NHS Health Scotland’s position statement on Electronic Nicotine Delivery Systems – ENDS - e-cigarettes and other smoking simulator products
31 October 2014

Introduction

NHS Health Scotland is the national agency for reducing health inequalities and for health improvement. The agency works to support programmes across diverse areas, focussing on measures that make a positive impact on public health. People’s health behaviours and choices are influenced by many social and economic factors. Scotland aims to become a tobacco-free country in the next 20 years, and replacing tobacco with nicotine delivery systems could help or hinder that ambition.

This statement addresses health matters relating to the availability, marketing, sale and use of Electronic Nicotine Delivery Systems – ENDS - including in public places, and in NHS premises and grounds. Our task is to ensure that arrangements and choices are well-informed and can promote and protect health. If these are not optimal, then choices should reduce harm where possible.

The term ENDS is used throughout this position statement to denote the entire range of electronic nicotine delivery systems, including e-cigarettes and simulator products. Tobacco, tobacco products and constituents, and ENDS and constituents, remain substances of addiction and potential harm. Nicotine in most forms is addictive and maintains addiction, but is relatively safe in most populations, and particularly if medically controlled as nicotine replacement therapy. Nicotine itself, while not harm-free, poses minimal risk to health in comparison with other tobacco product constituents such as tar and carbon monoxide except in large doses.

Principles

NHS Health Scotland stresses the requirement of all stakeholders to comply with existing legislation and regulations, and not to undermine them. In the case of tobacco and replacement products, any approach should enable Scotland to achieve a steady fall in the prevalence of tobacco use, and should enhance the policies of ‘smoke-free’ and of achieving ‘tobacco-free’ within a generation. As ENDS are relatively new products, many matters are unknown with respect to their mode of use, their efficacy and their safety. In the absence of adequate knowledge of the effects of unlicensed substitutes and simulators, which contain other ingredients besides nicotine, a precautionary approach to their use is prudent in the interests of public health.
What do we know about ENDS?

- ENDS are tobacco-free, battery-powered devices that heat a liquid often containing nicotine and flavourings into an inhalable form. Some ENDS are smaller and cigarette-like in appearance. However, within a growing range of newer products, many no longer resemble normal cigarettes.
- Most, but not all, contain nicotine; they also contain a variety of other ingredients, most commonly propylene glycol, glycerine and flavourings.
- The ranges of products have diverse contents and mechanisms of action.
- Products are currently not regulated to assure consumers about standard or regulated quantities of ingredients in products. Some regulation will be introduced over the next 2 years under the European Union Tobacco Products Directive, covering product marketing, quality and claims that products have medicinal uses, and requiring those with higher nicotine levels to register as medicines.
- ENDS represent a rapidly growing and diverse market. They encompass a variety of smoking simulator products (e.g. vapourisers, shisha pens) that have become increasingly popular in recent years. Rates of experimentation and regular use are rising rapidly in adults. Among current cigarette smokers, regular use of e-cigarettes has risen from 2.7% in 2010 to 17.6% in 2014, and ‘ever use’ from 8.2% in 2010 to 50.6% in 2014. Regular ENDS use so far has generally been confined to current and ex-smokers. Experimentation with e-cigarettes is higher than regular use, rising from 3.7% to 11.6% among ex-smokers and from 0.5% to 1.1% among never-smokers from 2012 to 2014. (ASH/YouGov, 2014).

What are likely to be the potential benefits of ENDS?

- ENDS, if used by established smokers or recent quitters and effective in keeping them off tobacco use, may offer one of several options for smokers who wish to reduce the harm that tobacco causes, by replacing addiction to tobacco with a less harmful alternative.

What are the uncertainties about ENDS?

- There is accumulating, but still patchy, evidence about the quality, safety and effectiveness of ENDS and their use, and little evidence on long-term use.
- Although ENDS are almost certainly less harmful than tobacco smoking, this is not an assurance of safety. Much is still unknown.
- Current reports describe the more common profile of ENDS users as established smokers who are seeking a means to cut down or quit. There is limited evidence of their effectiveness in this respect. The few studies to date, generally from weak or under-powered studies, show mixed results on the whole. The most promising evidence is of motivated ENDS users who are not using services to help quit, showing results that are as good as those with NRT patches or no nicotine replacement. If ENDS are effective in keeping smokers off tobacco use, they may
make a positive contribution to public health. But there are many potential uses (including frequency/mode of use) and users. ENDS may prolong habitual smoking behaviour and delay quitting cigarettes altogether (as evidenced by dual use). These results could have a negative impact on public health in future.

• Regular use has to date generally been confined to current and ex-smokers. Both experimentation and regular use has been rising among adults in recent years. It is too early to know how trends will unfold. experimentation rates among all groups may evolve into regular use, and provide a gateway into tobacco use.

• Unlike cigarettes, current ENDS do not produce carbon monoxide in any substantial quantity. Analyses of the contents of ENDS vapour indicate that they contain considerably lower concentrations of many of the major toxins in cigarette smoke. However, other chemical compounds may be emitted while the particle size, composition and other characteristics are yet to be established and may be very different from cigarette smoke. Thus, it is too early to be able to assess accurately the risk to users and second-hand inhalers of the vapour.

• Accurate assessment of the impacts of ENDS will take many years because disease and side-effect knowledge associated with a new product takes time to accumulate.

• The effect of dual use of cigarettes and ENDS is unknown. No level of continued tobacco use is safe. There are no clear benefits from reduced tobacco consumption – indeed, low levels of tobacco use are disproportionately harmful, generally as a result of ‘compensatory smoking’. The role of ENDS in reducing but not completely replacing consumption of cigarettes is still unclear, given that the extent of nicotine, tobacco and ENDS contents ultimately ingested from dual use is unknown.

What are the concerns about ENDS, their manufacture and marketing?

• Marketing and widespread use of ENDS risk undermining progressive measures aimed at creating a smoke-free Scotland, through modelling of smoking behaviour as normal once again.

• There is accumulating evidence that young people (age 13 and upwards) are aware of ENDS and experiment with them – in an ASH Scotland survey (2014), 24% of 13-14 year-olds, 48% of 15-16 year-olds and 46% of 17-18 year-olds had used an e-cigarette. 18% of those young people who had used an e-cigarette had not previously tried a normal cigarette while 78% had.

• Linked with levels of experimentation, the rapid gain in awareness and popularity of ENDS makes them attractive to young people, to others who have never smoked, or to former smokers.

• The tobacco industry is increasingly investing in the ENDS market. Recently one company successfully obtained a licence for an ENDS product via the MHRA. As a recent WHO report states: ‘While there are “independent” ENDS companies that have reported no interest in perpetuating tobacco use, the tobacco industry involved in the production and sale of ENDS certainly is.”
• There are reports of fires and other hazards resulting from improper use of the device or the charging mechanism. Young children can be at risk of nicotine poisoning if replacement cartridges and refill accessories are discarded within their reach.

NHS Health Scotland’s position is as follows:

General advice
• Tobacco remains the single substance that most commonly causes preventable deaths in Scotland. Smoking cessation (quitting smoking) is the best way to reduce tobacco-related illness and death.
• No usage of cigarette or tobacco products is safe, and abstinence from all tobacco products will provide the best health outcomes.
• Adults have the capacity to make informed choices on tobacco use, while many children do not. Arrangements should focus particularly on the protection of children.
• In terms of nicotine-containing products such as ENDS and the other nicotine replacement therapy products, the NHS only endorses use of licensed products which have proven evidence of effectiveness, safety and quality. These should be concentrated on helping people ultimately to quit tobacco use, and with a view to quitting tobacco and ENDS use entirely. Use of non-prescription items is a matter of personal choice.
• Abrupt quitting using a combination of social support, pharmaceutical treatment and behavioural support is the most effective way to stop smoking. For those who feel unable/unwilling to quit abruptly, other methods, combinations and routes may help, although quitting is the ideal ultimate outcome.
• Notwithstanding the ideal aim of quitting, NHS Health Scotland supports the principle of harm reduction for those smokers who are highly nicotine-dependent and who do not currently feel ready to quit tobacco or nicotine use completely in one step. A harm reduction approach, particularly one involving use of nicotine replacement therapy, may help smokers quit in the longer term.
• The recommended route for harm reduction would involve nicotine-containing products that are properly regulated, with proven safety and effectiveness profiles. Nicotine replacement therapy offers the option of replacing addiction to tobacco with a safe (rather than simply less harmful) alternative. Prescription use would be with clear purpose supported by binding guidelines for use in treatment. Further details of the various harm reduction options (e.g. ‘cutting down to quit’, NRT use for temporary abstinence or to remain quit) are available at [http://www.healthscotland.com/uploads/documents/4661-GuideToSmokingCessationHRAddendumMarch2014.pdf](http://www.healthscotland.com/uploads/documents/4661-GuideToSmokingCessationHRAddendumMarch2014.pdf)
• ENDS use presents opportunities for health professionals to guide users into smoking cessation services and for support to quit their tobacco use. Quitting tobacco use should be the main aim of ENDS use. Supporting current ENDS users
towards quitting tobacco and ENDS use entirely could minimise the risk of relapse to conventional cigarettes. Provision of behavioural support through smoking cessation services would be expected to enhance the likelihood of success.

- NHS Scotland has provided a Health & Safety advice note on hazards relating to ENDS and re-charging the device, available at: http://www.hfs.scot.nhs.uk/news/?item=264

For public policy including local authority and third sector planners
- ENDS should not be used in indoor public spaces. Such measures would seek to uphold rather than undermine current smoking restrictions, and reduce the risk of role-modelling of smoking to children.
- Balancing the current evidence and seeking to uphold current smoking restrictions, the use of ENDS that do not resemble cigarettes (or cigars, or pipes for tobacco) may be confined to outdoor areas, preferably designated - but separate from any smoking areas to avoid SHS exposure.
- Future regulation, marketing and public policy need to reflect the balance between maximising beneficial use and minimising harm.
- Restrictions on marketing and availability of ENDS should be consistent with products that are of potential harm, and especially to young people.
- NHS Health Scotland will monitor ENDS use and seek to address the gaps in available evidence, through the incorporation of questions in existing surveys, service databases, and through commissioning research, ensuring that data on dual use is captured too.

For the NHS, social care and care settings
- ENDS should not be used in any indoor areas and enclosed spaces. Such measures would seek to uphold rather than undermine current smoking restrictions, in line with health improvement principles.
- ENDS that resemble cigarettes should not be used in the grounds of NHS premises and related settings, consistent with and seeking to uphold restrictions on tobacco smoking. Sustaining smoke-free environments, and hospital premises and grounds (as they become fully implemented), is consistent with those of many private companies that provide services to the general public and that wish to provide safe and healthy environments.
- The use of ENDS that do not resemble cigarettes (or cigars, or pipes for tobacco) may be confined to outdoor areas, preferably designated - but separate from any smoking areas to avoid SHS exposure.
• Acknowledging that some licensed products may resemble cigarettes, prescribers should take the above issues into account as part of the decision about which products to prescribe, and/or advise of the alternative licensed nicotine-containing products that could be used on NHS premises.

• Those who wish support to quit smoking should receive support at the earliest practical opportunity. Those who experience symptoms of withdrawal from the constituents of tobacco smoking whilst a patient in NHS premises should also receive prompt and sympathetic support appropriate to patient needs, including the use of products with proven effectiveness. The evidence for effective interventions that support these measures is available at http://www.healthscotland.com/documents/4661.aspx.

• There should be particular attention to support people with unplanned hospital admissions, pregnant women, and those with underlying health problems and vulnerable characteristics, to ensure their needs are met.

Next steps

Accumulation of evidence around safety and efficacy of ENDS, particularly as they evolve, and changes in public opinion relating to ENDS, and developments and challenges to consumer protection and regulation, are inevitable over the next few years.

NHS Health Scotland will monitor the changing environment of evidence, marketing and sales, regulation and legislation, and public opinion on ENDS and related issues. NHS Health Scotland will review and update this position statement regularly, working closely with ASH Scotland and Scottish Government.

Revised 31 October 2014
NHS Health Scotland

Abbreviations

NRT – nicotine replacement therapy
WHO – World Health Organization
MHRA – Medicines and Healthcare products Regulatory Agency
SHS – second-hand smoke