National Institute for Health and Care Excellence

Guideline version (Final)

Smoking cessation interventions and services

[C] Evidence reviews for advice on e-cigarettes on general sale

NICE guideline NG92

Evidence reviews

[March 2018]

November 2021: NICE guideline NG92 (March 2018) has been updated and replaced by NG209. The recommendations labelled [2018] or [2018, amended 2021] in the updated guideline were based on these evidence reviews.

See www.nice.org.uk/guidance/NG209 for all the current recommendations and evidence reviews.

FINAL

These evidence reviews were developed by Public Health Internal Guideline Development team



Disclaimer

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The recommendations in this guideline are not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

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ISBN: 978-1-4731-2873-6

Contents

Advice on consumer e-cigarettes	5
Review question	5
Methods and process	5
Public health evidence	5
Evidence statements	5
Recommendations	5
Rationale and impact	. 5
The committee's discussion of the evidence	7

Review question

What advice and referral options are appropriate for people using consumer ecigarettes for smoking cessation?

Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual. The methods used for study identification are Methodology section (see Appendix A) and reviewing methods specific to this review question are described in the review protocol in Appendix B

Declarations of interest were recorded according to NICE's 2014 conflicts of interest policy.

Public health evidence

No published evidence was identified and the committee agreed to use expert testimony (see Appendix F2 and F3).

Evidence statements

The expert testimony covered the following themes

- the increase in popularity of vaping has been accompanied by reduction in smoking, with large numbers of smokers successfully switching to vaping in countries where vaping is allowed. (Expert testimony 2)
- Including an offer of a 'starter pack' e-cigarette within the English stop-smoking services is likely to increase their attractiveness and reach and may increase their efficacy (Expert testimony 2)
- the evidence that e-cigarettes are effective in smoking cessation in England is limited (Expert testimony 3)
- there is currently no published evidence on the long-term benefits and harms of these products (Expert testimony 3)

Applicability: This evidence is directly applicable as it is based on existing practice in the UK.

Recommendations

- C1 For people who smoke and who are using, or are interested in using, a nicotine-containing e-cigarette on general sale to quit smoking, explain that:
- although these products are not licensed medicines, they are regulated by the Tobacco and Related Products Regulations 2016
- many people have found them helpful to quit smoking cigarettes
- people using e-cigarettes should stop smoking tobacco completely, because any smoking is harmful

- the evidence¹ suggests that e-cigarettes are substantially less harmful to health than smoking but are not risk free
- the evidence in this area is still developing, including evidence on the long-term health impact. [2018]

Rationale and impact

Why the committee made the recommendations

People who smoke often ask healthcare practitioners about using nicotine-containing e-cigarettes, which are increasingly being used for quitting. Because of the misconceptions and confusion about the safety of e cigarettes, the committee agreed that advice should be given to allow an informed discussion on using them to stop smoking.

The long-term harms caused by smoking, even in the short term, are well established and are the reason people who smoke are advised to quit. The committee were aware of reports produced by Public Health England (E-cigarettes and heated tobacco products: evidence review) and the Royal College of Physicians (Nicotine without smoke: Tobacco harm reduction) stating that the constituents of cigarette smoke that harm health are either absent in e-cigarette vapour or, if present, are mostly at much lower levels.

However, the committee also concluded that because e-cigarettes have only been widely available for a short period, the evidence on the long-term impact of their short-term use as well as the long-term health impact of their long-term use was still developing.

The committee were concerned that people who smoke should not be discouraged from switching to e-cigarettes, and as a result continue to smoke, because the evidence is still developing. Although there is a little evidence on the effectiveness and safety of these as medicinal products, the committee expected that these products are likely to be less harmful than smoking. Although they didn't review the evidence detailed in the reports, they noted the recent reviews by Public Health England and others that stated that e-cigarettes are substantially less harmful than smoking. NICE was also aware of the reports produced by other national organisations as well as PHE. NICE agreed during post-committee discussions with PHE that the guideline should reflect the guidance produced by others when advising people who want to stop smoking about e-cigarettes

How the recommendations might affect practice

Many staff are not aware of what advice to give on e-cigarettes so staff will need information and training. Managers of services providing stop smoking support may need to ensure staff are aware of the latest information, but the costs should be minimal.

¹ See reports by Public Health England (E-cigarettes and heated tobacco products: evidence review), the British Medical Association (E-cigarettes: balancing risks and opportunities) and the Royal College of Physicians (Nicotine without smoke: Tobacco harm reduction).

The committee's discussion of the evidence

Interpreting the evidence

The outcomes that matter most

The committee agreed that quit rate was the most important outcome as it was a reliable proxy for all the benefits accrued after a smoker quits. This includes the reduction in risk to tobacco-related illnesses and the morbidity and mortality associated with these. For people with tobacco-related illness there is an increased benefit in terms of greater risk reduction, lessening of symptoms, fewer hospital admissions etc.

For people with other medical conditions, stopping smoking can reduce the risk of complications associated with those conditions, increase treatment options (for example in HIV), and reduce delays in recovery after surgery

From a population health aspect the committee noted that one of the largest risk factors for starting smoking is having a parent who smokes so any increase in quit rates will have a carry-on benefit in terms of further reducing the number of people who take up smoking. There is an additional benefit from reduced exposure to second-hand smoke.

The quality of the evidence

No evidence was reviewed and expert testimony was sought. The committee discussed the value of a statement on the evidence base when the recommendation relates on advice on e-cigarettes to be given to a person who smokes.

Benefits and harms

The committee accepted the expert testimony stating that nicotine-containing ecigarettes was effective as a harm reduction strategy but noted that the evidence for effectiveness as a smoking cessation aid was sparse and further research is needed. There was concern among some committee members about the lack of evidence on long-term benefits or harms of using these products and impact on those exposed to second-hand vapour.

The topic experts noted that there was a split amongst smoking cessation professionals internationally over the benefits of offering advice on nicotine-containing e-cigarettes with some professionals seeing them as an unproven harm reduction strategy for smokers and other professionals see e-cigarettes as a useful aid to help smokers quit or to reduce the number of cigarettes smoked. The committee noted the expert testimony stating that national trends had identified an increase in the popularity of e-cigarettes has been accompanied by reduction in smoking cigarettes, with large numbers of smokers successfully switching to e-cigarettes. One of the topic experts reported that preliminary 2015 data in the UK suggest that there are around 800,000 ex-smokers in the England who have successfully switched to e-cigarettes and another 640,000 who had smoked cigarettes and e-cigarettes but have quit smoking completely. It was noted that some professionals have expressed concern that nicotine-containing e-cigarettes may become a 'gateway' to smoking as the use of nicotine-containing e-cigarettes may normalise 'smoking' behaviours.

Cost effectiveness and resource use

No review of cost effectiveness evidence was undertaken. Instead, a bespoke model was developed which explored the threshold at which interventions are cost effective and assessed the cost effectiveness of a range of interventions identified in the effectiveness reviews.

This topic area was covered in the overall health economic modelling, with two studies including e-cigarette interventions. These both indicated that e-cigarettes were cost effective and potentially cost saving to both NHS and local authorities. The committee noted that nicotine-containing e-cigarettes are cheaper than cigarettes a fact which may be useful as a lever in a harm reduction strategy.

Other factors the committee took into account

Patient choice is sometimes restricted because patients do not have all the information they need to make an informed choice or develop their preferences. The committee wanted to ensure that this guideline should stipulate that the role of the clinician is to inform and empower the patient in relation to their options, so that they can make informed choices

The topic experts reported that personally-purchased nicotine-containing e-cigarettes are being used increasingly by people who smoke to help them stop smoking. While there is a paucity of evidence on the effectiveness and safety of these as medicinal products, the committee noted that these products appear to be substantially less harmful than smoking. The committee cited reports produced by Public Health England (E-cigarettes and heated tobacco products: evidence review) and the Royal College of Physicians (Nicotine without smoke: Tobacco harm reduction) which report that the constituents of cigarette smoke that harm health are either absent in e-cigarette vapour or, if present, they are mostly at levels much below 5% of smoking doses and also that the main chemicals present in e-cigarettes only have not been associated with any serious risk.

The topic experts were also aware of a recent UK study that that showed that e-cigarettes alone, but not dual-use of e-cigarettes and cigarettes, was associated with substantially reduced levels of measured carcinogens and toxins when compared to smoking. This was considered a key issue as the committee were keen to emphasize that any smoking is harmful and so wrote a recommendation stating this.

As the long-term harms caused by smoking, even in the short-term, are well established and are the reason people who smoke are advised to quit, the committee also considered the evidence base around the long-term health impact of e-cigarette use. The committee considered the health impact of long-term use of e-cigarettes and also the long-term health impact of short-term e-cigarettes. The committee concluded that as e-cigarettes have only been widely available for a short period, the evidence on long term health impact is still developing.

E-cigarettes are regulated by the EU Tobacco Products Directive transposed into UK law in the Tobacco and Related Products Regulations 2016. The Medicines and Healthcare products Regulatory Agency (MHRA) is the competent authority and it has decided that all nicotine-containing products should be regulated and have stated that adverse effects or e-cigarettes or re-fill containers can be notified via the Yellow Card system. To date one e-cigarette has been licensed for medical use but this product is not on the market at the time of publication. In this situation, the

committee decided that it would be harmful to ignore the fact the nicotine-containing e-cigarettes are being used as an aid to smoking cessation.

The topic experts emphasized that recent surveys of smokers indicated that there is a lot of uncertainty and confusion over the safety of nicotine-containing e-cigarettes with some smokers (around 20%) believing that they are at least as harmful as smoking cigarettes. The committee debated on how the recommendation should be worded to help negate some of the negative perceptions surrounding e-cigarettes, Some committee members were also concerned that NICE recommendations reflect what is known and to state otherwise would help perpetuate these misconceptions and so agreed to re-state the Public Health England position that e-cigarettes are substantially less harmful than cigarettes but are not risk free.

The precautionary principle was discussed. Some members of the committee considered that statements in the body of the recommendation about the lack of knowledge about long-term health impact risked the unintended consequence that it could discourage smokers from switching and as a result they might continue to smoke. Some committee members also noted that the evidence base on long term impact of short-term use of e-cigarettes as well as long-term health impact of long term use was still developing.