Public Health Intervention Guidance

Smokeless Tobacco – South Asians – Consultation on Draft Guidance
Stakeholder Comments Table

23rd February 2012 – 24th April 2012

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Stakeholder Organisation	Section Number	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
Action on Smoking and Health (ASH)	General		The guidance should include a statement about the public health problems caused by chewing tobacco products. There should be an acknowledgement that there are currently very few services to support people wishing to cease using smokeless tobacco. There is a current lack of incentive to provide services or support workers for people of South Asian origin who use smokeless tobacco and want to stop.	Associated health problems are covered in section 2 (Public health need and practice). This section (at the end) also lists the only systematic information we could find about service provision, and as suggested by this paragraph, service is patchy. However, we are aware that this reference is outdated. NICE recognises the role of incentives in service delivery, particularly in relation to what PHIAC recognised as an “emerging” issue for commissioners in many areas. One way of providing these incentives at the GP practice level would be through the Quality and Outcomes Framework (QOF). NICE has a role in helping develop the QOF, and we will be reviewing the QOF smoking indicators in terms of whether smokeless tobacco can be included. If this can be included, then current smoking indicators will be updated as part of the standard QOF process.
Action on Smoking and Health (ASH)	General		The guidance should make it clear that smokeless tobacco users may also smoke. Smokeless tobacco users should therefore also be asked about smoking and should be encouraged to stop using both forms of tobacco.	There is now more recognition in the guidance of the "crossover" between smoking and chewing tobacco, and recommendations 3 and 6 in particular are explicit about this connection.
Action on Smoking and Health (ASH)	General		Nicotine replacement therapy should be recommended to help users overcome their addiction to smokeless tobacco.	PHIAC considered the evidence for treatment using pharmacotherapy and, in particular, the use of NRT. It noted that the Cochrane review evidence on the use of NRT for smokeless tobacco cessation is equivocal.

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				Further, it relates to a different type of smokeless tobacco with populations other than South Asians living in England. Although there is some evidence to suggest that NRT can help South Asian users of smokeless tobacco in England to quit, this comes from non-randomised trials with limited follow-up. PHIAC was also aware that NRT is not licensed as a treatment for smokeless tobacco use, although it is on general sale. It also noted that clinicians can use their judgement to prescribe or recommend it. PHIAC made a research recommendation about the use of NRT for smokeless tobacco cessation.
Action on Smoking and Health (ASH)	Recommendation 1	7	Local needs assessments should be mandatory and undertaken by public health commissioners and specialists responsible for local tobacco cessation activities. Include Health and Well Being Boards in the list of those who should take action.	The current wording now refers to "Local authority specialists and public health commissioners responsible for local tobacco cessation activities". Health and wellbeing boards are now included on the list of those who should take action.
Action on Smoking and Health (ASH)	Recommendation 3	11	Outcomes should be the same as those for stop smoking services.	As specified by recommendation three, we now recommend 4 weeks as an outcome interval, the same as that used for smoking cessation services
Action on Smoking and Health (ASH)	Recommendation 4	12	Third bullet point – delete "When it is not possible to deliver a brief intervention or it does not appear to have worked".	Thank you, this change has now been made.
Action on Smoking and	Recommendation 5	12-13	The commitment to training is welcome. However, this	In terms of training, PHIAC felt the recommendation

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Health (ASH)			should be extended to community organisations such as faith centres. Last bullet point: Amend to read: 'deliver a brief intervention and refer people who want to quit to cessation services."	should focus on health and dental practitioners in areas of need. The "brief intervention" wording change has been made as you suggested.
Action on Smoking and Health (ASH)	Recommendation 6:	13	Under 'What action should they take?': 'Range of approaches' to help people quit needs to be defined as it's not clear.	This is now recommendation 5 in the completed guidance. This wording is no longer used in this recommendation.
Action on Smoking and Health (ASH)		13	Second bullet point: Delete "recommend or" from first sentence beginning "Ensure staff working in tobacco cessation…" .	This is now recommendation 5 in the completed guidance, but this actual point was moved into the new recommendation 6. The word "recommend" has been removed.
Action on Smoking and Health (ASH)		13	"Potential adverse effects of quitting" – an explanation and examples should be included here.	This is now recommendation 5 in the completed guidance. This has now been amended in line with your suggestion to mention oral pain, and withdrawal symptoms.
Action on Smoking and Health (ASH)	Section 5 Recommendations for research	23	It should be made clear that a randomised controlled trial of pharmacotherapy and behavioural support for chewing tobacco users wishing to stop their addiction is required. However this should not stop the provision of behavioural support and NRT being prescribed in the meantime.	See comment above regarding Nicotine Replacement Therapy (NRT). An NRT trial, however, is included within the research recommendations.
Action on Smoking and Health (ASH)	Section 5 Recommendations for research	23	Attached to this response is a paper just published by Csikar et al which adds to the evidence regarding the increased risk of oral cancer among South Asians in part due to their consumption of smokeless tobacco.	Thank you for this paper. This supports the current wording of section 2 (Public health need and practice). However, we decided to continue to quote Moles et al (2008) as the primary paper on this issue, because of the adjustment that these authors make for

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				socioeconomic deprivation.
Bangladeshi Stop Tobacco Project/Queen Mary University of London	General (1)		The draft recommendations fail to acknowledge and engage with the following: 1. That smokeless tobacco use by people of South Asian origin is a public health problem (Moles et al [2008] *Oral and pharyngeal cancer in South Asians and non-South Asians in relation to socioeconomic deprivation in South East England.* Br J Cancer doi: 10.1038/sj.bjc.6604191; Csikar et al [2012] *Incidence of oral cancer among South Asians and those of other ethnic groups by sex in West Yorkshire and England, 2001-2006.* Brit J Oral Maxillofac Surg doi: 10.1016/j.bjoms.2012.03.008). 2. That there is a current lack of incentive to provide services or support workers for people of South Asian origin who use smokeless tobacco and want to stop. Failure to provide clear recommendations will merely confirm the ongoing 'ad hoc' and unsustainable provision described by Crosier & McNeill (2003). 3. That smokeless tobacco products of South Asian origin are recognised as causing nicotine addiction. Nicotine replacement therapy is used to address the biological aspects of nicotine addiction. If PHIAC believe these not to be the case they should be explicitly argued and discounted.	The Csikar paper supports the current wording of section 2 (Public health need and practice). However, we decided to continue to quote Moles et al (2008) as the primary paper on this issue, because of the adjustment that these authors make for socioeconomic deprivation. NICE recognises the role of incentives in service delivery, particularly in relation to what PHIAC recognised as an "emerging" issue for commissioners in many areas. One way of providing these incentives at the GP practice level would be through the Quality and Outcomes Framework (QOF). NICE has a role in helping develop the QOF, and we will be reviewing the QOF smoking indicators in terms of whether smokeless tobacco can be included. If this can be included, then current smoking indicators will be updated as part of the standard QOF process. PHIAC considered the evidence for treatment using pharmacotherapy and, in particular, the use of NRT. It noted that the Cochrane review evidence on the use of NRT for smokeless tobacco cessation is equivocal. Further, it relates to a different type of smokeless tobacco with populations other than South Asians living in England. Although there is some evidence to suggest that NRT can help South Asian users of

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				smokeless tobacco in England to quit, this comes from non-randomised trials with limited follow-up. PHIAC was also aware that NRT is not licensed as a treatment for smokeless tobacco use, although it is on general sale. It also noted that clinicians can use their judgement to prescribe or recommend it. PHIAC made a research recommendation about the use of NRT for smokeless tobacco cessation
Bangladeshi Stop Tobacco Project/Queen Mary University of London	General (2)		The recommendations of West et al (2004) were optional and voluntaristic in their implementation, encouraging the creation of the current ad hoc support provision. Their recommendations are not current and have not been updated as is normal practice. The most current review (Ebbert J, Montori VM, Erwin PJ, Stead LF (2011) DOI: 10.1002/14651858.CDC004306.pub4) summarised its findings as follows: *Nicotine replacement therapy (patches or gum) and bupropion have not been shown to help people to stop using smokeless tobacco. However, one study shows that varenicline can help people stop. Dentists and hygienists may help their patients to stop, especially when they show the damage that smokeless tobacco causes in their mouths. Telephone counselling may assist smokeless tobacco users in quitting.* This review is not included in the reference list supporting the draft recommendations (pp26-28).	Although NICE public health guidance is also not mandatory, it can help local commissioners and providers to improve health outcome and reduce health inequalities. PHIAC considered the Ebbert et al 2011 review, most of the evidence relates to a different type of smokeless tobacco with populations other than South Asians living in England.

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Bangladeshi Stop Tobacco Project/Queen Mary University of London	General (3)		The need for clear research recommendations is welcome. These research recommendations should not, however, impede the implementation of service provision e.g. the current service outcome measure is reported at four weeks and not six or 12 months. These are both research driven outcomes.	Thank you, the outcome time has now been changed to 4 weeks, to bring it into line with smoking cessation services. However, the use of longer time periods is noted as an aspiration in the Considerations.
Bangladeshi Stop Tobacco Project/Queen Mary University of London	General (4)		Areca nut use is excluded from the guidance remit. Any harms of areca nut use should not be conflated to be regarded as equivalent to those attributed to smokeless tobacco use. References to areca nut e.g. pp15-16, pp 51-52 (Evidence statements 43 & 44) should be deleted.	Any mention of areca nut use in the list of evidence statements should not be interpreted as meaning that their harms are regarded as equivalent to those of smokeless tobacco use. The mention of it in this context is merely an acknowledgement that it is a common ingredient in the mixtures being researched.
Bangladeshi Stop Tobacco Project/Queen Mary University of London	General (5)		The evidence suggests that South Asian men are more likely to be dual users of both smoked and smokeless tobacco (Croucher, Islam & Pau [2007]) (not referenced) & (Croucher & Choudhury [2007]) (not referenced). The particular challenges for service provision are not considered in these recommendations. The inclusive focus should be on *tobacco* use and both smoked and smokeless tobacco should be enquired about (p12).	There is now more recognition in the guidance of the "crossover" between smoking and chewing tobacco, and recommendations 3 and 6 in particular are explicit about this connection.
Bangladeshi Stop Tobacco Project/Queen Mary University of London	General (6) (updated evidence)		This text *updates and replaces* Croucher 2011c: Croucher R , Shanbhag S, Dahiya M, Kassim S & McNeill A *Predictors of successful short-term tobacco cessation in UK resident female Bangladeshi tobacco chewers.* Addiction 2012 Jan 19. doi: 10.1111/j.1360-0443.2012.03819.x. Aim: to identify predictors of short-term smokeless tobacco cessation in Bangladeshi women resident in the United Kingdom (UK). Design:	Thank you for this reference.

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			prospective cohort study. Setting: a tobacco cessation service offering culturally tailored smokeless tobacco cessation support. Participants: 419 Bangladeshi women chewing paan with tobacco. Measurements: demographics, tobacco use and dependence and cessation attempt process and outcomes. Findings: client mean age was 48.92 (95% CI 47.5, 50.34) years and the mean area socio-economic deprivation score was 3.65 (95% CI 3.33, 3.97). Mean daily smokeless tobacco intakes, as paan, was 9.96 (95% CI 9.22, 10.7). 68.8% were recruited from primary care. 78.8% received behavioural support and nicotine replacement therapy (NRT) and the remainder behavioural support alone. Self reported four week continuous abstinence was 58.3%, predicted by NRT use (OR=4.93, 95% CI 2.02, 12.00), community recruitment (OR=1.84, 95% CI 1.01, 3.35) and relatively lower socio-economic deprivation (IMD) score (OR=1.98, 95% CI 1.18, 3.33). Conclusion: NRT use, community recruitment and relatively lower socio-economic deprivation (IMD) score predicted successful short-term cessation in UK resident Bangladeshi women chewing paan with tobacco.	
Bangladeshi Stop Tobacco Project/Queen Mary University of London	General (7)(amended evidence)		This text *updates and replaces* Croucher 2011b: Croucher R , Shanbhag S, Dahiya M, Kassim S, Csikar J & Ross L *Smokeless tobacco cessation in South Asian communities: a multi-centre prospective cohort study.* Addiction (*under revision following review*) *Aim:* to evaluate smokeless tobacco cessation in communities of South Asian origin. *Design:* multi-centre prospective cohort study. *Setting:* three tobacco cessation services offering specialist smokeless tobacco cessation outreach clinic support to South Asian (Bangladeshi, Indian and Pakistani) clients. *Participants:* 239 South Asian clients seeking to stop smokeless tobacco use	Thank you for this reference.

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			between November 2010 - December 2011. *Measurements:* socio-demographics, tobacco use and dependence, tobacco cessation attempt process and outcome measures. *Findings:* client mean age was 45 (95% CI 43.39, 46.6) years, were more likely female (75.7%), of Bangladeshi origin (73.9%), either home carers (52.8%) or not working (29.2%). Mean daily number of smokeless tobacco intakes was 10.42 (95% CI 9.49, 11.35) and the mean dependence score was 4.48 (95% CI 4.24, 4.72). 63.3% were recruited from community locations, 21.1% through a clinical contact and 15.6% through friends and family. 62.8% self-reported quit success at four weeks. Independent predictors of self-reported quits were receiving an intervention including both behavioural support and access to NRT (OR= 4.50, 95% CI 1.43, 14.16) and fewer (≤ 2) withdrawal symptoms at the start of the quit attempt (OR=4.40, 95% CI 2.24, 8.63). *Conclusion:* UK resident South Asian smokeless tobacco users accessing services to help them stop appear to have short-term success rates comparable with smokers attending stop-smoking services, with higher success rates being achieved by those using nicotine replacement therapy.	
Bangladeshi Stop Tobacco Project/Queen Mary University of London	General (8) (new evidence)		**Levels of satisfaction with service provision in the multi-centre trial (see General [7]):** A randomly selected sample (n=104) of the 239 service users were contacted. All respondents were either 'satisfied' or 'very satisfied' with the support they received from the service and over 97% (n=101) would recommend it to someone else. They all felt it had been 'easy' to contact the service, that the service was 'convenient' and waiting times were 'acceptable'. Male respondents (OR=4.90, 95% CI 1.24, 19.34) making a successful quit attempt (OR = 2.72, 95% CI 1.02, 7.22) were more likely highly satisfied.	Thank you for this material.
Bangladeshi Stop	General (9) (new		**Service costs in the multi-centre trial (see General [7]):** the	Thank you for this information.

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Tobacco Project/Queen Mary University of London	evidence)		total service delivery costs were £89,673, a cost per quitter of £735.03, inclusive of training, staff and resources.	
Bangladeshi Stop Tobacco Project/Queen Mary University of London	General 10 (new evidence)		Predictors of oral pain onset following a smokeless tobacco cessation attempt have been investigated and reported below: *Oral pain following smokeless tobacco cessation in UK resident Bangladeshi women: a prospective cohort study.* Croucher R , Haque MF, Kassim S Nicotine & Tobaco Research (*submitted for review*) Introduction: Paan quid with tobacco (PQT) use is common in South Asian populations. Oral pain following a PQT cessation attempt is commonly reported. Factors determining this await full exploration. Methods: This prospective cohort study of PQT chewers used a pre-piloted interview and clinical examination. Oral pain, socio-economic position, dental status, health service use, tobacco use and dependency, psychological distress and oral status measures were collected from UK resident Bangladeshi women during their quit attempts. Analysis included descriptive and analytical modelling of oral pain determinants, using multiple logistic regressions and a significance value of p=0.05. Results: 150 females (mean age 51.2 years [SD= 13.7]) completed the study. Baseline oral pain prevalence was 39% and 73% at follow up. Education level predicted baseline oral pain (OR = 3.43 (95% CI. 1.66, 7.11) (p=0.001). Follow up oral pain was predicted by education level (OR = 3.74, 95% CI 1.43, 9.79) (p=0.007), anxiety (OR = 3.52, 95% CI 1.23, 10.07) (P=0.019), choosing behavioural support alone in the cessation attempt (OR= 3.12, 95% CI 1.26, 8.70) (p=0.015), failure to stop tobacco chewing during the cessation attempt (OR = 4.16, 95% CI 1.44, 12.04) (P=0.009) and	Thank you for this reference.

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			tooth wear (attrition) (OR= 5.71, 95% CI 1.84, 12.04) (p=0.009). Lower dependency level (OR=0.79, 95%CI 0.64, 0.97) (p=0.023) was protective of oral pain. Conclusion: Dental care access, nicotine replacement therapy and anxiety management should be incorporated into service delivery to manage oral pain onset and facilitate a successful cessation attempt. Addressing socio-economic barriers will reduce tobacco cessation inequalities.	
Bangladeshi Stop Tobacco Project/Queen Mary University of London	Recommendation 1	Pp7-8	Needs assessment should be mandatory in whatever diverse commissioning structures are created in the 'new' NHS, using comparable questions taken from publically available instruments such as the Global Adult Tobacco Survey (Global Adult Tobacco Survey Collaborative Group. *Tobacco Questions for Surveys: a Subset of Key Questions from the Global Adult Tobacco survey (GATS), 2nd Edition.* Atlanta, GA: Centres for Disease Control and Prevention, 2011). It cannot be expected to take place unless there are external drivers promoting the activity. This is currently lacking. This recommendation should include a clear direction for central action to guide this local activity. The current draft assumes, inappropriately (final bullet point), that services and/or support will be provided without active commissioning – this will, in practice, seldom occur and should be deleted or clarified unless the explicit assumption is made that the provision will be *ad hoc*.	Thank you for these references. The guidance recommends that the local Joint Strategic Needs Assessment should consider smokeless tobacco. However, we do not anticipate that most localities will engage in such formal methods of data collection as outlined in the reference you provided. See also the previous comments about incentives and the Quality and Outcomes Framework (QOF). The committee appreciated the need for a step change in service provision. As a result of discussions during their second meeting on this topic, there is a new consideration (3.2) in which the committee expressed the view that there needs to be a concerted effort to increase the provision and consistency of smokeless tobacco cessation services across England.
Bangladeshi Stop Tobacco Project/Queen Mary University of	Recommendation 2	Pp8-10	This recommendation overlooks the need for an inclusive service approach to tobacco use rather than a focus on smokeless tobacco alone (see General [7] above). The list of	This recommendation notes the potential for integration of smoking and smokeless tobacco cessation activities, and this point is expanded on in

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London			potential participants should be clarified and expanded to include, amongst others, faith centres. Participants in awareness raising should be widened to include parents, imams, mosque and temple committees, health visitors, midwives and housing association managers.	recommendation three. Faith leaders and faith centres are now included in the recommendation, as are midwives and health visitors. PHIAC considered your suggestion of housing association managers, but in the end did not feel they were central enough to the issue to be included.
Bangladeshi Stop Tobacco Project/Queen Mary University of London	Recommendation 3	Pp10-11	This recommendation is 'inference based' and requires further development of the following points: - An appropriate mix and range of services (for clarity, will these services provide or not nicotine replacement therapy?) - 'existing smoking cessation provision' facilitates access to nicotine replacement therapy. As above, is this the intention for smokeless tobacco cessation provision? - Monitoring and evaluation of service provision and support is welcome. As previously noted, this won't be required unless there is a centrally driven requirement to provide this information. - The final bullet point (p11) refers to successful quits at six and 12 months. As noted above (General[5]) these outcomes are driven by research rather than service provision requirements. - The final bullet point (p11) refers to percentage with adverse effects (AE). Should this be '*adverse events*'? AE typically refer to the use of nicotine replacement therapy. Is it the intention to recommend use of nicotine replacement therapy? - The final bullet point (p11) omits references to monitoring other outcomes such as withdrawal symptoms and oral pain	Please see comments above regarding NRT, the QOF, and measuring times for quit rates. As for adverse events, other than that associated with NRT, the monitoring of these outcomes was not thought to be a best use of providers or commissioners time. In more general terms, recommendation 5 now covers the issue of oral pain and withdrawal. Potentially lay people can act as ambassadors to these services. Specifying who these contacts could be is suggested by recommendations 2, and we have expressed it generally enough to allow a variety of community members to act in this role.

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			onset in addition to adverse effects or events. Lay people may act as ambassadors. The community should contribute to evaluation activity.	
Bangladeshi Stop Tobacco Project/Queen Mary University of London	Recommendation 4	Pp11-12	The inappropriate reliance on West et al (2004) is noted above (General [4]). Greater clarity should include a requirement to amend current computer software to prompt questioning and recording of smokeless tobacco use in the context of tobacco use in general. This will require commissioning. A brief intervention and possible referral is the recommended norm for primary care (NICE Public Health Guidance 1 [2006]). It is not an optional intervention and shouldn't be suggested as such.	Please see comments above regarding the West et al (2004) guidance. At this stage we do not anticipate a national data collection system. If this type of tobacco was included in the Quality and Outcomes Framework (QOF), then this situation would of course change. The wording on brief interventions has now been changed and reference is made to NICE PH1 and PH10.
Bangladeshi Stop Tobacco Project/Queen Mary University of London	Recommendation 4	Pp11-12	The recommendation should provide the reasoning for its proposed use of brief interventions. The evidence base for using brief intervention with respect to South Asian smokeless tobacco use should be clarified. The effectiveness or not of brief interventions is noted as an area for future research (section 5.5, p24). The evidence base underpinning the recommendation that brief interventions should be supported by referral to behavioural support should be clarified.	PHIAC noted that brief advice and tailored, targeted services are a highly cost effective way of helping people to quit smoking (see NICE guidance on brief interventions and referral for smoking cessation; workplace interventions to promote smoking cessation; smoking cessation services and identifying and supporting people most at risk of dying prematurely). PHIAC also noted the importance of using existing NICE guidance on behaviour change and community engagement when developing interventions to help people from South Asian communities to stop using

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				smokeless tobacco.
Bangladeshi Stop Tobacco Project/Queen Mary University of London	Recommendation 5	Pp12-13	Whilst the commitment to training is welcome clarification is needed. The aim should be to develop a range of expertise with appropriate levels of training, incorporating clear referral protocols. What is the expectation with respect to the funding of the development of any training activity? Would the training be a specialist module? What outcomes would be expected from the training? Dual users create particular challenges and require a range of expertise, including intra-counsellor referral.	This is now recommendation 6. The intention was to outline in general terms the common features of training needed by a range of professionals.
Bangladeshi Stop Tobacco Project/Queen Mary University of London	Recommendation 6	Pp13-14	Clarification is needed of the phrase '*range of approaches*' to help people quit smokeless tobacco use. Would this include or exclude access to nicotine replacement therapy? Other recommendations (Rec 4, p12) propose the use of behavioural support as a follow up to a brief intervention. For consistency, the evidence base for using either brief intervention or referral for behavioural support with respect to South Asian smokeless tobacco use should be clarified. The definition of staff involved in smokeless tobacco cessation support should be more inclusive, including not only primary and secondary health care providers and staff in community-based cessation services but also community workers, faith workers and school teachers.	This is now recommendation 5. With respect to NRT, see our previous comments on this issue. With respect to behavioural support, this wording has now been revised. A reference to it is retained in the definition of brief intervention that appears before the recommendations. PHIAC noted the evidence for these approaches in relation to wider tobacco cessation. As for staff involved, while the other groups that you name could have a role in local services, the nature of the recommendation (i.e. being about specialist services) required a reasonably narrow definition of core staff.
Bangladeshi Stop	Recommendations	Pp23-25	This programme will require extensive funds to be made	With a general reference to "pharmacotherapy",

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Tobacco Project/Queen Mary University of London	for research (Section 5)		available. It has been divided into 'applied' and 'basic' science elements. Priority should be given to 'applied' science aspects of the programme: this is essentially driven by trials methodology comparing pharmacotherapy and behavioural support efficacy, who should deliver the intervention and alternative client recruitment processes. Despite the growing evidence base this might include a further need for a definitive RCT perhaps focusing on the use of varenicline (see comment: General [2]). One missing outcome is the impact of cessation on quality of life and self-efficacy. The 'basic science' elements (disease progression, epidemiology, dental service use) may already be available from existing national data sets such as the national Adult Dental Health Survey. A third Health Survey for England survey with a specific focus on the health of black and minority ethnic groups (HSE/BMEG) would be a second source of data. The last HSE/BMEG was undertaken in 2004. Other research questions could not be considered in the UK due to low recruitment numbers .	research recommendation 5.4 is flexible enough to be used as support for a trial of varenicline. Quality of life and self-efficacy may well be useful outcomes of such research, and may indeed be asked, but NICE's priorities is for research into effectiveness and cost effectiveness. Thank you for your suggestion on alternative ways to access data on dental service use. The relevant draft research recommendation has since been deleted.
Bangladeshi Stop Tobacco Project/Queen Mary University of London	Smokeless tobacco listing (Section 1)	P6	This listing is incorrect as it includes 'shupari' and 'pan marsala' which are now recognised as not containing tobacco (Stanfill S et al. *Global surveillance of oral tobacco products: total nicotine, unionised nicotine and tobacco-specific N-nitrosamines.* Tobacco Control 2011: 20e2. Doi: 10.1136/tc.2010.037465). The most readily available types of smokeless tobacco available for	Thank you. These references have been removed, and the list has been revised.

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			purchase in England are, in order: zarda, gutkha & khaini (Croucher R , Dahiya M, Gowda KK. *Unpacking the paan quid with tobacco: a cross sectional study. Under review*: Tobacco Control).	
Bangladeshi Stop Tobacco Project/Queen Mary University of London	Smokeless tobacco types (Appendix F)	P57	It is recommended that the Guidance adopts the typology proposed by: Stanfill S et al. *Global surveillance of oral tobacco products: total nicotine, unionised nicotine and tobacco-specific N-nitrosamines.* Tobacco Control 2011: 20e2. Doi: 10.1136/tc.2010.037465.	Thank you, the guidance now uses this typology.
Bangladeshi Stop Tobacco Project/Queen Mary University of London	Considerations 3.1, 3.2	P18	The assumptions that smokeless tobacco use is high amongst *older* Bangladeshi women (3.1) and that use is high in *young* South Asians (3.2) is illuminated by the following paper: Nunez, de la Mora, Jesmin F, Bentley G (2007) *Betel nut use among first and second generation Bangladeshi women in London, UK.* J Immigrant Minority Hlth 9 (4): 299-306. See also: Figure 1 in: Croucher R, Islam S (2002) *Socio-economic aspects of areca nut use.* Addiction Biology 7, 139-146.	Thank you for this reference.
Bangladeshi Stop Tobacco Project/Queen Mary University of London	Consideration 3.5	P19	Research indicates that oral pain onset is linked to tooth wear (see General [10]). Access to nicotine, either in smokeless tobacco or nicotine replacement therapy, will alleviate pain symptoms.	Thank you, the use of appropriate referrals to help people cope with pain relief is now listed in recommendation 5.
Bangladeshi Stop Tobacco Project/Queen Mary University of London	Consideration 3.7	P19	Slaked lime is added to smokeless tobacco products to act as an alkalinity modifier. The higher the alkalinity of the tobacco the greater the proportion of nicotine freely available for absorption. The pH of the tobacco and lime mix *in vitro* has been observed to vary between 12.2 and 12.5, indicating 99% free nicotine availability (Croucher R , Dahiya M, Gowda KK	Thank you for this comment.

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			Unpacking the paan quid with tobacco: a cross sectional study. Under review: Tobacco Control).	
Bangladeshi Stop Tobacco Project/Queen Mary University of London	Consideration 3.10	P20	It would seem inappropriate to require RCT evidence to support a contextual piece of evidence.	This comment was referring to the two types of evidence - RCT and contextual - that NICE public health guidance typically tries to make use of. However, the paragraph has been revised to clarify.
Bangladeshi Stop Tobacco Project/Queen Mary University of London	Correct author spelling	P51	Croucher & Chounhury should read *Croucher & Choudhury*	Thank you, we have changed these references.
British American Tobacco	General		British American Tobacco supports the underlying aim of this draft guidance, which is to reduce the population harm to health caused by the use of certain types of smokeless tobacco products (such as gutka, khaini and the other products specified on page 6 of the draft guidance) among people of South Asian origin living in England. However, limiting the current proposed recommendations in the draft guidance to primarily cessation initiatives in relation to these kinds of smokeless tobacco products (STPs) is unlikely to fully achieve this aim. In our view, additional alternative approaches to addressing use of STPs such as gutka should be considered as part of a broader harm reduction approach. The use of these types of STPs is traditional to South Asian communities with the result that a focus on cessation interventions alone does not recognise the reality that there will be consumers of these types of STPs who do not want to stop using these products or who find it hard to quit. Whilst we	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. 'Snus' and other similar oral tobacco products as defined in the European Union's Tobacco Product Directive(2001/37/EC) are prohibited from the U.K. market, so it would not be appropriate for NICE to

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			agree that no tobacco product is safe, low-toxicant STP products, like Swedish-style snus, could play an important role in a harm reduction approach among this population.	consider these. The Department of Health referral (see Appendix A of the scope) specifies that NICE should develop guidance for commissioners and providers on cessation interventions, so we would be going beyond our remit to develop recommendations on wider tobacco control measures such as regulatory issues.
British American Tobacco	General		'Smokeless tobacco' is not a single product. There are numerous different types of STPs used globally, which differ markedly in terms of their manufacture, form and content[1]. This leads to wide variations in tobacco constituents and hence the levels of toxicants and, consequently, wide variations in the reported risks to health associated with their use[2]. STPs, particularly those used widely in Asia & Africa are associated with the highest risk of adverse health outcomes[1]. The WHO Study Group on Tobacco Product Regulation (TobReg) has concluded that "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"[3]. The Royal College of Physicians has noted that "Smokeless tobacco products differ substantially in their risk profile in approximate relation to the content of toxins in the	Please see our previous response.

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			tobacco"[4]. In South Asia, the addition of additives such as areca nuts and lime to the tobacco considerably increases the carcinogenic potential of those types of STPs, and the use of such products is associated with an increased risk of oral cancer. In fact, the International Agency for Research on Cancer (IARC) found in a review that betel-quid and areca nut chewing was a cause of oral cancer independent of tobacco use[5].	
British American Tobacco	General		Swedish-style snus is a low-toxicant smokeless tobacco product manufactured to the Gothiatek Standard, which includes a heattreatment process to minimize the formation of certain toxicants in the tobacco. There is increasing consensus that the use of Swedish-style snus poses substantially lower (at least 90%) overall health risks than cigarette smoking[6],[7], including far lower risks of lung cancer and chronic obstructive pulmonary disease, which accounts for a considerable proportion of smoking-related morbidity and mortality[8]. As of 2000, Sweden, which has a long history of snus use, has the lowest rate of male lung cancer incidence than any comparable developed nation as well as low rate of oral cancer, which has been falling over the last 20 years as snus use has increased[8]. The Royal College of Physicians noted "On toxicological and epidemiological grounds, some of the Swedish smokeless products appear to be associated with the	Please see our previous response.

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			lowest potential for harm to health"[4].	
British American Tobacco	General	References	[1]. International Agency for Research on Cancer (IARC) (2007) Smokeless tobacco and some tobacco specific Nnitrosamines. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. 89:1-592. [2]. Boffetta et al., (2008) Smokeless Tobacco and Cancer, Lancet Oncol 9: 667 – 75 [3]. World Health Organisation (WHO) Study group on Tobacco Product Regulation (TobReg), (2009), Report on the scientific basis of tobacco product regulation, WHO Technical Report Series 955 [4]. Royal College of Physicians (2007) Harm reduction in nicotine addition: helping people who can't quit [5]. International Agency for Research on Cancer (IARC) (2004) Betel-quid and areca nut chewing and some areca nut nitrosamines IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 85 [6]. D.T. Levy et al., (2004) The Relative Risks of a Low-Nitrosamine Smokeless Tobacco Product Compared with Smoke Cigarettes: Estimates of a Panel of Experts, Cancer Epidemiol., Biomarkers and Prev. 13(12)2035 – 42 [7]. C. Bates et al., (2003) European Union policy on smokeless tobacco: a statement of favour of evidence based regulation of public health, Special Communication Tobacco Control 12: 360 – 7 [8]. J. Foulds et al., (2003) Effect of smokeless tobacco (snus) on smoking and public health in Sweden, Tobacco Control 12: 349 – 59	Thank you for these references.
British American	Section 1	Pages	Limiting the focus of the draft guidance to recommendations	Please see our previous response.

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Tobacco		13/14	relating primarily to cessation of smokeless tobacco products (STP) is unlikely to fully achieve the expected outcomes of the eventual guidance. This Recommendation 6 says that a "range of approaches" should be considered by providers of primary and secondary healthcare to help people quit smokeless tobacco. However, it is likely that some consumers of STPs will not want to stop using these products or may find it difficult to quit. Recognising this, our view is that, in addition to a focus on cessation initiatives, a further pragmatic approach to reduce the population harm associated with the consumption of unregulated, high toxicant Asian-style STPs, such as gutka, should also be considered, and low-toxicant STPs (such as snus) could play an important role within a broader tobacco harm reduction approach.	
British American Tobacco	Section 2	Page 15	It is possible that use of certain Asian-style STPs is linked to the increasing and significantly greater incidence of oral and pharyngeal cancer among South Asian women in the UK compared with other women in the UK. The Royal College of Physicians has noted that "…it seems clear that some forms of smokeless tobacco, primarily those with the highest concentrations of carcinogens, cause oral cancer. However, it is also clear that the risk of oral cancer associated with use of low-TSNA Tobacco products such as Swedish snus is small, and possibly non-existent".	Please see our previous response

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			The main evidence associating smokeless tobacco with oral cancer comes predominantly from studies in populations combining smokeless tobacco with other toxins (such as areca nut) or from populations using products that contain higher concentrations of carcinogenic compounds than are present in current moist snuff or new smokeless tobacco products available in the United States or Scandinavia"[1]. Internationally, Sweden has a low rate of oral cancer, which has been falling over time as snus use has increased[2]. [1]. Royal College of Physicians (2007) Harm reduction in nicotine addition: helping people who can't quit [2]. J. Foulds et al., (2003) Effect of smokeless tobacco (snus) on smoking and public health in Sweden, Tobacco Control 12: 349 – 59	
British American Tobacco	Section 2	Page 16	The draft guidance states that these Asian-style STPs are readily available in shops in South Asian neighbourhoods in England and that around 85% of these products are sold without any regulatory health warning. Under UK regulations it is an offence to supply tobacco for oral use unless the product is intended to be smoked or chewed – some of the STPs listed on page 6 of the draft guidance are not intended to be chewed and so are prohibited for supply to consumers. Smokeless tobacco products which are legally permitted as they are intended to be chewed, such as gutka, are required by law to carry on the most visible surface of the packet the warning: "This tobacco product can	Please see our previous response. In addition, the definition of smokeless tobacco in the guidance now notes that the products are legally required to carry the health warning: 'This tobacco product can damage your health and is addictive' on the most visible surface of the packet.

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			damage your health and is addictive". It is an offence to supply a tobacco product which does not comply with this health warning requirement. There should be full enforcement of these regulations so that retailers do not sell prohibited oral tobacco products and, for legally permitted oral tobacco products, that these all do carry the required regulatory health warning.	
British American Tobacco	Section 2	Page 16	In addition, there should be full enforcement of the UK regulations which require that a manufacturer or UK importer of a legally permitted smokeless tobacco product for oral use must provide to the Secretary of State a list of all ingredients by quantity, their function, effects on health and toxicological data before 1 October each year. Products which do not meet all relevant regulatory requirements should be removed from the UK market so that consumers do not have access to such products. We also think that these types of STPs should be regulated to quality standards aimed at potentially reducing the risks to health posed by such products. In Sweden the high manufacturing and quality standards for snus, which has low levels of tobacco toxicants, have resulted from a combination of governmental regulation and introduction of voluntary industry standards such as the Gothiatek standard[1]. We believe that all types of smokeless tobacco products should be appropriately regulated and we advocate the European Smokeless Tobacco Council (ESTOC) proposed regulatory framework[2].	Please see our previous response

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			[1]. L.E., Rutqvist et al, (2011), Swedish snus and the GothiaTek standard, harm Reduction Journal, 8:11 [2]. ESTOC, (2009), Proposed Regulation of Smokeless Tobacco Products within the EU – Part 1, http://www.estoc.org/uploads/Documents/documents/ESTOC_Regulation_Proposal_Part1.pdf.	
British American Tobacco	Section 5	Page 23	There is much independent scientific research available in the public domain relating to the chemical content and harm caused by smoked tobacco products (such as cigarettes) and smokeless tobacco products (STPs). All types of tobacco products pose risks to health. However, on a "product risk continuum", where tobacco products can be lined up in a decreasing order of risk, conventional cigarettes can be considered the riskiest and some forms of low-toxicant smokeless tobacco products (such as snus), while not risk free, as much less risky. There is increasing consensus that snus presents substantially lower overall health risks than cigarettes[1],[2] and that the risk of oral cancer is small, if not non-existent[3]. The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) was asked by the European Commission to evaluate the health effects of smokeless tobacco products with particular attention to tobacco for oral use, namely snus. The conclusions of the SCENIHR report published in 2008 included: "Overall therefore, in relation to the risks of the above major smoking diseases, and with the exception of pregnancy, smokeless tobacco products are clearly less hazardous, and in relation to	Please see our previous response

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			respiratory and cardiovascular disease substantially less hazardous, than cigarette smoking. The magnitude of the overall reduction is difficult to estimate, but as outlined above, for cardiovascular disease is at least 50%, for oral and GI cancer probably also at least 50%, and for respiratory disease close to 100%"[4].	
British American Tobacco	Section 5	Page 23	REFERENCES [1]. Royal College of Physicians, (2002), Protecting Smokers, saving lives: the case for a tobacco and nicotine regulatory authority [2]. P.N. Lee and J.S. Hamling, (2009), Systematic review of the relation between smokeless tobacco and cancer in Europe and North America, British Medical Journal, 7:36 [3]. Royal College of Physicians (2007) Harm reduction in nicotine addition: helping people who can't quit [4]. SCIENTIFIC COMMITTEE ON EMERGING AND NEWLY IDENTIFIED HEALTH RISKS (2008) Scientific Opinion on the Health Effects of Smokeless Tobacco Products 6 February 2008, http://ec.europa.eu/health/ph_ Risk/committees/04_scenihr_o_013.pdf.	Thank you for these references.
British Dental Association	general		The BDA supports smokeless tobacco cessation in South Asians and recognises the important role that dental practitioners can play in this. Dental practitioners are aware of the dangers of tobacco and appreciate that they are in a position to advise patients and recommend tobacco cessation. Practitioners are able to initiate discussion on prevention but this should then be picked up by local health agencies where language and cultural difficulties may be more readily addressed.	Thank you for your comments. The role of dental practitioners was central to the considerations of the committee, and they are referred to in a number of recommendations and considerations.

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Cheshire and Merseyside Public Health Network (ChaMPs)	General		In the initial scope for draft guidance we highlighted that there were other populations who also used smokeless tobacco (ST) and that it is important that they are not excluded from any intervention to help them stop. We would stress this point again and advise that the guidance could highlight this in a stronger fashion.	The introduction to the recommendations section makes it clear that people of South Asian origin are the focus of this guidance as they are the predominant users of smokeless tobacco products in England. But it also notes that others who use these products may also benefit from the recommendations, as health professionals, as a result, will be more aware of how to identify and help them
Cheshire and Merseyside Public Health Network (ChaMPs)	Who is guidance for?	Pg 1	We would advise that Directors of Public Health are specifically listed in this section.	Thank you, they are now included
Cheshire and Merseyside Public Health Network (ChaMPs)	Draft Recommendations	Pg 6 Smokeless Tobacco	The fact that ST is not always recognised by users as containing tobacco highlights the need to standardise labelling to show this and to include health warnings on all ST products. However, we also support an alternative name for services rather than 'smokeless tobacco services.'	Thank you for your comments. We have retained the recommendation about alternative names. As for labelling issues, the Department of Health referral and the resulting project 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. Nevertheless, the definition of smokeless tobacco in the guidance now notes that the products are legally

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				required to carry the health warning: 'This tobacco product can damage your health and is addictive' on the most visible surface of the packet.
Cheshire and Merseyside Public Health Network (ChaMPs)	General		We support increasing research and further analysis on local use of ST. We suggest it could be included as standard by services for data reporting.	The resources needed to organise this data gathering will need to be traded off against resources needed for other types of data collection and health provision.
Cheshire and Merseyside Public Health Network (ChaMPs)	General		We suggest the guidance could highlight the importance of confidentiality when people seek help with local services to stop using ST. This is particularly important for women in certain communities who do not want others to know that either, they use ST, or that they are seeking help to stop using ST if it is regarded as an inherent part of their culture.	Thank you. The issue of confidentiality has now been highlighted in recommendation 3.
Cheshire and Merseyside Public Health Network (ChaMPs)	Recommendation 6	Pg 14 Who should take action	We advise that people with a mental health condition and those in prisons also be included in this section for identifying socially isolated adults that use ST.	The wording on social isolation has now been revised to refer to "people who may find it difficult to use existing local services because of their social circumstances, gender, language, culture or lifestyle". This is now inclusive enough to be used to refer to people with a mental health condition, or those in prison.
Cheshire and Merseyside Public Health Network (ChaMPs)	Considerations	Pg 20 Section 3.12	We would like to highlight again, as we did in the initial scope, that the inclusion of an educational component relating to the economic and regulatory issues surrounding ST may complement cessation advice and also heighten awareness of the products amongst health professionals including doctors, dentists, nurses, midwives and health visitors.	In the first instance, the Department of Health referral (see 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 related to regulatory issues. However, the definition of smokeless tobacco in the guidance now notes that the

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				products are legally required to carry the health warning:'This tobacco product can damage your health and is addictive' on the most visible surface of the packet. . We appreciate that an educational component on this may be useful as general background information to health professionals. However, given the expensive of the time for training for health professionals, the training recommendation focuses only on the core topics that should be covered.
Cheshire and Merseyside Tobacco Alliance (CMTA)	General		In the initial scope for draft guidance we highlighted that there were other populations who also used smokeless tobacco (ST) and that it is important that they are not excluded from any intervention to help them stop. We would stress this point again and advise that the guidance could highlight this in a stronger fashion.	The introduction to the recommendations section makes it clear that people of South Asian origin are the focus of this guidance as they are the predominant users of smokeless tobacco products in England. But it also notes that others who use these products may also benefit from the recommendations, as health professionals, as a result, will be more aware of how to identify and help them We are held back from making more specific non-South Asian-related recommendations by a complete lack of statistics and treatment literature on these other groups in a UK context.
Cheshire and Merseyside Tobacco	Who is guidance for?	Pg 1	We would advise that Directors of Public Health are specifically listed in this section.	Thank you, they are now included.

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Alliance (CMTA)				
Cheshire and Merseyside Tobacco Alliance (CMTA)	Draft Recommendations	Pg 6 Smokeless Tobacco	The fact that ST is not always recognised by users as containing tobacco highlights the need to standardise labelling to show this and to include health warnings on all ST products. However, we also support an alternative name for services rather than 'smokeless tobacco services.'	Thank you for your comments. We have retained the recommendation about alternative names. As for labelling issues, see our previous response above.
Cheshire and Merseyside Tobacco Alliance (CMTA)	General		We support increasing research and further analysis on local use of ST. We suggest it could be included as standard by services for data reporting.	The resources needed to organise this data gathering will need to be traded off against resources needed for other types of data collection and health provision.
Cheshire and Merseyside Tobacco Alliance (CMTA)	General		We suggest the guidance could highlight the importance of confidentiality when people seek help with local services to stop using ST. This is particularly important for women in certain communities who do not want others to know that either, they use ST, or that they are seeking help to stop using ST if it is regarded as an inherent part of their culture.	Thank you. The issue of confidentiality has now been highlighted in recommendation 3
Cheshire and Merseyside Tobacco Alliance (CMTA)	Recommendation 6	Pg 14 Who should take action	We advise that people with a mental health condition and those in prisons also be included in this section for identifying socially isolated adults that use ST.	See previous comment on social isolation.
Cheshire and Merseyside Tobacco Alliance (CMTA)	Considerations	Pg 20 Section 3.12	We would like to highlight again, as we did in the initial scope, that the inclusion of an educational component relating to the economic and regulatory issues surrounding ST may complement cessation advice and also heighten awareness of the products amongst health professionals including doctors, dentists, nurses, midwives and health visitors.	We appreciate that an educational component on this may be useful as general background information to health professionals. However, given the expensive of the time for training for health professionals, the training recommendation focuses only on the core topics that should be covered.
ESTOC-European	general		ESTOC, European Smokeless Tobacco Council, was	Thank you for taking the time to respond.

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Smokeless Tobacco Council			established in 1989 and represents the interests of smokeless tobacco manufacturers and distributors as well as tobacco trade associations. ESTOC's objective is to secure the permission-to-sell smokeless tobacco products that comply with our regulatory framework in Europe and in other parts of the world.	
ESTOC-European Smokeless Tobacco Council	general		The focus of the draft guidance is on interventions that aim to help people of South Asian origin living in England to stop using smokeless tobacco products. Clearly, the only way to avoid the health risks associated with tobacco products is not to use them, and public health policies based on prevention and cessation continue to be effective. However, the reality is that there will be consumers of smokeless tobacco products who either do not want to stop using these products or who find it difficult to quit. Recognising this, ESTOC recommends consideration of a broader tobacco harm reduction based approach that, in addition to a continued emphasis on prevention and cessation initiatives, would allow those consumers the option of choosing alternative smokeless products that have been considered by a number of expert-bodies to present a lower risk to consumers. This could be achieved by implementing learnings from the wide body of evidence relating to the use in Sweden of Swedish-style snus, a low-nitrosamine smokeless tobacco product. The availability of snus in Sweden, which is manufactured according to strict quality standards and regulatory oversight, and its use by former adult smokers in place of cigarettes, has been associated with better tobacco-related public health outcomes than in any other European country where snus is not currently permitted to be sold.	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. 'Snus' and other similar oral tobacco products as defined in the European Union's Tobacco Product Directive(2001/37/EC) are prohibited from the U.K. market, so it would not be appropriate for NICE to consider these. The Department of Health referral (see Appendix A of the scope) specifies that NICE should develop guidance for commissioners and providers on cessation interventions, so we would be going beyond our remit to develop recommendations on wider

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				tobacco control measures such as regulatory issues.
ESTOC-European Smokeless Tobacco Council	1 general	7	We recognize that snus, as a product is outside the scope of the guidance; the purpose of the following comments is to highlight approaches and evidence which may assist NICE in its UK guidance for other smokeless product types. ESTOC recommends careful consideration of the situation in Sweden, which has an exemption to the European-wide ban on sales of snus and which has experienced the largest reduction in male smoking prevalence over the past 25 years of any country within Europe. A substantial proportion of these ex-smokers have switched to snus. In 2011, some 18% of Swedish men were daily snus users, while only some 10% were daily smokers.[1] There is increasing consensus that those using snus are not exposed to the majority of substances found in tobacco smoke and therefore its use presents substantially lower overall health risks than cigarettes (which some experts believe may result in at least a 90% reduction in relative risk for the use of low nitrosamine smokeless tobacco products when compared to cigarette smoking[2]). This shift in type of tobacco use among Swedish adult tobacco consumers has most likely contributed to a reduction in total tobacco-related harm on a population level.[3] [1] www.fhi.se [2] Levy, D.T. et al (2004) The Relative Risks of a Low-Nitrosamine Smokeless Tobacco Product Compared with Smoking Cigarettes: Estimates of a Panel of Experts. Cancer Epidemiol Biomarkers Prev.	Please see our previous response.

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			13,(12) 2035-2042 [3] National Board of Health and Social Welfare (2005) Folkhalsorapport (Public Health Report 2005)	
ESTOC-European Smokeless Tobacco Council	general		For instance, as of 2000, Sweden has a lower rate of male lung cancer incidence than any comparable developed nation.[4] Oral cancer rates have decreased and cardiovascular health has significantly improved. Furthermore, as concluded by the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR, 2007)[5] "The risk of cancer of the mouth, upper gastrointestinal tract or pancreas does appear to be increased by smokeless tobacco use, but a recent systematic review concluded that this effect varies considerably between types of product. Oral cancer risks were lower for the STP used in USA and Sweden than those in the Indian subcontinent." Results from meta-analyses conducted by Boffetta et al. (2008)[6], Weitkunat et al. (2007)[7], and Lee and Hamling (2009)[8] showed no increased risk of oral cancer associated with snus use. [4] Rodu, B. and Cole, P. (2009). Lung cancer mortality: Comparing Sweden with other countries in the European Union. Scand J Public Health 37:481-486. [5] SCENIHR (2007) Health Effects of Smokeless Tobacco Products Preliminary Report [6] Boffetta P, Hecht S, Gray N, Gupta P, Straif K. 2008. Smokeless tobacco and cancer. *Lancet Oncol* 9:667-75. [7] Weitkunat R, Sanders E, and Lee PN. 2007. Meta-analysis of the relation between European and American smokeless tobacco and oral cancer. *BMC Public Health* 7:334.	Please see our previous response.

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			[8] Lee PN and Hamling JS. 2009. Systematic review of the relation between smokeless tobacco and cancer in Europe and North America. *BMC Med* 7:36.	
ESTOC-European Smokeless Tobacco Council	general		As noted by the WHO Study Group on Tobacco Product Regulation (TobReg)[9],[10] ' "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." When discussing the implications for WHO programs TobReg notes that: "*The wide range of smokeless tobacco products and use characteristics means that WHO should support individual and population based research on specific products. Better knowledge about the effects and mechanisms of action of smokeless tobacco products and about what modifications can be made to alter the effects is needed so that governments can implement the WHO Framework Convention on Tobacco Control*."[11] The quality of snus has improved over the years through governmental regulation in Sweden and through introduction of voluntary industry standards such as the GOTHIATEK^{R} quality standard, which includes limits for toxicants such as carcinogenic tobacco-specific nitrosamines, TSNAs, some of which have been identified as human carcinogens.[11],[12],[13] [9] WHO Study Group on tobacco product regulation. The Scientific Basis of Tobacco Product Regulation: second report of a WHO study group. WHO Technical Report Series; no. 951. WHO, Geneva; 2008 [10] WHO Study Group on tobacco product regulation. The Scientific	Please see our previous response.

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			Basis of Tobacco Product Regulation: third report of a WHO study group. WHO Technical Report Series; no. 955. WHO, Geneva; 2009 [11] Rutqvist, L.E.. et al (2011). Swedish snus and the Gothiatek standard. Harm Reduction Journal, 8(11) 1-9 [12] Further information on the ESTOC proposal for regulation of smokeless tobacco products can be found via: http://www.estoc.org/regulation/estoc-s-way-forward [13] International Agency for Research on Cancer (IARC)[2007] monographs on the evaluation of carcinogenic risks to humans ; v. 89, Smokeless Tobacco and Some Tobacco-Specific Nitrosamines, Lyon, France	
ESTOC-European Smokeless Tobacco Council	general		South Asian smokeless tobacco products, such as gutka, tend to differ in many respects from snus and other types of low-toxicant smokeless tobacco products, with the levels of TSNAs in the tobacco for such South Asian smokeless tobacco products usually being much higher.[14],[15] Also, the levels of other toxicants can be significantly higher than the limits in the GOTHIATEK^{R} standard[11]. Some South Asian products contain areca nuts, which are reported by IARC to be carcinogenic[16]. Furthermore, South Asian style products are not always commercially manufactured products – some are prepared at the point of sale or by combination of ingredients at home - and, therefore, are not subject to strict quality assurance and other controls including any regulatory oversight. [11] Rutqvist, L.E.. et al (2011). Swedish snus and the Gothiatek standard. Harm Reduction Journal, 8(11) 1-9 [14] McNeill, A. et al (2006). Levels of toxins in oral tobacco products in the UK. Tob Control 15:64-7. [15] Stepanov, I. et al (2005). Tobacco-specific nitrosamines in	Please see our previous response.

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			smokeless tobacco products marketed in India. Int J Cancer 116:16-9.9. [16] International Agency for Research on Cancer (IARC)[2004] monographs on the evaluation of carcinogenic risks to humans ; v. 85 Betel-quid and Areca-nut Chewing and Some Areca-nut-derived Nitrosamines, Lyon, France	
ESTOC-European Smokeless Tobacco Council	general		We agree with the recommendation to "…collect and analyse local data about South Asian communities…" including on incidence, prevalence and demographics of smokeless tobacco use. In the survey by Longman et al. (2010),[17] the authors concluded that there is a "need to improve compliance with existing legal controls and enforcement to protect the South Asian community from health risks associated with chewing tobacco products." Longman et al. also stressed "the need to develop a publicly available database of these products whose ingredients have been systematically analysed in controlled laboratory conditions using uniform criteria." Such a strategy could be the first step in a comprehensive program aimed at not only prevention and cessation efforts in relation to South Asian smokeless tobacco products such as gutka, but also regulatory measures to improve the quality of such products so that these pose potentially reduced risks to health than is currently the case for those consumers who do not want to quit or who find it difficult to quit. [17] Longman, J.M.(2010). Accessibility of chewing tobacco products in England. J Public Health 32(3): 372–378.	Please see our previous response.

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ESTOC-European Smokeless Tobacco Council	general		To achieve this broader goal, there needs to be scientific evidence in place comprising for instance: • Study data on the use of these products (e.g. patterns of use of which types of products by which groups and in which settings). One such study has been carried out among South Asian immigrants in the Northeastern United States (Delnevo et al [2011][18]) • Data on the perception of risk of use by consumers of these products (and their perception of risk of alternative products) • Assessment of the risks to health posed by such products relative to other types of tobacco products and development of a legislative framework that takes account of this risk and that allows for adult tobacco consumers to receive clear and accurate information about the differing risk profiles of different products • Assessment of the ability to reduce the risks associated with these products (e.g. existing NHS advice to leave the tobacco out of the paan[19]) and whether the resulting products would be acceptable to those consumers that are either unwilling or find it difficult to cease using them • Implementation of a quality standard for the manufacture of such potentially reduced-risk products [18] Delnevo, C.D. et al (2011). Epidemiology of cigarette and smokeless tobacco use among South Asian immigrants in the Northeastern United States. Journal of Oncology: doi:10.1155/2011/252675 “~the use of indigenous smokeless tobacco among South Asians deserves attention in the context of the current “harm reduction” debate, where	Please see our previous response.

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			some tobacco control professionals argue that smokers should switch to smokeless tobacco if they cannot quit. This debate is largely focused around "snus" a very low tobacco-specific nitrosamine (TSNA) product with notably lower health risks than cigarettes. The data available regarding indigenous South Asian smokeless tobacco products are highly varied with the International Agency for Research on Cancer (IARC) finding higher levels of some TSNA (e.g. NNK) in the smokeless products used in India relative to North American and European smokeless tobacco products, and since levels of TSNA's are influenced by many factors (e.g. fermentation, processing, other nontobacco carcinogens such as areca nut) the products may be associated with substantially greater health risks than some Western products. For this reason, even though more data are needed describing the health risks and carcinogenic potential of South Asian smokeless tobacco products that are available in the US, what is clear is that they are certainly not without harm and should not be marketed to the South Asian community as a safe alternative to smoking. [19] South Asian Tobacco Use, available at http://smokefree.nhs.uk/advice-and-information/south-asian-tobacco-use/	
ESTOC-European Smokeless Tobacco Council	general		• Availability of scientifically substantiated potentially reduced-risk products for those consumers of such South Asian products who are either unwilling or find it difficult to quit using them Therefore the key ESTOC recommendations are that the NICE guidance considers not only prevention and cessation efforts but also other approaches for those within the South Asian community living in England who are either unwilling or find it difficult to quit using their traditional smokeless tobacco	Please see our previous response.

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			products. This could be achieved through, for example, application of strict standards for the control of quality during manufacture of smokeless tobacco products to reduce known toxin levels and the making available of use of alternative smokeless tobacco products with a recognized reduced-risk profile (such as snus) that are subject to effective regulatory oversight.	
Food Standards Agency	General		The FSA is concerned that areca (betel) nut is often present in chewable products that are consumed by S. Asian communities. Some of these are smokeless tobacco products and those that do not contain tobacco are regarded as foods. In 2008 the Committee on Carcinogenicity issued a statement concluding that there was sufficient epidemiological evidence to conclude that areca nut is carcinogenic. This evaluation applies primarily to oral cancers and is reflected in advice to the public from Cancer Research UK. Given these concerns it is important to ensure that any oral tobacco cessation advice also recognises the risk of consuming areca nut, particularly in the form of products that are held in the mouth for significant periods. The FSA notes that the NICE guidance is designed for tobacco cessation services but, given the clear link between the consumption of oral tobacco products and areca nut, the FSA is willing to work with NICE and health professionals, as required, to ensure that appropriate advice on all chewable products can be communicated as effectively as possible.	Thank you, while the focus is on the tobacco component of these mixtures, because of the remit of the guidance referral we were given, we do appreciate the crossover in consumption between the two substances. The introduction to the recommendations notes that a number of smokeless tobacco products contain areca nut, a mildly euphoric stimulant which is addictive and carcinogenic in its own right. A cross-reference to the FSA's forthcoming guidance is now included on page 7. We are aware that the NICE Implementation team has been in further discussions with you on this issue, and we welcome any further assistance that the FSA can give to health services on this issue.

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			The FSA is currently working with one Asian community to produce guidance regarding the consumption of areca nut and is also willing to assist the services who will be responsible for communicating advice to reduce smokeless tobacco consumption to ensure that information regarding areca nut is communicated effectively across S. Asian communities in the UK.	
Food Standards Agency	1	6	The suggestion to tailor advice to specific products is useful and, as detailed above, in circumstances where areca nut is present in individual products, it could be indicated that the FSA is willing to assist with the provision of appropriate advice regarding its consumption.	See previous response.
Food Standards Agency	3.7	*19*	The CoC's advice is that areca nut ***is*** carcinogenic and IARC also classes it as a known human carcinogen.	Thank you, we have made this change.
Food Standards Agency	3.14	20	We would also be concerned if users of smokeless tobacco were directed towards tobacco-free alternatives that contain the carcinogenic betel nut.	NICE shares this concern. Recommendations 3 and 5, and consideration 3.11 acknowledge this as a possible unintended consequence.
Heart of Mersey	General		In the initial scope for draft guidance we highlighted that there were other populations who also used smokeless tobacco (ST) and that it is important that they are not excluded from any intervention to help them stop. We would stress this point again and advise that the guidance could highlight this in a stronger fashion.	The introduction to the recommendations section makes it clear that people of South Asian origin are the focus of this guidance as they are the predominant users of smokeless tobacco products in England. But it also notes that others who use these products may also benefit from the recommendations, as health professionals, as a result, will be more aware of how to identify and help them

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Heart of Mersey	Who is guidance for?	Pg 1	We would advise that Directors of Public Health are specifically listed in this section.	Thank you, they are now included
Heart of Mersey	Draft Recommendations	Pg 6 Smokeless Tobacco	The fact that ST is not always recognised by users as containing tobacco highlights the need to standardise labelling to show this and to include health warnings on all ST products. However, we also support an alternative name for services rather than 'smokeless tobacco services.'	Thank you for your comments. We have retained the recommendation about alternative names. As for labelling issues, the Department of Health referral and the resulting project 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. Nevertheless, the definition of smokeless tobacco in the guidance now notes that the products are legally required to carry the health warning: 'This tobacco product can damage your health and is addictive' on the most visible surface of the packet.
Heart of Mersey	General		We support increasing research and further analysis on local use of ST. We suggest it could be included as standard by services for data reporting.	The resources needed to organise this data gathering will need to be traded off against resources needed for other types of data collection and health provision.
Heart of Mersey	General		We suggest the guidance could highlight the importance of confidentiality when people seek help with local services to stop using ST. This is particularly important for women in certain communities who do not want others to know that either, they use ST, or that they are seeking help to stop using ST if it is	Thank you. The issue of confidentiality has now been highlighted in recommendation 3

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			regarded as an inherent part of their culture.	
Heart of Mersey	Recommendation 6	Pg 14 Who should take action	We advise that people with a mental health condition and those in prisons also be included in this section for identifying socially isolated adults that use ST.	The wording has now been revised to refer to "people who may find it difficult to use existing local services because of their social circumstances, gender, language, culture or lifestyle" This is now inclusive enough to be used to refer to people with a mental health condition, or those in prison.
Heart of Mersey	Considerations	Pg 20 Section 3.12	We would like to highlight again, as we did in the initial scope, that the inclusion of an educational component relating to the economic and regulatory issues surrounding ST may complement cessation advice and also heighten awareness of the products amongst health professionals including doctors, dentists, nurses, midwives and health visitors.	In the first instance, the Department of Health referral (see 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 related to regulatory issues. However, the definition of smokeless tobacco in the guidance now notes that the products are legally required to carry the health warning: 'This tobacco product can damage your health and is addictive' on the most visible surface of the packet. We appreciate that education on this may be useful as general background information to health professionals. However, given the expensive of the time for training for health professionals, in the training recommendation (Rec 6), we specify only the most important core topics that we felt should be covered.
Imperial Tobacco Limited	general		Imperial Tobacco Group ("ITG") is the world's fourth largest international tobacco company. ITG's portfolio includes	Thank you for your submission.

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PO Box 244 Upton Road Bristol BS99 7UJ			cigarettes, fine-cut ("roll-your-own") tobacco, pipe tobacco, cigars, snuff and snus. ITG is a British company, listed on the London Stock Exchange and is the UK's market leader in tobacco products. It manufactures and markets a range of smokeless tobacco products including snus and nasal snuff. It does not manufacture or import any of the smokeless tobacco types referred to within the draft guidance.	
Imperial Tobacco Limited PO Box 244 Upton Road Bristol BS99 7UJ	1	5 to 14	ITG notes that the scope of this draft guidance excludes regulation (Section 3.11). However, we believe that the guidance has direct relevance, not just to smoking and tobacco cessation services, or health and social care practitioners, but also in informing potential regulation, even though this may not be its primary purpose. For example, page 6 describes the different products covered by the guidance and mentions that consumers are sometimes "unaware that the products contain tobacco". A more effective categorisation of these products and/or product definition would not only provide better guidance for consumers, it could also provide a basis for effective regulation of these products. For example, a recommendation that any such products that contain tobacco must be identified as tobacco products, and fall under tobacco regulation, (i.e. only be presented for sale and use by adults) would go some way to address the highlighted concerns.	In the first instance, the Department of Health referral (see 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 related to regulatory issue
Imperial Tobacco Limited	5	23	In order to make informed decisions relating to the relatively narrow usage of a specific type(s) of smokeless tobacco within a	We assume that this (and your next paragraph) is a reference to research recommendation 4 ("the

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PO Box 244 Upton Road Bristol BS99 7UJ			defined community, the research Recommendations at 5 should be supported by a wider evidence base, involving a comparison of the similarities and differences between different types of smokeless tobacco, including between those varieties used by the South Asian community and those types of product used in North America, Norway and Sweden. We have a research base of relevant data, reports and information which we would be willing to provide to NICE at their request in relation to building a bibliography of relevant research. A key reference is the EC Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) report on smokeless tobacco products released in 2008. (http://ec.europa.eu/health/archive/ph_risk/committees/04_scenihr/docs/scenihr_o_013.pdf)	similarities and differences between smokeless tobacco and smoked tobacco"). Thank you for your offer of data. However, NICE is not primarily a research organisation, and these recommendations specify research that external researcher might like to undertake, researchers who might be able to make use of your data. The wording of the research recommendation does not preclude a wider study of the type you suggest, involving other types of tobacco. In the first instance however, a research project on the types of smokeless tobacco currently being used in England by South Asians, would be our preferred option.
Imperial Tobacco Limited PO Box 244 Upton Road Bristol BS99 7UJ	5.4	23	This recommendation for research seeks to understand the similarities and differences between smokeless tobacco and smoked tobacco and the observed health outcomes that have been associated with those products. In investigating any observed difference between these product groups and the diseases associated with them, additional questions are required. These include: 1. What are the similarities and differences between the different types of smokeless tobacco used within the UK's SE Asian community and those used elsewhere in Europe and the USA in terms of chemical content and the observed	Again, we assume that this (and your next paragraph) is a reference to research recommendation 4 ("the similarities and differences between smokeless tobacco and smoked tobacco"). The focus of the research recommendation is harm, and treatment for that harm. To widen this to considerations of "displacement" also, we believe, takes the intent of the resulting research further from the issue of South Asian health.

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			health outcomes that have been associated with those products? 2. For those markets where smokeless tobacco is available, does the evidence indicate that it displaces the prevalence of smoking tobacco or not? 3. Are there differences in health outcomes between those populations/countries where use of smokeless tobacco is prevalent (e.g. UK SE Asian community, Sweden, Norway) and other populations in the EU or UK in which it is not?	
Imperial Tobacco Limited PO Box 244 Upton Road Bristol BS99 7UJ	5	23	The European Commission is currently reviewing the Tobacco Products Directive, which includes consideration of smokeless tobacco product regulation across Europe, and the findings from the recommendations for research are likely to be relevant for this process. We would hope that NICE would intend to make this research and evidence available to the relevant EU authorities.	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.
Imperial Tobacco Limited PO Box 244 Upton Road Bristol BS99 7UJ	general		Imperial Tobacco believes that there are great benefits in drawing together evidence from a wider base, asking additional questions from the data and using the evidence to inform the Tobacco Products Directive review. We would be willing to work with NICE in contributing to the evidence base, and in sharing the relevant data and expertise that we have.	See previous comments.

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Imperial Tobacco Limited PO Box 244 Upton Road Bristol BS99 7UJ	general		ITG has confined its comments to those points in the Consultation on the Draft Guidance relevant to its own area of expertise, and the absence of a response to a particular comment or question within the Consultation should not be taken to imply acceptance or agreement with that comment or question.	See previous comments.
Minority Ethnic Health Inclusion Service, NHS Lothian	General		An Oral Health and Trans-cultural Tobacco DVD has been produced by NHS Lothian's Minority Ethnic Health Inclusion Service (previously MEHIP) in partnership with ASH Scotland. This DVD has proved to be a very useful training resource for Health Professionals. The DVD is in English, Urdu / Punjabi, Arabic and Bengali. This makes it a very useful and effective resource when working with minority ethnic groups to raise awareness of the dangers of using smokeless tobacco. It would be useful for policy makers and practitioners to be aware of resources such as this DVD, so they can implement the NICE guidance on training and working with communities. The DVD is available from MEHIS. Tel : 0131 537 7565. The DVD has been independently reviewed in the BDJ and I attach a link for information. http://www.nature.com/bdj/journal/v212/n7/full/sj.bdj.2012.306.ht	Thank you for the link to this useful resources. We have passed this to our Implementation team for consideration.

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			ml Please contact Smita.Grant for any further information.	
NCSCT	General		Use of the term 'cessation' is known not to resonate well with the public. This is a broader issue but it is linked to the branding of services and is a possible point for further consideration. The term 'Tobacco Cessation Services' is also not a general term currently used nationally or locally.	Thank you for your comments. We now have a definition of what we refer to as "specialist tobacco cessation services" at the beginning of the guidance.
NCSCT	General		There doesn't appear to be any recognition of the fact that smokeless tobacco users may also use smoked tobacco and require support to stop using both forms of tobacco.	Thank you, we agree that this is an important issue. This overlap of users is now acknowledged in recommendations 1, 3, and 5, and in considerations 3.11 and 3.17.
NCSCT	Recommendation 1	8	Service data may be limited with regards to religion and ethnic sub origins – could a specific recommendation to collect this data be made?	The collection of this data broken down by age, ethnicity, gender, language, religion, disability status and socioeconomic status, is included in recommendation 1.
NCSCT	Recommendation 2	9	This assumes that local smokeless cessation services already exist and whilst they do in some areas this isn't the case for all. Perhaps it would be useful to cross reference recommendation 3 or swap the order of these two recommendations.	While recommendation 2 does make a reference to "existing community activities", we believe that the wording is flexible enough to account for the situation in those areas where there is no existing service provision.
NCSCT	Recommendation 2	9	It isn't clear whether recommendation 2 is suggesting that the local community is involved in designing the actual local cessation services or to plan local activities that raise the profile of the risks of smokeless tobacco use and promote the cessation services that already exist (where they exist).	It is intended that both activities could be covered by this recommendation, although with respect to the nature of the treatment activities of the cessation service itself, naturally issues of clinical effectiveness would drive this.
NCSCT	Recommendation 3	11	It's not clear why quit status at 6 and 12 months is required for	Thank you, the outcome time has now been changed

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			smokeless cessation when only 4 weeks is currently required for smoking cessation. It should also be clear whether this is self-report or biochemically validated acknowledging that validation by carbon monoxide measurement is not appropriate (unless the client is a smoker too).	to 4 weeks, to bring it into line with smoking cessation services
NCSCT	Recommendation 3	11	What is meant by the % with adverse effects – why is this specifically required?	Some additional detail has now been provided ("…such as someone switching to, or increasing, their use of smoked tobacco or areca nut-only products")
NCSCT	Recommendation 4	12	In terms of smoking cessation, it has been recognised that asking healthcare professionals to undertake a 10-15 brief intervention with patients is not realistic given the short amount of time they generally have with patients. This has resulted in a move towards very brief intervention which follows the ask, advise, act structure and takes only a few minutes. The current recommendation appears to ask a lot of the healthcare professionals for whom this isn't their area of expertise. It's also not clear why patients should only be referred onto support when time is limited or the brief intervention has not worked. Is there evidence to suggest that most users of smokeless tobacco only require a brief intervention to stop? It would appear more appropriate for all professionals to ask patients if they smoke and/or use smokeless tobacco, advise them of the risks if they do and refer on for support to stop.	Thank you. The guidance on brief interventions is inspirational. Issues of resource allocation to services are beyond the remit of NICE guidance. NICE is tasked with making judgements on cost-effectiveness, and the NICE implementation team will produce costing tools associated with this guidance that can be applied at the local level. How these needs should be prioritised against health needs in a particular local area is an issue for local decision making. The recommendation wording on referral has now been revised.
NCSCT	Recommendation 5	12	The recommendation specifically states that the NHS Centre for Smoking Cessation and Training (should now be National Centre for Smoking Cessation and Training (NCSCT)) should	Thank you, this has now been changed.

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			take action. It needs to be recognised that the NCSCT is not currently nationally funded and would therefore require funding to develop a specific training course(s) in this area.	
NCSCT	Recommendation 5	12	The recommendation suggests that health and dental services should take action but it's not clear what this action should be – is this to access relevant training?	Yes, it is. However, the wording of this recommendation (now recommendation 6) has now been clarified to put more onus on commissioners.
NCSCT	Recommendation 5	12	There is no recognition in this section of additional training that advisers working within stop smoking services may require in order to effectively support smokeless tobacco users.	Wording refers to training for health professionals in general so covers them
NCSCT	Recommendation 6	13	Whilst the guidance appears quite focused on the existence of tobacco cessation services, this recommendation doesn't include any reference to the type of support or structure of support that cessation services should follow.	This is now recommendation 5. To a large extent, we would expect the cessation service to apply general behaviour principles, analogous to their activities with smokers.
NCSCT	Recommendation 6	13	It would be useful to reference the limited evidence-base within this area and either have a specific recommendation for further research required here or cross reference to section 5.	Our current standard template for guidance does not usually include these cross-references. However, there is a dedicated set of Research Recommendations included in the guidance.
NHS Airedale, Bradford, Leeds	Recommendation 1 Assessing local need What action should they take? Collect and analyse local data	7	Recording prevalence and incidence of smokeless tobacco (ST) use needs to be a national requirement in the same way that smoking is required to be recorded in primary/secondary care e.g. GPs paid through QOF for recording smoking status. The recommendation would be to record Tobacco use status to encompass all tobacco use	NICE recognises the role of incentives in service delivery, particularly in relation to what PHIAC recognised as an "emerging" issue for commissioners in many areas. One way of providing these incentives at the GP practice level would be through the Quality and Outcomes Framework (QOF). NICE has a role in helping develop the QOF, and we will be reviewing the QOF smoking indicators in terms of whether smokeless tobacco can be included. If this can be included, then current smoking indicators will be

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				updated as part of the standard QOF process.
NHS Airedale, Bradford, Leeds	Recommendation 1 Collect and analyse local data - Local data collection and analysis on prevalence and incidence plus number of South Asians who have sought help, gather information on where, when and how often ST services are promoted/ provided etc	7/8	A national monitoring form would assist in consistent data collection comparable with the national smoking cessation gold standard monitoring form	We know of no current model for this type of form. Obviously it would have to be carefully designed to capture the different varieties of tobacco used by different local communities. If this type of tobacco was included in the QOF (see previous comment), then the need for a form of this type would be expedited.
NHS Airedale, Bradford, Leeds	General - Collect and analyse local data - Local data collection and analysis on prevalence and incidence plus number of South Asians who have sought help, gather information on where, when and how often	7/8	What plans are there for collection/submission of data regionally/nationally to facilitate data analysis and sharing of data?	At this stage we do not anticipate this happening. Again, if this type of tobacco was included in the QOF (see previous comment), then this situation would of course change.

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	ST services are promoted/ provided etc			
NHS Airedale, Bradford, Leeds	Recommendation 1 Assessing local need - Use consistent terminology to describe products	7	Recommend that products are referred to as tobacco and not only brand name to ensure that users are aware that the product is tobacco	Thank you - we have incorporated this suggestion into the guidance.
NHS Airedale, Bradford, Leeds	Recommendation 2 Working with local South Asian communities – who should take action and what action should be taken	8/9	Schools identified as taking action question whether schools would have the capacity, knowledge, resources to carry out the actions identified	We have provided more detail in the current draft, and made it clear that teachers need to be provided with information on this issue. We have also now specified that it could have a part of drug education, within personal, social, health and economic (PSHE) education.
NHS Airedale, Bradford, Leeds	Recommendation 2 Working with local South Asian communities – to plan design and coordinate activities involving them in all aspects of the plan	8	Without any constraints on funding or staffing then this may be possible. However with services under increasing financial pressures raising expectations within communities, increasing demand for support services and resources this may set service providers up to fail - unable to meet demand or provide identified local community service requirements	Issues of resource allocation to services are beyond the remit of NICE guidance. NICE is tasked with making judgements on cost-effectiveness, and the NICE implementation team will produce costing tools associated with this guidance that can be applied at the local level. How these needs should be prioritised against health needs in a particular local area is an issue for local decision making.
NHS Airedale, Bradford, Leeds	Recommendation 2 – refers to the products using the names people use locally	9	Recommend that products are also referred to as tobacco and not only 'names people use locally' to ensure and reinforce to users that the product is tobacco	Thank you - we have incorporated this suggestion into the guidance.

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NHS Airedale, Bradford, Leeds	Recommendation 3 – What action should they take?	10	'Separately branded services' – need more clarity on what this recommendation means.	Thank you, we have simplified the wording of this recommendation to refer to service name, rather than "branding".
NHS Airedale, Bradford, Leeds	Recommendation 3 – Regularly monitor and evaluate all local ST cessation services	11	Nationally developed and implemented monitoring sheet to ensure consistent national data collection	We believe that this may be helpful, although there also needs to be recognition of the fact that the problem is concentrated in specific places, rather than across England as a whole. The resources needed to organise this data gathering will also need to be traded off against resources needed for other types of data collection and health provision.
NHS Airedale, Bradford, Leeds	Recommendation 3 – Regularly monitor and evaluate all local ST cessation services	11	Percentage with adverse effects – further guidance required	Thank you, some additional detail has now been provided ("…such as someone switching to, or increasing, their use of smoked tobacco or areca nut-only products"). The possibility of adverse outcomes is present in any public health intervention. The intent of this part of the recommendation was to both raise awareness of this in relation to smokeless tobacco cessation, and to advise commissioners on how to monitor for signs of it.
NHS Airedale, Bradford, Leeds	Recommendation 4 – Providing brief advice and referral	12	Ask and record ST use– needs to be a Department of health directive for primary and secondary care in line with the recording of smoking status	See previous comment regarding data collection.
NHS Airedale, Bradford, Leeds	Recommendation 4 – What Action should they take?	12	Recommendation - treat ST users in the same way as a smoker carry out a brief intervention (BI) Ask ,Advise, Act	We have now provided a summary of a typical brief intervention in the introduction to the recommendations section, using language consistent with mentions of this intervention in previous NICE guidance.
NHS Airedale,	Recommendation 4 –	12	When it is not possible to deliver a brief intervention (BI) – as	See previous comment.

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Bradford, Leeds	Providing brief advice and referral what action should they take?		above recommend that BI is carried out in line with treating a smoker i.e. Ask, Advise, Act	
NHS Airedale, Bradford, Leeds	Recommendation 4 – Providing brief advice and referral what action should they take?	12	When it is not possible to deliver a brief intervention (BI), or 'it does no appear to have worked' –unsure how health professional would assess that BI had not worked	Thank you, this wording has now changed.
NHS Airedale, Bradford, Leeds	Recommendation 4 – Providing brief advice and referral what action should they take?	12	When it is not possible to deliver a brief intervention (BI), or it does no appear to have worked, refer – wording suggests to only refer when its not possible to deliver a BI or it does not appear to have worked – as above carry out a BI and refer in same way as a smoker	Thank you, this wording has now changed.
NHS Airedale, Bradford, Leeds	Recommendation 5 Training for practitioners – who should take action?	12	Health and dental services – would dental services have the knowledge, skills, capacity to carry out the action of ensuring the range of health professionals identified are trained to be aware of ST use?	This recommendation has now been reworded to put the onus of responsibility onto commissioners of health and dental services, rather than health and dental services themselves.
NHS Airedale, Bradford, Leeds	Recommendation 5 Training for practitioners – who should take action?	12	training for practitioners – in addition to NCSCT Public Health specialists responsible for local smoking and ST tobacco cessation services	We have rationalised the "who should take action" section of this recommendation, to make it clear that the local commissioners have prime responsibility for this recommendation.
NHS Airedale, Bradford, Leeds	Recommendation 6 Specialist cessation services in areas of identified need	13	'If possible validate a quit' – creates a cost implication for services	This is why "if possible" was used
NHS Airedale, Bradford, Leeds	Recommendation 6 Specialist cessation	13	As recommendation 2 page 8 comment above - Cost implication for services, ,may increase expectations without the ability for	See previous comment regarding resource allocation.

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	services in areas of identified need - Ask the local South Asian community whether it would be acceptable to include tobacco cessation services within mainstream or prefer separately branded services		services to deliver	
NHS Airedale, Bradford, Leeds	Recommendation 6 Specialist cessation services in areas of identified need – who should take action	13	In addition to those detailed also include : Managers of tobacco cessation and prevention services Public Health specialists responsible for local smoking and ST tobacco cessation services	This is now recommendation five. We decided to retain the general term of "provider", which includes all staff working in these services.
NHS Airedale, Bradford, Leeds	General		Order of recommendations: Recommendation 5 Training for practitioners should come before recommendation 4 Providing brief advice and referral	This recommendation was reordered, but in fact became the last recommendation. This was to bring it into line with standard NICE placement for training recommendations within its guidance.
NHS KIRKLEES	General		We welcome the draft guidance and feel it will be of value.	Thank you for your comments.
NHS KIRKLEES	General		While prevention activities are outside its scope, where action is required from prevention services clear info is required as to what messages they should deliver and how.	Thank you - the overlap between prevention and cessation is acknowledged in consideration 3.5. Some of the material provided in the recommendations may provide a starting point for informing what messages to deliver.
NHS KIRKLEES	General		Where possible images should accompany names of smokeless	We agree that classification and recognition can be

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			tobacco (ST) as there are so many different names for ST that it makes it difficult to identify it to users.	difficult, given the large number of smokeless tobacco. Recommendations 2 and 3 refer to visual aids for users, and recommendation 6 emphasises training health professionals to recognise the different products.
NHS KIRKLEES	Recommendation 1	7	Re – who should take action. Should local GP's and dentists, other professionals not also be required to take action to ensure that they ask and record about smokeless tobacco use as standard? PH needs the data before it can be analysed….(links with recommendation 4)	One way of providing these incentives at the GP practice level would be through the Quality and Outcomes Framework (QOF). NICE has a role in helping develop the QOF, and we will be reviewing the QOF smoking indicators in terms of whether smokeless tobacco can be included. If this can be included, then current smoking indicators will be updated as part of the standard QOF process.
NHS KIRKLEES	Recommendation 1	7	South Asian Community leaders and champions should help gather local intelligence as they will have access to intimate local knowledge.	We agree, although specifying who these contacts are is spread across both recommendations 1 and 2. Defining who are leaders and champions in a given community can be difficult, so we have chosen to express it generally, referring to members of voluntary and community organisations who work with South Asian communities; Faith leaders and others involved in faith centres; and others with responsibility for the health and wellbeing of South Asian communities.
NHS KIRKLEES	Recommendation 3	11	Rec 3- re monitoring and evaluating smokeless tobacco cessation services. Possible issues re budgets/funding – additional requirements made to commissioned smoking cessation services may result in additional costs; primary care may expect payments for activity	See previous comments about the QOF. Both 4 week quit and prevalence at a national level are important, but in the meantime while smoking cessation is still assessed at a local service level,

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			and for reporting on activity – to include this within existing local enhanced services has budgetary impact (also given changes to NHS structures how will such arrangements be funded/managed in future); there is shift from a focus on 4 week quit to prevalence at a national level within the PH outcomes framework – yet the focus here remains on quit rates.	smokeless tobacco should share the same metric.
NHS KIRKLEES	Recommendation 3 and 6	11 & 14	Home visits should be made available to all south Asian women and not just the socially isolated because south Asian women, for cultural reasons do not like to go to a public place for tobacco support and are limited in their ability to travel to centres for support especially full time housewives.	The wording has now been revised to refer to "people who may find it difficult to use existing local services because of their social circumstances, gender, language, culture or lifestyle" This is now inclusive enough to refer to the groups of women you refer to.
NHS KIRKLEES	Recommendation 4	11	Rec 4- re health professionals providing brief advice and referral Would agree that there is a need for this, but concern that practitioners will feel that they do not have the time to deliver. May only do if part of a LES, or if included in QOF etc – budget implications. Obviously there is need for training to ensure that staff are able to do this – feel recs 4 and 5 should be linked together.	See previous comments about the QOF. We are aware that there are potential budget implications. Issues of resource allocation to services are beyond the remit of NICE guidance. NICE is tasked with making judgements on cost-effectiveness, and the NICE implementation team will produce costing tools associated with this guidance that can be applied at the local level. How these needs should be prioritised against health needs in a particular local area is an issue for local decision making. We agree that there is an overlap between recommendations 4 and 5, but not enough for them to

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				be formally linked.
NHS KIRKLEES	Recommendation 5	12	Rec 5- re training Needs to link to rec 4. Positive to see training identified as a need. As with rec 4 risk that practitioners will feel time is a barrier – to both deliver intervention (however brief) and to access training. Also possible cost implications.	See previous comments about resource allocation.
NHS KIRKLEES	Recommendation 6	13	Rec 6- re specialist services As with rec 3, possible budget implications if adding additional elements to already commissioned services? Cost implication of cotinine test? As with rec 3, shift to more of a focus on prevalence with PH Outcomes Framework – how does this fit with continued focus on 4 week quit?	This is now recommendation 5. See previous comments about resource allocation.
NHS KIRKLEES	Recommendation 3 and 6	11 & 14	Home visits should be made available to all south Asian women and not just the socially isolated because south Asian women, for cultural reasons do not like to go to a public place for tobacco support and are limited in their ability to travel to centres for support especially full time housewives.	The wording has now been revised to refer to "people who may find it difficult to use existing local services because of their social circumstances, gender, language, culture or lifestyle" This is now inclusive enough to refer to the groups of women you refer to.
South Asian Health Foundation	General		We fully support the list of recommendations. It is pivotal that strategies be conceived that delink cultural value from these behavioural patterns to improve population health. This is especially important for individuals born in the “host” country	Thank you for your comments. The need to challenge the perceived health benefits of smokeless tobacco within the South Asian community is referred to a number of times.

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			who might grasp onto behavioural artefacts emblematic of their cultural origin. The misconceived medicinal properties of smokeless tobacco use for instance needs tackling.	
South Asian Health Foundation	General		In addition, while targeting users is vital, the need to address factors that act as facilitator and barriers (family, friends, physicians and media) to cessation is a pivotal factor in creating the supportive and encouraging environment which is imperative during the quitting process.	Such assumptions formed a core part of our thinking during this guidance development process.
South Asian Health Foundation	General		The widespread social acceptance and religious observance attached to this habit, particularly for the UK immigrant population, provide further social and psychological barriers to cessation, which should be dealt with sensitively by tailored and targeted cessation services.	Thank you, again these assumptions formed a core part of our thinking during this development process
South Asian Health Foundation	General		The role of community leaders and cultural “gatekeepers” becomes paramount in diffusing social and cultural change within these communities.	We have tried to specify engagement with such individuals as part of recommendation 2.
South Asian Health Foundation	General		The problem of the easy availability and increasing use of smokeless tobacco products by young people of south Asian origin in the UK needs to be urgently addressed. It is almost always present in the South Asian home	With respect to issues of product availability and supply, the Department of Health referral and the resulting project 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.
Southern Health NHS Foundation Trust	General		As the manager of an NHS smoking cessation service, I welcome and support the guidance. It appears to identify the correct organisations and individuals involved in each aspect and covers a comprehensive range of	Thank you for your comments. Issues of resource allocation to services are beyond the remit of NICE guidance. NICE is tasked with making judgements on cost-effectiveness, and the

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			recommendations. Equality of opportunity appears to be covered. My concerns relate - 1 - To the practicalities and financial costs of supporting non English speakers (often illiterate in their own language). Many areas have a relatively small populations of South Asians and the costs of translating materials and training staff are going to be disproportionate to outcomes. Whilst this work appears to be cost effective, the guidance needs to address the practicalities of financial support to implement the guidance or it risks being adopted by no one. 2. Currently smoking cessations services are targeted, measured and funded to support tobacco smokers. Smokeless tobacco users need to be included in their remit to ensure the appropriate monitoring and allocation of resources. 3. Lack of research and evidence of effective treatment needs to be addressed urgently through joint working and collaboration. A central repository of resources and evidence should then be available to all stakeholders.	NICE implementation team will produce costing tools associated with this guidance that can be applied at the local level. How these needs should be prioritised against health needs in a particular local area is an issue for local decision making. One way of providing these incentives at the GP practice level would be through the Quality and Outcomes Framework (QOF). NICE has a role in helping develop the QOF, and we will be reviewing the QOF smoking indicators in terms of whether smokeless tobacco can be included. If this can be included, then current smoking indicators will be updated as part of the standard QOF process. Finally, NICE's implementation team have been working to produce materials that we hope will go some way to acting as a repository of resources.
UK Centre for Tobacco Control Studies (UKCTCS)/ Cancer Research UK	General		UKCTCS/CRUK/RCP are grateful for the opportunity to respond to the draft guidance. We would like to make the following comments.	Thank you for your comments.

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(CRUK)/Royal College of Physicians (RCP)				
UK Centre for Tobacco Control Studies (UKCTCS)/ Cancer Research UK (CRUK)/Royal College of Physicians (RCP)	General		The guidance would merit inclusion of a statement about the public health problems caused by chewing tobacco products. It would also be useful to include a statement about how patchy or non-existent is the current support for smokeless tobacco users. It is therefore important that these recommendations clearly build on this current state of affairs. As stands, we do not believe that this step change in support is clear in the guidance.	Section 2 (Public health need and practice) contains material on the public health problems caused by these substances. Expressing these dangers to users is a large part of recommendation 2, and is implicit in other recommendations. The PHIAC committee recognised the patchy nature of existing services. Also, as a result of discussions during their second meeting on this topic, there is a new consideration (3.2) in which the committee expressed the view that there needs to be a concerted effort to increase the provision and consistency of smokeless tobacco cessation services across England.
UK Centre for Tobacco Control Studies (UKCTCS)/ Cancer Research UK (CRUK)/Royal College of Physicians (RCP)	General		The guidance refers to 'tobacco cessation services'. In general cessation services are referred to in England as NHS Stop Smoking Services. It needs to be made clear that in areas where there are South Asian communities these services and commissioners of these services need to consider providing support to smokeless tobacco users. This is likely to entail a change in name to tobacco cessation services, but at the moment such services do not really exist apart from one or two well established services offering smokeless tobacco use.	We have attempted to use wording in the guidance that is both flexible and future-proof, and the wording we have arrived at it "Specialist tobacco cessation services". However, we also now include a special section in the introduction to the recommendations explaining what this term means, and that currently these services are currently generally referred to as "stop smoking services". It is noted that there is scope for these services to be flexible with what they call themselves.
UK Centre for Tobacco Control Studies	General		The word 'habit' should not be used in relation to smokeless tobacco use as this is an addiction, similar to addiction to	In general we have used "habit" to refer to the behaviour of use, while using "addiction" in other

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(UKCTCS)/ Cancer Research UK (CRUK)/Royal College of Physicians (RCP)			smoked tobacco	places to describe the long-term effect. In recommendation 2, we suggest the substitution of the word "addiction" with "habit" in publicity material if there are particularly negative connotations attached to this former word among members of the local South Asian community (as we have been advised can be an issue). However this is up to the discretion of those involved.
UK Centre for Tobacco Control Studies (UKCTCS)/ Cancer Research UK (CRUK)/Royal College of Physicians (RCP)	General		The guidance should make clear that smokeless tobacco users may also smoke. Smokeless tobacco users should therefore also be asked about smoking and should be encouraged to stop both addictions with relevant discussions about relative risks of both products compared with non tobacco use. It is not sufficient to state that the proportion smoking after smokeless tobacco use should be monitored as this is akin to closing the gate after the horse has bolted. All health professionals need to ask and advise about smoking cessation too and the relative risks of the products.	There is now more recognition in the guidance of the "crossover" between smoking and chewing tobacco, and recommendations 3 and 6 in particular are explicit about this connection.
UK Centre for Tobacco Control Studies (UKCTCS)/ Cancer Research UK (CRUK)/Royal College of Physicians (RCP)	General		It is not clear why NRT is not being recommended. The evidence statements and evidence review indicates that there are studies demonstrating the effectiveness of NRT in these populations. There are no RCTs but the evidence comes from studies carried out in the UK with South Asian tobacco chewers and hence there should be a recommendation that NRT should be considered for use with this population.	PHIAC considered the evidence for treatment using pharmacotherapy and, in particular, the use of NRT. It noted that the Cochrane review evidence on the use of NRT for smokeless tobacco cessation is equivocal. Further, it relates to a different type of smokeless tobacco with populations other than South Asians living in England. Although there is some evidence to suggest that NRT can help South Asian users of smokeless tobacco in England to quit, this comes from

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				non-randomised trials with limited follow-up. PHIAC was also aware that NRT is not licensed as a treatment for smokeless tobacco use, although it is on general sale. It also noted that clinicians can use their judgement to prescribe or recommend it. PHIAC made a research recommendation about the use of NRT for smokeless tobacco cessation
UK Centre for Tobacco Control Studies (UKCTCS)/ Cancer Research UK (CRUK)/Royal College of Physicians (RCP)	General		In addition to West et al (2004), the Cochrane review on smokeless tobacco needs to be cited as the evidence base is more up-to-date.	Thank you, the 2011 version of this report was considered by PHIAC, and is referenced in the guidance.
UK Centre for Tobacco Control Studies (UKCTCS)/ Cancer Research UK (CRUK)/Royal College of Physicians (RCP)	1 Draft Recommendations	6	Whilst we can understand the need to tailor the services and support to the product used locally, it might be better to give examples of products covered in the terminology 'smokeless tobacco' rather than rename the service because of the potential to exclude users of other brands/products.	This is something we suggest (recommendation 3) as something that should be decided at a local level and the type of consultation that we specify in recommendation 2 would guide this decision making process. If, for example, 95% of smokeless tobacco products consumed in a given locality were gutkha, then referring to this in the service title might be a highly effective method to both raise awareness of gutkha as a health hazard, and also attract users to the service.
UK Centre for Tobacco Control Studies (UKCTCS)/ Cancer	Recommendation 1	7	Should 'Health and Well Being Boards' also be included? There is a QOF for asking about smoking but this should be	NICE recognises the role of incentives in service delivery, particularly in relation to what PHIAC recognised as an "emerging" issue for commissioners

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Research UK (CRUK)/Royal College of Physicians (RCP)			changed to ask about tobacco use so that tobacco chewers are not excluded. All these recommendations unlikely to be implemented without being made mandatory.	in many areas. One way of providing these incentives at the GP practice level would be through the Quality and Outcomes Framework (QOF). NICE has a role in helping develop the QOF, and we will be reviewing the QOF smoking indicators in terms of whether smokeless tobacco can be included. If this can be included, then current smoking indicators will be updated as part of the standard QOF process.
UK Centre for Tobacco Control Studies (UKCTCS)/ Cancer Research UK (CRUK)/Royal College of Physicians (RCP)	Recommendation 1	8	1st bullet – is ethnic status routinely collected by services? If not, this should be recommended.	This is included in recommendation 1.
UK Centre for Tobacco Control Studies (UKCTCS)/ Cancer Research UK (CRUK)/Royal College of Physicians (RCP)	Recommendation 3	11	As the NICE brief advice guidance shows there is an evidence gap in relation to smokeless tobacco. Nevertheless, it makes sense, given the evidence from smoking, that brief advice will be an effective approach. This evidence base, or lack of it, needs acknowledging however. Outcomes should be the same as those required of stop smoking services ie not 6 and 12 months? What does this mean: 'percentage with adverse effects'?	Thank you, appendix D of the guidance includes a list of all identified evidence gaps encountered during the guidance development process, and the document also features a list of research recommendations. Thank you, the outcome time has now been changed to 4 weeks, to bring it into line with smoking cessation services. Finally, as for "adverse effects" some additional detail has now been provided ("…such as someone switching to, or increasing, their use of smoked

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				tobacco or areca nut-only products")
UK Centre for Tobacco Control Studies (UKCTCS)/ Cancer Research UK (CRUK)/Royal College of Physicians (RCP)	Recommendation 4	11/12	This should be widened to community outreach professionals	This list has been expanded and generalised
UK Centre for Tobacco Control Studies (UKCTCS)/ Cancer Research UK (CRUK)/Royal College of Physicians (RCP)	Recommendation 4	12	The statement: 'When it is not possible to deliver a brief intervention, or it does not appear to have worked' This is unclear. It should always be possible to deliver a brief intervention. It will not be possible to see if it has worked (ie whether they stop smokeless use). It would be better to deliver the brief intervention and signpost support that is locally available. Same bullet point: '...refer... to tobacco cessation services that use counsellors trained in behavioural support ' As above, counsellors should also be trained to give NRT.	Thank you, this wording has now been revised. See also the above comment on NRT.
UK Centre for Tobacco Control Studies (UKCTCS)/ Cancer Research UK (CRUK)/Royal College of Physicians (RCP)	Recommendation 5	12/13	'NHS Centre for Smoking Cessation and Training' This centre would need commissioning to offer training for smokeless tobacco cessation support as it currently does not offer this. Final bullet' 'deliver a brief intervention, or refer people who want to quit to cessation services'	Thank you, we have revised the wording of this recommendation.

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			This should read 'deliver a brief intervention AND refer people who want to quit to cessation services'	
UK Centre for Tobacco Control Studies (UKCTCS)/ Cancer Research UK (CRUK)/Royal College of Physicians (RCP)	Recommendation 6	13	***"Recommendation 6 Specialist cessation services in areas of identified need.*** **Who should take action?** Providers of primary and secondary healthcare. This includes those working in general practice, dental practices and pharmacies...Staff working in community-based cessation services. " It is unclear why this recommendation is headed as it is if individual providers are also being targeted? Any cessation service should be a focus here. Bullet 2: "In addition, they should be able to advise on how to cope with the potential adverse effects of quitting" What are these adverse effects of quitting? These would need to be spelt out to them as providers will largely not be aware of these. Bullet 3: "Following a quit attempt, cessation services should offer help to prevent a relapse" Whilst this is good practice, this would need to be made clearer. Is this part of the acute cessation support or are you suggesting more prolonged support? If so, what is the evidence for this?	This is now recommendation 5. The list of affected staff has now been changed. As for adverse effects, oral pain and withdrawal symptoms are now specifically listed. With respect to relapse prevention, to a large extent, we would expect the cessation service to apply general behaviour principles, analogous to their activities with smokers.

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UK Centre for Tobacco Control Studies (UKCTCS)/ Cancer Research UK (CRUK)/Royal College of Physicians (RCP)	Recommendation 6	13	Ensure staff working in tobacco cessation are trained to recommend or provide brief advice to people who use smokeless tobacco " It is unclear how staff can 'recommend brief advice', this does not make sense. Furthermore, it is unclear who these staff are who are working in tobacco cessation. This should instead apply to all staff in primary and secondary care in areas with South Asian communities who should be trained to give brief advice and refer. Staff working in stop smoking services in relevant areas need to be trained to give specialist intensive behavioural support and NRT to smokeless tobacco users.	Thank you. Recommendations 4 and 6 (now recommendation 5) have been reworded along these lines. The confusing reference to "recommend brief advice" has now gone, and now all primary and secondary healthcare professionals are included.
UK Centre for Tobacco Control Studies (UKCTCS)/ Cancer Research UK (CRUK)/Royal College of Physicians (RCP)	3.7	19	Areca nut possibly carcinogenic – IARC has stated this categorically. Unclear why included given areca nut excluded from scope?	Thank you, this change has now been made
UK Centre for Tobacco Control Studies (UKCTCS)/ Cancer Research UK (CRUK)/Royal College of Physicians (RCP)	Section 2 Public Health Need and Practice	17	The statement: 'A 2003 review listed 17 local services in England that claimed to focus on smokeless tobacco – and many South Asians are using such services (Crosier and McNeill 2003)' is misleading. This study indicated that any projects identified were temporary with short term funding. An examination of 5 projects funded two years earlier, found only one still in existence. This report concluded, "There are concerns about the lack of any clear strategy and focus on smokeless tobacco". What was identified	We acknowledge these issues and the fluid nature of these services. Unfortunately we were unable to locate any other more recent service audit or breakdown. However we have amended the tense of this paragraph to make it clear that we are referring to the situation in 2003. Also, as a result of discussions during the second PHIAC meeting on this topic, there is a new consideration (3.2) in which the committee expressed the view that there needs to be a concerted effort to increase the provision and consistency of

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			in that report is the same as the current situation, ad hoc services with short-term funding. We believe this guidance is unlikely to change that situation.	smokeless tobacco cessation services across England.
UK Centre for Tobacco Control Studies (UKCTCS)/ Cancer Research UK (CRUK)/Royal College of Physicians (RCP)	Research	24	It should be made clear that there is a need for an RCT of pharmacotherapy and behavioural support for chewing tobacco users in the UK. Given differences in the products used and cultures using the products internationally, a trial is needed in the UK. However, in the meantime, this should not hinder the provision of behavioural support and NRT given the growing evidence base that it is effective.	A recommendation concerning such a trial forms part of what is now research recommendation 5.4.
UK Centre for Tobacco Control Studies (UKCTCS)/ Cancer Research UK (CRUK)/Royal College of Physicians (RCP)		24	"Specialist smokeless tobacco services (including outreach services), compared to smokeless tobacco support provided by standard smoking cessation services" The meaning of this is unclear. Support will always need to be tailored to tobacco chewers and the specific community members who use it although the components may be the same (ie behavioural support and pharmacotherapy) as for stop smoking support. This could be through a trained advisor within a current service or a separate service.	We now include a formal definition of what we call "Specialist tobacco cessation services" at the start of the guidance. We note that services traditional focus on people who smoke tobacco. However, a service might also brand itself as a generic tobacco cessation service, to emphasise a focus on more than one form of tobacco. Recommendation 3 is designed to encourage local commissioners to think about a range of models for service delivery, specific to their areas.
UK Centre for Tobacco Control Studies (UKCTCS)/ Cancer Research UK (CRUK)/Royal College of Physicians (RCP)	Appendix F		The diagram should be replaced with an existing one eg Stanfill et al, 2011	Thank you, the categorisation of smokeless tobacco types has been replaced with a new scheme based on this reference.

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University of Edinburgh	General	7	We have with interest read the draft "Smokeless tobacco cessation - South Asians". We have reviewed the literature on South Asians' beliefs, attitudes and cultural perspectives on smokeless tobacco. The abstract of this paper, which is In Press, is given below this response together with the full reference. We would be glad to supply the manuscript. We fully support the list of recommendations, in particular the cultural acceptance of the habit which has resulted in a high prevalence particularly in vulnerable groups i.e women; the need to dispel myths; general ignorance associated around the health concern s (particularly in Bangladeshis compared with Indians and Pakistanis); and misconceived medicinal properties of smokeless tobacco use. The widespread social acceptance and religious observance attached to this habit, particularly for the UK immigrant population, provide further social and psychological barriers to cessation, which should be dealt with sensitively by tailored and targeted cessation services.	Thank you very much for this paper, which we have since obtained from you. We are pleased to see that your results express many of the same issues and themes as our own literature review.
University of Edinburgh	General (contd)	7	Our paper reiterates and emphasises the need to both educate users and refer them to organisations that provide cessation support, particularly as users who want to quit have reported a lack/unawareness of available cessation support. In addition, while targeting users is vital, the need to address factors that act as facilitator and barriers (family, friends, physicians and media) to cessation is a pivotal factor in creating the supportive and encouraging environment which is imperative during the quitting	See previous comment.

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			process. The development of cessation programmes will benefit from considering the views of users, as we see this as an essential step in ensuring long-term abstinence. Although the "Smokeless tobacco cessation - South Asians: draft guidance" does not cover wider tobacco control measures, we recognise this as a vital aspect for effective cessation programmes, e.g. emphasising the need for and importance of addressing behind the counter sales, use of signage for underage sales and health warnings.	
University of Edinburgh	General (contd)	7	**ABSTRACT** Objectives - Smokeless tobacco (SLT) is an addiction resulting in serious health problems including cancers. To help inform interventions for its prevention and cessation, the social context around SLT use among South Asians was reviewed. Study Design - Systematic Review Methods - Electronic databases were searched to identify studies examining social context of SLT use. As heterogeneous qualitative, quantitative and mixed method studies were included meta-analysis was not appropriate. Results - Of the 428 studies identified, 17 conducted in India, Nepal, Pakistan and UK during 1994-2009 were reviewed. SLT use among South Asians was culturally widely acceptable due to its association with socialising, sharing and family tradition (100% in Anwar et al's study) use among family members. Other	See previous comment.

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			reasons for use were addiction, easy accessibility, low cost and lack of prohibiting legislation. SLT users had limited awareness of its association with oral cancer (29.3% in Ahmed et al's study); however there was a distinct lack of knowledge regarding other health effects, i.e. cardio-vascular disease (0.85%). Users attempted to quit (32.7% in Prabhu et al's study) but success was low (8.2%).	
University of Edinburgh	General (contd)	7	Conclusions - Cessation programmes for South Asians should address cultural acceptance, limited knowledge of health effects, inadequate legislation and controls, scarce social support and insufficient SLT cessation services. Full Reference - S Kakde, R S Bhopal, C M Jones, A systematic review on the social context of smokeless tobacco use in the South Asian populations - Implications for Public Health, Public Health, In Press	See previous comment.
Western Cheshire Tobacco Control Alliance	General		There are other populations who also used smokeless tobacco (ST) and that it is important that they are not excluded from any intervention to help them stop.	The introduction to the recommendations section makes it clear that people of South Asian origin are the focus of this guidance as they are the predominant users of smokeless tobacco products in England. But it also notes that others who use these products may also benefit from the recommendations, as health professionals, as a result, will be more aware of how to identify and help them.
Western Cheshire Tobacco Control	Who is guidance for?	Pg 1	Directors of Public Health should be included in this section.	Thank you, they are now included.

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Alliance				
Western Cheshire Tobacco Control Alliance	Draft Recommendations	Pg 6 Smokeless Tobacco	The fact that ST is not always recognised by users as containing tobacco highlights the need to standardise labelling to show this and to include health warnings on all ST products. However, we also support an alternative name for services rather than 'smokeless tobacco services.'	Thank you for your comments. We have retained the recommendation about alternative names. As for labelling issues, the Department of Health referral and the resulting project 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. Nevertheless, the definition of smokeless tobacco in the guidance now notes that the products are legally required to carry the health warning: 'This tobacco product can damage your health and is addictive' on the most visible surface of the packet.
Western Cheshire Tobacco Control Alliance	General		We support increasing research and further analysis on local use of ST. We suggest it could be included as standard by services for data reporting.	The resources needed to organise this data gathering will also need to be traded off against resources needed for other types of data collection and health provision.
Western Cheshire Tobacco Control Alliance	General		We suggest the guidance could highlight the importance of confidentiality when people seek help with local services to stop using ST. This is particularly important for women in certain communities who do not want others to know that either, they use ST, or that they are seeking help to stop using ST if it is regarded as an inherent part of their culture.	Thank you. The issue of confidentiality has now been highlighted in recommendation 3

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Western Cheshire Tobacco Control Alliance	Recommendation 6	Pg 14 Who should take action	We advise that people with a mental health condition and those in prisons also be included in this section for identifying socially isolated adults that use ST.	The wording has now been revised to refer to "people who may find it difficult to use existing local services because of their social circumstances, gender, language, culture or lifestyle" This is now inclusive enough to be used to refer to people with a mental health condition, or those in prison.
Western Cheshire Tobacco Control Alliance	Considerations	Pg 20 Section 3.12	The inclusion of an educational component relating to the economic and regulatory issues surrounding ST may complement cessation advice and also heighten awareness of the products amongst health professionals including doctors, dentists, nurses, midwives and health visitors.	In the first instance, the Department of Health referral (see 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 related to regulatory issues. We appreciate that an educational component on this may be useful as general background information to health professionals. However, given the expensive of the time for training for health professionals, the training recommendation focuses only on the core topics that should be covered.