NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Smoking: harm reduction

Date of Quality Standards Advisory Committee post-consultation meeting:
26 March 2015

2 Introduction

The draft quality standard for smoking: harm reduction was made available on the NICE website for a 4-week public consultation period between 5 February and 5 March 2015. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 18 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the Quality Standards Advisory Committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the Committee as part of the final meeting where the Committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the Committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the Committee should read this summary alongside the full set of consultation comments, which are provided in appendix 1.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

3. For each quality statement what do you think could be done to support improvement and help overcome barriers?

Stakeholders were also invited to respond to the following statement specific questions:

4. For draft quality statement 1: In order to make this quality statement measureable, the setting where it occurs needs to be defined. Which healthcare practitioner(s) carrying out this statement would give it the most impact (e.g. GPs, pharmacists, etc.)?

5. This quality standard should be read closely in conjunction with NICE's quality standard on smoking cessation (Smoking cessation: supporting people to stop smoking [NICE quality standard 43]). With this in mind, should this topic be published

as a separate quality standard or be incorporated within the existing NICE quality standard on smoking cessation? Please state the reasons for your answer.

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- The quality standard was welcomed as it will put harm reduction on the agenda for healthcare professionals.
- A concern was raised that tobacco manufacturers were included as stakeholders.
- This quality standard needs to clarify that harm reduction approaches should not be prioritised over stopping smoking abruptly. The quality standard should also ensure that those motivated to quit are not inadvertently directed towards a harm reduction approach.
- Suggestion that the quality standard should specifically refer to electronic cigarettes – noting the attraction of these products to consumers and the fact that electronic cigarettes can be both licenced and unlicensed (as medicines) products.
- Suggestion to include how unlicensed nicotine-containing products could be used to complement licenced products in a harm reduction strategy (particularly for people who find licensed products unsatisfactory). The stakeholder acknowledged that NICE cannot recommend unlicensed nicotine-containing products but suggested including mention of when the use of unlicensed products might be beneficial to health.
- Suggestion to include medical conditions (including oral cavity cancer and gum disease) in the introduction.
- Suggestion that the quality standard should be accessible to people who are visually impaired.
- Concern raised on referring to cotinine levels in children as an overarching outcome as this is not commonly measured and is more specific than the other outcomes listed. To 'reduce tobacco exposure to children' was suggested as an alternative outcome.

Consultation comments on data collection

- Data collection for the proposed quality measures was reported as possible if systems and process were available; however current data capture would be difficult. Mechanisms for centralised data collection may be required.
- A quality indicator linked to harm reduction would be necessary to drive data recording in GP surgeries and pharmacies.
- Stop smoking services already have robust databases for data capture however only a small proportion of people utilising harm reduction approaches will access these services, so measuring uptake will be difficult for people who attempt this approach on their own.
- For effective data collection, there would need to be a systematic approach to recording smoking status and interventions in electronic health records. It was reported that some hospitals have started to do this.
- Retail audit data may be needed to measure any uptake of unlicensed nicotine-containing products.
- The data was supported as collectable but may incur extra costs for providers.
- Data could be collected at medical consultations when smoking status is determined, advice is given and treatment initiated.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

People who decline a referral to a stop smoking service are offered a harm reduction approach to smoking.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- To aid measurability and understanding the statement needs to define the setting in which harm reduction approaches should be offered and which practitioners should carry out the statement.

- Concern raised that this statement should not be limited to people who decline a referral to a stop smoking service, but rather that discussions about harm reduction approaches should occur with all people after it has been established that they are not ready or willing to quit (regardless of their willingness to be referred to a stop smoking service).
- Harm reduction approaches also could be appropriate for people who have stopped smoking cigarettes but are concerned about relapse if they stop using licensed nicotine-containing products and people who have made an unsuccessful quit attempt.
- This statement does not consider those individuals who have declined referral to a stop smoking service but are willing to make a supported quit attempt through an alternative route which should be explored before a harm reduction approach is offered. Statement wording should refer to people who are unwilling or unable to make a quit attempt.
- People who smoke would benefit from receiving information about potential harm reduction approaches from sources other than a one-to-one discussion with a healthcare professional, as many people quit smoking without the support of services.
- Making a person who declines a referral to a stop smoking service as the subject of this statement was supported to ensure that quitting smoking is the preferred option.
- Suggestion that the statement should specify that harm reduction approaches should lead to quitting smoking.
- Suggestion that electronic cigarettes or other unlicensed nicotine-containing products should be specifically mentioned under the 'harm reduction approaches' definition section in this statement.

Consultation question 4

For draft quality statement 1: In order to make this quality statement measureable, the setting where it occurs needs to be defined. Which healthcare practitioner(s) carrying out this statement would give it the most impact (e.g. GPs, pharmacists, etc.)?

Stakeholders made the following comments in relation to consultation question 4:

- All healthcare practitioners (and potentially social care practitioners) who come into contact with people who smoke should be able to deliver advice on quitting and reducing harm and not just at one-to-one clinical conversations.
- Pharmacists are well equipped to provide fast and convenient advice and can be more accessible than GPs and other services.
- GPs and nurses in primary and community care settings.
- Clinicians in all NHS services.
- Primary care would be best however community pharmacies, secondary care and stop smoking services can also have a role.
- Mental health care staff (community and provider) and drug and alcohol services.
- The role of midwives, obstetricians and stop smoking advisors was also raised.
- Pre-op assessment nurses are a key group for short term cessation.
- Therapeutic radiographers, anaesthetists, surgeons and people responsible for booking elective surgery were also highlighted.
- Dental professionals (dentists and wider dental team) already discuss lifestyle habits as a standard part of a regular check-up. They have an opportunity to discuss harm reduction approaches with people who are 'healthy' and would not otherwise attend a healthcare setting.

5.2 Draft statement 2

People who decline a referral to a stop smoking service are advised that most health problems associated with smoking are caused by components in tobacco smoke other than nicotine, and about using nicotine-containing products.

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- The importance of explaining the relative safety of nicotine-containing products and misconceptions around nicotine was recognised as important by stakeholders.

- To aid measurability the statement must define specific occasions where the actions described in it would occur and which practitioners who would carry them out.
- The provision of information on nicotine and nicotine-containing products should not be limited to conversations with people who have refused referral to stop smoking services but should be proactively shared with all people who smoke. This statement misses the opportunity to reach all people who smoke with important information.
- Access to nicotine-containing products as part of a harm reduction approach (e.g. provision for temporary abstinence in care settings) is not included. This was felt to be another missed opportunity.
- Suggestion to amend the statement to refer only to licenced nicotine-containing products. Concerns were raised about the promotion of e-cigarettes and advising the use of unlicensed nicotine-containing products in general.
- Suggestion that the statement should focus on all nicotine-containing products not just licenced products.
- Suggested that the statement should also detail how to handle enquiries in relation to e-cigarettes.
- Suggestion of using more cautious wording around the use of nicotine-containing products, as nicotine is not without harmful effects.
- Concern raised over the phrasing in the quality standard that the safety, effectiveness and quality of unlicensed nicotine-containing products cannot be assured. This may cause people to reject unlicensed products.

5.3 Draft statement 3

Stop smoking services provide harm reduction approaches alongside existing approaches to stopping smoking in 1 step.

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- Statement supported for being important and straightforward.

- Concern raised that this statement misses the opportunity to reach people who would not access stop smoking services, and that part of the focus of harm reduction approaches is to reach people who are further away from making a quit attempt (i.e. who wouldn't access stop smoking services).
- Concern raised that although stop smoking services should offer harm reduction approaches, so should other healthcare professionals who engage with smokers.
- Concern raised on potential confusion between this statement and reference to people who decline a referral to stop smoking service (as per statement 1). This statement appears to suggest that referral to a stop smoking service is needed for access to harm reduction approaches.
- Suggestion that unlicensed e-cigarettes should be explicitly mentioned in the definitions section of harm reduction approaches in this statement.

5.4 Consultation question 5

This quality standard should be read closely in conjunction with NICE's quality standard on smoking cessation (Smoking cessation: supporting people to stop smoking [NICE quality standard 43]). With this in mind, should this topic be published as a separate quality standard or be incorporated within the existing NICE quality standard on smoking cessation? Please state the reasons for your answer.

Consultation comments

Stakeholders made the following comments in relation to consultation question 5:

- It is appropriate to combine the two quality standards because:
  - The supporting guidance encourages all smokers to reduce their risk of harm from smoking.
  - Supported as its essentially one concept and it would be better to have one unified smoking quality standard.
  - Challenges for commissioning and data collection for these two topics will be more efficient if addressed together
  - These measures are closely linked to the smoking cessation quality standard
  - It is important that people reading one of the quality standards would also read the other as they are complementary approaches.

  - Supported for its significant degree of overlap.
- It is not appropriate to combine the two quality standards, because:
  - It is important that harm reduction is not just seen as something to be done specifically by stop smoking service practitioners. There is a role for all practitioners around offering harm reduction approaches.
  - The harm reduction and smoking cessation quality standards are aimed at two different and distinct patient groups and no person who wants to quit should be inadvertently directed towards a harm reduction strategy rather than being supported to quit.
  - They are different concepts so should remain separate.
  - Keeping the two topics separate clarifies the primary goal is to support people who smoke to quit altogether (however these quality statements should be cited in the smoking cessation quality standard).
  - As there are separate guidance documents on smoking cessation (PH10) and harm reduction (PH45), the quality standards should also be separate for continuity.
- Several stakeholders highlighted that if these topics are not combined there should be close linkage and references between the two quality standards.

6 Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- Stakeholders commented that the statements do not include opportunities to reach people who do not currently access healthcare services.
- Stakeholders noted that access to nicotine-containing products as part of a harm reduction approach was not included in the quality statements. This would be useful in the context of temporary abstinence for those in care settings and medication provision for those where relapse is identified as a risk and for those with a recent failed quit attempt.

Appendix 1: Quality standard consultation comments table

ID	Stakeholder	Statement No	Comments[1]
General comments			
1	Action on Smoking and Health (ASH)	General	We were concerned to see in table three of the consultation document (summary of suggested quality improvement areas) that two major tobacco manufacturers are listed as "stakeholders", Imperial Tobacco Limited, and Phillip Morris International. We would draw your attention to Article 5.3 of the Framework Convention on Tobacco Control (FCTC), (http://www.who.int/tobacco/wntd/2012/article_5_3_fctc/en/) to which as you know the UK is a Party. Article 5.3 states that: *"In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law."* The Guidelines for implementation of Article 5.3, (http://www.who.int/fctc/guidelines/article_5_3.pdf) which were agreed by the FCTC Conference of the Parties at its third session in November 2008, further state that: *"The guidelines apply to setting and implementing Parties' public health policies with respect to tobacco control. They also apply to persons, bodies or entities that contribute to, or could contribute to, the formulation, implementation, administration or enforcement of those policies."* (Introduction paragraph 9) *"In setting and implementing public health policies with respect to tobacco control, any necessary interaction with the tobacco industry should be carried out by Parties in such a way as to avoid the creation of any perception of a real or potential partnership or cooperation resulting from or on account of such interaction. In the event the tobacco industry engages in any conduct that may create such a perception, Parties should act to prevent or correct this perception."* (Recommendations paragraph 20) *"The tobacco industry should not be a partner in any initiative linked to setting or implementing public health policies, given that its interests are in direct conflict with the goals of public health."* (Recommendations paragraph 21) *"Parties should ensure that all branches of government and the public are informed and made aware of the true*

[1]PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees.

ID	Stakeholder	Statement No	Comments[1]
			purpose and scope of activities described as socially responsible performed by the tobacco industry." (Recommendation 6.1) *"Parties should not endorse, support, form partnerships with or participate in activities of the tobacco industry described as socially responsible."* (Recommendation 6.2) It is evident that quality standards for tobacco harm reduction fall squarely within the areas of public policy covered by the FCTC, and therefore within the provisions of Article 5.3 and the accompanying guidelines. We would suggest that to treat tobacco manufacturers as "stakeholders" in relation to this area of public policy could create the impression that the tobacco industry is being accorded inappropriate access. We would therefore recommend that NICE reconsider its definition of stakeholders in this context, and that any future interactions with the tobacco industry which may be necessary are conducted and reported in terms which are unarguably consistent with Article 5.3.
2	British American Tobacco	General	We support the development of the "*Smoking: harm reduction*" quality standard (the "Quality Standard") and welcome the opportunity to comment on its development. The Quality Standard, and the guidance on which it is based, pragmatically recognises the reality that some smokers may not want to quit smoking in one step or may not want to quit at all. By seeking to provide alternative options that assist in reducing harm to these types of smoker, this may ultimately increase the number of people who quit smoking and have very real benefits for public health.
3	British Dental Health Foundation	General	Why this quality standard is needed: People who smoke are more likely to have gum disease which is still the most common cause of tooth loss in adults. Smoking may change the type of bacteria in dental plaque, increasing the number of bacteria that are more harmful. It also reduces the blood flow in the gums and supporting tissues of the tooth and makes them more likely to become inflamed. Smokers' gum disease will get worse more quickly than in people who do not smoke. Because of the reduced blood flow smokers may not get the warning symptoms of bleeding gums as much as non-smokers. The knock-on effect of gum disease can be linked with general health conditions such as diabetes, strokes, cardiovascular (heart) disease, poor pregnancy outcomes and even dementia. While we need more research to understand how these links work, there is more and more evidence that having a healthy mouth and gums can help improve general health and reduce the costs of medical treatment.
4	British Dental Health Foundation	General	Smoking tobacco is still the leading cause oral cancer, responsible for an estimated 65% (70% in males and 55% in females) of oral and pharyngeal cancers in the UK.[1] Oral cavity cancer risk is three times higher in current smokers compared with never-smokers, a meta-analysis showed. Pharyngeal cancer risk is nearly seven times higher in current smokers compared with never-smokers.[2] Oral cancer incidences have increased by a third in the last decade[3-6] – representing one of largest case-increasing cancers in the UK. Children and young people are also affected by witnessing smoking as a normal adult behaviour. For example,

ID	Stakeholder	Statement No	Comments[1]
			children who live with parents or siblings who smoke are up to three times more likely to become smokers themselves than children of non-smoking households.[7] **References:** 1. Parkin DM. Tobacco-attributable cancer burden in the UK in 2010. Br J Cancer 2011; 105 (S2):S6-S13. 2. Gandini S, Botteri E, Iodice S, et al. Tobacco smoking and cancer: a meta-analysis. Int J Cancer 2008; 122(1):155-64. 3. Data were provided by the Office for National Statistics on request, July 2013. Similar data can be found here: http://www.ons.gov.uk/ons/rel/vsob1/cancer-statistics-registrations--england--series-mb1-/index.html 4. Data were provided by ISD Scotland on request, May 2013. Similar data can be found here: http://www.isdscotland.org/Health-Topics/Cancer/Publications/index.asp 5. Data were provided by the Welsh Cancer Intelligence and Surveillance Unit on request, June 2013. Similar data can be found here: http://www.wales.nhs.uk/sites3/page.cfm?orgid=242&pid=59080. 6. Data were provided by the Northern Ireland Cancer Registry on request, June 2013. Similar data can be found here: http://www.qub.ac.uk/research-centres/nicr/CancerData/OnlineStatistics/. 7. Leonardi-Bee J, Jere ML, Britton J. Exposure to parental and sibling smoking and the risk of smoking uptake in childhood and adolescence: a systematic review and meta-analysis. Thorax 15 Feb. 2011 doi:10.1136/thx.2010.153379.
5	British Dental Health Foundation	General	Levels of achievement: While the British Dental Health Foundation agrees that expected levels of achievement should aspire to 100% (or 0% if the quality statement states that something should not be done), we believe that by recognising potential difficulties and allowing targets of success to be set at local level, the chances of achieving maximum success is decreased. It should be stated that in spite of potential difficulties local authorities are expected to achieve 100% success (or 0% if the quality statement states that something should not be done).
6	British Thoracic Society	General	• Should the statement 1 & 2 be re-phrased as 'People that do not express interest in stopping smoking...'? • On page 2, the reference to cotinine levels in children seems out of place - this is not commonly measured, and the other outcomes are more generic. Would 'Reduce tobacco exposure to children' be more appropriate? Although it mentions on many occasions that stopping in one-step is recommended, we suggest an even more strongly worded message emphasising that the aspiration with harm reduction is for a smoker to cut down before stopping smoking (followed by reduction or temporary abstinence where this is not achievable)
7	Cochrane Tobacco Addiction Group (TAG)	General	Introduction pg2 Suggest changing '…contribute to improvements in the following outcomes' to 'contribute to the following changes in outcomes.' and to then go on to specify which direction we would wish these outcomes to go e.g. '**a reduction in** consumption of tobacco containing products' and '**an increase in** life expectancy at 75'. Otherwise the reader is

ID	Stakeholder	Statement No	Comments[1]
			forced to make assumptions themselves. Although these assumptions may seem obvious we think it is best to clarify.
8	Imperial Tobacco Limited	General	We welcome the opportunity to comment on the draft quality standard. Imperial Tobacco Limited, through its fully owned subsidiary company, Fontem Ventures, manufactures non-tobacco, nicotine containing products i.e. e-cigarettes for sale in the UK and France.
9	Imperial Tobacco Limited	General	Regarding the NICE statement that "not everyone who smokes is able or wants to stop smoking. For such people, a harm reduction approach to smoking could be an option, even though this may involve the continued use of nicotine.", we agree that such an approach could be an option for individuals who find it difficult to stop smoking.
10	Johnson & Johnson Limited	General	Whilst tobacco harm reduction strategies offer the NHS an opportunity to engage with smokers not ready, willing or able to quit tobacco and nicotine use it should not be seen as an optimal end-point in its own right. It can offer an opportunity to support smokers to behave in ways less harmful to their own health, or the health of those around them, than did their previous level of smoking, but it should always be seen by the NHS as an opportunity to start and to support them on a journey where the desired outcomes is a life free from tobacco use and nicotine addiction. It should be acknowledged that this may not always be possible and that the length of the journey will vary widely for different smokers, but optimal individual and public health outcomes will only be secured if these smokers are supported to become free from tobacco and nicotine in their own time. It is critical that no smoker motivated to quit be inadvertently directed towards an alternative harm reduction strategy.
11	Nicoventures	General	General & Why this quality standard is needed & Definition of terms used in this statement: Harm Reduction Approaches We support NICE on the rationale behind proposing the draft quality standard. We do however believe that a key public health education and health technology access opportunity may be missed if the quality standard does not directly address the potential role of reduced-risk nicotine containing products such as e-cigarettes in tobacco harm reduction. An important population level change in the UK over the past five years is the increased incidence of e-cigarette use as a substitute for conventional cigarettes predominantly among smokers. Research from 2014 by the UK anti-smoking charity ASH showed that e-cigarette use had grown threefold in the previous two years from 700,000 to 2.1 million users. In their briefing document on e-cigarettes from November 2014, based on the emerging evidence from population level studies such as the Smoking Toolkit Study, ASH UK state that e-cigarettes "are proving more attractive to smokers than NRT while providing them with a safer alternative to cigarettes. There is evidence that they can be effective in helping smokers' quit and little evidence that they are being used by never smokers". (Reference: http://www.ash.org.uk/files/documents/ASH_715.pdf accessed 26/02/2015). We believe it is important to recognise that there is growing consensus among many scientists and public health professionals that e-cigarettes are in general significantly less risky than conventional cigarettes and that a switch to e-cigarettes by smokers has the potential to lead to an unprecedented public health success in terms of tobacco harm

ID	Stakeholder	Statement No	Comments[1]
			reduction. [Letter to Dr Margaret Chan, Director General WHO. Signed by 53 leading public health leaders from around the world. Reference: http://nicotinepolicy.net/documents/letters/MargaretChan.pdf accessed 26/02/2015] We think e-cigarettes can have great consumer appeal and, therefore, could significantly help in reducing smoking-related disease. There continues to be much debate about the role that e-cigarettes can play in public health policies. We hope that the growing weight of evidence and arguments in support of harm reduction which are being made by the scientific community, the industry and public health campaigners will help to guide future policies. E-cigarettes and e-liquids are currently sold as consumer goods at a diverse range of retail venues such as supermarkets, convenience stores, vape shops, pharmacies and online. These retail venues are the source of e-cigarettes for all of the estimated over 2 million e-cigarette users in the UK. This uptake has happened among smokers outside the boundaries of the NHS, financed by smokers themselves, supplied by an innovative, consumer-need-focussed e-cigarette industry. The revised EU Tobacco Product Directive (TPD) that became law in May 2014 provides a clear dual-track framework for e-cigarette regulation. The dual track in the TPD allows a regulated (but not licensed as medicines) consumer goods alternative to the conventional medicines route (e.g. medicinal nicotine replacement therapy products). We believe that when the TPD is implemented in the EU member states including the UK, critical attributes of the products such as quality and safety will be addressed, thus giving regulators, consumers and the public health community the confidence in recommending unlicensed (i.e. regulated, but not licensed as medicines) e-cigarettes to smokers. To that end, we are actively contributing technically and scientifically to the work of the British Standards Institution and other similar standards initiatives across the EU in elaborating product quality and safety standards for e-cigarettes. We have a robust approach to product stewardship, including toxicological testing, using only pharmaceutical-grade nicotine in our e-liquid and compliance with all rules relevant to manufacture, content and labelling. The NICE quality standard needs to acknowledge that millions of smokers may choose to access unlicensed e-cigarettes (i.e. regulated but not licensed as medicines and allowed on the market as consumer goods under the TPD dual track) manufactured to high quality and safety standards and sold responsibly. The quality standard needs to provide balanced, accurate and relevant information to the NHS and related services that can support even more smokers by offering a credible reduced-risk alternative in e-cigarettes along with established smoking harm reduction options. We believe that this needs to be reflected in the definitions of the term “harm reduction approaches” by including e-cigarettes and other reduced-risk nicotine containing products alongside conventional approaches that are currently stated there.
12	Pfizer	General	Pfizer agrees with NICE’s statement in the related Briefing Paper that stopping in one step (‘abrupt quitting’) offers the best chance of lasting success. Pfizer also welcomes the statement on page 9 of the draft Quality Standard stating that HCPs should ensure they still prioritise stopping smoking as the best approach to take. In addition to these, Pfizer believes the Quality Standard would benefit from a similar statement in the Introduction section so the reader immediately understands that harm reduction is not being prioritised over stopping smoking abruptly.

ID	Stakeholder	Statement No	Comments[1]
			An example of such a statement would be: “A harm reduction approach should only be used as a secondary measure once it is established that the priority approach of abrupt quitting is absolutely not a viable option for the smoker.”
13	Pfizer	General	Pfizer agree with NICE over the inclusion of the statement that those public health and social care practitioners (HCPs/SCPs) involved in assessing, caring and treating people who smoke should have appropriate training. By providing smokers with complete information on the range of services including prescription only pharmacotherapy, smokers are best informed to choose the pathway with their HCP/SCP that is right for them.
14	Proprietary Association of Great Britain	General	PAGB is committed to supporting the public health community on the journey to a society free from tobacco use and nicotine addiction and believes that harm reduction should always be considered part of the quitting process not as an alternative option. Whilst reducing the number of cigarettes or other tobacco products smoked could lower the risk of death and disability associated with smoking, quitting is the best thing a smoker can do for their health. We recognise that not everyone who smokes is able or wants to stop smoking and that harm reduction strategies have an important role in reducing the impact of smoking on health. However, we want to ensure that no smoker motivated to quit is inadvertently directed towards a harm reduction strategy rather than support to quit.
15	Royal National Institute of Blind People	General	About the RNIB: Royal National Institute of Blind People (RNIB) is the UK's leading charity providing information, advice and support to almost two million people with sight loss. We are a membership organization with over 13,000 members throughout the UK and 80 percent of our Trustees and Assembly members are blind or partially sighted. We encourage members to get involved in our work and regularly consult them on matters relating to Government policy and ideas for change. As a campaigning organization we act or speak for the rights of people with sight loss in each of the four nations of the UK. We also disseminate expertise to the public sector and business through consultancy on products, technology, services and improving the accessibility of the built environment. RNIB is pleased to have the opportunity to respond to this consultation
16	Royal National Institute of Blind People	General	Accessible information: We believe this guideline should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English." The Equality Act expressly includes a duty to provide accessible information as part of the reasonable adjustment duty. Online information on websites should conform to the W3C's Web Accessibility Initiative Web Content Accessibility Guidelines (WCAG) 1.0, level AA, as required by the NHS Brand Guidelines and the Central Office of Information. With regard to the accessibility of print materials, including downloadable content such as PDF files, we would request that wherever possible they comply with our "See it Right" guidelines:

ID	Stakeholder	Statement No	Comments[1]
			http://www.rnib.org.uk/professionals/accessibleinformation/Pages/see_it_right.aspx
17	Royal National Institute of Blind People	General	Both Age Macular Degeneration (AMD) and Cataracts are the leading causes of blindness and visual impairment. There is strong evidence demonstrating that both AMD and development of Cataracts are significantly associated to smoking (Thornton et al., 2005; Kelly et al., 2005; Nakayama et al., 2014; Swanson et al., 2014; Kar et al., 2014; Khanna et al., 2014). Other common ocular disorders, which are also linked to smoking are: anterior ischemic optic neuropathy (Hayreh et al., 2007) and GravesDisease (Bartalena et al.,1989). Therefore, owing to the clear evidence of links between smoking and blindness and visual impairment, RNIB would like any initiatives and patient materials (i.e. patient leaflets) persuading patients to stop smoking to include a reference to sight loss. References: • Bartalena L, Martino E, Marcocci C, Bogazzi F, Panicucci M, Velluzzi F, Loviselli A, Pinchera A. More on smoking habits and Graves' ophthalmopathy. J Endocrinol Invest. 1989 Nov;12(10):733-7. • Hayreh SS, Jonas JB, Zimmerman MB Nonarteritic anterior ischemic optic neuropathy and tobacco smoking. Ophthalmology. 2007 Apr;114(4):804-9. • Kar T, Ayata A, Aksoy Y, Kaya A, Unal M. The effect of chronic smoking on lens density in young adults. Eur J Ophthalmol. 2014 Sep-Oct;24(5):682-7. • Kelly SP, Thornton J, Edwards R, Sahu A, Harrison R. Smoking and cataract: review of causal association. J Cataract Refract Surg. 2005 Dec;31(12):2395-404. • Khanna RC, Murthy GV, Giridhar P, Krishnaiah S, Pant HB, Palamaner Subash Shantha G, Chakrabarti S, Gilbert C, Rao GN Cataract, visual impairment and long-term mortality in a rural cohort in India: the Andhra Pradesh Eye Disease Study. PLoS One. 2013 Oct 25;8(10):e78002. doi: 10.1371/journal.pone.0078002. eCollection 2013. • Nakayama M, Iejima D, Akahori M, Kamei J, Goto A, Iwata T. Overexpression of HtrA1 and exposure to mainstream cigarette smoke leads to choroidal neovascularization and subretinal deposits in aged mice. Invest Ophthalmol Vis Sci. 2014 Sep 9;55(10):6514-23. doi: 10.1167/iovs.14-14453. • Swanson MW[1]. Smoking deception and age-related macular degenerationOptom Vis Sci. 2014 Aug;91(8):865-71. • Thornton J, Edwards R, Mitchell P, Harrison RA, Buchan I, Kelly SP. Smoking and age-related macular degeneration: a review of association. Eye (Lond). 2005 Sep;19(9):935-44. Review
18	Royal College of Physicians of Edinburgh	General	Table 1 & 2 The College agrees this is a good summary of objectives.
19	Royal College of Physicians of Edinburgh	General	Table 1 & 2 We would query the use of 75 as average life expectancy; however we agree this is a good age to use as a reference point.
20	Society and College of	General	We are not totally clear what this new quality standard will add to previous NICE guidance, other than providing

ID	Stakeholder	Statement No	Comments[1]
	Radiographers		measures, although it is welcomed it in terms of putting harm reduction on the agenda for the health professionals and Trusts. Therapeutic radiographers will increasingly play a significant role to play in health promotion and health improvement of their patients, both during the patients' treatment and into their survivorship phase. So on this basis a focus on achieving harm reduction from smoking is a key component of this role and is welcomed in principle.
21	The Association of Directors of Public Health	General	We welcome the continuing development of quality standards and tools that support Directors of Public Health and their local authorities to fulfil the potential for significant cross-sector/departmental public health innovations and gains; and through integrated pathway approaches. ADPH also recommends that those who are new to the public health role are given a robust guidance to enable them to make policy decisions based on the best evidence available.
22	The Electronic Cigarette Industry Trade Association (ECITA)	General	ECITA welcomes the public consultation on the NICE quality standard draft on Smoking: harm reduction, and trusts that our submission will be considered carefully alongside other responses. We believe that NICE has a real opportunity, with this guidance, to fully embrace tobacco harm reduction – in all its forms – and that this opportunity is not yet fully realised in the draft for consultation. We hope that we can provide evidence to support our additional suggestions for areas that NICE might like to consider including in this important guidance for healthcare professionals. In 2011, the UK Department of Health published its 'Healthy Lives Healthy People: Tobacco Control Plan', which states: "**New approaches to help tobacco users who cannot quit to instead use safer sources of nicotine** 6.10 Smokers are harmed by the tar and toxins in tobacco smoke, not necessarily by the nicotine to which they are addicted. There is no way of avoiding these deadly toxins if you inhale the smoke from burning tobacco. [...] 6.11 We will work in collaboration with the public health community to consider what more can be done to help tobacco users who cannot quit, or who are unwilling to, to substitute alternative safer sources of nicotine, such as NRT, for tobacco. In support of this, NICE will produce public health guidance on the use of harm reduction approaches to smoking cessation (to be published in spring 2013). We will also encourage the manufacturers of safer sources of nicotine, such as NRT, to develop new types of nicotine products that are more affordable and that have increased acceptability for use in the longer term." [https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213757/dh_124960.pdf] This will, no doubt, have drawn on the Behavioural Insights Team's Annual Update of 2010-11, which described: "**exploring new products for people addicted to nicotine** – products that deliver nicotine quickly in a fine vapour instead of as harmful smoke could prove an effective substitute for 'conventional smoking'. It will be important to get the regulatory framework for these products right, to encourage new products, which smokers can use as safer nicotine alternatives, to be made available in the UK. [Footnote: "Treating smoking-related diseases costs the NHS £2.7 billion each year in England. Only 21% of adults now smoke, compared with nearly half of all adults in the 1960s. A review by the Medicines and Healthcare products Regulatory Agency concludes that 'nicotine, while addictive, is actually a very safe drug'. BIT is working with DH on how to encourage smokers to substitute to safer but

ID	Stakeholder	Statement No	Comments[1]
			nonetheless appealing sources of nicotine, noting that products that produce a fine vapour appear to reproduce the pleasant 'hit' without the harm associated with smoking."] A tenet of behaviour change is that it is much easier to substitute a similar behaviour than to extinguish an entrenched habit (an example was the rapid switch from leaded to unleaded fuel). If more alternative and safe nicotine products can be developed which are attractive enough to substitute people away from traditional cigarettes, they could have the potential to save tens of thousands of lives a year;"2 [https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/60537/Behaviour-Change-Insight-Team-Annual-Update_acc.pdf][our emphasis]. We believe that one of the most important messages which needs to be understood from this is the need to get the right regulatory framework to "encourage new products" which are "appealing"; medicinal products are simply not appealing in the way that consumer products can be. Certainly, in the case of electronic cigarettes, their appeal is undeniable: "Consumer support for the product is evident from the user sites that a brief internet search on electronic cigarettes or vaping generates. To our knowledge, no users of NRT have ever felt sufficiently passionate about the product to establish a user website."3 [https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/Ecigarettes_report.pdf] Please see: http://ukvapers.org/index.php http://www.planetofthevapes.co.uk/forums/ http://www.e-cigarette-forum.com/forum/ http://ukvapefest.com/ amongst many others. (In 2010, the first UK Vapefest was held, and approximately 50 people turned up in a pub; by 2014, it needed the Malvern Showground to accommodate the thousands of vapers who attended. In 2015, it is likely that there will be even greater numbers attending Vapefest. When did you last hear of Patchfest?) Fortunately, the UK government has recognised that attempting to bring all electronic cigarettes into medicinal regulation would be a mistake. While the Tobacco Products Directive does seek to reclassify some electronic cigarettes as medicinal products, this is the subject of a Judicial Review, scheduled for a hearing at the European Court of Justice in the autumn of 2015. We trust that this will have the positive effect of not introducing the wrong regulatory framework, which would stifle innovation, rather than "encourage new products", and significantly reduce the appeal that these consumer products are currently having for smokers unable or unwilling to quit using nicotine. Indeed, data from Professor Robert West's Smoking Toolkit Study4 [http://www.smokinginengland.info/latest-statistics/] continue to demonstrate that electronic cigarettes are having a significantly positive impact on the UK's smoking prevalence, and successful quit attempts. [IMAGES REMOVED] These UK data are also supported by recent findings in France, where the French National Institute for Prevention

ID	Stakeholder	Statement No	Comments[1]
			and Health Education (INPES) recently published its Health Barometer for 2014 5[http://www.inpes.sante.fr/CFESBases/catalogue/pdf/1613.pdf], which found: "Parmi l'ensemble des 15-75 ans, 6,0 % declarent utiliser la cigarette electronique (entre 2,6 et 3 millions d'individus), 2,9% de maniere quotidienne (entre 1,2 et 1,5 million d'individus) et 1,0% sont des vapoteurs exclusifs (c'est-a-dire qu'ils ne fument pas ou plus de tabac). Meme si les methodologies d'enquete differentes ne permettent pas de comparer ces prevalences de facon rigoureuse, ces chiffres s'averent tres proches de ceux obtenus dans l'enquete ETINCEL realisee par l'OFDT fin 2013. Il reste difficile de se prononcer sur l'impact de la cigarette electronique sur le comportement tabagique: la hausse de la proportion d'ex-fumeurs, parmi lesquels environ 400 000 sont des vapoteurs, sera-t-elle durable? Quelle part d'entre eux recommencera a fumer apres avoir arrete un temps avec la cigarette electronique? Une autre publication fera le point specifiquement sur les caracteristiques d'usage et l'impact de la cigarette electronique sur le tabagisme, que ce soit sur l'arret du tabac ou l'initiation.6 [http://www.inpes.sante.fr/CFESBases/catalogue/pdf/1611.pdf]" **(Our translation)** Among all the 15-75 year-olds, 6.0% self-declare as using electronic cigarettes (between 2.6 and 3 million individuals), 2.9% using them daily (between 1.2 and 1.5 million individuals) and 1.0% exclusively vaping (that is, they neither smoke any more, nor use tobacco). Even if the different survey methodologies do not allow comparison of these prevalences in a rigorous way, these figures correlate very closely to those obtained in the ETINCEL survey carried out by the OFDT [The French Monitoring Centre for Drugs and Drug Addiction] at the end of 2013. It remains difficult to draw definitive conclusions on the impact of electronic cigarettes on smoking behaviour: will the increase in the proportion of ex-smokers, of which approximately 400,000 are vapers, be sustainable? How many of them will relapse to smoking, having once stopped with an electronic cigarette? Another publication will specifically review the characteristics of use and the impact of electronic cigarettes on smoking behaviour, whether it is a 'gateway out' of tobacco use, or a 'gateway in' to smoking initiation. Professor West's data further demonstrate that the use of licensed NRT products – such as those preferentially recommended by NICE in its guidance – continues to decline: [IMAGES REMOVED] Britton, J., and Bogdanovica, I., (2014), Electronic cigarettes, A report commissioned by Public Health England7 [https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/Ecigarettes_report.pdf], Public Health England: "The increase in electronic cigarette use over recent years appears to reflect in part, smokers using electronic cigarettes instead of NRT; and in part, users who would not otherwise have used NRT. This is particularly true of smokers attempting to quit, among whom electronic cigarettes are now the first choice. In this group, increasing use of electronic cigarettes has been associated with reductions in numbers using NHS stop smoking support, or buying over-the-counter NRT, but there has also been an increase in the total number of smokers using any form of support to quit. The net result appears to be an increase in the proportion of smokers who have quit within the past year." In light of this, isn't it time for NICE to fully embrace the Tobacco Harm Reduction potential of this disruptive

ID	Stakeholder	Statement No	Comments[1]
			technology, and advance beyond the somewhat blinkered approach of emphasising the traditional licensed NRT products while downplaying the merits of electronic cigarettes? In the draft quality standard, NICE suggests: "For such people, a harm reduction approach to smoking could be an option, even though this may involve the continued use of nicotine. It is important to extend the reach of harm reduction approaches as widely as possible, particularly to people who would not necessarily consider using existing stop smoking services."
23	The Electronic Cigarette Industry Trade Association (ECITA)	General	NICE pathway / General Furthermore, the NICE pathway specifies "that people receiving care should be... supported to understand their options and make fully informed decisions."
24	The Electronic Cigarette Industry Trade Association (ECITA)	General	Indeed, the scientific evidence appears to demonstrate the limited effectiveness and low appeal of the licensed nicotine-containing products, particularly when contrasted with the growing body of evidence supporting the effectiveness and appeal of electronic cigarettes: Alpert, H.R., Connolly, G.N., and Biener, L., (2011), A prospective cohort study challenging the effectiveness of population-based medical intervention for smoking cessation8 [http://tobaccocontrol.bmj.com/content/early/2012/01/03/tobaccocontrol-2011-050129.short], Tobacco Control: "**Objective** To examine the population effectiveness of nicotine replacement therapies (NRTs), either with or without professional counselling, and provide evidence needed to better inform healthcare coverage decisions. **Methods** A prospective cohort study was conducted in three waves on a probability sample of 787 Massachusetts adult smokers who had recently quit smoking. The baseline response rate was 46%; follow-up was completed with 56% of the designated cohort at wave 2 and 68% at wave 3. The relationship between relapse to smoking at follow-up interviews and assistance used, including NRT with or without professional help, was examined. **Results** Almost one-third of recent quitters at each wave reported to have relapsed by the subsequent interview. Odds of relapse were unaffected by use of NRT for >6 weeks either with (p=0.117) or without (p=0.159) professional counselling and were highest among prior heavily dependent persons who reported NRT use for any length of time without professional counselling (OR 2.68). **Conclusions** This study finds that persons who have quit smoking relapsed at equivalent rates, whether or not they used NRT to help them in their quit attempts. Cessation medication policy should be made in the larger context of public health, and increasing individual treatment coverage should not be at the expense of population evidence-based programmes and policies." Britton, J., and Bogdanovica, I., (2014), Electronic cigarettes, A report commissioned by Public Health England9 [https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/Ecigarettes_report.pdf], Public Health England: "NRT products have been designed to deliver low doses of nicotine, and most products to do so relatively slowly, in relation to absorption from cigarettes.[23] This, and the fact that the products can be expensive relative to cigarettes at the point of sale, provide few if any of the behavioural characteristics of cigarettes

ID	Stakeholder	Statement No	Comments[1]
			that contribute to addiction,[7] lack social acceptability as an alternative to smoking, and medicalise the act of trying to quit smoking, limits their attractiveness to smokers." and "Electronic cigarettes also appeal to smokers by mimicking the sensation and appearance of smoking a cigarette, and by their market positioning as lifestyle rather than medical products. Electronic cigarettes, and the various new generation nicotine devices in development, clearly have potential to reduce the prevalence of smoking in the UK. The challenges are to harness that potential, maximise the benefits, and minimise risks [https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/Ecigarettes_report.pdf].
25	The Electronic Cigarette Industry Trade Association (ECITA)	General	According to NICE's website17 [https://www.nice.org.uk/about/nice-communities/social-care]: "Our guidelines make evidence-based recommendations on "what works" in terms of both the effectiveness and cost-effectiveness of social care interventions and services." The cost effectiveness of NRT is limited by its low long-term success as a tool for quitting smoking, combined with the heavy subsidy it receives through the NHS. Even old and relatively inefficient electronic cigarettes appear to have a success rate as good as that of NRT, with more recent designs likely to be much more effective – and at no cost to the NHS: Tackett, A.P., Lechner, W.V., Meier, E., Grant, D.M., Driskill, L.M., Tahirkheli, N.N., and Wagener, T.L., (2015), Biochemically verified smoking cessation and vaping beliefs among vape store customers18 [http://www.ncbi.nlm.nih.gov/pubmed/25675943], Addiction: "**AIMS:** To evaluate biochemically verified smoking status, and electronic nicotine delivery systems (ENDS) use behaviors and beliefs among a sample of customers from vapor stores (stores specializing in ENDS). **DESIGN, SETTING, PARTICIPANTS:** A cross-sectional survey of 215 adult vapor store customers at four retail locations in the Midwestern United States; a subset of participants (n=181) also completed exhaled carbon monoxide (CO) testing to verify smoking status. **MEASUREMENTS:** Outcomes evaluated included ENDS preferences, harm beliefs, use behaviors, smoking history and current biochemically verified smoking status. **FINDINGS:** Most customers reported starting ENDS as a means of smoking cessation (86%), using newer generation devices (89%), vaping non-tobacco/non-menthol flavors (72%), and using e-liquid with nicotine strengths of ≤20 mg/ml (72%). There was a high rate of switching (91.4%) to newer generation ENDS among those who started with a first generation product. Exhaled CO readings confirmed that 66% of the tested sample had quit smoking. Among those who continued to smoke, mean cigarettes per day decreased from 22.1 to 7.5 ($p < .001$). People who reported vaping longer (OR=4.7, 95% CI = 2.0-10.8), using newer generation devices (OR=3.0, 95% CI = 1.0-8.4) and using non-tobacco and non-menthol flavors (OR=2.6, 95% CI = 1.1-6.1) were more likely to have quit smoking. **CONCLUSIONS:** Among vapor store customers in the US who use electronic nicotine delivery devices to stop smoking, vaping longer, using newer generation devices, and using non-tobacco and non-menthol flavored eliquid

ID	Stakeholder	Statement No	Comments[1]
			appear to be associated with higher rates of smoking cessation." Indeed, acknowledgement of the vitally important role for **unlicensed** nicotine-containing products, such as electronic cigarettes – with the growing body of evidence supporting their effectiveness (and cost-effectiveness) at helping smokers transition away from smoking tobacco, is singularly lacking from the NICE pathway Smoking: tobacco harm-reduction approaches overview19 [http://pathways.nice.org.uk/pathways/smoking-tobacco-harm-reduction-approaches]: [IMAGE REMOVED] which instead focusses on the promotion, production and sale of **licensed** nicotine-containing products, such as NRT, despite their limited success in truly addressing the issues of both effectiveness and cost-effectiveness, in accordance with NICE's stated aims. According to Professor Robert West20 [http://www.addictionjournal.org/press-releases/e-cigarette-use-for-quitting-smoking-is-associated-with-improved-success-rates]: "E-cigarettes could substantially improve public health because of their widespread appeal and the huge health gains associated with stopping smoking." To maximise the gain in Quality-Adjusted Life Years (QALYs) with the minimum outlay of (very limited) NHS funds, the popularity, combined with the self-funding nature, of electronic cigarettes needs to be taken into account.
26	The Electronic Cigarette Industry Trade Association (ECITA)	General	Conclusion / general In conclusion, it seems best to leave the last word to Louise Ross25 [http://test.guidelinesinpractice.co.uk/dec_14_ross_smoking#.VPXUSy6tb0x], Manager of Leicestershire's Stop Smoking Service: "**Outcomes** The proof that this approach works, and that embedding guidelines into practice is a winner, was the change in success rates in our service for the first quarter this year. We saw that there were 20% more successful quitters in the group that had used ecigs, either with or without nicotine replacement therapy, compared with the average success rate for all types of treatment.3 The clarity offered by the NCSCT guidelines, and the reminder that services can now include ecig users in their national data returns, will hopefully reassure those who have remained nervous about what to do and say when faced with the ecig dilemma. We have seen a worldwide shower of scare-stories, public policies based on guesswork, prejudice, moralising, and supposition; smokers, advisors, commissioners, and the general public are likely to be unsettled by this. Despite the fears that ecigs will act as a gateway to increased numbers of people starting to smoke, we continue to see smoking rates fall, with no evidence of young never-smokers starting regular use. Far from the scenario of worsening smoking prevalence, it appears that visible 'vaping' promotes more switching from tobacco.4 Professor West highlighted this trend in an interview on BBC Radio 4's Today programme in September 2014.5 **Brands, strengths, and flavours**

ID	Stakeholder	Statement No	Comments[1]
			My team have also used the NCSCT recommendations to help advise service users about brands, strengths and flavours. We have to be clear that we cannot be experts in this area, especially with the accelerated pace of developments in the ecig market. Our advisors encourage people to: · do their own research · always buy from a reputable retailer · always use the correct charger supplied with the device and never leave it charging unattended or overnight · experiment with what works best for them. As with other treatments in our 'usual care' package, listening carefully to what individuals say and ask is crucial to person-centred care and a good outcome. **Summary** I would like to encourage other stop smoking services and commissioners, healthcare workers, and smokers to read the NCSCT guidelines, and consider how they could take a positive view of this unanticipated opportunity to help lifelong smokers to switch from combustible tobacco to a less harmful form of nicotine. Some people may be uncomfortable with endorsing a nicotine-containing product that people enjoy so much that they want to continue its use long after they decide they will never smoke again. Think of this though: NICE PH45 states that longterm nicotine use may be used as a way of reducing the harm from smoking. As Professor Peter Hajek said, following the MHRA announcements on e-cigarette regulation earlier this year:6 'E-cigarettes... are the best chance we had so far to end the tobacco epidemic – and to do it with no government expenditure. The product needs to develop further to give smokers exactly what they want, but it is on the way to remove tobacco related harm on the population scale. Medical licensing of [e-cigarettes] would seriously undermine this opportunity.' In the author's opinion, the only thing that really matters is whether smoking rates are going up, or going down. Smoking prevalence in England is dropping faster than ever before, and ecigs have a real potential to accelerate this trend. To save more lives that will otherwise be lost through smoking, the end justifies the means. 3 Health & Social Care Information Centre. Stop Smoking Services quarterly monitoring return 2014-2015, quarter one. Leicester City. 4 Action on Smoking and Health. ASH briefing. Electronic cigarettes. November 2014. Available at: www.ash.org.uk/files/documents/ASH_715.pdf 5 BBC Radio 4. Today. Interview with Professor Robert West, 5 September 2014. Available at: https://www.youtube.com/watch?v=GAHJ1IfdwkQ&feature=youtu.be (accessed 1 December 2014). 6Science Media Centre. Expert reaction to EU vote on tobacco regulation. 8 October 2013. Available at: www.sciencemediacentre.org/expert-reaction-to-eu-vote-on-tobacco-regulation/ "
27	The Electronic Cigarette	General	Signatories to this submission:

ID	Stakeholder	Statement No	Comments[1]
	Industry Trade Association (ECITA)		ECITA (EU) Ltd, comprising: Blu, Edinburgh Clipper, Basildon Cuts Ice, Wembley Decadent Vapours, Swansea ECig Wizard, Peterborough ECigarette Direct, Swansea House of Liquid, Nottingham iBreathe, Oldham JacVapour, Edinburgh Liberro, Buntingford Liberty Flights, Darwen Mirage Cigarettes, Sheffield No-Match, Preston Socialites, Chesterfield Tablites, Manchester Vaper Trails, Bournemouth Vapestick, Borehamwood Vaporized, Edinburgh Vapourlites, Co. Durham VIP, Manchester **Other Industry Colleagues:** DB Vapes, Derby Rojeans, Liverpool The Best E Cigarette, Derby The Electric Tobacconist Ltd, Hemel Hempstead Uniqbuy, Blackburn Vape For Life Ltd, Blackwood Fumus Electronic Cigarettes, Hartlepool ezSmoke, Co. Galway Bumblebee Eliquid, Blackburn
28	UK Centre for Tobacco and Alcohol Studies (endorsed by the Royal College of Physicians)	General	The exclusion of any discussion of how unlicensed nicotine products could complement licensed products in this setting both ignores a product group that has a great deal to offer to some smokers, particularly those who have tried licensed nicotine and found it unsatisfactory, and also indicates that NICE is avoiding engaging with the reality with the most widely used harm reduction strategy in the UK – which is the use of electronic cigarettes. We recognise that

ID	Stakeholder	Statement No	Comments[1]
			NICE cannot recommend unlicensed products but suggest that it would be pragmatic and appropriate to make some statement to explain where the use of unlicensed products might be beneficial to health.
29	UK Centre for Tobacco and Alcohol Studies (endorsed by the Royal College of Physicians)	General	We note with dismay the description of two transnational tobacco companies, PMI and ITL, as "stakeholders". Article 5.3 of the WHO Framework convention on tobacco control advises that "The tobacco industry produces and promotes a product that has been proven scientifically to be addictive, to cause disease and death and to give rise to a variety of social ills, including increased poverty. Therefore, Parties should protect the formulation and implementation of public health policies for tobacco control from the tobacco industry to the greatest extent possible." We do not think that tobacco companies should be contributing in any way to NICE quality standards.
Quality statement 1			
30	Action on Smoking and Health (ASH)	Quality statement 1	The quality statement as currently drafted is not adequate for the range of discussions health professionals should be having with smokers. Discussions about taking a harm reduction approach should occur after it has been established that a smoker is not yet ready or willing to quit but should not be limited just to those who decline a referral to a stop smoking service. While the current evidence demonstrates that quitting with the support of a service is the most effective route, if a smoker is not happy to accept a referral there are a range of other options, such as quitting using a prescribed medication, which can also improve their chances of success. It may also be appropriate to explore a harm reduction approach for those who have already quit smoking but are concerned about relapse if they stop using licenced NCPs and for those who have made an unsuccessful quit attempt. Furthermore, smokers may benefit from receiving information about harm reduction from sources other than a one-to-one discussion with a health professional. As many smokers quit without the support of services it is important that they are provided with good quality information about the range of options to reduce harm from smoking to ensure that harm reduction opportunities are maximised.
31	British American Tobacco	Quality statement 1	QS 1: People who decline a referral to smoking cessation services are offered a harm reduction approach to smoking Q1: Key areas for improvement **Plug missed opportunities in the harm reduction approach to smoking** Evidence from around the world suggests that smokers are increasingly looking to try, or are trying, alternative tobacco or nicotine products. Our view remains that potentially reduced-risk tobacco products should not have been excluded from the scope of the guidance of the Quality Standard. Therefore, by not considering potentially reduced risk tobacco products as additional harm reduction approach is a missed opportunity. □ Smokers are substituting their usual cigarettes with alternatives such as electronic cigarettes and smokeless tobacco products. Among those who have done so, a proportion have been successful in reducing their use or completely quitting cigarettes (Brown et al). □ Those smokers who do not want to be referred to a smoking cessation service, do not want to quit smoking in one step, do not want to quit at all or do not want to use medicinal cessation products would benefit from clear and

ID	Stakeholder	Statement No	Comments[1]
			accurate information to enable them to understand the relative risks of different tobacco and nicotine products and their potential to reduce harm (Nutt et al.). Not considering potentially reduced risk tobacco products as additional harm reduction approach is a missed opportunity. It means there is a serious gap in the knowledge of health care providers as to the products available. Additionally, it is a missed opportunity to help those smokers who do not want to quit tobacco altogether and a missed opportunity to advise those smokers who are already using or considering using alternative tobacco products to their conventional cigarettes. There is a growing consensus among scientists that a switch to reduced-risk products has the potential to lead to unprecedented public health success in terms of tobacco harm reduction. **Reduced-Risk Smokeless Tobacco Products**: Independent evidence, as noted below, shows that certain low-toxicant smokeless tobacco products, including products such as Swedish-style snus, present substantially lower overall health risks than cigarette smoking. The Tobacco Advisory Group of the Royal College of Physicians in their 2008 report entitled “Ending tobacco smoking in Britain” said at page 4: “All smokeless tobacco products are…more hazardous than medicinal nicotine and, in some cases especially so, but all are also substantially less hazardous than smoking” and that “It is possible that some of the associated tobacco characteristics of [smokeless tobacco] products, such as taste and smell, help to make them acceptable to smokers as a substitute for tobacco smoking.” In the USA, the Food and Drug Administration is currently considering an application by Swedish Match AB to have 10 sub-brands of the General snus brand recognised as modified risk tobacco products (MRTPs). Categorisation of snus as an MRTPs, as defined in the USA Family Smoking Prevention and Tobacco Control Act 2009 would confirm and acknowledge snus as a reduced-risk tobacco product with the potential to reduce the risk of tobacco-related disease. **e-cigarettes:** The past five years has seen an increased incidence of e-cigarette use as a substitute for conventional cigarettes predominantly among smokers. These products could significantly help in reducing smoking-related disease. E-cigarettes and e-liquids are currently sold as consumer goods at a diverse range of retail venues including, but not limited to, supermarkets, convenience stores, vape shops, pharmacies and online. These retail venues are the source of e-cigarettes for over 2 million smokers in the UK (ASH study) who have or are switching away from tobacco cigarette smoking. This switch from tobacco to e-cigarettes is financed by smokers directly and supplied by an innovative, consumer-need focussed e-cigarette industry. Furthermore this switch has happened outside of the NHS. The revised EU Tobacco Product Directive (2014/40/EC) (“TPD”), which entered into force on 19 May 2014, provides a clear dual-track framework for e-cigarette regulation i.e. either regulated as a consumer product under TPD or regulated as a medical device under Council Directive 93/42/EEC. Thus, the dual track allows a ‘consumer good’ alternative to the conventional medicines route (e.g. medicinal nicotine replacement therapy products). Furthermore, when TPD is implemented (by 20 November 2016 for e-cigarettes), critical attributes such as quality and safety will be addressed, which will give regulators, consumers and public health bodies confidence in recommending (medicinally)

ID	Stakeholder	Statement No	Comments[1]
			e-cigarettes to smokers. The Quality Standard acknowledges that millions of smokers may choose to continue to use tobacco or to use e-cigarettes or other nicotine products. However, the Quality Standard fails to address how these smokers might be provided with balanced, accurate information about potentially reduced risk tobacco products such as e-cigarettes. This information can support efforts to reduce harm in conjunction with already established smoking harm reduction options.
32	British Dental Association	Quality statement 1 & Quality statement 2	Dentists are well placed to discuss both smoking cessation and harm reduction opportunistically with patients who are otherwise "healthy" and might not attend a GP or other healthcare setting. The latest Adult Dental Health Survey (2009) indicated that 61 per cent of dentate adults in England reported attending the dentist for a regular check-up, 10 per cent on an occasional basis, and 27 per cent when they experienced dental problems. The BDA supports the Smokefree and Smiling guidance from PHE recommending that dentists offer only "Very Brief Advice" (30 seconds), which may include a mention of harm reduction approaches if appropriate, plus referral to specialist services.
33	British Dental Association	Quality statement 1 & Quality statement 2	Under the current NHS contract, local audits of process and outcome in relation to Quality statements 1 and 2 (pp. 8-9, 12-13) would be very time-consuming for general dental practitioners, and are unlikely to be carried out in the absence of recognition within the payment system. However, assuming a computerised oral health assessment is carried out under the reformed contract, it may be possible to collect these data more straightforwardly in the future. (Outcome data would be obtained at a follow-up visit after the initial recording of advice given.) A mechanism for centralised collation and analysis of the information would be required, which should be the responsibility of service commissioners. It should be noted that the reformed contract will not be in place before 2018-19.
34	British Dental Health Foundation	Quality statement 1	In regards to the service providers who are best equipped to carry this out – dental professionals – the dentist and the wider dental team. Dental professionals are in the ideal position to talk with smokers about stop smoking services, harm reduction and the health implications of smoking. This is already part of their role and discussing lifestyle habits is a standard part of a regular check-up. Post-Direct Access, the dental hygienists and therapists role is to advise the patient on matters such as smoking cessation and stop smoking services. We should also be encouraging smokers to visit their dentist more regularly as smokers' have increased oral health disease, including higher chances of developing mouth cancer – which again, the dental team are in a prime position to help diagnose at an early stage which could be pivotal to survival. As per PHE's guidance document 'Smokefree and smiling: Helping dental patients to quit tobacco'.[8] 8 Public Health England (2013) 'Smokefree and smiling: Helping dental patients to quit tobacco', PHE Publications, March 2014
35	Pfizer	Quality statement 1	Pfizer believe this statement is well-worded in that only people who decline a referral to a stop smoking service are offered a harm reduction approach. It is important to maintain that quitting for good is the preferred approach for those who smoke.

ID	Stakeholder	Statement No	Comments[1]
			As there is limited evidence suggesting any health benefits in different levels of smoking, Pfizer believe it is important that harm reduction should lead to quitting for good and we would like to see this should be explicitly incorporated into the quality statement. The concern is that if this final step of eventual quitting is not included then the result is that, although lower levels of smoking are achieved, there still remains the same number of people smoking and there remain high risks to health. Quitting for good results in a greater life expectancy than merely reducing smoking [1], and it is also the most cost-effective use of resources as quitting smoking is a more cost-effective option in the long run than reducing smoking (demonstrated through the reduced cost of smoking-related morbidity treatment to the NHS) [1]. [1] http://www.nice.org.uk/guidance/ph45/documents/tobacco-harm-reduction-economic-analyses2
36	Royal College of Physicians of Edinburgh	Quality statement 1	The College supports this statement.
	Royal College of Physicians of Edinburgh	Quality statement 1	We would appreciate clarification if the quality standard is recommending the commissioning of additional services to provide this advice in a controlled environment, or is the expectation for it to be provided in the setting of the initial consultation?
37	The Electronic Cigarette Industry Trade Association (ECITA)	Quality statement 1	Pg.9 However, in order to "understand their options and make fully informed decisions", patients and healthcare service users must actually be given information about all their options, not just some of them, as suggested by: "**People who smoke and don't want to go to a stop smoking service** are offered ways of reducing their harm from smoking that don't necessarily mean having to give up nicotine. These are called 'harm reduction approaaches', and include things like cutting down, using licensed nicotine-containing products and/or stopping smoking for a while." No mention is made here of the opportunity to use an unlicensed nicotine-containing product, such as an electronic cigarette, and where this option is mentioned, under the definition of the 'Harm reduction approach', it is significantly downplayed, only receiving passing mention as "without using licensed nicotine-containing products". Indeed, the contrast between the active promotion of the licensed products over those which are unlicensed is continually emphasised, for example: "Stopping smoking, but using 1 or more licensed nicotine-containing products **as long as needed to prevent relapse**. Cutting down before stopping smoking ('cutting down to quit') - with the help of 1 or more licensed nicotine-containing products (**which may be used as long as needed to prevent relapse**) - without using licensed nicotine-containing products. Smoking reduction - with the help of 1 of more licensed nicotine-containing products (**which may be used as long as needed to prevent relapse**) - without using licensed nicotine-containing products. Temporary abstinence from smoking

ID	Stakeholder	Statement No	Comments[1]
			- with the help of 1 or more licensed nicotine-containing products - without using licensed nicotine-containing products." [**our emphasis**]
38	The Electronic Cigarette Industry Trade Association (ECITA)	Quality statement 1	No mention is made here – or elsewhere – of the opportunity for smokers wishing to embrace a harm reduction approach to use unlicensed nicotine-containing products, such as electronic cigarettes, for "as long as needed to prevent relapse". The omission of this vital information, for patients and users of healthcare services, would result in their not being able to "understand their options and make fully informed decisions". The National Centre for Smoking Cessation and Training recently published a briefing paper on electronic cigarettes, which makes the following recommendations for practice: "1. Be open to electronic cigarette use in people keen to try them; especially in those that have tried, but not succeeded, in stopping smoking with the use of licensed stop smoking medicines 2. Provide advice on electronic cigarettes that includes: Electronic cigarettes can provide some of the nicotine that would otherwise have been obtained from smoking regular cigarettes Electronic cigarettes are not a magic cure, but some people find them helpful for quitting, cutting down their nicotine intake and managing temporary abstinence There is a wide range of electronic cigarettes available and clients may need to try various brands, flavours and nicotine dosages before they find a brand that they like Electronic cigarette use is not exactly like smoking and users may need to experiment and learn to use them effectively (e.g. longer 'drags' are required and a number of short puffs may be needed initially to activate the 'vapouriser' and improve nicotine delivery) Although some health risks from electronic cigarette use may yet emerge, these are likely to be, at worst, only a small fraction of the risks of smoking. This is because electronic cigarettes do not contain combusion chemicals which cause lung and heart disease and cancer 3. Multi-session behavioural support, as provided by trained stop smoking practitioners, is likely to improve the efficacy of electronic cigarettes in the same way such support markedly increases the efficacy of NRT 4. Stop smoking services can provide behavioural support to clients who are using electronic cigarettes and can include these clients in their national data returns.* As with other unlicensed nicotine containing products, the stop smoking service cannot provide or prescribe them until such time as there are licensed options available 5. If a client being seen at a stop smoking service is using an electronic cigarette but also wants to use NRT, then it is OK for them to use the two in conjunction. They do not need to have stopped using the electronic cigarette before they can use NRT * providing they adhere to the national data definitions in the service and monitoring guidance, which are based upon the Russell Standard: http://www.ncsct.co.uk/usr/pub/assessing-smoking-cessationperformance-in-nhs-stop-smoking-services-the-russell-standard-clinical.pdf"11

ID	Stakeholder	Statement No	Comments[1]
			This is one of the key points we would have expected NICE to address in its guidance: the opportunity to promote a health intervention in smoking cessation which is eminently measurable, offers significant health benefit for negligible risk, and crucially, **at no cost to the NHS or the taxpayer**. Vapers are extraordinarily willing to invest in electronic cigarette products for themselves, particularly since vaping is currently so much cheaper than smoking, due to the absence of 'sin tax'. Indeed, the cost difference is a motivation for switching for many people, particularly those from lower sociodemographics.
39	UK Centre for Tobacco and Alcohol Studies (endorsed by the Royal College of Physicians)	Quality statement 1	No. This statement misses the point. Harm reduction is an option to promote to all smokers who feel unwilling or unready to try to quit. Willingness to be referred to a stop smoking service is irrelevant to that. Many smokers who are willing to quit will decline a referral. In all cases healthcare practitioners should promote cessation as the best option, and harm reduction as the next best, and support those activities to the best of their ability irrespective of willingness to be referred.
Quality statement 2			
40	Action on Smoking and Health (ASH)	Quality statement 2	It is important that all smokers understand the relative safety of nicotine containing products compared with smoking and are encouraged to use these alternatives. The provision of this information should not be limited to conversations with smokers who have refused a referral to services but be proactively shared with all smokers. Again, thinking about harm reduction only in terms of a one to one clinical discussion between a health professional and a smoker misses the opportunity to reach all smokers with important information. Access to nicotine containing products as part of a harm reduction approach – for example on prescription – is not included which is a missed opportunity. In particular it would be useful to include the provision of medication for temporary abstinence for those in care settings, provision of medication for those where relapse is identified as a risk and the provision of medication for those with a recent failed quit attempt.
41	British Dental Health Foundation	Quality statement 2	The document does not reference which nicotine-containing products are to be advised. If the proposal includes promotion of e-cigarettes, the British Dental Health Foundation would issue caution around this. More research on the long-term effects of e-cigarettes should to be completed before actively promoting e-cigarettes as alternative therapy to smoking. The long-term effect of vapour inhalation needs to be studied, while studies also suggest that e-cigarettes are a gateway for younger people to start smoking. The British Dental Health Foundation believes the document should be revised as to recommend and refer 'Licensed' nicotine-containing products as an effective way of reducing the harm from tobacco for smokers and those around them.
42	Imperial Tobacco Limited	Quality statement 2	Rationale We share the view of NICE that many people have misconceptions "…about the role of nicotine in causing harm", which may "…act as a barrier that prevents them considering the use of such products". These misconceptions around nicotine apply to both manufacturers of licenced and unlicensed nicotine containing products (e.g. Ref: http://www.nicorette.co.uk/help-and-support/nicotine-myths), we welcome initiatives that will flow from this quality standard which seek to address this.

ID	Stakeholder	Statement No	Comments[1]
43	Imperial Tobacco Limited	Quality statement 2	We agree with NICE that certain products that make claims with regards to their effectiveness, safety and quality have not been assured and therefore consider the MHRA approach for evidence based regulatory controls for all products making claims as a positive measure. Notwithstanding the introduction of such measures, the present regulatory environment has nonetheless enabled adult smokers ready access to nicotine containing products. We welcome this recognition by NICE of un-licenced nicotine containing product use. Furthermore, we would cite a report published earlier this year, (Electronic cigarettes in England - latest trends, Smoking In England, January 2015 http://www.smokinginengland.info/latest-statistics/) which reported that "*E-cigarettes may have helped approximately 20,000 smokers to stop last year who would not have stopped otherwise*". This additional evidence further supports the Quality Statement on the potential of all nicotine containing products as part of a wider harm reduction strategy, a view echoed by the EU in announcing the pending Tobacco Product Directive (http://europa.eu/rapid/press-release_MEMO-14-134_en.htm).
44	Pfizer	Quality statement 2	When advising patients about using nicotine-containing products, it is appropriate for HCPs and SCPs to advise on the full range of options that could be used in a harm reduction approach that have been recommended by NICE. A new study has been published for the pharmacotherapy varenicline (recommended by NICE [2]) demonstrating its efficacy among cigarette smokers not willing or able to quit but willing to reduce cigarette consumption and make a longer term quit attempt [3]. Smokers were offered a gradual quit approach with a 12-week harm reduction phase followed by a 12-week abstinence phase. Those treated with varenicline had significantly higher continuous abstinence rates vs. placebo after 24 weeks (32.1% vs. 6.9%, respectively) and also at one year (27% vs. 9.9%, respectively) [3]. In light of this new data supporting the use of varenicline in a harm reduction approach, we believe this should be included when discussing options with patients. [2] NICE. Varenicline for smoking cessation (TA123). July 2007. Available at: https://www.nice.org.uk/guidance/ta123 [3] Ebbert J, Hughes J, West R et al. Effect of Varenicline on Smoking Cessation Through Smoking Reduction A Randomized Clinical Trial. Journal of the American Med Assoc. 2015 Feb 17;313(7):687-94
45	Pfizer	Quality statement 2	When advising patients about: "using nicotine-containing products", Pfizer feels this should be amended to: "using licensed nicotine-containing products", as healthcare practitioners should not advise the use of non-licensed therapies.
46	Royal College of Physicians of Edinburgh	Quality statement 2	Nicotine is not without harmful effects and the College queries if the quality statement should be slightly more cautious in its wording on the use of nicotine-containing products. An example is the use of e-cigarettes, as a paper published by the American Industrial Hygiene Association "*White paper; Electronic Cigarettes in the Indoor Environment*" https://www.aiha.org/government-affairs/Documents/Electronc%20Cig%20Document_Final.pdf highlights a number of concerns including chemical exposures to bystanders, and the lack of good evidence about exposure to many of the flavourings etc, employed in e-cigarettes. The paper concludes that while they may carry lower risks than tobacco cigarettes, there is not enough evidence of their safety.
47	Royal College of	Quality	Should a recommended dosage of nicotine be included in this statement?

ID	Stakeholder	Statement No	Comments[1]
	Physicians of Edinburgh	statement 2	
48	Royal College of Physicians of Edinburgh	Quality statement 2	Page 14 of 26 The College queries the wording around licensed nicotine-containing products as a "safe way" of reducing smoking. They are safer but not without risks.
49	The Electronic Cigarette Industry Trade Association (ECITA)	Quality statement 2	Pg. 14 In this context, it seems irrational for NICE to advise that healthcare providers should: "Tell people that some nicotine-containing products are not regulated by the Medicines and Healthcare products Regulatory Agency (MHRA) and, therefore, their effectiveness, safety and quality cannot be assured." This is not sufficiently mitigated by the following sentence: "Also advise them that these products are likely to be less harmful than cigarettes" since, by that stage, the healthcare service user has been primed to reject unlicensed nicotine-containing products, including all electronic cigarettes, despite the growing body of scientific evidence demonstrating their effectiveness, cost-effectiveness and appeal: McRobbie, H., Bullen, C., Hartmann-Boyce, J., and Hajek, P., (2014), Electronic cigarettes for smoking cessation and reduction: Cochrane Review12, Cochrane Library: "**Key results:** Combined results from two studies, involving over 600 people, showed that using an EC [electronic cigarette] containing nicotine increased the chances of stopping smoking long-term compared to using an EC without nicotine. We could not determine if EC was better than a nicotine patch in helping people stop smoking because the number of participants in the study was low. More studies are needed to evaluate this effect. This study showed that people who used EC were more likely to cut down the amount they smoked by at least half than people using a patch. The other studies were of lower quality, but they supported these findings. There was no evidence that using EC at the same time as using regular cigarettes made people less likely to quit smoking. None of the studies found that smokers who used EC short-term (for 2 years or less) had an increased health risk compared to smokers who did not use EC." Hajek, P., Etter, J-F., Benowitz, N., Eissenberg, T., and McRobbie, H., (2014), Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit13 [http://www.ncbi.nlm.nih.gov/pubmed/25078252], Addiction: "**CONCLUSIONS:** Allowing EC to compete with cigarettes in the market-place might decrease smoking-related morbidity and mortality. Regulating EC as strictly as cigarettes, or even more strictly as some regulators propose, is not warranted on current evidence. Health professionals may consider advising smokers unable or unwilling to quit through other routes to switch to EC as a safer alternative to smoking and a possible pathway to complete cessation of nicotine use." Lechner, W.V., Meier, E., Wiener, J.L., Grant, D.M., Gilmore, J., Judah, M.R., Mills, A.C., and Wagener, T.L., (2015), The Comparative Efficacy of 1st vs. 2nd Generation Electronic Cigarettes in Reducing Symptoms of Nicotine Withdrawal14 [http://www.ncbi.nlm.nih.gov/pubmed/25639148], Addiction:

ID	Stakeholder	Statement No	Comments[1]
			"**BACKGROUND AND AIMS**: Presently, electronic cigarettes (e-cigarettes) are studied as though they are a homogeneous category. However, there are several noteworthy differences in the products that fall under this name including potential differences in the efficacy of these products as smoking cessation aids. The current study examined the comparative efficacy of 1st and 2nd generation e-cigarettes in reducing nicotine withdrawal symptoms in a sample of current smokers with little or no experience using e-cigarettes. **DESIGN:** Twenty-two mildly to moderately nicotine dependent individuals were randomized to a crossover design in which they used 1st and 2nd generation e-cigarettes on separate days with assessment of withdrawal symptoms directly prior to and after product use. **SETTING AND PARTICIPANTS:** A community based sample recruited in the Midwest region of the United States reported a mean age of 28.6 (SD = 12.9), the majority were male (56.5%), Caucasian (91.3%), reported smoking an average of 15.2 (SD = 9.6) tobacco cigarettes per day, and a mean baseline carbon monoxide (CO) level of 18.7 ppm. **MEASUREMENTS:** Symptoms of withdrawal from nicotine were measured via the Mood and Physical Symptoms Scale. **FINDINGS:** Analysis of changes in withdrawal symptoms revealed a significant time by product interaction $F(1,21) = 5.057$, $p = .036$, $n2p = .202$. Participants experienced a larger reduction in symptoms of nicotine withdrawal after using 2nd generation e-cigarettes as compared with 1st generation e-cigarettes. **CONCLUSIONS:** Second generation e-cigarettes seem to be more effective in reducing symptoms of nicotine withdrawal than 1st generation e-cigarettes." Etter, J-F., and Eissenberg, T., (2015), Dependence levels in users of electronic cigarettes, nicotine gums and tobacco cigarettes15 [http://www.ncbi.nlm.nih.gov/pubmed/25561385], Drug and Alcohol Dependence: "**RESULTS:** Dependence ratings were slightly higher in users of nicotine-containing e-cigarettes than in user of nicotine-free e-cigarettes. In former smokers, long-term (>3 months) users of e-cigarettes were less dependent on e-cigarettes than long-term users of the nicotine gum were dependent on the gum. There were few differences in dependence ratings between short-term (≤3 months) users of gums or e-cigarettes. Dependence on e-cigarettes was generally lower in dual users than dependence on tobacco cigarettes in the two other samples of daily smokers. **CONCLUSIONS:** Some e-cigarette users were dependent on nicotine-containing e-cigarettes, but these products were less addictive than tobacco cigarettes. E-cigarettes may be as or less addictive than nicotine gums, which themselves are not very addictive." Berg, C.J., Boyd Barr, D., Stratton, E., Escoffery, C., and Kegler, M., (2014), Attitudes toward E-Cigarettes, Reasons for Initiating E-Cigarette Use, and Changes in Smoking Behaviour after Initiation: A Pilot Longitudinal Study of Regular Cigarette Smokers16 [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4304080/], Open Journal of Preventive Medicine: "**Objectives:** We examined 1) changes in smoking and vaping behavior and associated cotinine levels and

ID	Stakeholder	Statement No	Comments[1]
			health status among regular smokers who were first-time e-cigarette purchasers and 2) attitudes, intentions, and restrictions regarding e-cigarettes. **Methods**: We conducted a pilot longitudinal study with assessments of the aforementioned factors and salivary cotinine at weeks 0, 4, and 8. Eligibility criteria included being ≥18 years old, smoking ≥25 of the last 30 days, smoking ≥5 cigarettes per day (cpd), smoking regularly ≥1 year, and not having started using ecigarettes. Of 72 individuals screened, 40 consented, 36 completed the baseline survey, and 83.3% and 72.2% were retained at weeks 4 and 8, respectively. **Results:** Participants reduced cigarette consumption from baseline to week 4 and 8 (p's <0.001); 23.1% reported no cigarettte use in the past month at week 8. There was no significant decrease in cotinine from baseline to week 4 or 8 (p's = ns). At week 8, the majority reported improved health (65.4%), reduced smoker's cough (57.7%), and improved sense of smell (53.8%) and taste (50.0%). The majority believed that e-cigarettes versus regular cigarettes have fewer health risks (97.2%) and that e-cigarettes have been shown to help smokers quit (80.6%) and reduce cigarette consumption (97.2%). In addition, the majority intended to use ecigarettes as a complete replacement for regular cigarettes (69.4%) and reported no restriction on e-cigarette use in the home (63.9%) or car (80.6%). **Conclusions:** Future research is needed to document the long-term impact on smoking behavior and health among cigarette smokers who initiate use of e-cigarettes."
50	The Electronic Cigarette Industry Trade Association (ECITA)	Quality statement 2	Again, as indicated above, this needs to be extended so that the focus is on all the nicotine-containing product options, and not just those licensed as medicines.
51	UK Centre for Tobacco and Alcohol Studies (endorsed by the Royal College of Physicians)	Quality statement 2	No. Again, willingness to be referred is irrelevant. The advice described is also an inherent component of delivering a harm reduction approach as per QS1, so this statement needs to be completed by provision of alternative sources of nicotine to smokers willing to consider using them, rather than just information and advice..
Quality statement 3			
52	Action on Smoking and Health (ASH)	Quality statement 3	While it may be appropriate for stop smoking services to engage in harm reduction activity, particularly among smokers who fear relapse or who have relapsed, part of the opportunity from harm reduction approaches is to reach those smokers who are further away from making a quit attempt. As such, confining activity to the work of services misses the opportunity to reach smokers who do not access the services.
53	Pfizer	Quality statement 3	Quality statement 3 conflicts with statement 1. Quality statement 1 says that those who decline a referral to cessation services can be offered harm reduction. However quality statement 3 says that for harm reduction, a patient requires a referral to cessation services. Clarity is perhaps needed in statement 1 to show the initial referral declined is one specifically for abrupt quitting, and not all services.
54	Pfizer	Quality	When incorporating nicotine-containing products in harm reduction approaches, it is appropriate to not omit options

ID	Stakeholder	Statement No	Comments[1]
		statement 3	for which there is supporting harm reduction evidence, which now includes varenicline [3]. [3] Ebbert J, Hughes J, West R et al. Effect of Varenicline on Smoking Cessation Through Smoking Reduction A Randomized Clinical Trial. Journal of the American Med Assoc. 2015 Feb 17;313(7):687-94
55	Royal College of Physicians of Edinburgh	Quality statement 3	The College agrees this is a straight forward and important statement.
56	The Electronic Cigarette Industry Trade Association (ECITA)	Quality statement 3	As above
57	UK Centre for Tobacco and Alcohol Studies (endorsed by the Royal College of Physicians)	Quality statement 3	No. Stop Smoking Services tend by definition to see people who want to stop smoking. Harm reduction is a strategy to offer those who do not, as well as those who do access services. So whilst it is right for services to offer harm reduction, so should other health professionals who engage with smokers.
Consultation question 1			
58	Action on Smoking and Health (ASH)	Consultation question 1	No – the statements as written do not reflect appropriate one to one conversations between a health professional and a smoker and do not include opportunities to reach smokers who do not currently access services.
59	British Thoracic Society	Consultation question 1	Quality Statement 1, 2 & 3 Question 1 - Does this draft quality standard accurately reflect the key areas for quality improvement? Yes the QS reflects the areas of quality improvement - as stated, harm reduction is extremely important for those who are unable to stop smoking completely, and ensures that those who cannot stop have a 'next best' alternative. The Quality Standard encourages this approach, which will reduce harms from tobacco.
60	Cochrane Tobacco Addiction Group (TAG)	Consultation question 1	Yes, however e-cigarettes are now a significant focus within harm reduction approaches. We note that the quality statements are specified to not cover unlicensed products, however it may be worth broaching this more specifically in this document as it is an issue that providers are consistently coming up against, and want to know how to deal with. Statement 2 (specifically): As noted above providing this type of information is very likely to turn focus to electronic cigarettes and anecdotal evidence suggests that providers do not know how to deal with these queries. This may mean that they are reluctant to bring up the issue at all. It is likely that the information regarding NRT and electronic cigarettes could become blurred and confusing. As well as providing information on the safety of NRT it also is important to focus on the efficacy of these approaches- for example the cut-down to quit trials which found that using NRT to support reduction is more effective than using no product
61	Johnson & Johnson Limited	Consultation question 1	Quality statement 1 Referral to stop smoking services and the subsequent provision of behavioural support and a licensed smoking cessation medicine with the support of a trained smoking cessation advisor should always be the preferred choice in order to maximize the chance of a successful quit attempt. However, not all smokers willing and able to make a quit

ID	Stakeholder	Statement No	Comments[1]
			attempts will be prepared to do so through referral to stop smoking services, some may for example be willing to quit with support from their GP or a nurse within their local GP practice but not be referred to a specific stop smoking service. It is critical that no smoker motivated to quit be inadvertently directed towards an alternative harm reduction strategy. The present wording of Quality Statement 1 does not therefore cover all appropriate routes to be explored before moving to the point of offering a harm reduction approach to smoking. Wording such as "People unwilling or unable to make a quit attempt, which should ideally be supported through referral to a stop smoking service, are offered a harm reduction approach to smoking." would more accurately describe the point at which a harm reduction approach should be offered and goes some way to maximising the potential for a quit attempt to be made rather than prematurely signposting an alternative harm reduction strategy. Subject to the comments above Johnson & Johnson Limited believes this draft quality standard accurately reflects a key area for quality improvement.
62	Johnson & Johnson Limited	Consultation question 1	Quality statement 2 Referral to stop smoking services and the subsequent provision of behavioural support and a licensed smoking cessation medicine with the support of a trained smoking cessation advisor should always be the preferred choice in order to maximize the chance of a successful quit attempt. However, not all smokers willing and able to make a quit attempts will be prepared to do so through referral to stop smoking services, some may for example be willing to quit with support from their GP or a nurse within their local GP practice but not be referred to a specific stop smoking service. It is critical that no smoker motivated to quit be inadvertently directed towards an alternative harm reduction strategy. The present wording of Quality Statement 2 does not therefore cover all appropriate routes to be explored before moving to the point of offering a harm reduction approach to smoking and discussing the harms of tobacco vs. nicotine and providing advice about using nicotine-containing products. Wording such as "People unwilling or unable to make a quit attempt, including those who decline a referral to a stop smoking service, are advised that most health problems associated with smoking are caused by components in tobacco smoke other than nicotine, and about using nicotine-containing products." would more accurately describe the point at which a harm reduction approach should be offered or information be supplied on the risks associated to tobacco use/smoking vs. nicotine as well as about the use of nicotine containing products. Subject to the comments above Johnson & Johnson Limited believes this draft quality standard accurately reflects a key area for quality improvement.
63	Johnson & Johnson Limited	Consultation question 1	Quality statement 3 Wording such as "Stop smoking services provide harm reduction approaches for smokers not ready, willing or able to quit alongside existing approaches to stopping smoking in 1 step for those able to make a quit attempt." would reinforce the critical message that harm reduction strategies should only ever be seen as an appropriate individual and public health strategy for those smokers not yet ready, willing or able to quit tobacco and nicotine. It is critical that no smoker motivated to quit be inadvertently directed towards an alternative harm reduction strategy. Subject to the comments above Johnson & Johnson Limited believes this draft quality standard accurately reflects a

ID	Stakeholder	Statement No	Comments[1]
			key area for quality improvement.
64	NHS England	Consultation question 1	I agree
65	Nicoventures	Consultation question 1	We believe the draft quality standard accurately reflects the key areas for quality improvement. However, as stated in our first comment, unlicensed e-cigarettes (i.e. regulated but not licensed as medicines and allowed on the market as consumer goods under the TPD dual track) need to be explicitly mentioned as a reduced-risk nicotine containing product and included under 'harm reduction approaches' in the definition of terms section which will then be reflected in Statements 1 through 3. The potential role of e-cigarettes as a tobacco harm reduction approach is supported by existing scientific evidence and the implementation of the TPD can be reasonably expected to address any remaining safety and quality concerns from current e-cigarettes.
66	Proprietary Association of Great Britain	Consultation question 1	Quality statement 1 It is accepted that combinations of prescribed medicines and psychological support supplied via NHS Stop Smoking Services are more likely to lead to successful quit attempts than other approaches and hence this route should be encouraged wherever possible. However, this approach is not suitable for everyone and some smokers willing to quit may wish to do this with support from other advisors such as their GP, practice nurse or pharmacist. PAGB believes that Statement 1 does not take into consideration those individuals who have declined referral to a stop smoking service but are willing to make a supported quit attempt through an alternative route. As previously stated, to maximise potential health benefits, we want to ensure that no smoker motivated to quit is inadvertently directed towards a harm reduction strategy rather than support to quit. To provide clarification, maximise all potential quit attempts and ensure that harm reduction approaches are offered at the appropriate point, PAGB suggests that Statement 1 is amended to read: "People unwilling or unable to make a quit attempt, which should ideally be supported through referral to a stop smoking service, are offered a harm reduction approach to smoking."
67	Proprietary Association of Great Britain	Consultation question 1	Quality statement 2 PAGB believes that Statement 2 does not take into consideration those individuals who have declined referral to a stop smoking service but are willing to make a quit attempt through an alternative route, for example with support from their practice nurse, GP or pharmacist. To maximise potential health benefits, we want to ensure that no smoker motivated to quit is inadvertently directed towards a harm reduction strategy rather than support to quit. To provide clarification, maximise all potential quit attempts and ensure that harm reduction approaches are offered at the appropriate point, PAGB suggests that Statement 2 is amended to read: "People unwilling or unable to make a quit attempt, including those who decline a referral to a stop smoking service, are advised that most health problems associated with smoking are caused by components in tobacco smoke other than nicotine, and about using nicotine-containing products."
68	Proprietary Association of Great Britain	Consultation question 1	Quality statement 3 To reinforce that harm reduction approaches are appropriate only for individuals who are unable or unwilling to stop smoking and to ensure that no smoker motivated to quit is inadvertently directed towards a harm reduction strategy

ID	Stakeholder	Statement No	Comments[1]
			rather than support to quit, PAGB suggests that the wording of Statement 3 is changed to read: "Stop smoking services provide harm reduction approaches for smokers not ready, willing or able to quit alongside recognised effective approaches to stopping smoking in 1 step for those able to make a quit attempt."
69	Public Health England	Consultation question 1	Does this draft quality standard accurately reflect the key areas for quality improvement? We agree that the three statements selected cover three key areas where action will have greatest effect. 1. commissioning and delivery of services that promote harm reduction 2. nicotine is not significantly associated with the harms of smoking 3. the importance of an offer of a harm reduction approach when abrupt cessation is not taken up However, we believe that highlighting the importance of the public health benefits in engaging with harm reduction approaches; • For people who go on to stop smoking • The benefits of temporary abstinence during pregnancy • The benefits of temporary abstinence in the peri-operative period In these cases then it is suggested that the healthcare practitioners who would have most impact in carrying out this statement are; • Stop smoking advisors • Midwives and obstetricians • Anaesthetists, surgeons and those people responsible for booking elective surgery Further information on the outcomes of harm reduction which will deliver public health benefits, would enhance understanding about the role that it plays in supporting smokers to stop smoking and the opportunities where cessation does not happen. There is a requirement for training to support this pathway which is especially important in dispelling any myths around perceived harm of nicotine.
70	Society and College of Radiographers	Consultation question 1	Yes – when aligned to the existing NICE quality standard (QS43)
71	The Electronic Cigarette Industry Trade Association (ECITA)	Consultation question 1	ECITA agrees that "[t]he best way for a person to reduce illness and mortality associated with smoking is to stop smoking in 1 step. People who smoke should be offered a referral to an evidence-based smoking cessation service [...]. However, some people are not ready or don't want to stop smoking, and so would be unlikely to accept an offer to use stop smoking services. **It is important that these people are encouraged to try a harm reduction approach to smoking**." [**Our emphasis.**] However, unless the "harm reduction approach to smoking" is extended to include all the possible interventions, including those demonstrated to be most effective and have the highest appeal, i.e. electronic cigarettes, this quality standard will fall short of its aims – at the cost of significant numbers of premature deaths which could otherwise have been avoided: "'Adding up the resulting avoided deaths through 2014Q4 gives approximately 16,000 premature deaths already

ID	Stakeholder	Statement No	Comments[1]
			avoided, 13,000 from CVD [cardiovascular disease] and 3,000 from other causes. About half of these would have occurred in the last 20 months.' Furthermore: 'another 19,000 smoking-caused premature deaths have already been averted but would not have occurred yet.' [...] One of the major long-term failures of smoking cessation is the high rate of relapse, so adopting a lower-risk alternative for the rest of the lifetime has the potential not only to reach more people sooner, but also to change the entire pattern of nicotine use and relapse. Encouraging smokers to switch to a safer alternative could achieve the long sought-after tobacco 'endgame'. Embracing this new disruptive technology could bring this about quicker. Is this an opportunity we can afford to miss?" [http://www.ecita.org.uk/ecita-blog/why-quitting-smoking-may-not-be-safe-alternative-harm-reduction]
72	UK Centre for Tobacco and Alcohol Studies (endorsed by the Royal College of Physicians)	Consultation question 1	No. See above. [Comments 39, 51 and 57]
Consultation question 2			
73	Action on Smoking and Health (ASH)	Consultation question 2	The statements as currently drafted would allow some information to be collected about who refused services and who were then given further advice. However, as there is nothing in the above statements regarding follow up with those offered advice, this information could be of limited value.
74	British American Tobacco	Consultation question 2	E-cigarettes have already proven to be very useful substitutes for conventional cigarettes. However, e-cigarettes, although regulated, are not licensed as medicines, and therefore there are no e-cigarettes on any formularies. Although, this may well change in the future, at this time it can be reasonably expected that the majority of e-cigarettes on sale in the UK are medically unlicensed (under the TPD consumer goods track) and their sale/purchase will occur outside the conventional prescription/reimbursement model. This makes it difficult to accurately collect data to measure the implementation of the Quality Standard. Accurately measuring the implementation of the Quality Standard in practice, shall require cross-referencing local data with national datasets such as the smoking toolkit study and the annual ASH-YouGov surveys, overlaid on commercially available retail audit. Despite the fact that snus is banned in the EU and cannot be marketed in the UK, it may be consumed. Measuring the implementation of the Quality Standard in practice may, therefore, also require collecting data on smokers who switched to snus in place of their conventional cigarettes.
75	British Thoracic Society	Consultation question 2	Quality Statement 1, 2 & 3 Question 2 - If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

ID	Stakeholder	Statement No	Comments[1]
			Yes - if the systems and structures were available. Currently capturing the data is difficult. • In GP surgeries and pharmacies advice to reduce harm could be created as a QOF/ performance indicator. Without some sort of quality indicator being attached to harm reduction recording is likely to be poor. • Pharmacies in particular may be a way of reaching people who are not prepared to talk to their doctor about smoking for fear of being pressured towards quitting when they don't feel able. • Recording of those accessing Stop Smoking Services for harm reduction will be easy to capture as they already have a robust database for capturing information, but this will only represent a small proportion of people being offered harm reduction as the numbers accepting referral to stop smoking services for harm reduction is likely to be small. • Secondary care offers an invaluable opportunity to raise awareness about harm reduction, especially given that Smoke Free NHS Premises should all be providing NRT widely to smokers who are not prepared to quit in order to manage withdrawal. However NRT prescriptions in inpatients are low and this needs to be addressed through education/training of secondary care staff and also by the development of secondary care smoking cessation services which are still too few. Investment in the recording systems of smoking status and cessation advice/ therapies throughout secondary care, for example through a performance indicator, would help to record outcomes relevant to this and other smoking-related quality standards. • The overall sale/ prescriptions of NRT and Varenicline could provide an indicator of uptake of harm reduction alongside smoking cessation rates. This would work both in community and in secondary care but would be an indirect indicator.
76	Cochrane Tobacco Addiction Group (TAG)	Consultation question 2	**Quality statement 1 & 2:** Yes, if a system were available for health/social care providers to clarify the number of times advice was given and the nature of that advice. It is harder to monitor the number of people adopting harm reduction approaches as it is likely that many people may go way and attempt these unsupported but the Smoking Toolkit Study is an established resource which already measures these outcomes. **Quality statement 3:** Yes, for example the National Centre for Smoking Cessation Training (NCSCT) already carries out a survey of smoking cessation providers that could be used to collect this information.
77	Johnson & Johnson Limited	Consultation question 2	Yes, given the availability of systems and structures it should be possible to collect data for the proposed quality measures. Indeed it is critical for individual smokers and for public health that data is collected in order to both ensure that: 1. Harm reduction strategies are only offered to those smokers not yet ready, willing or able to try and quit tobacco and nicotine, and 2. An evidence base is developed that tracks the success of NHS harm reduction strategies in engaging those smokers who would otherwise not be reached.
78	NHS England	Consultation question 2	For data collection would need systematic approach to recording smoking status and interventions given included in electronic health records – some hospitals have started to do this e.g. Whittington
79	Nicoventures	Consultation	Currently, there are no e-cigarettes that are licensed as medicines for smoking cessation, and hence are currently not

ID	Stakeholder	Statement No	Comments[1]
		question 2	on any formularies. Although this may change in the future, it can be reasonably expected that majority of the e-cigarettes may be unlicensed (i.e. regulated but not licensed as medicines and allowed on the market as consumer goods under the TPD dual track) and their sale/purchase may occur outside the conventional prescription/reimbursement model. Therefore, to accurately measure the implementation of the quality standard in practice by public health and healthcare professionals, cross reference of local data with national datasets such as the smoking toolkit study and the annual ASH-YouGov surveys, overlaid on commercially available retail audit data (e.g. Nielsen), would be required
80	Pfizer	Consultation question 2	Issues may arise with regards to the metrics used to collect data to measure the success of harm reduction. Carbon monoxide testing can be used to determine whether a smoker has quit smoking completely or not, but often this outcome relies on the patient self-reporting whether or not they have stopped. However, self-reporting is more difficult in harm reduction as recall bias becomes an issue. Stating simply whether you have quit smoking or not is a much easier question to answer than stating the exact number of cigarettes you are now smoking each day and if this number has been constant every day over the last two weeks, four weeks, twelve weeks or longer. Furthermore, if the harm reduction approach agreed with the patient includes inhaling less deeply or to not smoke the whole cigarette, measuring the success of these is very subjective and risks bias in self-reported answers. As a consequence, Pfizer feels the success of a harm reduction approach would prove more challenging to measure than the success of abrupt quitting. Whereas targets for healthcare organisations and practitioners for abrupt quitting are based around smoking prevalence and sustained quits, Pfizer believe it would be challenging to construct outcome measures for harm reduction.
81	Proprietary Association of Great Britain	Consultation question 2	PAGB believes that it should be possible to collect the data for the proposed quality measures. Collecting and analysing this data will provide an important measure of the effectiveness of these interventions and a means of determining if and what other interventions may be needed to continue to support and increase the number of individuals quitting or reducing smoking. Collecting data will help to: • ensure that harm reduction strategies are targeting only those smokers not yet ready, willing or able to try to quit tobacco use and nicotine addiction develop an evidence base that tracks the success of NHS harm reduction strategies in engaging with smokers who would otherwise not be reached.
82	Public Health England	Consultation question 2	If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures? QS1: Yes this data is collectable, however there will be costs associated with its collection, not only for the providers, but also nationally in collating and reporting this data. Where there is an increasing pressure to reduce costs within the health system further burden in areas that do not directly contribute to health outcomes, even though the return on investment is thought to be within acceptable limits, may not be appealing. QS2: Yes this data is collectable; however the comments above apply to the collection of this data as well. In addition there may be some confusion created about reporting the use of unlicensed nicotine containing products as this is not

ID	Stakeholder	Statement No	Comments[1]
			addressed in this standard. QS3: Yes this data is collectable. It is also worth considering that keeping this data collection as simple as possible will increase the consistency and return of data. With this in mind collection of information on, “harm reduction approach offered” would seem to be a fairly simple metric. More complicated, yet still of use would be the data on, “offer of harm reduction approach taken up” and so the quality standards may benefit from further consideration of what these data sets would look like and how they would be collected.
83	Society and College of Radiographers	Consultation question 2	There are existing datasets and processes within the scope of radiotherapy that could be amended to help with providing this information, although not entirely clear that all the standards would be measurable.
84	The Electronic Cigarette Industry Trade Association (ECITA)	Consultation question 2	Either by following the example of the Leicestershire Stop Smoking Service, managed by Louise Ross22 [http://www.uknscc.org/uknscc2014_presentation_338.php], or by making arrangements with specific partner companies in the electronic cigarette industry, it would not be difficult to ensure that referrals to vaping products provide measureable data, so that NICE can continually monitor and evaluate the intervention. This could run harmoniously alongside the existing data collection and measurement facilities already in operation in the tobacco control/smoking harm reduction arena. Furthermore, there is precedent for this kind of collaboration with the private sector, in the NICE guidelines PH43, Managing overweight and obesity in adults – lifestyle weight management services23 [http://www.nice.org.uk/guidance/ph53/chapter/1-recommendations], which recommends the sort of integrated approach which, in our view, is required for addressing smoking harm reduction: “Identify local services, facilities or groups that could be included in the local obesity pathway, meet the needs of different groups and address the wider determinants of health. Examples include community walking groups or gardening schemes.” Indeed, the later information about tier 2 service providers makes it clear that NICE is in a position to make recommendations for referrals to products and services which are not medically licensed, in addition to recommending medicinal interventions. In the context of unlicensed electronic cigarettes for smoking harm reduction, this would seem to be an integral part of any smoking harm reduction plan which will actually fully address the health issues – and the costs to the NHS associated with them – caused by smokers who cannot or will not quit.
85	UK Centre for Tobacco and Alcohol Studies (endorsed by the Royal College of Physicians)	Consultation question 2	Yes. The information could be recorded and collected at the point at which smoking status is ascertained, advice given and treatment initiated in all medical consultations
Consultation question 3			
86	Action on Smoking and Health (ASH)	Consultation question 3	There is a need for better training of all health professionals to have more sophisticated conversations with smokers about their options. This includes the provision of good quality evidence based information regarding NCPs. In addition, services and public health teams would benefit from further information on good practice delivery models for tobacco harm reduction.

ID	Stakeholder	Statement No	Comments[1]
87	British American Tobacco	Consultation question 3	**Improved product awareness and a better understanding of nicotine would support improvement and help overcome barriers** **Nicotine illiteracy:** Quality Statement 2 rightly refers to the fact that most health problems associated with smoking are caused by components in the smoke and not nicotine. However, research suggests that there is a worrying lack of understanding of this fact among General Practitioners ("GPs"). A recent study assessed knowledge, perceptions and attitudes to tobacco and nicotine products of 220 GPs (100 in England and 120 in Sweden). When asked to rank various products on a risk continuum, GPs rated cigarettes as riskiest and tobacco cessation and nicotine-containing products as least risky. However, when asked to rank various components of cigarette smoking based on their health risks, GPs ranked nicotine as the third riskiest (74 [74 %] England, 104 [87 %] Sweden), after tar and carbon monoxide, but before smoke or tobacco. **Training and competencies:** The parallels with other fields of medicine where harm reduction is accepted and put into practice successfully, may need to be explicitly drawn upon to educate and inform healthcare practitioners on concepts such as relative risk and harm reduction. Medical curricula should be revised to include the tobacco harm reduction paradigm and information on the product risk continuum. This would engender a greater understanding of the relative risks of different tobacco and nicotine products and their potential to reduce harm (Nutt et al.).
88	British Thoracic Society	Consultation question 3	Quality Statement 1, 2 & 3 Question 3 - For each quality statement, what do you think could be done to support improvement and help overcome barriers? • Providers may be reluctant to address the issue of harm reduction in those who have already declined to discuss smoking cessation. It would be important that education packages such as Very Brief Advice from the National Centre for Smoking Cessation and Training (NCSCT) incorporate this approach into their training to give confidence that it can work. • Advertising campaigns highlighting the difference between nicotine and other components of cigarettes may be useful but would need careful evaluation to ensure they did not confuse the public in terms of dampening down the harms of smoking. More focus on electronic nicotine delivery systems (for example, e-cigarettes) may be important given how widespread they have become in popular usage. • Smoking cessation services will need to be expanded to accommodate a potential increase in users through those wishing to access help in cutting down or temporary abstinence. Secondary care facilities should have access to smoking cessation services for inpatients and outpatients who can reinforce this approach. • Training of pharmacy staff should be a high priority as this offers a point of community access to NRT without smokers having to engage with their doctor/ surgery. • Awareness needs to increase, both for healthcare professionals and for the public. Mass media/ social marketing techniques are likely to be needed.

ID	Stakeholder	Statement No	Comments[1]
			Possibility of NRT products being subsidised to encourage usage by smokers who do not feel able to seek medical help, and to whom the cost is prohibitive?
89	Cochrane Tobacco Addiction Group (TAG)	Consultation question 3	We feel that the main barrier to all statements as it stands is the lack of detailed guidance and training specification for offering harm reduction approaches. A small survey of smoking advisors carried out as background to a funding application (carried out by NLH) found that although advisors supported the implementation of harm reduction services they didn't feel that there was sufficient guidance available to support them in offering this. This is in part due to a lack of quality research, for example in the area of cigarette reduction. Unlike abrupt quitting there are many different ways a person could reduce their smoking and these could vary in effectiveness. There is no clear, concise evidence available. On the other hand there is good evidence to suggest that cutting down smoking (with no clear aim to quit) supported by nicotine replacement therapy (NRT) is more effective than cutting down without NRT; however it is unclear how aware practitioners are likely to be of this. The NCSCT does not currently offer training resources for harm reduction. This issue is especially pertinent if the goal is to co-ordinate services nationally. **Statement 2 (specifically):** As stated above there is some concern about the training available for providers in harm reduction approaches. Statement 2 would assume that providers have the knowledge to inform service users. Many providers have worked for a long time in a system where abrupt quitting was the only method of cessation endorsed and were told to actively discourage harm reduction approaches. This means that a process of re-education is needed for providers as well as service users. **Statement 3 (specifically):** The paragraphs above could also be applied to commissioners. The lack of detailed evidence based information on how to carry out successful harm reduction will make it difficult for commissioners to be informed enough to make good choices regarding commissioning optimal services. It also relies on the assumption that commissioners are well informed about the evidence and health information associated with licensed nicotine containing products. Until recently the summary of product characteristics for NRT stated that smokers should not smoke and use NRT at the same time. It is not unlikely that in some cases this belief persists and so an important first step is to educate people higher up the chain than the service users themselves.
90	Johnson & Johnson Limited	Consultation question 3	The success of all NHS smoking cessation or harm reduction activity is based upon the level to which smokers are motivated to quit or to reduce harm (hopefully with the long-term outcome of becoming tobacco and nicotine free), which in turn are significantly dependent upon broader tobacco control measures that denormalize smoking and increase smoker dissonance. It is therefore critical that the UK effectively implements the 2014 revision of the EU Tobacco Products Directive and that a new national tobacco control strategy is put in place during 2015 as the present "national ambitions" listed in "Healthy Lives, Healthy People: A Tobacco Control Plan for England" are set with a target timeline of "by the end of end of 2015". More specific to the actual draft quality standard, Johnson & Johnson Limited believes that all three quality statements could be effectively supported by comprehensive and authoritative multi-media public health education and awareness campaigns delivered nationally. Such campaigns would need to include the following critical elements:

ID	Stakeholder	Statement No	Comments[1]
			• Information on the harms of starting or continuing to smoke • Educating on the role and health impacts of tobacco use/smoking vs. nicotine • Advising smokers that the number one thing that they can do for their health, and for the health of those around them, is to end their tobacco use and nicotine addiction. • Advising all smokers who are willing and able to try and quit to do so – and signposting the most effective way to source support (particularly stop smoking services) as well as explaining what specific support is available. • Engaging those who are not yet ready, willing or able to quit and recruiting only them in harm reduction strategies with the support of the NHS.
91	NHS England	Consultation question 3	To support the improvement and help overcome barriers need healthcare provider organisations to implement NICE behaviour change guidance and 'make every contact count' This is particularly important for mental health providers, including community mental health services
92	Nicoventures	Consultation question 3	**For Statement 1,** as stated in our responses above, we believe that service providers, public health and healthcare practitioners, and commissioners, may need an in-depth training to understand the emerging scientific evidence base (e.g. Cochrane reviews) and the regulatory framework for e-cigarettes under the TPD that allows for quality and safety assured but unlicensed e-cigarettes (i.e. regulated but not licensed as medicines and allowed on the market as consumer goods under the TPD dual track) to be available as an appealing harm reduction alternative to smokers to switch out of smoking. **For Statement 2,** perceptions and beliefs towards nicotine's safety and addiction potential among healthcare practitioners are a significant barrier to accepting the role of reduced-risk nicotine containing products in tobacco harm reduction. This was highlighted in our survey of GPs in the UK and Sweden (Reference: http://www.emeraldinsight.com/doi/abs/10.1108/DAT-02-2013-0010 accessed 26/02/2015). The parallels with other fields of medicine where harm reduction is accepted and successfully practiced, such as needle exchange programmes for prevention of HIV transmission, may need to be explicitly drawn to educate and inform healthcare practitioners on concepts such as relative risk and harm reduction. We also believe that medical curricula may need to be revised to include the tobacco harm reduction paradigm where appropriately regulated safer nicotine containing products can offer a viable alternative out of smoking. **For Statement 3:** We believe that unlicensed e-cigarettes (i.e. regulated but not licensed as medicines and allowed on the market as consumer goods under the TPD dual track) should be available as educational (and not promotional) materials to enable healthcare practitioners to give practical and practicable advice to their smoker patients.
93	Proprietary Association of Great Britain	Consultation question 3	PAGB believes that a clear national strategy for tobacco control is essential to underpin the quality standard. A national strategy will help to promote an environment in which smoking is unacceptable and individuals are motivated to quit or reduce their tobacco use and nicotine addiction. Objectives in the current Tobacco Control Plan for England are set with a target timeline of "by the end of 2015." PAGB would like to see a new national plan in place that updates these targets and addresses other key

ID	Stakeholder	Statement No	Comments[1]
			developments such as: • reduction in use of NHS Stop Smoking Services – the combination of prescribed medicines and psychological support supplied via NHS Stop Smoking Services is more likely to lead to successful quit attempts than other approaches. However, use of the services dropped by 20 per cent between 2011/12 and 2013/14 and is likely to fall further to as much as 50% by 2014/15 (Will Smoking Meet its Match? Taylor D et al. UCL School of Pharmacy. Available at: https://www.ucl.ac.uk/pharmacy/pharmacynews/smokingreport2015) • the role and regulation of e-cigarettes • the effective implementation of the updated EU Tobacco Products Directive in 2016.
94	Public Health England	Consultation question 3	For each quality statement what do you think could be done to support improvement and help overcome barriers? QS1: Introduction of a national harm reduction training module for practitioners QS2: Further information to support providers and commissioners in the recording of the use of unlicensed nicotine containing products and greater clarity on the use of nicotine vapourisers as a harm reduction option QS3: Greater clarity on the return on investment for engagement with harm reduction, such as how many people would be expected to go on to make a successful attempt at stopping smoking following a harm reduction intervention, for there to be a net public health gain.
95	Society and College of Radiographers	Consultation question 3	Training is a key potential barrier. Practitioners have in the past cited lack of knowledge as a barrier to instigating the conversation around smoking cessation or reduction.
96	The Association of Directors of Public Health	Consultation question 3	Quality Statements 1, 2 and 3 ADPH is currently considering the emerging evidence on the impact of nicotine vapourisers and we are cognisant of arguments for the potential impact of nicotine vapourisers as a means of quitting or reducing harm by substituting for conventional tobacco products. However we believe that more research is needed to establish clear evidence of safety and their long term impact on health - as well as on wider questions relating to re-normalisation of smoking behaviour, and the impact on young people of product development, advertising and marketing. The involvement of the tobacco industry in product development raises concerns, and whilst efforts to de-normalise tobacco use are welcomed, attempts to maintain a population addicted to nicotine (including tobacco) are not. ADPH supports the updates within this quality standard and in considering your recommendation, on supplying licensed nicotine-containing products, we recognise that this should be interpreted based on the available evidence for the effectiveness of those products and the clients' needs. In our 2014 survey we asked Directors of Public Health for their views on whether nicotine vapourisers have a role in niche settings to enable them to become smoke free. The survey results indicated that there was support for their potential use in supporting mental health trusts (65% agreed) and in prisons (64% agreed) to become smoke free. However 50% of respondents felt it was not appropriate to extend their use to hospital grounds. Concerns were also raised regarding the need for improved safety of product packaging (including clear advisory warnings).

ID	Stakeholder	Statement No	Comments[1]
			Our full interim position statement on nicotine products and associated products can be viewed via the link below: http://www.adph.org.uk/wp-content/uploads/2014/12/ADPH-Position-Statement-Nicotine-vapourisers-2014.pdf
97	The Electronic Cigarette Industry Trade Association (ECITA)	Consultation question 3	Quality statement 1 As indicated above, we believe that the overall harm reduction approach needs to be all-encompassing, and certainly extended to include a positive emphasis on the opportunities offered by unlicensed nicotine-containing products, such as electronic cigarettes. We believe that this would fit very well with the stated aim "to support improvement and help overcome barriers". That said, there is a further opportunity here, to engage more people with the notion of referral to a stop smoking service, if the broader range of products is explained to them in the context of what those services can offer. As the Leicestershire example clearly demonstrates, the Stop Smoking Service can see an increase in referrals, as well as increased successful quit attempts, if the full range of harm reduction approaches is expanded to include electronic cigarettes. Since it continues to be a well-supported case that the success or failure of a quit attempt – by whatever means, including by switching to a low risk alternative such as electronic cigarettes – is positively influenced by the addition of behavioural support, the best possible option will be for smokers to be directed to the behavioural support offered by a Stop Smoking Service which can give them full and detailed information about the whole range of options available to them.
98	UK Centre for Tobacco and Alcohol Studies (endorsed by the Royal College of Physicians)	Consultation question 3	Train healthcare professionals to deliver smoking interventions, and require that smoking status and interventions discussed and delivered are recorded. The main barriers are lack of skills and inclination to intervene in smoking.
Consultation question 4			
99	Action on Smoking and Health (ASH)	Consultation question 4	All healthcare professionals who come into contact with smokers should be able to deliver advice about options to quit and reduce harm. However, as stated above, limiting the provision of information to smokers only to one to one clinical conversations misses the opportunity to reach a wider group of smokers.
100	British American Tobacco	Consultation question 4	**Pharmacists**. Ideally, all practitioners should be equipped to advise on harm reduction approaches to smoking. However, access to GPs and other services can be limited, whereas access to pharmacists is fast, efficient and convenient, making it possible to get harm reduction advise without a trip to the GP. Pharmacists are trained experts who can help people find the right product to treat their complaint. They can advise on the safe use of both prescription and over-the-counter medicines. In addition, they can dispense medicines and advise on the use of other products, provide information about potential side effects, ensure new medicines are compatible with any existing medication and that the laws controlling medicines are followed. In addition, Pharmacists can monitor the effects of treatment to ensure that it is safe and effective.
101	British Thoracic Society	Consultation	Quality Statement 1, 2 & 3

ID	Stakeholder	Statement No	Comments[1]
		question 4	Question 4 - In order to make quality statement 1 measurable, the setting where it occurs needs to be defined. Which healthcare practitioner ...would give it most impact? Overall primary care would be best, due to the established focus on very brief advice and QOF targets. However, incorporating community pharmacy, secondary care and stop smoking services working in both community and secondary care may help target hard-to-reach groups.
102	Cochrane Tobacco Addiction Group (TAG)	Consultation question 4	We feel that it is important that any health/social care provider who discusses smoking cessation with a person suggests/offers harm reduction as an alternative if the person feels they can't or won't quit. Different providers are likely to come into contact with different individuals and in order for harm reduction to have maximum impact we should aim to maximise the reach of education and services.
103	Johnson & Johnson Limited	Consultation question 4	NICE Guidance on Brief interventions and referral to stop smoking services (PH1) states in addition to GPs and nurses in the primary and community care setting that "All other health professionals, such as hospital clinicians, pharmacists and dentists, should refer people who smoke[3] to an intensive support service (for example, NHS Stop Smoking Services)". For the sake of consistency Johnson & Johnson Limited believes that all such healthcare practitioners will need to be involved in measuring the impact of Quality Statement 1. However, it also proposes that GPs, nurses in the primary and community care settings and pharmacists are likely to have the greatest potential to give this quality statement the most impact.
104	NHS England	Consultation question 4	I think most impact via GPs and mental health care staff (community and provider) and drug and alcohol services. For short term cessation then pre-op assessment nurses also key group
105	Nicoventures	Consultation question 4	We believe that all healthcare practitioners have a collective role and responsibility in giving objective harm reduction advice to their smoker patients. However, in the case of e-cigarettes, we believe that **pharmacists** in particular are in a position of authority and access for smokers who are seeking appealing and viable alternatives to conventional cigarettes. Pharmacies offer a convenient, credible, neutral, free-market environment where smokers can make informed choices about which of the (regulated) unlicensed and/or licensed e-cigarette products best meet their needs. The high quality training standards and compliance requirements among pharmacists also ensure that risk communication and product promotion can be balanced and scientific evidence based.
106	Proprietary Association of Great Britain	Consultation question 4	As per NICE Guideline (PH1), Brief interventions and referral for smoking cessation (http://www.nice.org.uk/guidance/PH1) "All other health professionals, such as hospital clinicians, pharmacists and dentists, should refer people who smoke[3] to an intensive support service (for example, NHS Stop Smoking Services)". PAGB believes that in order to ensure consistency, the quality standard should align with this guidance and ensure that these healthcare professionals are involved in measuring the impact of Quality Statement 1. GPs, nurses in the primary and community care settings and pharmacists are likely to have the greatest potential to give this quality statement the most impact.
107	Public Health England	Consultation question 4	For draft quality statement 1: In order to make this quality statement measureable, the setting where it occurs needs to be defined. Which healthcare practitioner(s) carrying out this statement would give it the most impact (e.g. GPs, pharmacists, etc.)?

ID	Stakeholder	Statement No	Comments[1]
			There is good evidence that Brief Interventions delivered by medical staff provide a small but measureable effect on increasing likelihood of attempted cessation. What is not clear is to what degree adding the option of a suggestion of a harm reduction intervention contributes to or competes with smoking cessation. The guidance states that harm reduction interventions should not detract from abrupt cessation pathways, therefore more research is required into the effect that this offer of an alternative will have on abrupt cessation. That said the offer of harm reduction interventions should be made in every case where the offer of support with an abrupt quit is rejected. In addition to this highlighting the impact that one professional group over the other can have risks giving the message that this intervention is less important for other professional groups to engage with. The quality standard should focus on how the intervention is delivered. Increasing the understanding in all practitioners' minds as to where this offer fits in the cessation spectrum and how to recognise when the intervention is appropriate would help with this. The quality standard would benefit from greater clarity around the role that all health and social care professionals have play. This is more around brief advice and sign posting, rather than delivering interventions necessarily as this more detailed activity might be done best by specially trained advisors. Recording of intervention setting is a secondary measurement that would allow local commissioners to see where the offer and take up of this intervention occurs most frequently allowing dialogue to be developed to improve the frequency of the offer. We would suggest that the data collected for intervention setting matches that of the national local stop smoking service data return.
108	Society and College of Radiographers	Consultation question 4	As well as those already identified in the document. The Society and College of Radiographers wishes to emphasise the role of the therapeutic radiographers, who are key healthcare professionals in the treatment of patients with cancer. Although it is a challenging time for these patients, there are significant benefits in terms of the reduction of treatment side effects and effectiveness of treatment, for patients who are successfully stop smoking. So although achieving smoking cessation should be the primary goal, it is acknowledged that reduction or short term abstinence during treatment is also a successful outcome as it is a positive step. So effective training is key so this can be sensitively addressed by therapeutic radiographers.
109	The Electronic Cigarette Industry Trade Association (ECITA)	Consultation question 4	ECITA believes that the best possible way to implement the harm reduction approach at the population level will be to take a 'joined up' approach, i.e. bringing guidance into every area of healthcare interaction. This would include, GPs, pharmacists, Stop Smoking Services, hospital departments, all other healthcare service providers, local government, etc. As Professor John Britton put it: "Electronic cigarettes therefore increase smoking cessation to the extent that they draw in smokers who would not otherwise use a nicotine substitute in an attempt to quit, but reduce it to the extent that they take smokers away from SSS. The optimum solution for population health is to maximise both the use of electronic cigarettes among smokers, and the proportion of users who engage with SSS. This will require some changes to current SSS practice. The key requirement of harm reduction research, in our view, is to monitor and where necessary identify

ID	Stakeholder	Statement No	Comments[1]
			opportunities to intervene to ensure that uptake and use follow patterns most likely to benefit public health; and act to prevent loopholes or practices that run counter to this objective. Priorities in this regard therefore include: methods of integrating electronic cigarette or other nicotine devices into health services, in general and particularly in mental health settings, where conventional approaches have failed24 [https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311887/Ecigarettes_report.pdf]". It would seem likely that SSS should not be relied upon to attempt to deliver the whole smoking harm reduction agenda in isolation, so joining up with every other area of healthcare provision and/or information services seems a more sensible and effective approach.
110	UK Centre for Tobacco and Alcohol Studies (endorsed by the Royal College of Physicians)	Consultation question 4	It should apply to all healthcare practitioners, but particularly clinicians in all NHS services
Consultation question 5			
111	Action on Smoking and Health (ASH)	Consultation question 5	It would seem appropriate to integrate tobacco harm reduction and smoking cessation since the harm reduction guidance encourages **all** smokers to reduce their risk of harm from smoking. In addition it would be useful for appropriate references to be made to any standards around smoking in secondary care.
112	British American Tobacco	Consultation question 5	NO This Quality Standard should not be incorporated within the existing NICE quality standard on smoking cessation. This is on the basis that the two quality standards seek to support two different and distant patient groups. • The NICE quality standard on smoking cessation includes support for people to stop smoking and for people accessing smoking cessation services. • This 'smoking harm reduction' Quality Standard, and the guidance that supports it, pragmatically recognises that some smokers do not want to cut down or quit and/or do not want to be referred to smoking-cessation services. This standard is designed to support these smokers in an effort to reduce harm.
113	British Thoracic Society	Consultation question 5	Quality Statement 1, 2 & 3 Question 5 - Should this topic be published as a separate standard or incorporated within the existing NICE quality standard on smoking cessation? Yes it should be incorporated in the existing quality standard. There is in essence one key concept here, and we do not feel this justifies a separate document. It would be simpler and more efficient to have one sole quality standard related to smoking. Incorporating the QS together will make more of a unified approach towards reducing harm from smoking. Also many of the challenges for commissioning services, referral pathways and collecting data may be more efficient and effective if addressed together.
114	Cochrane Tobacco Addiction Group (TAG)	Consultation question 5	Separate- however these quality statements should be cited heavily in the smoking cessation quality statements. By keeping the two separate it helps to clarify that the primary and most important goal is to support smokers to quit altogether; however where this does not appear to be possible at the current time citation of the harm reduction

ID	Stakeholder	Statement No	Comments[1]
			statements will offer an alternative.
115	Imperial Tobacco Limited	Consultation question 5	Yes. This topic should be incorporated within the existing NICE quality standard 43, which sets out existing measures to which those in the NICE Smoking: harm reduction quality standard may be adjunctive.
116	Johnson & Johnson Limited	Consultation question 5	Johnson & Johnson Limited believes there are good arguments either way to support this topic being published as a separate quality standard or to be incorporated within the existing quality standard on smoking cessation. However, as there are distinct and separate NICE public health guidelines on smoking cessation services (PH10) and on tobacco harm reduction (PH45) it believes the clearest, most consistent and most appropriate strategy is to keep the two associated quality standards separate. That said, Johnson & Johnson Limited again reiterates the messages stated in its general comments: Whilst tobacco harm reduction strategies offer the NHS an opportunity to engage with smokers not ready, willing or able to quit tobacco and nicotine use it should not be seen as an optimal end-point in its own right. It can offer an opportunity to support smokers to behave in ways less harmful to their own health, or the health of those around them, than did their previous level of smoking, but it should always be seen by the NHS as an opportunity to start and to support them on a journey where the desired outcomes is a life free from tobacco use and nicotine addiction. It should be acknowledged that this may not always be possible and that the length of the journey will vary widely for different smokers, but optimal individual and public health outcomes will only be secured if these smokers are supported to become free from tobacco and nicotine in their own time. It is critical that no smoker motivated to quit be inadvertently directed towards an alternative harm reduction strategy.
117	NHS England	Consultation question 5	It makes more sense for this to be combined with the smoking cessation QS, mainly to ensure that people reading one also read the other since are complementary approaches. The title needs to be chosen carefully to reflect the breadth of the new standard
118	Nicoventures	Consultation question 5	We believe that this quality standard should not be incorporated into the quality standard for smoking cessation. The NICE quality standard on smoking cessation includes support for people accessing smoking cessation services and for people to stop smoking. The proposed 'smoking- harm reduction' quality standard and the NICE guidance that supports it [Tobacco: Harm Reduction Approaches to Smoking, NICE PH 45, https://www.nice.org.uk/guidance/ph45/resources/guidance-tobacco-harmreduction-approaches-to-smoking-pdf], pragmatically recognise that some smokers may not want to stop smoking in one step or may want to stop smoking without giving up nicotine or may want to reduce their smoking without stopping or may want to abstain temporarily from smoking. This standard is designed to support these smokers in an effort to reduce harm. These standards are complementary as they support two distinct smoker groups to achieve broader public health goals. We believe that they should cross reference each other but not be merged into one.
119	Proprietary Association of Great Britain	Consultation question 5	As expressed earlier in this document, PAGB is keen to ensure that harm reduction strategies are targeting only those smokers not yet ready, willing or able to try to quit tobacco and nicotine and that no smoker motivated to quit is inadvertently directed towards a harm reduction strategy rather than support to quit. As a result, it believes that this

ID	Stakeholder	Statement No	Comments[1]
			quality standard should be kept separate and not incorporated within the existing NICE quality standard on smoking cessation.
120	Public Health England	Consultation question 5	This quality standard should be read closely in conjunction with NICE's quality standard on smoking cessation (Smoking cessation: supporting people to stop smoking [NICE quality standard 43]). With this in mind, should this topic be published as a separate quality standard or be incorporated within the existing NICE quality standard on smoking cessation? Please state the reasons for your answer. We believe that the QS should be separate to the existing NICE QS on smoking cessation. There is a need to ensure they are strongly linked, however it is important that harm reduction is not simply seen as an intervention to be carried out by stop smoking service practitioners. There is a wider role for all practitioners around the offer of a harm reduction approach as part of very brief advice. Where there are some distinct items within each as well as a different evidence base there should be a mechanism for cross referencing and linking them. In addition it may make sense to review these QS at the same time, as one will necessarily have an impact on how the other is delivered.
121	Society and College of Radiographers	Consultation question 5	The Society and College of Radiographers feels this guidance could be incorporated into the existing NICE quality standard on smoking cessation as there appears to be a significant amount of overlap.
122	The Association of Directors of Public Health	Consultation question 5	The quality standard on smoking cessation focuses on the process of discontinuing tobacco smoking, whilst this standard focuses on ways of reducing harm from smoking. This includes those who are highly dependent on nicotine and who may not be able (or want) to stop smoking in 1 step, those who may want to stop smoking without giving up nicotine, those who may want to reduce the amount they smoke without stopping and those who want to abstain temporarily from smoking. We suggest that the two standards remain separate. We also ask that it is emphasised that quitting remains the best option and that this should be promoted above harm reduction. However, in cases where quitting is not possible then the harm reduction approach should be offered, which may include the continued use of nicotine.
123	The Electronic Cigarette Industry Trade Association (ECITA)	Consultation question 5	The existing NICE quality standard on smoking cessation could stand alone, since 'smoking cessation' is a rather different concept than 'smoking: harm reduction'. However, both NICE quality standard 43 and the draft quality standard for Smoking: harm reduction have the same vitally important gaps, as identified throughout this submission. If NICE takes the view that smoking cessation is an intervention exclusively designed to achieve full cessation of both smoking and nicotine use in one step (which would seem to be indicated by the list of quality statements in quality standard 43, allowing for pharmacotherapy products to be offered as a full and finite course), then this is clearly an entirely separate approach to the suggestions outlined in this draft quality standard for Smoking: harm reduction. In the harm reduction context, the emphasis is on offering support and help to smokers who are unable and/or unwilling to quit completely, and this draft usefully recommends the offering of alternative nicotine-containing products to enable such smokers to at least stop smoking tobacco, even if they are going to continue to use nicotine. As we have already made clear, there needs to be a greater focus on the opportunities offered by the unlicensed nicotine-containing products, alongside the medicinal products, but these would seem to be two entirely different quality

ID	Stakeholder	Statement No	Comments[1]
			standards.
124	UK Centre for Tobacco and Alcohol Studies (endorsed by the Royal College of Physicians)	Consultation question 5	It should be published as part of a comprehensive single quality standard for all NHS services
125	Department of Health	Thank you for the opportunity to comment on the draft for the above quality standard. I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	
126	Royal College of Nursing	This is to inform you that Royal College of Nursing members working in this area of health have reviewed this document, feedback suggests that there are no comments to submit to inform on the consultation at this present time.	

Stakeholders who submitted comments at consultation

- Action on Smoking and Health (ASH)
- British American Tobacco
- British Dental Association
- British Dental Health Foundation
- British Thoracic Society
- Cochrane Tobacco Addiction Group (TAG)
- Imperial Tobacco Limited
- Johnson & Johnson Limited
- NHS England
- Nicoventures
- Pfizer
- Proprietary Association of Great Britain

- Public Health England
- Royal College of Physicians of Edinburgh
- Royal National Institute of Blind People
- Society and College of Radiographers
- The Association of Directors of Public Health
- UK Centre for Tobacco and Alcohol Studies (endorsed by the Royal College of Physicians)