Public Health Intervention Guidance

SMOKELESS TOBACCO: SOUTH ASIANS - Consultation on Draft Scope – Stakeholder Comments Table
Monday 21st March – Monday 18th April 2011

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Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
ASH	4.1.1		We support the focus of the intervention on people of South Asian origin. However, there may be other populations who also use smokeless tobacco (ST) and it is important that they are not accidentally excluded from any intervention to help them stop using ST. Therefore it would be helpful if the guidance could be adapted in such a way as to be relevant to any users of ST. Nevertheless, we recognise that in terms of priority communities, those of South Asian origin should take precedence given the relatively large numbers compared to other minority groups. Furthermore we understand that other products do not necessarily have the same toxicity as the smokeless tobacco products used predominantly by people of South Asian origin.	Thank you for your comment. While there may be other populations using smokeless tobacco, NICE needs to prioritise given limited time and resources. Therefore, the final scope remains focused on South Asians because of: (a) the size of the population within the UK affected by smokeless tobacco use; (b) the ethnic health inequalities in the rates of oral cancer and other disorders that need addressing as a consequence of this use; and (c) the need for NICE to ensure that there is a reasonable amount of evidence on which to base recommendations.
ASH	4.2.1		Add new category: peer and community based interventions	Thank you, this suggestion has been added.
ASH	4.21.		Interventions should also aim to raise awareness and knowledge about ST among health professionals	Thank you, this suggestion has been added.
ASH	4.2.2 [a]		We question the logic of separating prevention from cessation since the two are clearly linked. However, provided that	This split between cessation and prevention has been used previously on

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			interventions that cover both elements are deemed to be permissible interventions, the existing wording of clause (a) may not need to be changed since it does state that only interventions *solely* aimed at prevention will be excluded.	NICE smoking guidance, and is a way of making the topic a manageable size. We expect to find some evidence on interventions that - intentionally or unintentionally - serve a dual purpose of both cessation and prevention.
ASH	4.2.2 [c]		While we understand the need for interventions to be specifically focused on helping people to stop using smokeless tobacco it is impossible to ignore the context in which ST use occurs. Inclusion of an educational component relating to the economic and regulatory issues surrounding ST may complement the cessation advice. For example the lack of statutory health warnings on many products could provide a teaching moment for both the user of ST and health professionals.	Thank you for your comments. The final scope now includes a broader range of interventions than the draft scope, including community-based interventions to raise awareness of the problem. The terms of the Department of Health referral (see Appendix A of the draft scope) mean that statutory health warnings are out of the potential scope of this guidance.
ASH	4.3		Q. 3 We recommend the following wording: "What opinions, attitudes or cultural practices encourage (or predispose) South Asian people in England to use **the different forms** of smokeless tobacco?"	Thank you – the question has been amended to also cover the variety of tobacco used.
ASH	4.3		In the expected outcomes, we recommend amending the final bullet point to: "A rise in health professionals' awareness of the prevalence and variety of smokeless tobacco use."	Thank you – we have revised this point in line with this suggestion.
ASH	General		The draft scope does not specify to whom the guidance should be	There is a list of targeted professionals

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			targeted. We suggest the following groups should be included in the target audience: Health Practitioners (incl. those involved with diabetes care) Health trainers Local religious/community leaders or community champions Stop Smoking Services Local authority public health teams (including Directors of public health) Local authority elected members Retailers/suppliers of smokeless tobacco products	contained in point 2(d) and this has been revised to incorporate many of your suggestions.
Bangladeshi Stop Tobacco Project	4.1.1		There may be other groups of users but it is a question of evidence to provide a rationale. In terms of priority communities, those of South Asian origin numbered more than 2 million permanently resident at the 2001 Census. Other smokeless products do not necessarily have the same toxicity as South Asian smokeless tobaccos (Stanfill SB, Connolly GN, Zhang L et al [2010] Global surveillance of oral tobacco products: total nicotine, unionised nicotine and tobacco-specific *N*-nitrosamines. *Tobacco Control* doi:10.1136/tc.2010.037465).	Thank you for your comments, and for this reference.
Bangladeshi Stop Tobacco Project	4.1.2		There are proprietary branded products which contain areca nut but not tobacco, the users of which should also be excluded (www.ntpd.lacors.gov.uk).	Thank you for your comments.
Bangladeshi Stop Tobacco	4.1.2		There should be clarity in the scope with respect to 'dual' i.e smoked and smokeless tobacco use. This has been estimated at	In the current wording of the scope, dual users are not excluded. The only people

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Project			22% in a random sample of UK resident Bangladeshi men (Croucher RE, Pau AK & Islam SS [2007] Concurrent tobacco use in a random sample of UK resident Bangladeshi men. *J Public Health Dent* 67 (2): 83-8).	who are explicitly excluded (section 4.1.2) are those "who smoke but who do not use smokeless tobacco products".
Bangladeshi Stop Tobacco Project	4.2.1 a		Use of the term 'stop smoking services' may be interpreted to refer to the English NHS Stop Smoking Services. These services currently have little, if any, interest in smokeless tobacco. Using the term would be unnecessarily restrictive in terms of service development and/or staff expertise and, indeed, potentially create contradictory and/or confusing (smoked tobacco vs smokeless tobacco) messages. The experience of the Bangladeshi Stop Tobacco Project's work with Bangladeshi smokeless tobacco users demonstrates a need to adopt a more inclusive approach. A recent retrospective review of 419 client (UK resident female Bangladeshi smokeless tobacco [paan with tobacco] chewers) records recruited between April 2005 and September 2009 has recently been completed. Over three quarters (78.8%) received behavioural support and nicotine replacement therapy and the remainder behavioural support alone. Self reported continuous abstinence at four weeks was 58.3%. Key independent predictors of a successful cessation attempt were use of nicotine replacement therapy (OR=5.38, 95% CI 2.71, 10.7) and community recruitment (OR=1.84, 95% CI 1.01, 3.32).	We have revised point 4.2.1(a). The scope now refers more generically to "evidence-based cessation services".
Bangladeshi Stop Tobacco	4.2.1 b		This, again, seems unnecessarily narrow. It has the potential to exacerbate existing inequalities because of the proposed need to	Thanks for this comment. There are now two separate points – 4.2.1(b) and

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Project			access health care services. Brief interventions may be delivered by a range of appropriately trained people offering evidence based support. For clarity, 'appropriately trained' would be defined as having met the training standards developed within the NHS Centre for Smoking Cessation and Training (www.ncsct.co.uk).	4.2.1(c) – and this revision widens out the range of people who could potentially deliver these interventions. Thank you for the suggestion of an additional potential stakeholder organisation - we will notify them of this guidance development process.
Bangladeshi Stop Tobacco Project	Group Discussion Q 3		Any practitioner and/or organisation responsible for commissioning tobacco cessation and where there is an identified local need for smokeless tobacco cessation support. Potential service providers such as the third sector/NGOs should be aware of the advice. The NHS Centre for Smoking Cessation and Training (www.ncsct.co.uk) can lead in the development of training modules and should be aware of the advice.	Changes made to paragraphs 2(d) and section 4.2.1 now acknowledge the wide range of practitioner and organisations who may have an interest in the guidance.
Bangladeshi Stop Tobacco Project	4.3 Key question 3		This question should be amended to focus on 'opinions, attitudes and cultural practices which encourage South Asians to make *smokeless tobacco quit attempts'* i.e the focus of the guidance.	In practice the suggested revision is a mirror of the version as it stood, but other stakeholders preferred the question as it was. Question one in this section will examine quantitative and qualitative literature on interventions focused on quitting, and will therefore shed some light on your revised question.

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Bangladeshi Stop Tobacco Project	4.3 Proposed additional key question		An additional question is proposed, reflecting the wide range of environmental factors such as commissioning guidance and restrictions on commissioning, target setting and primary health care QOFs, supply of smokeless tobacco products: *'What influences in the broader regulatory and contextual environment are identifiable as preventing or facilitating the motivation and support of South Asian smokeless tobacco users seeking to stop using smokeless tobacco in England?'* This question might also be expanded to include the content of 4.3 Key question 3 (opinions, attitudes and cultural practices).	The Department of Health referral (see Appendix A of the draft scope) specifies that NICE should develop guidance for commissioners and providers on cessation interventions, and we would be going beyond our remit to develop recommendations on wider tobacco control measures such as regulations. However, the list of potential considerations (Appendix C) has now been revised to include the wider contextual factors that may impede effective implementation.
Bangladeshi Stop Tobacco Project	4.3 Outcomes		The longer term outcomes are aspirational and any cause/effect relationship will be hard to identify.	Measuring the impact of a factor like smokeless tobacco use on oral cancer is difficult. This section of the scope is intended to discuss general and aspirational "ideal" outcomes that will results from proper implementation of the completed guidance.
Bangladeshi Stop Tobacco Project	4.3 Outcomes		Short and medium term *client* outcomes could be: resolution of pre-cancerous oral lesions (leukoplakias) following successful cessation, increases in numbers of smokeless tobacco users setting quit dates and making successful cessation attempts, levels	This section has been revised to now include those setting quit dates, and successful quit attempts.

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			of service satisfaction, impact on quality of life.	The other suggestions might qualify as "secondary" outcomes, and were therefore not central enough to be listed in the scope. The treatment of pre-cancerous lesions would not in itself be regarded as an central outcome of interventions specified by this guidance.
Bangladeshi Stop Tobacco Project	4.3 Outcomes		There is current developmental work to establish the sensitivity and specificity of self-reported cessation using salivary cotinine analysis.	Thank you for your comments.
Bangladeshi Stop Tobacco Project	4.3 Outcomes		Short and medium term *cessation worker* outcomes could be: improved level of professional awareness of smokeless tobacco prevalence and its dangers, uptake and successful completion of NHS Centre for Smoking Cessation and Training modules, a greater number of referrals to specialist smokeless tobacco services following a brief intervention.	The relevant bullet point in section 4.3 has now been revised to include professional awareness. The other outcomes you suggest are reasonable ones, albeit probably too specific for inclusion in the scope
Bangladeshi Stop Tobacco Project	General – impact on health inequalities		NRT is widely available whilst other pharmacotherapies (bupropion, varenicline) are not currently licensed for smokeless tobacco use and are only available on prescription (Lancaster T & Stead L. (2010) Drug treatment for users of smokeless tobacco. *BMJ* 341:c6598 doi:10.1136/bmj.c6598).	Thank you for your comments.
Bangladeshi Stop Tobacco	General – impact on		There is some 'grey' literature suggesting that 'community champions' such as, in the Tower Hamlets context, faith leaders	We will be undertaking a call for evidence among stakeholders, and we

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Project	health inequalities		and shopkeepers can provide brief interventions and stop smokeless tobacco referrals.	would appreciate being sent any literature of this sort following this call. In the meantime, paragraphs 2(d) and 4.2.1(c) have been revised, and now include some of the groups you suggest.
Bangladeshi Stop Tobacco Project	General – impact on health inequalities		Addressing inequality requires an holistic approach addressing both the supply of and demand for smokeless tobacco – see additional proposed key question.	See response above.
Bangladeshi Stop Tobacco Project	General – impact on health inequalities		Principles identified for adoption in this guidance should be considered for their potential generalisability to other priority population groups such as routine/manual smokers (NHS Stop Smoking Services: service and monitoring guidance 2010/2011 [www.dh.gov.uk/publications]).	Thank you for your comments. This guidance will recommendations for smokeless tobacco interventions with South Asians. It is for others to determine whether they are generalisable to other circumstances.
Bradford and Airedale Community Health Services	4.1.2 Groups not covered		Chewing areca nut without tobacco should be included supari (which contains areca nut without current evidence of any tobacco content) (ref. Niche Tobacco Products Directory).	The detrimental effect that areca nut has on oral health, independent of tobacco, is recognised. However, NICE is constrained by the referral from the Department of Health, which specified smokeless tobacco. Areca nut will of course be covered in any guidance interventions that focus on mixtures of

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				this nut and tobacco.
Bradford and Airedale Community Health Services	4.2.1 a)		*Support or counselling offered by* ***stop smoking services*** may create confusion for individuals accessing a service when they do not smoke and therefore may create barriers to accessing the service	We have revised point 4.2.1(a). The scope now refers more generically to "evidence-based cessation services".
Bradford and Airedale Community Health Services	4.2.1 b)		Brief interventions by …. Needs to include social care and community settings	Thanks for this comment. There are now two separate points – 4.2.1(b) and 4.2.1(c) – and this revision widens out the range of settings where these interventions could be delivered.
Bradford and Airedale Community Health Services	4.3 Expected outcomes		There needs to be a mechanism of gathering data on who is using ST and who has been supported to quit. This should be a national standardised process to enable comparability. Doctors should have tobacco use included in their QoF points instead of smoking. Enabling this differentiation will support data collection and enable targeting of services. NHS Stop Smoking Services should have clear targets as with smoking to prioritise this work. We cannot determine if a reduction of smokeless tobacco use will lead to a reduction in oral cancer incidence amongst this group as oral cancer has other associated risk factors such as diet, alcohol use, smoking and sunlight to name but a few. The outcome should be re-worded to capture this multi-factorial disease and ST being	At this stage we are focusing on the scope, and setting the parameters for the evidence to be considered. It is acknowledged that enhanced data gathering may improve the situation in the long term, but the cost effectiveness of this sort of activity may have to be traded off against the effectiveness of other interventions. The multi-factorial nature of oral cancer causation is also acknowledged. To keep the scope readable and user friendly, these other factors are not

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			one of them**.**	mentioned. An assumption is made that, all other things being equal, a reduction in smokeless tobacco use will be associated with a lowering of oral cancer rates.
British American Tobacco	General		British American Tobacco supports the underlying aim of this Guidance i.e. reducing the population harm to health caused by the use of smokeless tobacco products (STP) among people of South Asian origin living in the UK. However, we would suggest that the limitation of the draft Scope solely to cessation of STP use may not achieve the expected outcomes of the Guidance, and that additional alternative approaches to addressing STP use should be considered. In this context, it is important first to note that users of STP may find it difficult to achieve total cessation based solely on the interventions proposed in the draft Scope. In the context of smoking, the majority of people who attempt to quit using NRT are unsuccessful1,2. An EU commissioned report on the Health Effects of Smokeless Tobacco Products3 concluded that STP are addictive and that withdrawal symptoms are broadly similar to those seen in smokers. The report stated that STP can deliver quantities of nicotine comparable to those typically absorbed from cigarette smoking. It has been acknowledged by the WHO Study Group on Tobacco Product Regulation (TobReg)4 which looked at smokeless tobacco products that, in general, 'users of STP generally have lower risks	Thank you for your comments. We are aware of the literature on the levels of toxins in Swedish 'snus' and other forms of smokeless tobacco (and in particular the many forms of smokeless tobacco used by South Asian groups). We are also aware that DG SANCO has conducted a public consultation on a possible revision of the Tobacco Products Directive and that the scope of the Directive and the position on snus and other smokeless tobacco products is being considered. However, the Department of Health referral (see Appendix A of the draft scope) specifies that NICE should develop guidance for commissioners and providers on cessation interventions, so

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			for tobacco-related morbidity and mortality than users of combustible products such as cigarettes' but also, that there are substantial differences between types of STP and that '…it would be scientifically inappropriate to consider STP as a single product for the purposes of estimating risk or setting policies.' The Royal College of Physicians (RCP) reached similar conclusions in its 2007 report "Harm reduction in nicotine addiction".[5] Therefore, in order to deliver the expected outcome of the Guidance - 'a reduction in morbidity and mortality caused by smokeless tobacco use' - we believe that additional, more sophisticated, interventions should be considered alongside those suggested in this draft Scope. In particular, some members of the public health community have suggested that current regulation of STP in Europe should be reassessed.[6] The current situation is that the sale of a type of a Swedish-style STP called 'snus', commonly accepted as having amongst the lowest reported health risks associated with tobacco use, is banned; yet the sale of many other forms of STP, including those typically used by the South Asian communities in the UK, which are known to be associated with significant health risks, is permitted. Regulation of levels of certain toxicants within STP has been suggested as a possible way to differentiate between them. Differentiating risk could help ensure that the STP with the lowest levels of toxicants and lowest risk profiles are allowed on the market, whereas those with high	we would be going beyond our remit to develop recommendations on wider tobacco control measures such as regulations.

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			toxicant levels and high risk are not. Such a regulatory framework has been put forward by the European Smokeless Tobacco Council (ESTOC), based on limits for certain toxicants[7]. This voluntary industry standard for STP is based on the GothiaTek standard for snus, which has been recognised by TobReg, the RCP and other public health stakeholders.[8 9 1] As Bates et. al. observed, adopting such a regulatory approach would 'provide an opportunity to shape the ST market and ensure that if such products are used, they are placed on the market with a high level of protection for human health and the consumer, and to ensure that the worst products are either removed from the market or do not come in. Regulation should apply to all ST, including chewing tobaccos, that are currently allowed on the market unregulated.'[11] This approach has been endorsed by a further WHO TobReg report on STP, which stated 'Regulatory lowering of the concentrations of carcinogens in STP might reduce the numbers of cancers resulting from their use' and went on to suggest regulatory limits be set for 3 of the known carcinogens in STP, the tobacco specific nitrosamines NNN and NNK, and benzo(a)pyrene[10]. Similarly, in a study investigating levels of toxicants in STP in the UK, McNeill et. al.[12] concluded that 'Smokeless tobacco products should be regulated and standards set for maximum levels of toxins and carcinogens'. The authors added that 'As the UK STPs have	

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			established usage within Asian communities in the UK and are very much part of their culture, we are not suggesting that these products be banned. Instead, toxin standards should be set for all the STP available on the UK market, with a reasonable timescale for compliance. The toxin standards set by parts of the industry – for example, the Gothiatek Standard by Swedish Match – could be used as a starting point, but it should be possible over a short time frame to reduce the key toxins and carcinogens to the lowest levels which are technically feasible which in most cases would be non-detectable levels (shown in this study and other research to be technically feasible)'[12].	
British American Tobacco	References		References – 1 Le Houezec et al, Tobacco, nicotine and harm reduction, Drug and Alcohol Review March 2011, 30, 119-123 2 Ferguson et al, The English smoking treatment services-one year outcomes. Addiction 2005, 100 (supp.2):59-69 3 Scientific Committee on Emerging and Newly Identified Health Risks, 'Health Effects of Smokeless Tobacco Products' , European Commission 2008. 4 World Health Organisation (2008) The Scientific Basis of Tobacco Product Regulation, WHO Technical report Series 951.	Thank you for details of these references.

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			5 GROUP OF THE ROYAL COLLEGE OF PHYSICIANS, 2007. *Harm reduction in nicotine addiction Helping people who can't quit* [online], p. 161. Available from: http://www.rcplondon.ac.uk/pubs/contents/bbc2aedc-87f7-4117-9ada-d7cdb21d9291.pdf [Accessed 29 November 2009] 6 C. Bates et al, European Union policy on smokeless tobacco: a statement in favour of evidence based regulation for public health. Special communication 2003, Tobacco Control 2003 12:360-367 www.tobaccocontrol.com= 7 ESTOC, Response to the TPD Public Consultation Document 2010 http://www.estoc.org/uploads/Documents/documents/ESTOC%20response%20TPDR%20public%20consultation%20-%20leave%20behind.pdf 8 Ibid Bates et al, Tobacco Control 2003 9 Le Houezec et al, Tobacco, nicotine and harm reduction, Drug and Alcohol Review March 2011, 30, 119-123 10 World Health Organization (2009) Report on the Scientific Basis of Tobacco Product Regulation: Third Report of a WHO Study Group, WHO Technical report Series 955. 11Ibid Bates et al, Tobacco Control 2003 12 McNeill et al, Levels of toxins in oral tobacco products in the UK, Tobacco Control 2006;15:64-67	
British	General		In general summary, we believe that taking regulatory steps to	It is not within the scope of this guidance

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American Tobacco			manage the constituents of STPs could potentially provide a reduction in morbidity and mortality caused by STP use and complement initiatives to promote cessation among STP users. There is wide variation between different types of STP and their associated risks. We believe that future regulation of STP should be based upon scientific evidence associated with different types. We support the use of constituent limits for STP and advocate those being proposed by ESTOC.	to make recommendations on substitutions of different types of smokeless tobacco products. The Scope for this guidance must reflect the referral from the Department of Health (Appendix A) which asked NICE to develop guidance for commissioners and providers on services to help people stop using smokeless tobacco, so we would be going beyond our remit to develop recommendations on the regulation of tobacco products.
British American Tobacco	Section 2 (d)		Currently, the EU Directive on tobacco products (TPD) does not permit the sale of Swedish-style snus outside of Sweden in the EU. However, the status of this ban is being reviewed as part of the current TPD review process. In our view, the ban on Swedish-style snus is inappropriate when it is manufactured to the Gothiatek standard and is associated with lower risks to health compared with other tobacco products, while other potentially more harmful STPs are available and largely unregulated in the EU. We believe that all smokeless tobacco should be regulated in the same manner across the EU and that this should be done based upon toxicant levels and associated risks not by method of use as is the current situation. Inconsistent regulation cannot assist with information or education designed to persuade STP users to change their habits. In	See previous comment

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			developing the guidance, NICE should take account of both the relative risk of Swedish-style snus, the epidemiology from Sweden and the scientific evidence that has been published around this type of STP.	
British American Tobacco	Section 2 (e)		If this guidance is to be based upon the best available evidence then we would recommend that the Institute seek the input of both the Swedish and Norwegian Governments and take account of their evidence. This information could inform a fuller picture of the differences between different types of STP and health outcomes.	See previous comment
British American Tobacco	Section 4.2		The limitation of the proposed interventions solely to cessation advice and pharmacotherapies may not achieve the expected outcomes of the Guidance. Additional alternative approaches to addressing STP use should be considered, including recommending the setting of regulatory limits for toxicants within STP based on the Gothiatek standard and the epidemiology from Sweden over the past 30 years. We appreciate that substitution may not be preferred to cessation in public health guidance but it is a pragmatic approach to harm reduction used elsewhere in public health.	See previous comment
British Dental Association	General		The BDA supports the focus of the guidance on South Asians as the highest risk group for ST use. We recommend that a wider, "whole journey", approach be taken to interventions than the	The key importance of dentists in relation to the problem of smokeless tobacco use is recognised by NICE, and efforts will be

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			scoping document suggests, however. Dental professionals are largely aware of the dangers of all types of tobacco use and will refer appropriately where resources permit. Raising awareness among dental professionals should be only a part of the guidance; the same emphasis should be given to any health professional who is likely to come into contact with users of ST. Information on the reasons people use ST would be useful to help health professionals engage with patients and encourage them into services that will help them stop use. The focus of the guidance should be on ensuring that the providers of the services referred into are aware of the cultural issues and can offer supportive cessation techniques. There should be a clear path from the community to cessation services that do not require a health professional to be the gatekeeper, as this will be impractical if access to health services is not increasing. We also consider that it would be appropriate to direct the guidance to community leaders and gatekeepers, who will have a stronger voice and wider reach than health professionals. As stated, a dentist will refer into services where appropriate; to ensure that this is possible we recommend that the guidance make it clear to commissioners of stop smoking services that these are necessary, especially in areas of high ST use, and that there be a concerted effort to increase awareness among this group of the need for regular attendance at their dentist so that they can be referred.	made to locate all relevant evidence on their possible role. A new point (4.2.1(e)) has been added that now makes interventions that raise awareness of professionals one of the areas for investigation. Revisions have been made to paragraphs 2(e) and 4.2.1(b), and a new point 4.2.1(c) has been added. These changes are partially in response to your point about widening out the professionals and gatekeepers involved in delivering these services. The NICE guidance will recommend a range of cost effective interventions, however it is for local commissioners to determine the what local services are provided to meet the needs of their population.

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			In short, we recommend that the focus of the document should be on community intervention, which includes increasing access to dental and other health services, and on ensuring that there are adequate stop smoking services commissioned and that the deliverers of stop smoking services are fully trained to help people stop using ST products.	
British Dental Health Foundation	General		The British Dental Health Foundation has actively promoted awareness of Mouth Cancer for the past decade. We run Mouth Cancer Action Month every November, called 'If in doubt, get checked out'. The dangers of chewing tobacco features highly in our campaign, alongside the other major risk factors such as smoking, alcohol, poor diet and HPV. Prevention runs at the heart of our campaigns, although our experience and research suggests there is considerably more work to do to ensure the messages for good oral health and the risks which cause mouth cancer are communicated effectively and understood. **Overall, we welcome the initiative and approach adopted in this scoping document.**	Thank you for this information, and these comments.
British Dental Health Foundation	3b		We believe around 5,300 new cases of mouth cancer are diagnosed each year. We estimate this has increased by 41 per cent over the past decade. Our data indicates that 1,822 people died from mouth cancer in 2008. It is unclear what proportion of these deaths result from chewing tobacco. **It is recommended that this is an area where more research is needed and further**	Thank you for your comments. The exact strength of the link between smokeless tobacco use and oral cancer is uncertain. This will be taken into consideration as part of the economic analysis.

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			evidence gathering is included into the scope of the document.	
British Dental Health Foundation	3f		Raising awareness of mouth cancer with dental professionals and encouraging them to take preventive action is a key objective of Mouth Cancer Action Month. Information is issued to over 20,000 practitioners each year. They are encouraged to offer free examinations, undertake publicity and improve their own general understanding of the disease, especially the symptoms. Whilst it is likely that *health* professionals generally have a low level of awareness, *dental* professionals will have a greater knowledge of mouth cancer. **As health professionals are likely to play a key role in this strategy, it is recommended that the scoping document is refined to determine and differentiate between the levels of knowledge of dental practitioners, versus other health professionals who are likely to have a key role.**	Thank you for your comments. A new point (4.2.1(e)) has been added that now makes interventions that raise awareness of professionals one of the areas for investigation.
British Dental Health Foundation	3f		Language seems to have been omitted from this potential list of barriers. This issue may be exacerbated further by health and dental terminology. **It is recommended that the issue of language is included into the scoping document.**	This suggestion has now been incorporated into paragraph 3(f).
British Dental Health Foundation	4.3		There may be some more fundamental questions to ask – prior to interventions - in relation to accessing dental health practitioners, and if there are any cultural attitudes which may inhibit people of	This issue is probably already covered under the last bullet point in paragraph 3(f).

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			South Asian origin accessing services. Our data suggests that around 58 per cent of the population have visited their dentist in the past six months. Around ten per cent of the population still don't have a dentist. **It is recommended that an additional question is considered to determine personal dental health practices by the South Asian people and barriers to their usage of dental health services.**	
British Dental Health Foundation	4.3		Question 2: It is likely that the most effective intervention strategy and impact will need to be designed around population clusters in England. **It would be helpful if the scoping document considered and gave guidance on the issue of population clusters and regionality for targeting purposes.**	Thank you - your comment, along with the comments of other stakeholders, led to a revision in paragraph 3(f) ("The heterogeneity of the various sub-populations using smokeless tobacco presents challenges in developing interventions"). Your suggestion that this be a formally stated outcome, will be considered, although it is unlikely that there will be sufficient evidence develop a specific set of recommendations for each population cluster.
British Dental Health Foundation	4.3		Expected outcomes. As prevention and detection is fundamental to improving early diagnosis and survival rates for mouth cancer, we would expect to see a clear outcome linked to the adoption of good	This is a potential "intermediate" outcome, and this part of the scope only focuses on primary or "key" outcomes.

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			personal oral health management. **It is suggested that one behaviour outcome should be linked to regular visits and check-ups by a dentist by people of South Asian origin.**	
British Telecom	4.2.2 c)		I realise the focus is on cessation but some linkage should be made to prevention and a position stated on some of the key drivers for behaviour change in smoking that are likely to be as relevant here, i.e. legislation, pricing, advertising, health awareness.	This split between cessation and prevention has been used previously on NICE smoking guidance, and is a way of making the topic a manageable size. We expect to find some evidence on interventions that - intentionally or unintentionally - serve a dual purpose of both cessation and prevention. The Department of Health referral (see Appendix A) specifies that NICE should develop guidance for commissioners and providers on cessation interventions, and we would be going beyond our remit to develop recommendations on wider tobacco control measures such as legislation, pricing, and advertising.
British Thoracic Society	4.3 Question 4		Within secondary care there is very little awareness of smokeless tobacco use, and secondary care physicians will rarely ask about it. There is certainly ignorance around the different forms of smokeless tobacco and their relative health risks. Any proposed	It is hoped that there will be sufficient evidence to allow NICE to make recommendations on the delivery of interventions in different settings, such

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			interventions would need to define awareness amongst primary and secondary care doctors, and in secondary care could focus on specific areas such as diabetes care where there may be higher proportions of South Asian patients. It should also aim to educate doctors about the health risks of smokeless tobacco as most are not aware of the major risks and the differences between preparations.	as for example secondary care. A new point (4.2.1(e)) has been added that now makes interventions that raise awareness of professionals one of the areas for investigation.
British Thoracic Society	General		Smokeless tobacco, although harmful to health, does not cause respiratory disease in the same way that smoked tobacco does and therefore may not be perceived as a major problem by respiratory physicians. Indeed, there have been moves for some time to medicalise smokeless tobacco in the UK in some of its forms for use in harm reduction for smokers, so this needs to be balanced with the scope of this consultation in terms of reducing usage in this particular group.	The Department of Health referral (see Appendix A) specifies that NICE should develop guidance for commissioners and providers on interventions to help people stop using smokeless tobacco. You might like to know that NICE is also developing guidance on 'Harm reduction approaches to smoking cessation' – see http://guidance.nice.org.uk/PHG/Wave23/23
C3 Collaborating for Health	General		**Prevention:** Promote oral health; may be with a special focus on South Asians; Dentists' Association should be engaged for its advocacy; developing a registry for SLT users could be very helpful.	At this stage we are focusing on the scope, and setting the parameters for the evidence to be considered. It is acknowledged that enhanced data gathering may improve the situation in the long term, but the cost effectiveness of this sort of activity may have to be

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
				traded off against the effectiveness of other interventions.
C3 Collaborating for Health	General		**Cessation and health coverage:** Link health insurance or the overall health care (NHS) with appropriate disincentives to the SLT user after an optimal time- window to let users quit on a priority or subsidized basis, as is suitable.	Our guidance will primarily be of interest to services funded as part of the NHS or local authority services, and because these are public services, it would be difficult to see where personal financial disincentives could be built into these systems.
C3 Collaborating for Health	General		**Prevention of cross border smuggling:** Adopt stringent measures to halt smuggling of SLT (New Zealand has a case in best practices; Dr. Sunder Lokhande, Compliance Officer, New Zealand).	The Department of Health referral (see Appendix A) specifies that NICE should develop guidance for commissioners and providers on cessation interventions, and we would be going beyond our remit to develop recommendations on wider tobacco control measures such as smuggling prevention measures.
C3 Collaborating for Health	General		**Taxation on SLT:** Raise tax to an international norm of the retail price i.e. up to 70-80%; and link it to the consumer price index for a steady increase accordingly every year (the latter is the part of best practices adopted by Thailand for Cigarettes since late 1990s).	The Department of Health referral (see Appendix A) specifies that NICE should develop guidance for commissioners and providers on cessation interventions, and we would be going beyond our remit to develop recommendations on wider tobacco control measures such as taxation rates.

Public Health Intervention Guidance

SMOKELESS TOBACCO: SOUTH ASIANS - Consultation on Draft Scope – Stakeholder Comments Table
Monday 21st March – Monday 18th April 2011

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Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
C3 Collaborating for Health	General		**License SLT:** Tobacco is as much an addictive substance as Heroin, Cocaine, etc. It will be useful to initiate a debate to license SLT with a time line to phase-out the use of SLT (all tobacco products in fact) from UK, after 10- 15- 20 years. *The analogy could be based on the guidelines of International Narcotics Control Declaration and/or the law that controls licensing of oral opium.*	The Department of Health referral (see Appendix A) specifies that NICE should develop guidance for commissioners and providers on cessation interventions, and we would be going beyond our remit to develop recommendations on wider tobacco control measures such as substance licensing.
C3 Collaborating for Health	General		**Promote Tobacco-free workplaces:** It will help to eliminate the potential of increasing dual-users; and will motivate smokers to quit.	NICE offers existing guidance on the workplace as a setting for discouraging smoking (http://www.nice.org.uk/PHI005). It is hoped that there will be sufficient evidence to allow NICE to make recommendations on the delivery of smokeless tobacco interventions in different settings, such as for example, the workplace.
Cardio Wellness – Solutions for Health	General		The paucity of research on tobacco use behaviors in South Asians is due in part to the fact that despite a distinct cultural and geographical background, South Asians are almost always aggregated into a broad “South Asian” category, thus potentially masking subgroup differences and preventing identification of potential health disparities between subgroups. Hence, why there is	Thank you - your comment, along with the comments of other stakeholders, led to a revision in paragraph 3(f) ("The heterogeneity of the various sub-populations using smokeless tobacco presents challenges in developing

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			a need to understand the prevalence amongst specific subgroups such as Bangladeshi, Gujarati, Rajasthanhi, Tamil, Maratis – whom have a higher prevalence than other subgroups such as Punjabi's. Indeed it is also important to focus on other sub-groups such as the Somali populations, e.g. Somali's that have originated from regions such as the Gedo region have a significantly high (>80%) addiction to tobacco chewing.	interventions").
Cardio Wellness – Solutions for Health	4.2.1 Interventions		A Cochrane review by Ebbert J, Montori VM, Erwin PJ, Stead L suggests that Nicotine replacement therapy (patches or gum), and bupropion have **not** been shown to help people to stop using smokeless tobacco (ST). From our experience of actually delivering interventions at a grass root level, using a combination of 1-1 or group behavioral support combined with NRT (patches or gums) over a 6 week period (based on smoking cessation interventions) has helped people to stop. Suggest that this section can be strengthen to reflect this.	Thank you. We are aware of the Ebbert et al review, and its findings, along with other literature that we uncover, will be carefully considered when formulating the guidance.
Cardio Wellness – Solutions for Health	General		Tobacco use is the greatest identifiable contributor to inequalities in health & life expectancy, those living in deprived areas, R&M workers and BME groups are more likely to consume tobacco. It is also well understood that there is a higher incidence of CHD, diabetes and certain cancers amongst South Asian groups and tobacco use significantly increases these risks. Hence the scope of this guidance could be amended to reflect this and take a more holistic approach.	Thank you for your comments. We feel that the scope as it stands does not impede us from developing guidance that is suitable for all people, regardless of socioeconomic status and occupation group. While the additional conditions you name

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
				may have an increased prevalence in these communities, the remit of this project, as specified to us by the Department of Health, requires a focus only on smokeless tobacco. However, if we were to come across literature on "combined interventions" (for example smokeless tobacco and CHD, or smokeless tobacco and diabetes), this material may be reflected in our recommendations.
Cardio Wellness – Solutions for Health	4.1.2 Groups that will not be covered		Should chewing of Areca nut be included in this scope? Agreed that it is not contain tobacco, however, according to the International Agency for Research on Cancer (IARC) regards the chewing of betel and areca nut to be a known human carcinogen. Regular chewers of betel leaf and areca nut have a higher risk of damaging their gums and acquiring cancer of the mouth, pharynx, esophagus and stomach. Studies have found tobacco and caustic lime increase the risk of cancer from areca nut preparations. Also, chewing of areca nut, can subsequently lead to use of a mix of areca nut and tobacco in ingredients when mixed with other preparations e.g. in paan.	The detrimental effect that areca nut has on oral health, independent of tobacco, is recognised. However, NICE is constrained by the referral from the Department of Health, which specified smokeless tobacco. Areca nut will of course be covered in any guidance interventions that focus on mixtures of this nut and tobacco.

Public Health Intervention Guidance

SMOKELESS TOBACCO: SOUTH ASIANS - Consultation on Draft Scope – Stakeholder Comments Table
Monday 21st March – Monday 18th April 2011

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted. If comments forms do have attachments they will be returned without being read. If the stakeholder resubmits the form without attachments, it must be by the consultation deadline

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
Chartered Institute of Environmental Health	4.1.1		We support the intention to focus on 'people of south asian origin' and the definition employed. However, it will be important to consider how this focus will be explained to and understood by the members of this population group. There are issues of cultural context and sensitivity that need to be taken into account. The approach we recommend is that while the focus is on a particular population group, for justifiable reasons, the intervention will not only be appropriate to this population group, but will also be applicable to all users of ST.	While there may be other populations using smokeless tobacco, NICE needs to prioritise given limited time and resources. Therefore, the final scope remains focused on South Asians because of: (a) the size of the population within the UK affected by smokeless tobacco use; (b) the ethnic health inequalities in the rates of oral cancer and other disorders that need addressing as a consequence of this use; and (c) the need for NICE to ensure that there is a reasonable amount of evidence on which to base recommendations. Your point is taken about the possibility of community sensitivity to this targeting. Conversely, however, some members of these communities may welcome the focusing of resources where they are most needed.
Chartered Institute of Environmental	4.2		The guidance also needs to cover the content of the brief intervention as this will be necessarily different to stop smoking interventions and will need to be appropriate for both the user of	It is anticipated that a number of models of these intervention types will be found in both the formal research literature, and

Public Health Intervention Guidance

SMOKELESS TOBACCO: SOUTH ASIANS - Consultation on Draft Scope – Stakeholder Comments Table
Monday 21st March – Monday 18th April 2011

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Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
Health			smokeless tobacco products as well as the type of smokeless tobacco product being used.	"grey" literature. As far as it is possible, NICE will provide a standardised definition of the content of a "brief intervention" (or definitions, if there is more than one appropriate model) is recognised. We anticipate that the other questions as far as our guidance goes will be the settings they are best used in with respect to South Asian populations, and also the nature of the person delivering them.
Chartered Institute of Environmental Health	4.2.1		The interventions need to take into account consideration of harm reduction from the use of tobacco products generally. This would include people wishing to change from smoking tobacco to using it in smokeless forms as well as people wishing to change or reduce their use of smokeless tobacco.	The Department of Health referral (see Appendix A) specifies that NICE should develop guidance for commissioners and providers on interventions to help people stop using smokeless tobacco. You might like to know that NICE is also developing guidance on 'Harm reduction approaches to smoking cessation' – see http://guidance.nice.org.uk/PHG/Wave23/23
Chartered Institute of	4.2.1		Include an additional sub para (c) Peer and community based interventions	Thank you - we have made this suggested revision.

Public Health Intervention Guidance

SMOKELESS TOBACCO: SOUTH ASIANS - Consultation on Draft Scope – Stakeholder Comments Table
Monday 21st March – Monday 18th April 2011

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Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
Environmental Health				
Chartered Institute of Environmental Health	4.2.1		Include an additional sub para (d) Raising awareness and knowledge amongst health professionals	Thank you - we have made this suggested revision.
Chartered Institute of Environmental Health	4.2.1		Include an additional sub para (e) Motivating quit attempts through health and social care referral processes	Section 4.2.1 is stated quite generally at present – as is appropriate for a NICE public health guidance scope, prior to the main literature review that will take place. However, if the evidence of effectiveness and cost effectiveness suggests that modified referral processes are effective and cost-effective, then the guidance will of course recommend them.
Chartered Institute of Environmental Health	4.2.2		In subpara (a) we do not understand why preventing the uptake of smokeless tobacco products is not to be covered. We think it is unrealistic to exclude this and that it is a key element of effective practice that we address both reduction and prevention together.	This split between cessation and prevention has been used previously on NICE smoking guidance, and is a way of making the topic a manageable size. We expect to find some evidence on interventions that - intentionally or unintentionally - serve a dual purpose of both cessation and prevention.

Public Health Intervention Guidance

SMOKELESS TOBACCO: SOUTH ASIANS - Consultation on Draft Scope – Stakeholder Comments Table
Monday 21st March – Monday 18th April 2011

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Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
Chartered Institute of Environmental Health	4.2.2		In subpara (c) We believe that it will be essential to consider the influence that the lack of, and the lack of enforcement of, regulatory controls on smokeless tobacco products is having. In particular, the supply of illegal imported products, the low price of smokeless tobacco products, the absence of health warnings in the same manner as required for smoked tobacco products and the failures to deal with underage sales.	The Department of Health referral (see Appendix A) specifies that NICE should develop guidance for commissioners and providers on cessation interventions, and we would be going beyond our remit to develop recommendations on wider tobacco control measures such as enforcement, the supply of illegal imported products, price, health warnings, and underage sales.
Chartered Institute of Environmental Health	4.3		In Question 3: What opinions, attitudes or cultural practices encourage (or predispose) South Asian people in England to use **the different forms** of smokeless tobacco?	Thank you – we have revised question three in accordance with this suggestion.
Chartered Institute of Environmental Health	4.3		In the expected outcomes, amend the final bullet pint to: A rise in **health professionals** awareness of the **prevalence and variety** of smokeless tobacco use.	Thank you - we have made this suggested revision
Chartered Institute of Environmental Health	General		In the context of the proposed new arrangements for public health and the need to address inequalities in health, the role and responsibility of the local authority needs to be considered. In particular the role of elected members, the Director of Public Health and education providers.	Thank you - we have made this suggested revision

Public Health Intervention Guidance

SMOKELESS TOBACCO: SOUTH ASIANS - Consultation on Draft Scope – Stakeholder Comments Table
Monday 21st March – Monday 18th April 2011

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Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
European Smokeless Tobacco Council (ESTOC)			The European Smokeless Tobacco Council (ESTOC) represents the majority of the smokeless tobacco manufacturers in Europe. All of its members follow a rigorous quality standard for the production of smokeless tobacco. ESTOC's objective is to secure the permission-to-sell smokeless tobacco products that would comply with our proposed regulatory framework[1] in Europe and in other parts of the world. There are numerous forms of smokeless tobacco products available, varying in their manufacturing methods, chemical composition, modes of use and health risks. In the EU smokeless tobacco is regulated according to the intended use of the product and not the risk profile associated with it. ESTOC believes that smokeless tobacco should be regulated according to a mandatory quality standard. The Royal College of Physicians[2] state *"Smokeless tobacco is not a single product, but rather a summary term for a range of different tobacco products which deliver nicotine without combustion. Smokeless tobacco products differ substantially in their risk profile in approximate relation to the content of toxins in the tobacco."* Within Europe, both oral and nasal smokeless tobacco products have been traditionally used in several countries. For instance, snus, a moist form of oral tobacco, has been used for over 200 years in Sweden.	We are aware of the literature on the levels of toxins in Swedish 'snus' and other forms of smokeless tobacco and of the recommendations of the Royal College of Physicians and others. While we follow the debates on the possible revision of the Tobacco Product Directive with interest, snus-type products are not currently legally available in the UK and NICE cannot make recommendations on their use.

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			A study by Ann McNeil et al "Levels of toxins in oral tobacco products in the UK" (2006)[3] advocates a regulation for smokeless products *"As the UK products have established usage within Asian communities in the UK and are very much part of their culture, we are not suggesting that these products be banned. Instead toxin standards should be set for all the smokeless tobacco products available on the UK market, with a reasonable timescale for compliance. The toxins standards set by part of the industry – for example, the Gothiatek Standard by Swedish Match[4] – could be used as a starting point, but it should be possible over a short time frame to reduce the key toxins and carcinogens to the lowest levels which are technically feasible which in most cases would be non-detectable levels (shown in this study and other research to be technically feasible)".* This suggested approach is supported by a number of bodies and groups. The European Commission's European Monitoring Centre for Drugs and Drug Addiction[5] states: *"Levels of nitrosamines in Swedish snus have decreased over the past 20 or so years in response to the development of an industry standard (Hatsukami et al., 2007; Österdahl et al., 2004). The development of portion snus in the 1970s (tea-bag-like sachets of snus) has produced a more user-friendly version that has increased prevalence of snus use among Swedish men. The fact that until recently snus was taxed at a much lower rate than cigarettes may also have contributed to its*	

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			increased popularity. Increased snus use by Swedish men has been accompanied by decreased cigarette smoking and tobacco-related disease mortality (Foulds et al., 2003; Ramström, 2003)." The Second report of the WHO study group on tobacco product regulation[6]: "The Scientific Basis of Tobacco Product Regulation" (951) (2008) states *"Cigarette smoke is the most hazardous form of nicotine intake, and medicinal nicotine is the least hazardous. Among the smokeless tobacco products on the market, products with low levels of nitrosamines, such as Swedish snus, are considerably less hazardous than cigarettes, while the risks associated with some products used in Africa and Asia approach those of smoking" (pg 273). (Emphasis added.) The same report also suggests "that the differences in risks associated with use of different smokeless tobacco products mean that it would be scientifically inappropriate to consider smokeless tobacco as a single product for the purposes of estimating risk or setting policies" (pg 20).* The Third report of the WHO study group on tobacco product regulation[7]: "The Scientific Basis of Tobacco Product Regulation" (955) (2009) recommends: • All products that deliver nicotine for human consumption should be regulated. • Smokeless tobacco products should be regulated by controlling the contents of the products. • The metric for measuring toxicants in smokeless tobacco should	

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			be the amount per gram of dry weight of tobacco. Cessation of tobacco use is the important goal but there will be many smokeless tobacco users that are unwilling or unable to stop and therefore a risk reduction approach should also be considered. In such a case a less hazardous product[8], such as Swedish snus could be substituted in place of the more hazardous products in current use in the UK South Asian origin population. There is the example from Sweden where substituting the use of snus for conventional cigarette smoking has had a public health impact. Should you require more information, please do not hesitate in contacting us. . [1] ESTOC Proposed Regulation of Smokeless Tobacco Products within the EU [2] Royal College of Physicians and Surgeons (2007) *Harm reduction in nicotine addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians*. London. [3] McNeill A et al. Levels of toxins in oral tobacco products in the UK. *Tobacco Control*, 2006, 15:64–67. [4] *Gothiatek standard.* Stockholm, Swedish Match Company. http://www.swedishmatch.com/en/Snus-and-health/Our-quality-	

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			standard-GothiaTek/ [5] *European Monitoring Centre for Drugs and Drug Addiction* - Harm reduction: evidence, impacts and challenges: *http://www.emcdda.europa.eu/attachements.cfm/att_101257_EN_EMCDDA-monograph10-harm%20reduction_final.pdf* [6] *The scientific basis of tobacco product regulation: second report of a WHO study group*. Geneva, World Health Organization, 2008 (WHO Technical Report Series, No. 951) [7] *The scientific basis of tobacco product regulation: third report of a WHO study group*. Geneva, World Health Organization, 2009 (WHO Technical Report Series, No. 955) [8] *Global surveillance of oral tobacco products: total nicotine, unionised nicotine and tobacco-specific N-nitrosamines,* Stanfill SB, Connolly GN, Zhang L, et al. Tobacco Control (2010). doi:10.1136/tc.2010.037465	
GASP	2 a)		Why only targeted at cessation services? Any reduction in tobacco needs a comprehensive approach – price, prevention, media messages, supply and 'de-normalisation. The draft scope does this by stating all the other related policy documents you will link to but it should be broader in scope in itself.	This split between cessation and prevention has been used previously on NICE smoking guidance, and is a way of making the topic a manageable size. We expect to find some evidence on interventions that - intentionally or unintentionally - serve a dual purpose of both cessation and prevention.

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
				The Department of Health referral (see Appendix A) specifies that NICE should develop guidance for commissioners and providers on cessation interventions, and we would be going beyond our remit to develop recommendations on wider tobacco control measures such as price, prevention, media messages, and supply. Finally, it is possible that some of the recommendations may cover interventions that have a 'de-normalisation' component.
GASP	2 e)		Sometimes the evidence is not robust but examples of projects targeting South Asians do exist and can be used as the basis for formulating ideas on how to reach the groups in question. When working for the HEA many years ago I chaired the UK BMEG and Smoking group of tobacco control workers that met to support each other. They did wonderful work reach parts of the community that other professionals did not reach! The other part of this section needs to be broadened to include a lot more community, religious, cultural, media, businesses, educational settings and committed leaders of the community. There also needs to be a broad brush approach to include other	Thank you for your comments. In accordance with our process manual, we will in the first instance look for the highest quality evidence available, but we will turn to other sources (including existing examples of UK-based best practice) where necessary. In the revised draft, section 2(e) and section 4.2.1 has been revised and, in accordance with your comments, the

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			health issues to link tobacco with other causes of ill health amongst these communities – heart disease, diabetes, thalassemia etc. The focus should be as much on what works to reach this community as what works to reduce smokeless tobacco use.	range of both the intervention settings and the involved practitioners has been expanded. While the groups at risk from the additional conditions you name may frequently overlap with groups at risk from smokeless tobacco use, the remit of this project, as specified to us by the Department of Health, requires a focus only on smokeless tobacco. However, if we were to come across literature on "combined interventions" (for example smokeless tobacco and CHD, or smokeless tobacco and diabetes), this material may be reflected in our recommendations.
GASP	3 a)		There is need for guidance on what is smokeless tobacco. But what is also needed is some sort of 'mapping' to show who uses what. Questions of How?, Where? and When? would also be useful. Most of the evidence quoted is from Tower Hamlets but having a map of the UK showing a profile of what is known about the smokeless tobacco use in the different areas would help to set the scene for the guidance. It could be an added objective. Smokeless tobacco use may vary greatly with age, gender and	Thank you - your comment, along with the comments of other stakeholders, led to a revision in paragraph 3(f). The inclusion of area profiles in the guidance could be useful, although it is unlikely that there will be sufficient demographic information on smokeless

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			ethnicity. Are there South Asian groups who do not use smokeless tobacco? Sikhs? Sri Lankans? The list of medical conditions should also be extended to include short term impacts. These are often more powerful motivators to quit. So hairy tongue, yellow teeth, bad breath, money it costs related to family needs etc. I use an American film 'Truth or Dare' which I show to young people about smoking and tobacco use. It has a whole section on smokeless tobacco use. The images of oral cancer have huge impact. The most memorable images are those of hairy tongue. I ask kids which out of the horrid things they see (lung cancer, COPD, heart attacks and oral effects) most put them off. Hairy tongue wins 8 out of 10 votes every time!	tobacco users to develop a specific set of recommendations for each population cluster. It is also possible that this information could date quickly. However, information of this sort may be presented, if there is confidence that this can be done comprehensively. The specific outcomes you suggest might qualify as "secondary" outcomes, and were therefore not central enough to be listed in the scope.
GASP	General		Because oral tobacco is common in the USA, tobacco prevention education agencies have a range of resources about smokeless tobacco use. This includes models, films, PowerPoint talks, leaflets, posters as well as TV and radio ads that could be a good starting point to review for ideas and evaluations of what programmes have been effective. Because smokeless tobacco in the US is mainly used by young men and baseball players the resources would have to be adapted and made more culturally appropriate. But having a range of useful resources to reinforce and support cessation work and education work would be very important. I have a collection of some of these resources from visits to US agencies.	At this stage we are just focusing on the scope, and setting the terms for the literature review that our guidance will involve. While it is likely that the measures that you suggest will emerge from the literature as being effective and cost effectiveness, all approaches considered will need to be examined in depth and traded off against the effectiveness of other interventions and approaches that we will encounter while reviewing the literature.

Public Health Intervention Guidance

SMOKELESS TOBACCO: SOUTH ASIANS - Consultation on Draft Scope – Stakeholder Comments Table
Monday 21st March – Monday 18th April 2011

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Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
GASP	3 b)		Should areca nut also be included in the smokeless tobacco message? Not sure if this confuses the message or should be targeted at those groups who use Areca nut with their tobacco.	The detrimental effect that areca nut has on oral health, independent of tobacco, is recognised. However, NICE is constrained by the referral from the Department of Health, which specified smokeless tobacco. Areca nut will of course be covered in any guidance interventions that focus on mixtures of this nut and tobacco.
GASP	3 c)		In addition to the sub-groups information it would be useful to know where best to reach those groups – home, shopping areas, religious settings, workplaces?	We hope that the research literature will be of sufficient detail to allow us to make recommendations on the delivery of interventions in different settings.
GASP	3 d)		This seems to be a large part of the problem! Price is the single most effective control on tobacco use. So if 85% are outside of regulation then this needs tackling! 49% use is extremely high even if only in one area of UK.	The Department of Health referral (seen in Appendix A of the draft scope) only specifies that NICE should develop guidance for commissioners and providers on cessation intervention, and we would be going beyond our remit to develop recommendations on wider tobacco control measures such as price control and labelling.
GASP	3 f)		The 'barriers' seem a 'déjà vu' of tobacco smoking. With 50 years of 'what works?' for smoking, we have a good blueprint for action.	We are aware of the immense amount of research that exists around smoking, but

Public Health Intervention Guidance

SMOKELESS TOBACCO: SOUTH ASIANS - Consultation on Draft Scope – Stakeholder Comments Table
Monday 21st March – Monday 18th April 2011

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Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			Smoking has a cultural element and this has been the focus of the 'de-normalisation' campaigns.	we do not feel that this is always automatically applicable to smokeless tobacco as a substance, and to South Asians as a population group. However, it is conceded that there may be some learning from smoking cessation initiatives among South Asians.
GASP	4.2.1 a and b		I strongly believe that to promote cessation you must include a level of education and motivation. It is obvious that raising awareness needs to move those not ready to quit towards thinking about or wanting to quit then trying to quit. The baseline of professionals needs to be broadened to include all sorts of community leaders and other professionals.	Thanks for your comments - we believe that the alterations that we now made to paragraphs 2(d) and 4.2.1 increases the baseline of people who will be included in the scope of this guidance.
GASP	4.2.2		Prevention and other measures are essential! No cessation programme could function without the forces that drive people towards wanting to quit or not to start.	This split between cessation and prevention has been used previously on NICE smoking guidance, and is a way of making the topic a manageable size. We expect to find some evidence on interventions that - intentionally or unintentionally - serve a dual purpose of both cessation and prevention.. The Department of Health referral (seen in Appendix A of the draft scope) only

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				specifies that NICE should develop guidance for commissioners and providers on cessation intervention, and we would be going beyond our remit to develop recommendations on wider tobacco control measures.
GASP	4.3 Q.1		As stated earlier, there may be few evidence based research papers about reducing smokeless tobacco use but we can look at projects that have been successful at reaching the target groups and then look at how to present the messages. Some I have known about: • To reach large numbers - use Asian radio programmes. After a radio piece went out we had a queue of Bangladeshis wanting help to quit smoking. Only 2 turned up from posters! • Stalls in busy areas with a volunteer doctor. Asians don't want to see their own GP about health checks BUT ones at community events are VERY popular. • Workplace programmes for Asian women (or men) • Work with Asian taxi drivers • After hours (1am) Heart Health Fair for all the workers in Indian restaurants (who are mainly Bangladeshi). • Ramadan projects before during and after the time of fasting. • Asian lunch events with food demos, BP testing, lung testing • Asian women swimming sessions • Places of worship and community centres	Thank you. NICE will consider the best available evidence of effectiveness and cost effectiveness. In some cases, this may include other sources (including existing examples of UK-based best practice) where necessary.

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			• Community festivals, melas and events – there are lots! • Outside Nursery Schools – to reach women with children ESOL classes – in Bristol a project called Maternity Links taught English to pregnant Asian women. This could be adapted.	
GASP	Q.2		As above (Q1) but in addition; by religion, by cultural festivals (e.g Eid festivals), where you find children to reach women, via schools to reach parents, workplaces, shops selling Asian food, GPs.	Thank you - we have inserted "religion" into question two. There may or may not be literature around that addresses the issue of differences in use between religious groups, but any demographic information we find on users will be useful.
GASP	Q.4		Yes this is true but the stop smoking services only measure success by SMOKERS quitting.	We have revised point 4.2.1(a) in line with this suggestion, and in line with the suggestion of several other stakeholders. The scope now refers more generically to "evidence-based services".
GASP	Expected outcomes		These are fine. But to achieve these necessitates media campaigns of some sort and educational awareness raising programmes.	The original phrase "as local initiatives to increase the uptake of these interventions" was meant to include this element. However, the scope has been revised to include these types of interventions as a separate category in 4.2.1.
GASP	General		In addition to the resources to target the public, we also need	Thank you for your comments.

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			resources and information for professionals. These can include health risks but also visual displays such as the range of smokeless tobacco products that always intrigue and engage people.	
GASP	General		If you combine smoking with other health messages it often gets diluted. However, combining education about smokeless tobacco with food and health programmes may work better.	Thank you for your comments.
GASP	General		The scope feels a bit too 'Top down', too health professional dominated. The scope states that South Asian don't associate screening with seeing a health professional before disease appears. Needs some 'bottom up' approaches.	Thank you - paragraph 4.2.1(b) has now been expanded into points 4.2.1(b) and 4.2.1(c), and these points now include a greater range of people who might deliver interventions - in other words, we have expended this beyond health professionals.
GASP	General		I have worked in tobacco control in the UK at a national and local level and I have visited many tobacco prevention projects in the US and Australia. A strategy that works well on two fronts is to offer small grants for community projects that set out to do something about the goals you are trying to achieve. Sometimes the outcomes are not that good BUT what this approach does achieve is get people involved. Community project grants raise awareness and pilot innovative projects some of which prove cost-effective and repeatable. In California the tobacco prevention programme has a community grant programme for all sorts of groups who know their	We are intending to initiate a call for evidence, and we hope that any relevant "grey literature" on services you have been involved with can be made available to us.

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			community best but who want to tackle tobacco in an appropriate way. These can be ethnic groups, sexual orientation groups, workplace groups or church groups etc. South Tyneside attracted a wide range of applicants to their community tobacco control grants programme some of which were successful in terms of participation. After the end of the grants round they took medical students and health workers to visit these projects. This increased the practical skills and understanding of the issues. They called these the 'Barefoot Public Health Tours'. Involving the South Asian community in challenging the issue with ideas and even grants for projects might work in this case too.	
Heart of Mersey / ChaMPs / CMTA	4.1.1		We support the focus of the intervention on people of South Asian origin. However, there may be other populations who also use smokeless tobacco (ST) and it is important that they are not accidentally excluded from any intervention to help them stop using ST. Therefore it would be helpful if the guidance could be adapted in such a way as to be relevant to any users of ST.	While there may be other populations using smokeless tobacco, NICE needs to prioritise given limited time and resources. Therefore, the final scope remains focused on South Asians because of: (a) the size of the population within the UK affected by smokeless tobacco use; (b) the ethnic health inequalities in the rates of oral cancer and other disorders that need addressing as a consequence of this use; and (c) the need for NICE to ensure that there is a reasonable amount of

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
				evidence on which to base recommendations. Of course, local commissioners and providers may choose to extrapolate the recommendations to other users of smokeless tobacco.
Heart of Mersey / ChaMPs / CMTA	4.2.1		Add new category: peer and community based interventions	Thank you - we have accepted this suggestion, and this is now the new point 4.2.1(c).
Heart of Mersey / ChaMPs / CMTA	4.21.		Interventions should also aim to raise awareness and knowledge about ST among health professionals	Thank you - we have accepted this suggestion, and this is now the new point 4.2.1(e).
Heart of Mersey / ChaMPs / CMTA	4.2.2 [a]		We question the logic of separating prevention from cessation since the two are clearly linked. However, provided that interventions that cover both elements are deemed to be permissible interventions, the existing wording of clause (a) may not need to be changed since it does state that only interventions *solely* aimed at prevention will be excluded.	This split between cessation and prevention has been used previously on NICE smoking guidance, and is a way of making the topic a manageable size. However, we expect that some interventions that we find evidence on in the literature will - intentionally or unintentionally - serve a dual purpose of both cessation and prevention, so some prevention-related interventions could be covered.
Heart of Mersey	4.2.2 [c]		While we understand the need for interventions to be specifically	The Department of Health referral (see

Public Health Intervention Guidance

SMOKELESS TOBACCO: SOUTH ASIANS - Consultation on Draft Scope – Stakeholder Comments Table
Monday 21st March – Monday 18th April 2011

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/ ChaMPs / CMTA			focused on helping people to stop using smokeless tobacco it is impossible to ignore the context in which ST use occurs. Inclusion of an educational component relating to the economic and regulatory issues surrounding ST may complement the cessation advice. For example the lack of statutory health warnings on many products could provide a teaching moment for both the user of ST and health professionals.	Appendix A of the draft scope) only specifies that NICE should develop guidance for commissioners and providers on cessation interventions, and we would be going beyond our remit to develop recommendations on wider tobacco control measures such as economic issues, regulatory issues, and health warnings.
Heart of Mersey / ChaMPs / CMTA	4.3		Q. 3 We recommend the following wording: "What opinions, attitudes or cultural practices encourage (or predispose) South Asian people in England to use **the different forms** of smokeless tobacco?"	Thank you - we have accepted this suggestion.
Heart of Mersey / ChaMPs / CMTA	4.3		In the expected outcomes, we recommend amending the final bullet point to: "A rise in health professionals' awareness of the prevalence and variety of smokeless tobacco use."	Thank you - we have accepted this suggestion.
Heart of Mersey / ChaMPs / CMTA	General		The draft scope does not specify to whom the guidance should be targeted. We suggest the following groups should be included in the target audience: Health Practitioners (incl. those involved with diabetes care) Health trainers Local religious/community leaders or community champions	There is a list of targeted professionals contained in point 2(d), but we have considered and accepted these additional suggestions

Public Health Intervention Guidance

SMOKELESS TOBACCO: SOUTH ASIANS - Consultation on Draft Scope – Stakeholder Comments Table
Monday 21st March – Monday 18th April 2011

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			Stop Smoking Services Local authority public health teams (including Directors of Public Health) Local authority elected members Retailers/suppliers of smokeless tobacco products	
NHS Bradford & Airedale	4.1.2		Areca nut use contributes to submucous fibrosis which has been suggested may lead to oral cancers. Many users of smokeless tobacco are unaware if tobacco is added to paan for example, or are not willing to admit the use of tobacco. Areca nut cessation should be provided as we may exclude those who are unaware of the product's incorporation in the oral preparation they are using. There is evidence to suggest that children use paan without tobacco at social occasions and this ritual often leads to paan with tobacco in later life.	The detrimental effect that areca nut has on oral health, independent of tobacco, is recognised. However, NICE is constrained by the referral from the Department of Health, which specified smokeless tobacco. Areca nut will of course be covered in any guidance interventions that focus on mixtures of this nut and tobacco.
NHS Bradford & Airedale	4.2.2		Inclusion of social care and community settings should also be included as some people do not attend primary care facilities.	Thank you - your comments, and the comments of other stakeholders, have led to changes in section 4.2.1, which increases the range of settings that will be covered by the guidance.
NHS Bradford & Airedale	4.3 (Expected outcomes)		We cannot determine if a reduction of smokeless tobacco use will lead to a reduction in oral cancer incidence amongst this group as oral cancer has other associated risk factors such as diet, alcohol use, smoking and sunlight to name but a few. The outcome should	We agree that exactly measuring the impact of a factor like smokeless tobacco use on oral cancer is difficult or impossible.

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			be re-worded to capture this multi-factorial disease and ST being one of them. Identification of pre-malignant lesions could be an appropriate indicator.	The identification of pre-malignant lesions would not in itself be regarded as an central outcome of interventions specified by this guidance.
NHS Bradford & Airedale	General		This document needs to link to NHS Stop Smoking Services annual monitoring and guidance.	Wherever possible, we attempt to draw links between the final guidance and/or related implementation tools with relevant documents produced by other organisations.
NHS Tower Hamlets	3 d/e		Range of products are widely available are cheap and are often sold in general grocery stores rather than bespoke tobacconists. There is a need for work to enforce tobacco labelling laws.	The Department of Health referral (seen in Appendix A of the draft scope) only specifies that NICE should develop guidance for commissioners and providers on cessation interventions, and we would be going beyond our remit to develop recommendations on wider tobacco control measures such as economic issues, regulatory issues, and health warnings.
NHS Tower Hamlets	3f		It would be useful to include a commentary on the role of faith/religion here. For example Muslims will stop using it during the fasting hours in Ramadan. It is our experience with the Bangladeshi community that oral tobacco use is cross generational and socially acceptable- eg it comes out at weddings, children will prepare it for	Religious belief associated with smokeless tobacco is cited in paragraph 3(f) as a potential barrier to cessation, although it is also possible that some effective programmes may be associated

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			their grand parents.	with religion or delivered in religious settings. Religion has now also been added as a potential consideration in Appendix C.
NHS Tower Hamlets	4.1.1		South Asians should remain the focus, but reference should be made to other smokeless products which are used in this country. Khat is often described as a tobacco product (which it is not)	We agree that khat is not a tobacco product. Whether we would make reference to it would depend on whether there is evidence on interventions that were intended to reduce both smokeless tobacco and khat addiction. Otherwise, it would be out of scope for this NICE guidance.
NHS Tower Hamlets	4.2.2		Interventions on preventing up take should be included. It should also be noted that some people both smoke and use oral tobacco simultaneously.	This split between cessation and prevention has been used previously on NICE smoking guidance, and is a way of making the topic a manageable size. We expect to find some evidence on interventions that - intentionally or unintentionally - serve a dual purpose of both cessation and prevention.
NHS Tower Hamlets	4.2.1		There needs to recognition of grass roots community outreach/engagement ways of recruiting smokers, Eg a project we did with Social Action for Health recruited women from the community who were brought together in “groups” and had lay led discussions about the use of Paan, potential risks and health	Thank you - we are intending to initiate a call for evidence, and stakeholders will be notified of this, and we would welcome any published or unpublished material you have on your activities.

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			available. Sessions were held in community centres and women's homes. (I can send a report if helpful)	
NHS Tower Hamlets	4.3		There are pockets of very local behaviour and what is very important is for commissioners to have an understanding of their local population (eg via the JSNA)	Thank you - your comment, along with the comments of other stakeholders, led to a revision in paragraph 3(f) ("The heterogeneity of the various sub-populations using smokeless tobacco presents challenges in developing interventions"). The recommendation that commissioners compile a local population profile is a common part of NICE public health guidance, and could conceivably form part of this guidance.
Oxfordshire PCT	General		I work in north Oxfordshire (Banbury.) Five years ago I came across the use of 'tobacco' being used by South Asian women.	Thank you for your comments.
Oxfordshire PCT			Users of smokeless tobacco use it by rubbing it on their gums.	Thank you for your comments.
Oxfordshire PCT			I was very concerned and I tried to get it analyzed but I had no budget to do so. I wanted betel nut to also be targeted as a health risk issue.	Thank you for your comments.
Oxfordshire PCT			Health professionals are unawares of this practice and omit asking the question of smokeless tobacco or chewing habits when they	The issue of health professional awareness will be considered during this

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			ask patient if they smoke. This should become standardised questioning especially in high South Asian population health authority areas.	guidance development process.
Oxfordshire PCT			Media should be used to get the message of oral cancer to the target group as many households subscribe to South Asian television channels, and are avid viewers. South Asian celebs should front the campaigns as they will be listened to more than any health promotion slogan.	Initiatives to raise awareness of the harm caused by smokeless tobacco are now explicitly referred to in the scope in paragraph 4.2.1(d), and we will do what we can to assess these initiatives for effectiveness and cost effectiveness.
Oxfordshire PCT			Many south Asian NHS workers have good cultural knowledge of the target group and their expertise should be sort in each target locality.	Thank you - your comment, along with the comments of other stakeholders, led to a revision in paragraph 3(f) ("The heterogeneity of the various sub-populations using smokeless tobacco presents challenges in developing interventions"). The idea that commissioners compile a local population profile is a common part of NICE public health guidance, and could conceivably form part of this guidance.
Oxfordshire PCT			South Asian shops should also be targeted as many sell imported products some of which are out of date when on the shelves. They should be also considered as partners in the campaigns so they do not fear their livelihood is being jeopardized.	Thank you, we have added the words "retailers and suppliers of smokeless tobacco products" into paragraph 2(d).

Public Health Intervention Guidance

SMOKELESS TOBACCO: SOUTH ASIANS - Consultation on Draft Scope – Stakeholder Comments Table
Monday 21st March – Monday 18th April 2011

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Oxfordshire PCT			Woman practice this chewing of tobacco as it is deemed more acceptable than being seen with a cigarette hanging out of ones mouth.	Thank you for your comments.
Oxfordshire PCT			I would be happy to assist in the campaign if required.	Thank you for your comments.
QUIT – Asian Quitline	3C		At Asian Quitlines we find that the social mix of London and the UK has changed dramatically and a new group at higher risk than Bangladeshi's has emerged. These are the Indian students and IT workers living in the UK and chewing gutka tobacco (bought and smuggled into the UK via India) There are over 20,000 Indian students and 50,000 Indian HMPS Visa holders entering the UK each year and at any one time there may be over 200,000 Indian student visa holders in the UK (Home Office and Migration Watch), they primarily live in London and over 40% may be usingsmokeless Gutka tobacco users.	Thank you - your comment, along with the comments of other stakeholders, led to a revision in paragraph 3(f) ("The heterogeneity of the various sub-populations using smokeless tobacco presents challenges in developing interventions"). The recommendation that commissioners compile a local population profile is a common part of NICE public health guidance, and could conceivably form part of this guidance.
QUIT – Asian Quitline	4.3 Question 1		At Asian Quitlines we found that diagnosing the addiction levels in a proper clinical method is essential in any successful treatment option. We use simple near patient saliva tests to determine nicontine levels (eg Saliva Smokescreen Rapid Test by Surescreen Mermaid Diagnostics Derby). This is very important to get an objective feel (especially if they are dual users) and then you can combine it with Karl Fagerstrom's Smokeless Tobacco	Thank you for this information

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			Algorithm	
QUIT – Asian Quitline	4.3 Question 2		At Asian Quitlines we find that treatment should be provided by product type used. Gutka users and their aadiction, pattern of use, socio-economic status and nationality is quite different from the Bangladeshi Zarda/Paan users.	See comment above regarding heterogeneity of users.
QUIT – Asian Quitline	4.3 Question 3		At Asian Quitlines we monitor ethnic media and find that it shapes most of the positive attitude towards gutka. We run health promotion campaigns against smokeless tobacco annually on ethnic media and find we are reaching key targets like yound gutka chewers in the Indian student population.	Thank you for your comments.
QUIT – Asian Quitline	4.3 Question 4		In Birmingham, London and Leicester, most NHS staff are aware of smokeless tobacco use and its health impacts. Treatments are offered in proportion to the local population and their product use. In East London there are well established (over 5 years) paan projects for Bangladeshi users. But what we do not have are Gutka cessation projects in West London and North London and the Midlands for Indian Gutka usres.	Thank you for your comments. We are intending to initiate a call for evidence process later, and we hope that any relevant evidence on UK services will become available to us.
QUIT – Asian Quitline	General		The smokeless tobacco treatment focus should shift from Bangladeshi communities towards the young Indian students and IT professionals settling in the UK now.	See comment above regarding heterogeneity of use.

Public Health Intervention Guidance

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Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
Royal College of Nursing	General		The Royal College of Nursing welcomes proposals to develop this guidance. It is timely. There are no further comments to make on the draft scope at this stage.	Thank you for your comments.
Royal College of Paediatrics and Child Health	General		The College has no comments on this draft scope. We note with approval that the guideline will apply to people of all ages.	Thank you for your comments
Royal College of Physicians	4.1.1		Our experts believe that the focus is correct. Although smokeless tobacco is used by other groups in the UK, use by South Asian communities is the most important focus given that smokeless tobacco use is common in these communities and that there are more than 2m people from South Asian communities living in the UK. It might be helpful to acknowledge that other groups use smokeless tobacco and that some of this guidance might be applicable to these other groups. However, the heterogeneity of smokeless tobacco products and cultural factors might preclude generalisability overall.	While there may be other populations using smokeless tobacco, NICE needs to prioritise given limited time and resources. Therefore, the final scope remains focused on South Asians because of: (a) the size of the population within the UK affected by smokeless tobacco use; (b) the ethnic health inequalities in the rates of oral cancer and other disorders that need addressing as a consequence of this use; and (c) the need for NICE to ensure that there is a reasonable amount of evidence on which to base recommendations.

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
				With respect to the heterogeneity issue, your comment, along with the comments of other stakeholders, led to a revision in paragraph 3(f) ("The heterogeneity of the various sub-populations using smokeless tobacco presents challenges in developing interventions").
Royal College of Physicians	4.1.2		The second bullet should include proprietary products that contain areca nut without tobacco.	The detrimental effect that areca nut has on oral health, independent of tobacco, is recognised. However, NICE is constrained by the referral from the Department of Health, which specified smokeless tobacco. Areca nut will of course be covered in any guidance interventions that focus on mixtures of this nut and tobacco.
Royal College of Physicians	4.2.1 a)		We would query the wording of this intervention. Stop *smoking* services are not currently encouraged to focus on smokeless tobacco users/chewers. So the reference to stop smoking services should be deleted. It might be better not to specify who should deliver these interventions so that the evidence base can be used to identify what the key characteristics are and what training is needed for those providing the interventions. There is emerging evidence of the effectiveness of trained community outreach workers providing effective smokeless cessation support in the UK.	We have revised point 4.2.1(a) in line with this suggestion, and in line with the suggestion of several other stakeholders. The scope now refers more generically to "evidence-based cessation services".

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			We agree that it is important to include pharmacotherapies as well as behavioural support as there is also emerging evidence that pharmacotherapies are effective with tobacco chewers in the UK. We would suggest rewording this intervention to read: 'Behavioural support or counselling for individuals or groups. This may involve the use of pharmacotherapies.' Some attention needs to be placed to the interaction between smoking and smokeless use such that smokeless users are encouraged to stop smoking as well as appropriate.	
Royal College of Physicians	4.2.1 b)		We would suggest that this be left broad so that the evidence base can be interrogated to identify the key characteristics/training of those providing brief interventions and that this should not be restricted to healthcare professionals given that there may be accessibility and/or usage issues with healthcare for these groups. It may be that community workers such as faith leaders could play an important role here. We would suggest the following rewording 'Brief interventions which may involve a referral or the use of pharmacotherapies.';	Thank you - paragraph 4.2.1(b) has now been expanded to two separate points, and the range of potential intervention deliverers has been expanded.
Royal College of Physicians	4.2.1 and 4.2.2. c)		Whilst we understand that wider tobacco control measures and prevention of smokeless tobacco may be outside of the scope of this guidance, we do nevertheless believe that these wider measures, such as price and health warnings and the mass media, are critically important at motivating and supporting tobacco	The Department of Health referral (seen in Appendix A of the draft scope) only specifies that NICE should develop guidance for commissioners and providers on cessation interventions, and

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			chewers to quit as well as raise awareness of the use of these products among relevant health and social care professionals. These issues will also help to reduce initiation to smokeless tobacco use. Our research (Longman et al, J Public Health 2010; 32:372-8) showed wide availability and accessibility of smokeless tobacco products in the UK. We suggest therefore that there should be a new intervention worded along the lines of 'What broader regulatory or contextual factors prevent or facilitate the motivation and support of South Asian smokeless tobacco users seeking to stop using smokeless tobacco in England'. The wording could be broadened to include preventive efforts if appropriate. See also the report found at: http://www.ukctcs.org/ukctcs/research/topics/harmreduction.aspx for further information on this issue.	we would be going beyond our remit to develop recommendations on wider tobacco control measures such as price, health warnings, and the role of the mass media. However, local initiatives to raise awareness of the harm caused by smokeless tobacco are now explicitly referred to in the scope in paragraph 4.2.1(d), as are interventions to raise awareness and knowledge among health and social care professionals in paragraph 4.2.1(e)
Royal College of Physicians	4.3 Expected outcomes		An additional bullet point would be helpful to include the number of South Asian smokeless tobacco users setting a quit date and quitting at short and long term follow ups. Quit success could be self-report or validated using a biomarker such as cotinine (currently being studied through a DH funded UKCTCS project). Client satisfaction and quality of life could also be also be considered.	Thank you, we have revised this section and accepted the suggestion about the number setting a quit date.
Royal College of Physicians	4.3 Expected		The third bullet could be modified to include some shorter term health indicators such as pre cancerous mouth lesions.	The identification of pre-cancerous lesions would not in itself be regarded as

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
	outcomes			an central outcome of interventions specified by this guidance.
Royal College of Physicians	4.3 Expected outcomes		The final bullet point should be amended to say ' A rise in health and social care professional awareness of smokeless tobacco use and its dangers'	Thank you, we have revised this section and incorporated this suggestion
South Asian Health Foundation	General		We at SAHF strongly commend this guidance, as this in an equity issue on which we have lobbied on for a number of years	Thank you for your comments.
South Asian Health Foundation	General		The link between smokeless tobacco and outcomes is now evidenced - there are research recommendations which need to be made by NICE on identifying the efficacy of interventions to reduce risk.	Research recommendations are a routine and required part of the NICE guidance development process.
South Asian Health Foundation	General		The issue is one of equity of risk reduction when it comes to tobacco control which includes smokeless tobacco (we managed to get this into the DH framework and prior NICE PDG guidance - both of which changed from smoking to 'tobacco control' on this basis)	Thanks for your comments.
South Asian Health Foundation	General		Commendably, there are parts of the NHS which see addressing tobacco control as an important fight against health inequality - parts of the West Midlands offer access to stop smoking services [SSS]for smokeless tobacco users (something we have developed and encouraged) - though do we do not as yet have outcomes from	Thank you for this information

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			this access.	
South Asian Health Foundation			Smokeless tobacco is just as addictive and harmful as smoked tobacco. With the social unacceptability of smoked tobacco, commercial providers of tobacco products will increasingly use innovative mechanisms to stimulate the market, such as promoting use of smokeless tobacco as a 'less harmful' product.	Thank you for these comments.
South Asian Health Foundation	General		The problem of the easy availability of smokeless tobacco products by people of south Asian origin in the UK needs to be urgently addressed. It is almost always present in the South Asian home. Its use is, however, far from benign, as shown by a study among Gujaratis in northwest London, which found that paan chewers had cocaine-like dependency with withdrawal symptoms of headaches and sweating. Paan is unfortunately also readily and cheaply available to both children and adults. Research in Bangladeshi people aged 12–18 years in east London found high levels of regular paan use, for both the tobacco-containing and tobacco-free forms. Of concern is that only a third of these young people knew of the association between tobacco-containing paan and cancer. A similarly high prevalence of use has also been shown among south Asian adults in the UK. Not addressing these disproportionate uses will engender inequities and iniquities in disease prevalence.	Thanks for your comments. NICE's focus in developing this guidance is very much on trying to address the health inequalities that currently exist.
South Asian	General		We are concerned that there are still many forms of smokeless	The Department of Health referral (seen

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Health Foundation			tobacco do not adhere to the Tobacco Advertising and Promotion Act. This is an inequitable application of the Advertising and Promotion Act and should be applied to oral tobacco products, which have been proven to increase the rates of cardiovascular disease similarly to smoking tobacco. Therefore, a lack of parity in the portrayed harm of oral tobacco with smoked tobacco, will make the drive to tackle inequalities in health driven by cardiovascular disease more challenging. Regulation of smokeless tobacco should at least be equivalent to smoked tobacco.	in Appendix A of the draft scope) only specifies that NICE should develop guidance for commissioners and providers on cessation interventions, and we would be going beyond our remit to develop recommendations on wider tobacco control measures such as advertising and promotion issues.
South Asian Health Foundation	3c		We agree that this guidance must be specific and local. This will increase its cost-effectiveness. This problem is one that mostly afflicts 1st-generation South Asian women, who are lower down the socio-economic and educational leader, who often speak little English.	Thank you - your comment, along with the comments of other stakeholders, led to a revision in paragraph 3(f) ("The heterogeneity of the various sub-populations using smokeless tobacco presents challenges in developing interventions"). We have also now added "language" as a barrier in paragraph 3(f)
UKCPA (endorsed by Royal Pharmaceutical Society)	General		The UKCPA Respiratory Group welcomes the development of this guidance on cessation services for users of smokeless tobacco.	Thank you for these comments.
UKCPA	3.a		Paan (a mixture of betel leaf with areca nut and slaked lime paste)	Thank you for this information. Our

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
(endorsed by Royal Pharmaceutical Society)			is commonly used in Leicestershire in the South Asian population/muslim communities. Also “Khat” is chewed and its use is prevalent in the Somali community in Leicestershire. We would support the inclusion of the both the above products.	understanding is that khat is not a tobacco product. Whether we would make reference to it would depend on whether there is evidence on interventions that were intended to reduce both smokeless tobacco and khat addiction. Otherwise, it would be out of scope for this NICE guidance. The detrimental effect that areca nut has on oral health, independent of tobacco, is recognised. However, NICE is constrained by the referral from the Department of Health, which specified smokeless tobacco. Areca nut will of course be covered in any guidance interventions that focus on mixtures of this nut and tobacco.
UKCPA (endorsed by Royal Pharmaceutical Society)	3.c / 4.1		The umbrella term South Asian should include religions including Hindu, Jain etc. Also the scope should include communities from the Arabian and African sub-continent as well.	We consider that all these groups would be included within the term "South Asian". While there may be other populations using smokeless tobacco, NICE needs to prioritise given limited time and

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
				resources. Therefore, the final scope remains focused on South Asians because of: (a) the size of the population within the UK affected by smokeless tobacco use; (b) the ethnic health inequalities in the rates of oral cancer and other disorders that need addressing as a consequence of this use; and (c) the need for NICE to ensure that there is a reasonable amount of evidence on which to base recommendations.
UKCTCS	4.1.1		We believe that this focus is correct. Although smokeless tobacco is used by other groups in the UK, use by South Asian communities deserves most attention given that smokeless tobacco use is common in these communities and that there are more than 2m people from South Asian communities living in the UK. It might be helpful to acknowledge that other groups use smokeless tobacco and that some of this guidance might be applicable to these other groups. However, the heterogeneity of smokeless tobacco products and cultural factors might preclude generalisability overall.	While there may be other populations using smokeless tobacco, NICE needs to prioritise given limited time and resources. Therefore, the final scope remains focused on South Asians because of: (a) the size of the population within the UK affected by smokeless tobacco use; (b) the ethnic health inequalities in the rates of oral cancer and other disorders that need addressing as a consequence of this use; and (c) the need for NICE to ensure that there is a reasonable amount of

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				evidence on which to base recommendations.
UKCTCS	4.1.2		The second bullet should include proprietary products that contain areca nut without tobacco.	The detrimental effect that areca nut has on oral health, independent of tobacco, is recognised. However, NICE is constrained by the referral from the Department of Health, which specified smokeless tobacco. Areca nut will of course be covered in any guidance interventions that focus on mixtures of this nut and tobacco.
UKCTCS	4.2.1 a)		This intervention is worded strangely. Stop *smoking* services are not currently encouraged to focus on smokeless tobacco users/chewers. So the reference to stop smoking services should be deleted. It might be better not to specify who should deliver these interventions so that the evidence base can be used to identify what the key characteristics are and what training is needed for those providing the interventions. There is emerging evidence of the effectiveness of trained community outreach workers providing effective smokeless cessation support in the UK. We agree that it is important to include pharmacotherapies as well as behavioural support as there is also emerging evidence that pharmacotherapies are effective with tobacco chewers in the UK. We would suggest that this be reworded: 'Behavioural support or counselling for individuals or groups. This may involve the use of	We have revised point 4.2.1(a) in line with this suggestion, and in line with the suggestion of several other stakeholders. The scope now refers more generically to "evidence-based cessation services".

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			pharmacotherapies.' Some attention needs to be played to the interaction between smoking and smokeless use such that smokeless users are encouraged to stop smoking as well as appropriate.	
UKCTCS	4.2.1 b)		Again we suggest that again this be left broad so that the evidence base can be interrogated to identify the key characteristics/training of those providing brief interventions and that this should not be restricted to healthcare professionals given that there may be accessibility and/or usage issues with healthcare for these groups. It may be that community workers such as faith leaders could play an important role here. Hence we suggested that this be reworded 'Brief interventions which may involve a referral or the use of pharmacotherapies.';	Thanks for this comment. There are now two separate points 4.2.1(b) and 4.2.1(c), and the effect of this revision has been to widen out the range of people who we think could deliver these interventions.
West Yorkshire Trading Standards	4.1.1		There are other groups of ST users though not as commonly used by compared to the South Asian Community. Those from south east Asia should be considered.	While there may be other populations using smokeless tobacco, NICE needs to prioritise given limited time and resources. Therefore, the final scope remains focused on South Asians because of: (a) the size of the population within the UK affected by smokeless tobacco use; (b) the ethnic health inequalities in the rates of oral cancer and other disorders that need

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
				addressing as a consequence of this use; and (c) the need for NICE to ensure that there is a reasonable amount of evidence on which to base recommendations.
West Yorkshire Trading Standards			The support service needs to carry a name more appropriate to the service. As the “smoking service” is misleading and will exclude some users of ST. Also from a cultural and religious point of view those who don’t smoke don’t want to be associated with the smoking service as smoking is frowned upon and forbidden in certain communities.	We have revised point 4.2.1(a) in line with this suggestion, and in line with the suggestion of several other stakeholders. The scope now refers more generically to "evidence-based cessation services".
West Yorkshire Trading Standards	4.1.2		Chewing areca nut and using slaked lime without tobacco in paan should be included as Areca nut use contributes to submucous fibrosis.	The detrimental effect that areca nut has on oral health, independent of tobacco, is recognised. However, NICE is constrained by the referral from the Department of Health, which specified smokeless tobacco. Areca nut will of course be covered in any guidance interventions that focus on mixtures of this nut and tobacco.
West Yorkshire Trading Standards	4.2.2		Interventions aimed at preventing the uptake of ST should be covered as it will be easier and cheaper for the Health Service to prevent people from starting something they don’t use in the first place than it is to support and cure those who use and enjoy and/or	This split between cessation and prevention has been used previously on NICE smoking guidance, and is a way of making the topic a manageable size. We

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			are potentially addicted to ST.	expect to find some evidence on interventions that - intentionally or unintentionally - serve a dual purpose of both cessation and prevention.
West Yorkshire Trading Standards			Wider tobacco control measures such as legislation, product labelling and health warnings should be considered so people can make an informed choice regarding their usage. We don't want to create a misconception that ST is a safe alternative as cigarette tobacco carry health warnings and these do not and also have laws in place to limit the sale of such tobacco.	The Department of Health referral (see Appendix A of the draft scope) specifies that NICE should develop guidance for commissioners and providers on cessation interventions, and we would be going beyond our remit to develop recommendations on wider tobacco control measures such as legislation, product labelling and health warnings.
West Yorkshire Trading Standards	4.3 Question 3		Religious rulings which promote the uptake or prevention of ST use should be considered.	Thanks for your comments. We have anticipated this issue, and our literature search for this project is specified widely enough so that interventions that include this as a component will be located. We have also added religion as a potential consideration in Appendix C.
West Yorkshire Trading Standards	4.2.1		Other settings for brief interventions should also be included as not everyone has access/attends primary care services. Locations such as Schools, community centres, religious settings and sure start centres where BI could be provided by qualified tobacco	The research literature that the Public Health Interventions Advisory Committee (PHIAC) will be considering may be of sufficient detail to allow us to make

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			cessation workers.	recommendations on the delivery of interventions in different settings. Paragraph 4.2.1(b) has been expanded to two points 4.2.1(b) and 4.2.1(c) – and this revision widens out the range of settings where these interventions could be delivered.
West Yorkshire Trading Standards	4.3 Question 4		Are health professionals aware that Stop Smoking Services can receive referrals for users of these products?	The scope now includes an additional point – paragraph 4.2.1(e) – which focuses on clinician awareness, and this may shed some light on this issue. We have also revised point 4.2.1(a) and the scope now refers more generically to "evidence-based cessation services", instead of specifically stop smoking services.
West Yorkshire Trading Standards	Expected outcomes		A rise in clinicians asking about TOBACCO use as oppose to the focus on cigarette use.	The original outcome relating to health and social care professionals' awareness of the issue has now been revised in response to stakeholder comments. In addition, the new point 4.2.1(e) now covers clinician awareness. An increased general awareness among

Public Health Intervention Guidance

SMOKELESS TOBACCO: SOUTH ASIANS - Consultation on Draft Scope – Stakeholder Comments Table
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Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
				clinicians of smokeless tobacco use may lead to the outcome that you suggest.

Public Health Intervention Guidance

SMOKELESS TOBACCO: SOUTH ASIANS - Consultation on Draft Scope – Stakeholder Comments Table
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Poole Hospital NHS Foundation Trust	General		Legislation-wise (complying with WHO FCTC and UK/EU directive), it shall need implementations of - o Restrictions (total/partial?) of ST import: Illicit cross-border trade o Individual point-of-production and home-based trade o ST vendors in SE Asian and Caribbean shops and outlets in the UK. o Uniform taxation policy for all kinds of tobacco products (including ST) o Ban of mass-media/TV commercial for ST business promotions o How to ban red/brown spitting in the public places (noticed in every 1/4th miles of the pavements of the areas where SE Asian population are living in the UK) o School awareness programme, especially for the SE Asian students o Stop ST in NHS Hospital and GP practices (development of ST cessation programme) o Stop ST programme through dentists and dental hygienists (short online training/orientation course could be developed) o Community programme (through community Involvement for ST control initiative- access to information on ST and Stop ST services in websites) o Review and vigilance through operational research (could be done linking with interested voluntarily organisations as a pilot project) o International treaty/cooperation for banning ST and cross-border trade	The Department of Health referral (see Appendix A of the draft scope) specifies that NICE should develop guidance for commissioners and providers on cessation interventions, and we would be going beyond our remit to develop recommendations on wider tobacco control measures such as legislation, cross-border trade, taxation, or international agreements.
Poole Hospital NHS Foundation Trust	Practitioners and organisations should the approached with a guidance		• GP Surgeries (emphasis on SE Asian). GP nurses will be given a brief online orientation course for ST prevention and control. • General dental practitioners and hygienists will be trained for detection and management of ST related oral health ailments. Special emphasis will be taken for detection and screening of deadly oral diseases, such as- mouth cancer and pre-cancer. (online stuff could be developed in collaboration with interested voluntary organisation)	Thank you for these comments. Depending on what emerges from the evidence reviews, the types of interventions that you list may be recommended.

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			• Higher risk group of ST users such as diabetics will be given special counselling to quit the ST habit in order to prevent metabolic syndrome and diabetic dental complications. • Charity organisations will be requested to come forward with joint programmes on ST control and prevention • Public health nurse/school nurses will be trained and engaged • NGOs will be requested to develop joint action programmes • Public health promotion and education related organisations- such as RSPH, IHPE, RIPH, UK-public Health forum, Health protection Agency etc. will be communicated for development of strategic support and cost-effective action programme for ST prevention and Control	

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Poole Hospital NHS Foundation Trust	Additional outcomes for ST prevention and control measures would be undertaken		The situation analysis will be required for-. • Collection of data-information in SE Asian community regarding pattern of ST habit • Cost-effective approach for ST control will be developed	Thank you for these comments.
Poole Hospital NHS Foundation Trust	Development of guidance in order to reduce the ST related health inequalities in SE Asian Population		• KAP survey and surveillance would develop an outcome measure to check any findings of inequalities • All the regulatory measures will be implemented, followed-up and reviewed • Cost-effective educational and awareness programme (in school, public places-such as community hubs, mosques, temples etc) will be developed • A working group will be formed to witness, examine and review the outcome in order to reduce the inequalities. The health effects of ST consumption in risk /vulnerable group of population will be estimated • ST related health and environment issue will be addressed • Guideline protocol for ST prevention and control will need to be developed for the clinical staff and administrators.	Thank you for these comments.
Poole Hospital NHS			The SE Asian population may be the main focus, but other migrants will	While there may be other populations

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
Foundation Trust			not be ignored, because, there are significant proportion of population in Far East has the habit of ST, and they are also importing such habits in the UK from their own countries. Other migrant population in the UK --consuming ST, mainly the East African population, such as- East Africa: • Sudanese migrants • Somalis migrants • Yemenis migrants • Kenya, Uganda, S Africa (eastern part), Also Europe: • Native English whites living in the areas where the SE Asian, Sudanese and Yemenis are more. • A proportion of Scandinavian migrants (Snus users) and the Eastern part of East European countries living in the UK **A significant proportion of Far East population migrated in the UK has a ST habit**, such as- Migrants from Brunei, Cambodia, People's Republic of China · Republic of China (Hunan province), East Timor, Hong Kong, PRC · Indonesia, Japan, North-Korea, Mongolia, Laos, Macau, Malaysia, Papua-new Guinea, Viet-num, Far-East Russia. **Japan:** Zero-Style-Mint.	using smokeless tobacco, NICE needs to prioritise given limited time and resources. Therefore, the final scope remains focused on South Asians because of: (a) the size of the population within the UK affected by smokeless tobacco use; (b) the ethnic health inequalities in the rates of oral cancer and other disorders that need addressing as a consequence of this use; and (c) the need for NICE to ensure that there is a reasonable amount of evidence on which to base recommendations.
Poole Hospital NHS Foundation Trust	Is the Electronic		Whether shall we allow E-cigarettes in the UK market, and perhaps, we may need to examine them properly before marketing them in the UK,	Thank you for these comments. As they relate to products that are outwith the

Stakeholder Organisation	Section	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
	cigarette is smokeless and could be used as one of the NTRs?		The producers of E-cigarette claim that the product can be considered as one of the smokeless substance which is alternative to cigarette, and could be consumed in the public places (even in trains), and will be used as one of the NRTs. To note that FDA and WHO –FCTC do not recommend the E-cigarette as alternative to cigarette smoking and both of the organisations have suggested series of extensive studies to exclude any health risks of the users. Therefore, we need to know on E-Cigarette- - • Is it safe? • Is it smokeless? • Is the vapour inert? • In which class will it fall? • Is it allowable to sale in the public places? • Will it be considered as one of the NRTs? • Who will regulate them? REF. Tobacco Control : BMJ http://tobaccocontrol.bmj.com/letters/?first-index=&hits=80&days=&submit=Go	scope of this guidance, as agreed we will respond to them as part of the consultation on the draft scope for 'Tobacco – harm reduction approaches to smoking'.
Poole Hospital NHS Foundation Trust	Identification of risk group population of ST		Following evidence shows that adolescents and early adults are the vulnerable group of ST. But we need to understand the situation in the UK, probably many early adults and adolescents (who born and brought-up in the UK) are attracted by *Shisha* (a kind of water pipe filtrate tobacco device imported from Golf and Arab countries). And the migrated youths from SE Asia may have ST addictions – which prevalent in their countries.	Thank you for this material.
Poole Hospital NHS Foundation Trust	Identification of risk group population of		**YOUNG ADULTS** (13-15 yrs old): Source: Global Youth Tobacco Surveys (GYTS) This age group is most vulnerable group of population for ST consumption in all WHO administrative regions.	Thank you for this material.

Public Health Intervention Guidance

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	ST		**Country** **Gender** Marshal Island* M 43.3% F 21.6% Micronesia (Federated states) 41.8% 32.1% Gongo (democratic Republic) 29.3% 27.6% Sweden 28.9% - Mauritania 17.3% *Highest	
Poole Hospital NHS Foundation Trust	SNUS business Introduction of replacement therapy of Smokeless tobacco?		Illegal trade and import of Snus from Scandinavian countries will be restricted in the UK. Study and trail is required to get a suitable replacement of STs used by SE Asian community. Some of the pilot studies have been undertaken- and those will need to be reviewed for any application.	Thank you for these comments.
Department of Health	General		I wish to confirm that the Department of Health has no substantive comments to make regarding this consultation.	Thank you.

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