sup>Hamilton 2000

<sup>8</sup>Beard 2011a

<sup>9</sup>Joseph 2005

<sup>10</sup>Shiffman 2007

<sup>11</sup>Cheong 2007

<sup>12</sup>Thomsen 2009

<sup>13</sup>Haddock 1997

### **Applicability statement for evidence statements 4.1.8–4.1.18**

Of the 22 studies reporting smokers views regarding tobacco harm reduction, just 6 studies were solely conducted in the UK (1 [++]<sup>1</sup>, 4 [+]<sup>2-5</sup>, and 1 [-]<sup>6</sup>), 1 (+) study in multiple countries including the UK<sup>7</sup> and 1 (+) study in a country deemed to have high applicability to the UK<sup>8</sup>.

<sup>1</sup> Jones 2011

<sup>2</sup> Beard 2011a

<sup>3</sup> Haddock 1997

<sup>4</sup> Robinson 2010

<sup>5</sup> Phillips 2007

<sup>6</sup> Thomsen 2009

<sup>7</sup>Cheong 2007

<sup>8</sup>Hamilton 2000

### **Evidence statement 4.1.37 Smokers' attitudes, beliefs and experiences regarding e-cigarette use to assist THR: belief that e-cigarettes do not help with smoking craving**

There was limited evidence from 1 cross-sectional survey (+)<sup>1</sup> that a small proportion of e-cigarette users (10%) believed that the product did not help with cravings in smokers aiming to cease or reduce smoking.

<sup>1</sup>Etter 2011

### **Evidence statement 4.1.42 Smokers' attitudes, beliefs and experiences regarding e-cigarette use to assist THR: e-cigarettes are perceived as less harmful than smoking**

There was evidence from 2 cross-sectional surveys that a facilitator to change was the perception that e-cigarettes are less harmful to others or their own health than smoking by the majority of participants (1 [+]<sup>1</sup> and 1 [-]<sup>2</sup>) and perceived to help with withdrawal and craving symptoms of nicotine<sup>2</sup>.

<sup>1</sup>Etter 2011

<sup>2</sup>Foulds 2011

### **Applicability statement for evidence statements 4.1.37–4.1.43**

The evidence has limited applicability to the UK. One (+) study<sup>1</sup> included UK participants, although the majority were from USA and other countries. One (-) study<sup>2</sup> was conducted in a potentially biased sample of USA e-cigarette users attending an e-cigarette enthusiast meeting.

<sup>1</sup>Etter 2011

<sup>2</sup>Foulds 2011

## Evidence statement 4.2.6

Five studies (2 [+]<sup>1,2</sup>, 3 [-]<sup>3-5</sup>) examined barriers and facilitators encountered by mental health populations, from the perspective of patients and health workers. Common themes were boredom and a strong dependence on smoking<sup>1,3,4</sup>. Many patients believed they were not offered adequate advice or assistance to address their smoking<sup>1,4</sup>. This is supported in two studies by the relatively low proportion of mental health workers who considered smoking advice was an important part of their role<sup>2,5</sup>.

**Applicability statement for evidence statements 4.2.1–4.2.6** Three studies were based in the UK<sup>1,2,6</sup> and two studies were identified from Australia that is likely to have UK applicable evidence regarding adolescents<sup>5</sup> and psychiatric services<sup>7</sup>.

<sup>1</sup>Ratschen 2010

<sup>2</sup>Ratschen 2009

<sup>3</sup>Keizer 2009

<sup>4</sup>Green 2005

<sup>5</sup>Ashton 2010

<sup>6</sup>Jones 2011

<sup>7</sup>Hamilton 2000

## Evidence statement 5.1 Long-term NRT use

There is moderate evidence of long-term (12 months) NRT use in a small number of people who had quit smoking. The evidence is provided by 3 RCTs<sup>1-3</sup> (all [++]), 2 prospective cohort studies<sup>4,5</sup> (both [+]) and 1 (-) UBA<sup>6</sup>. This extended use is beyond the length of time that is recommended, treatment is usually between 8 and 12 weeks before the dose is reduced and eventually stopped. From the studies that provided 12-month follow-up data, 7% (range 3–11%) of individuals who had quit smoking were still using NRT. This evidence is for nasal spray<sup>1,3,5</sup> nicotine gum<sup>2,6</sup> and a range of NRT products<sup>4</sup>.

<sup>1</sup>Blondal 1999

<sup>2</sup> Bjornson-Benson 1993; Murray 1996; Nides 1995

<sup>3</sup> Sutherland 1992

<sup>4</sup> Hajek 2007

<sup>5</sup> Schneider 2003

<sup>6</sup> Hatsukami 1993

## Evidence statement 5.2 Long-term NRT use

There is moderate evidence that most long-term (12 months or over) use of nicotine gum or spray is within recommended dosage limits. The evidence is provided by 2 RCTs<sup>1,2</sup> (both [++]), 1 (+) prospective cohort study<sup>3</sup> and 2 cross-sectional surveys<sup>4,5</sup> (both [-]). For this dosage evidence participants in 3 studies<sup>1,2,3</sup> had quit smoking but the smoking status was not reported for participants in the other 2 studies<sup>4,5</sup>.

<sup>1</sup> Blondal 1999

<sup>2</sup> Bjornson-Benson 1993; Murray 1996

<sup>3</sup> Schneider 2003

<sup>4</sup> Hughes 2004

<sup>5</sup> Johnson 1991

## Evidence statement 5.3 Long-term NRT use

There is moderate evidence from 1 (++) RCT<sup>1</sup> and 1 (+) prospective cohort study<sup>2</sup> that nicotine dependence at baseline is a predictor of long-term NRT use at 12 months<sup>1,2</sup>. The data was from participants who had all quit smoking.

<sup>1</sup> Bjornson-Benson 1993

<sup>2</sup> Hajek 2007

## Applicability statement for evidence statements 5.1–5.3

This evidence is directly applicable to people in the UK who attempt to quit smoking abruptly. Of the studies that reported NRT use at 12 months in former smokers, 2 studies were conducted in the UK (1 [++]<sup>1</sup> and 1 [+]<sup>2</sup>) and 3 were conducted in community settings (2 [++]<sup>3,4</sup> and 1 [-]<sup>5</sup>).

<sup>1</sup> Sutherland 1992

<sup>2</sup> Hajek 2007

<sup>3</sup> Blondal 1999

<sup>4</sup> Bjornson-Benson 1993; Murray 1996; Nides 1995

<sup>5</sup> Hatsukami 1993

## Evidence statement 5.4 Long term e-cigarette use

There is no evidence of e-cigarette use for periods of 12 months or longer in individuals who quit smoking abruptly and insufficient evidence of the pattern of use.

## Evidence statement 5.5 Long term e-cigarette use

There is weak evidence from 3 cross-sectional surveys (1 [+]<sup>1</sup> and 2 [-]<sup>2,3</sup>), possibly of e-cigarette enthusiasts, that e-cigarettes are used for 12 months or longer. Only 1 study<sup>3</sup> reports that some individuals have completely replaced cigarettes with e-cigarettes. There was no evidence related to the dosage used by long term e-cigarette users.

<sup>1</sup> Etter 2011

<sup>2</sup> Foulds 2011

<sup>3</sup> Heavner 2010

## Evidence statement 5.6 Long term e-cigarette use

No evidence was identified on predictors or purchase patterns of e-cigarette use.

## Applicability statement for evidence statements 5.4–5.6

The evidence is only partially applicable to people in the UK who quit smoking abruptly. This is because e-cigarettes are not licensed for smoking cessation. There is evidence from 3 cross-sectional surveys (1 [+]<sup>1</sup>, 2 [-]<sup>2,3</sup>) in which participants were possibly e-cigarette enthusiasts<sup>3</sup>. However, the evidence does indicate that e-cigarettes are used in the UK<sup>1,2</sup> though it does not indicate if any of the e-cigarette users quit smoking abruptly.

<sup>1</sup> Etter 2011

<sup>2</sup> Heavner 2010

<sup>3</sup> Foulds 2011

## Economic modelling

Overall, tobacco harm reduction approaches were found to be cost effective.

Five comorbidities (lung cancer, chronic obstructive pulmonary disease, stroke, myocardial infarction and coronary heart disease) were included in the model, as well as all-cause mortality.

Seven key 'quit' or 'reduce' scenarios, using various delivery routes, were assessed. A total of 21 scenarios (that is, individual or multi-component interventions) were modelled in the main analysis. The comparator in all cases was 'no intervention'.

Of the scenarios which sought to help someone quit or reduce their consumption, 3 were cost saving and 12 were highly cost effective. The latter ranged from an estimate of £437 per quality-adjusted life year (QALY) to £8464 per QALY. Of the scenarios based around temporary abstinence, 5 were highly cost effective and 1 showed no benefit. The former ranged from an estimated £765 per QALY to £8464 per QALY.

A sensitivity analysis of abrupt quitting supported by long-term nicotine-containing products estimated that the use of nicotine-containing products was cost effective for nearly all the scenarios. (Effectiveness of quit rate varied from 0–20%; duration of use of nicotine-containing products varied from 6 months to 10 years.)

The costs only potentially outweighed the benefits when nicotine-containing products were provided for more than 5 years, and the quit rate was less than 4%, or the products were provided for more than 10 years and the quit rate was less than 6%.

## Supplementary analysis

A supplementary analysis assumed there were no benefits from smoking reduction (in terms of QALYs and comorbidities), other than an increased likelihood of quitting at 6 months. It showed that, as the effectiveness of an intervention diminishes, so the time during which it is considered cost effective to provide NCPs reduces. For example, the costs potentially outweigh the benefits when the reduction rate is 6% or less, and someone uses a nicotine-containing product for 12 months or longer. If a reduction of 20% or more is achieved, the product can be used for up to 2 years before it exceeds the £20,000 QALY threshold for cost effectiveness.

It was anticipated that there may be some trade-off between the number of people quitting and the number who reduce the amount they smoke, according to the approach used. For example, by offering services to help people to reduce their smoking intake, it is plausible that some people who may otherwise have chosen (or attempted) to quit decide not to.

An analysis of the benefits associated with either quitting smoking or reducing smoking for a person aged 50 was undertaken. The model estimated that an intervention that achieves 1 additional 'reducer' will provide an additional 0.45 QALYs. It will also save the NHS approximately £767 over the person's lifetime. An intervention that achieves 1 quitter, however, will gain 0.84 QALYs and will save the NHS £1412 over the same period.

In other words, the benefits of reducing are approximately half those of quitting. So, for each 'quitter' drawn into reducing instead, any intervention would need to get at least 2 more people to reduce their smoking to offset that loss. The supplementary analysis showed that, for each potential quitter lost, 6 more 'reducers' would be needed to offset the lost benefits.

Clearly, it would be better to gain 1 quitter rather than 1 reducer. However, by offering services to help people to reduce the amount they smoke, more people may present for treatment, leading to additional benefits to society.

## Fieldwork findings

Fieldwork aimed to test the relevance, usefulness and feasibility of putting the recommendations into practice. The PDG considered the findings when developing the final recommendations. For details, go to [Fieldwork](#) and [Tobacco: harm-reduction approaches to smoking – final fieldwork report](#).

Fieldwork participants who work with smokers were fairly positive about the recommendations

and their potential to help reduce the harm from smoking, so long as the harm-reduction approaches were a step towards stopping smoking.

Many participants stated that provision of support for tobacco harm-reduction would involve a substantive addition to current practice. However, some services were already using a 'cut down to quit approach'.

The majority of participants did not welcome the idea of encouraging people to reduce their smoking without ever planning to stop.

Many participants were positive about those parts of the recommendations that emphasised abrupt quitting as the best way to improve the health of people who smoke. There were, nonetheless, widespread concerns about the potential negative impact that the recommendations as a whole could have.

Some thought that presenting smokers with an option to reduce their smoking (indefinitely as they understood it) rather than stopping smoking, presented an 'easy way out'.

Most commissioners thought that the evidence for the health benefits and cost effectiveness of a harm reduction approach were insufficient to justify the significant changes and costs required to implement the recommendations. Concern about costs also focused on long-term funding of NRT and funding of services within 'payment by results' contract models (where payment is typically attached to someone stopping smoking).



## 10 Gaps in the evidence

The Programme Development Group (PDG) identified a number of gaps in the evidence related to the programmes under examination based on an assessment of the evidence, stakeholder and expert comment and fieldwork. These gaps are set out below.

1. Health professionals' and service users' views about the barriers to, and facilitators for, implementing tobacco harm-reduction strategies.

(Evidence review 4)

2. Service users' and providers' views on offering free NRT and its potential impact on the success of tobacco harm-reduction strategies.

(Evidence review 4)

3. GPs' and other prescribers' attitudes towards (and views on) the barriers to and facilitators for using licensed nicotine-containing products.

(Evidence review 4)

4. The pharmacokinetics of new nicotine containing products such as electronic cigarettes

(Evidence review 1)

5. The safety and long-term use of licensed nicotine-containing products among different subgroups. This includes potential drug interactions and contraindications.

(Evidence review 1)

6. The effectiveness and cost effectiveness of the following in relation to helping people cut down prior to stopping smoking or trying to reduce the amount they smoke:

- different combinations of licensed nicotine-containing products
- other nicotine delivery systems
- using products for more than a year
- group support models as part of a 'cutting down prior to stopping smoking' approach
- consumer-driven harm reduction, such as social norms and product demand

- different initiatives to prevent relapse.

(Evidence reviews 2 and 3)

7. The effectiveness and cost effectiveness of different behavioural strategies to support different harm-reduction approaches.

(Evidence reviews 2 and 3)

8. The effectiveness and cost effectiveness of self-help materials.

(Evidence reviews 2 and 3)

9. The health benefits of smoking reduction, rates of relapse and progression to stopping smoking among people who have opted to reduce the amount they smoke.

10. The long-term psychological effects of nicotine use in relation to smoking status and the harm-reduction approach used. (In relation to people who have not cut down, those who have reduced the amount they smoke and people who have stopped smoking and switched to licensed nicotine products.)

11. The extent to which compensatory smoking occurs when someone is trying to cut down prior to stopping smoking or trying to reduce the amount they smoke. (Compensatory smoking includes taking deeper inhalations or smoking more of the cigarette). For example, there is a lack of data on whether the behaviour persists over time, and whether the amount of compensation differs across groups. (It could differ by the degree of nicotine addiction, amount of cigarettes smoked and whether or not NRT is used.)

(Evidence reviews 2 and 3)

12. The effect of population-level policies and interventions to support harm reduction.

(Evidence reviews 2, 3, 4 and 5)

13. The impact of different marketing strategies on the uptake of harm-reduction approaches.

(Evidence reviews 2, 3, 4 and 5)

14. Data on:

- services offering harm reduction strategies
- level of compliance with different tobacco harm-reduction strategies

- relapse rates following an attempt to cut down, temporary abstinence and quitting completely – and whether smoking increases following a relapse
- combined use of NRT and cigarettes as a harm-reduction approach
- long-term health effects of a harm-reduction approach
- behavioural effects of long-term nicotine use
- alcohol use and its association with the motivation to stop smoking, cut down prior to stopping or reduce the amount they smoke.

15. The relationship between pharmacokinetic profiles and user responses to new nicotine-containing products, such as electronic cigarettes.

The Group made 10 recommendations for research into areas that it believes will be a priority for developing future guidance. These are listed in Recommendations for research.

# 11 Membership of the Programme Development Group (PDG) and the NICE project team

## Programme Development Group

PDG membership is multidisciplinary. The Group comprises public health practitioners, clinicians, representatives of the public, academics and technical experts as follows.

### **Deborah Arnott**

Chief Executive, Action on Smoking and Health (ASH)

### **Paul Aveyard**

Professor of Behavioural Medicine, Department of Primary Care Health Sciences, University of Oxford and UK Centre for Tobacco Control Studies

### **Gretel Baron**

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### **Linda Bauld (Chair)**

Professor of Health Policy, University of Stirling and UK Centre for Tobacco Control Studies

### **John Britton**

Director, UK Centre for Tobacco Control Studies, University of Nottingham

### **Barrie Dwyer**

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### **Ian Gray**

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### **Martin Jarvis**

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## About this guidance

### Why is this guidance being produced?

NICE public health guidance makes recommendations on the promotion of good health and the prevention of ill health.

The Department of Health (DH) asked the National Institute for Health and Care Excellence (NICE) to produce this guidance.

The guidance should be implemented alongside other guidance and regulations (for more details see [Implementation](#) and [Related NICE guidance](#) respectively).

### How was this guidance developed?

The recommendations are based on the best available evidence. They were developed by the Programme Development Group (PDG).

Members of the PDG are listed in [Membership of the Programme Development Group and the NICE project team](#).

For information on how NICE public health guidance is developed, see the NICE [public health guidance process and methods guides](#).

### What evidence is the guidance based on?

The [evidence](#) that the PDG considered included:

- Evidence reviews:
  - Review 1: 'Safety, risks and pharmacokinetics profiles of tobacco harm reduction technologies' was carried out by Cedar, Cardiff and Vale University Health Board. The principal authors were: Stephen Jones, Andrew Cleves, Fiona Morgan, Kathleen Withers, Judith White and Megan Dale.
  - Review 2: 'The effectiveness of tobacco harm reduction approaches with the intention of quitting (that is, cutting down to quit or reduction to stop smoking), with and without assistance' was carried out by the Support Unit for Research Evidence (SURE), Cardiff University. The principal authors were: Fiona Morgan, Alison Weightman, Sarah Whitehead, Helen Morgan, Ben Carter, Ellie Byrne, Ruth Turley and Andrew Cleves.
  - Review 3: 'The effectiveness of long-term harm reduction approaches without the prior intention of quitting' was carried out by SURE. The principal authors were: Fiona Morgan, Alison Weightman, Sarah Whitehead, Helen Morgan, Ben Carter, Stephen Jones, Ellie Byrne and Ruth Turley.
  - Review 4: 'Barriers and facilitators to implementing tobacco harm reduction approaches (including user and provider perspectives)' was carried out by SURE. The principal authors were: Ruth Turley, Helen Morgan, Jane Noyes, Alison Weightman, Fiona Morgan, Sarah Whitehead and Elizabeth Halstead.
  - Review 5 'Long term use of non-tobacco nicotine containing products in individuals who have quit smoking abruptly' was carried out by SURE. The principal authors were: Helen Morgan, Fiona Morgan, Alison Weightman and Sarah Whitehead.
- Review of economic evaluations: 'A rapid review of economic evidence on tobacco harm reduction strategies' was carried out by Mapi Values and York Health Economics Consortium. The principal authors were: Paul Truman, Kristel Janssen, Margreet van Eerd, Evelien Bergrath and Catherine Mulvany.
- Economic modelling: 'An economic evaluation of different interventions to promote tobacco harm reduction', and a supplementary analysis entitled 'An economic evaluation of different interventions to promote tobacco harm reduction: supplementary report', was carried out Mapi Values and York Health Economics Consortium. The principal authors were: Matthew Taylor, Paul Truman, Kristel Janssen, Margreet van Eerd, Evelien Bergrath and Catherine Mulvany.



- Expert papers:
  - Expert paper 1: 'Electronic cigarettes: nicotine delivery, efficacy in smoking cessation and potential for harm reduction' by Maciej L Goniewicz, Queen Mary University of London
  - Expert paper 2: 'The prevalence and "effectiveness" of the use of NRT for smoking reduction and temporary abstinence among English smokers' by Emma Beard, University College London
  - Expert paper 3: 'Routes to quit' by Melanie McIlver, National Centre for Smoking Cessation and Training
  - Expert paper 4: 'Harm reduction – views from a smokers' panel' by Ann McNeill, UK Centre for Tobacco Control Studies
  - Expert paper 5: 'Smokefree mental health review' by Ian Gray, Chartered Institute of Environmental Health and Hilary Wareing, Co-Director, Tobacco Control Collaborating Centre
  - Expert paper 6: 'Prison service tobacco policy' by Suzy Dymond-White, National Offender Management Service (NOMS)
  - Expert paper 7: 'Harm reduction: mapping the ripples' by Gerard Hastings, Institute for Social Marketing and the Centre for Tobacco Control Research, University of Stirling
  - Expert paper 8a: 'E-cigarettes: views from UK smoking cessation practitioners' by Deborah Arnott, Action on Smoking and Health (ASH)
  - Expert paper 8b: 'E-cigarette use in Great Britain: 2010 and 2012' by Deborah Arnott, Action on Smoking and Health (ASH)

Note: the views expressed in the expert papers above are the views of the authors and not those of NICE.

- Expert testimony:
  - Chris Marriott, King's College London, provided verbal commentary on review 1.
- Fieldwork report: 'Tobacco: Harm-reduction Approaches to Smoking – Final Fieldwork Report' was carried out by ICF GHK.

The [reviews, expert papers and economic analysis](#) are available.

In some cases the evidence was insufficient and the PDG has made recommendations for future research.

## Status of this guidance

The draft guidance, including the recommendations, was released for consultation in October 2012. At its meeting in February 2013, the PDG amended the guidance in light of comments from stakeholders and experts and the fieldwork. The guidance was signed off by the NICE Guidance Executive in April 2013.

The guidance is available on NICE's website. The recommendations will also be available in a [pathway](#) for professionals whose remit includes public health and for interested members of the public.

## Implementation

NICE guidance can help:

- Commissioners and providers of NHS services to meet the requirements of the [NHS outcomes framework 2013–14](#). This includes helping them to deliver against domain one: preventing people from dying prematurely.
- Local health and wellbeing boards to meet the requirements of the [Health and Social Care Act \(2012\)](#) and the [Public health outcomes framework for England 2013–16](#).
- Local authorities, NHS services and local organisations determine how to improve health outcomes and reduce health inequalities during the joint strategic needs assessment process.
- NHS, local authority, public health and social care services meet the outcomes as detailed in [Improving outcomes: a strategy for cancer \(2011\)](#).
- Local authorities and NHS-commissioned services to contribute to the delivery of [Healthy lives, healthy people: a tobacco control plan for England \(2011\)](#).

NICE has developed [tools](#) to help organisations put this guidance into practice.

## Updating the recommendations

This guidance will be reviewed 3 years after publication to determine whether all or part of it should be updated. Information on the progress of any update will be posted at the [NICE website](#).

## Changes after publication

September 2015: Minor maintenance.

July 2013: The guidance was updated in July 2013 to reflect the MHRA decision that all nicotine-containing products should be regulated. This is expected to come into effect in 2016. For further details, see the [MHRA website](#).

## Your responsibility

This guidance represents the views of the Institute and was arrived at after careful consideration of the evidence available. Those working in the NHS, local authorities, the wider public, voluntary and community sectors and the private sector should take it into account when carrying out their professional, managerial or voluntary duties.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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## Accreditation

