

Tobacco suite: prevention, cessation and harm reduction (update)

Consultation on draft scope Stakeholder comments table

14/05/2018 to 11/06/2018

Stakeholder	Page no.	Line no.	Comments	Developer's response
			Please insert each new comment in a new row	Please respond to each comment
Action on Smoking and Health	General	General	<p>Question 1: consideration of inclusion of heated tobacco products in the scope.</p> <p>ASH does not believe that it would be appropriate to include heated tobacco products in the scope of this guidance.</p> <p>Awareness of heated tobacco products is low as is usage, and this is likely to continue to be the case during the time the committee is reviewing the evidence. Furthermore there is little evidence of these products effectiveness in supporting quitting, and what there is has been conducted by the tobacco industry and is not independent.</p> <p>The UK is a party to the WHO Framework convention for Tobacco Control, and NICE and PHE are covered by its obligations, including those in Article 5.3 with respect to protecting public health policy with respect to tobacco control from the commercial and vested interests of the tobacco industry. NICE needs to review the Article 5.3 Guidelines carefully to help it consider how it will interpret data emanating from the tobacco industry. NICE has satisfied its public commitment to consult on whether heated tobacco products are in scope and the current lack of independent evidence means further work would be premature at this time.</p> <p>References: WHO FCTC Article 5.3</p>	<p>Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include 'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.</p>

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			<p>guidelines.http://www.who.int/entity/fctc/treaty_instruments/adopted/article_5_3/en/index.html</p> <p>McNeill A, Brose LS, Calder R, Bauld L & Robson D. Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England:https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review</p> <p>Committee on toxicity, carcinogenicity and mutagenicity of chemicals in food, consumer products and the environment. Statement on the toxicological evaluation of novel heat-not-burn tobacco productshttps://cot.food.gov.uk/sites/default/files/heat_not_burn_tobacco_statement.pdf</p>	
Action on Smoking and Health	General	General	<p>Question 2: draft scope position on use of incentives and whether this should be broadened out from pregnant women to other groups.</p> <p>The scope should be broadened out to look at groups other than pregnant women – in particular where there may be immediate benefit from quitting both to the smoker and to the NHS, for example surgical patients (where smoking delays recovery) or patients with pre-existing smoking-related disease where quitting can</p>	<p>Thank you for this comment. A surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified on incentives for cessation which would change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-</p>

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			improve outcomes (e.g. COPD, CVD and lung cancer). Evidence should be gathered both on effectiveness and cost-effectiveness of incentives under these conditions.	ph48-4424254962/chapter/Surveillance-decision?tab=evidence In addition, the majority of the evidence identified is related to pregnant women. Therefore the scope of this update is limited to pregnant women. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.
Action on Smoking and Health	General	General	<p>Question 3: Which interventions or forms of practice might result in cost saving recommendations if included in the guideline?</p> <p>Some interventions may be 'cost-saving', but this is a very high bar which is not used for interventions to treat the diseases caused by smoking. Interventions to prevent smoking uptake and encourage cessation are all highly cost-effective, and it would be helpful if the guidelines spelt out the relative cost-effectiveness of smoking prevention and cessation interventions compared to interventions to treat the most common smoking-related diseases such as lung cancer, CVD and COPD.</p> <p>In order to ensure that commissioners make informed judgements in determining how to spend their tobacco control budgets it is crucial that the NICE guidance</p>	<p>Thank you for this comment. NICE's preferred approach is to undertake a full incremental analysis where possible. However, this approach and likewise the development of a league table, may not be appropriate given the disparate nature of tobacco control measures that are likely to be covered by the guideline and difference in methods used to assess them. Take the following three interventions as an example:</p> <p>Intervention A: NRT + GP advice vs usual care (undefined) Intervention B: mass media campaign aimed at adults who smoke vs background quit rate Intervention C: school based prevention programme vs usual practice (undefined)</p> <p>A full incremental analysis would involve comparing</p>

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			<p>identify the relative cost-effectiveness of different interventions. In particular as smoking rates among young people fall, the cost-effectiveness of interventions targeted at schools need to be reviewed and their cost-effective compared to measures focusing on helping adult smokers quit. Young people who grow up in smoking households are much more likely to become smokers than those growing up in non-smoking households, so helping adult smokers quit can have a dual impact in also reducing youth initiation. It would be helpful to be able to compare the relative cost-effectiveness of these interventions.</p> <p>Although mass media interventions are listed in section 2 and 3.3 as coming under both prevention and promotion of quitting; in the sections setting out key questions (3.5) and the appendix setting out what NICE plans to do mass media is only included as prevention and not promotion of quitting. Mass media can be effective and cost-effective both in discouraging uptake and motivating quitting, particularly at national and regional level and should be included in both sections.</p> <p>References: Mass media interventions for preventing smoking in young people. Cochrane Tobacco Addiction Group</p>	<p>interventions A, B and C sequentially in rank order of effectiveness (or cost). This assumes interventions A, B and C are mutually exclusive but there is nothing to say that is the case so a commissioning body could decide to fund all three.</p> <p>Although a league table of ICERs for these interventions could be created, differences in settings, population groups, comparators and in the case of smoking prevention – outcomes - would make it difficult to interpret in any meaningful way. There are other important considerations too such as the quality of evidence and uncertainty around the estimates, the size of the population likely to benefit and the impact on inequalities. In the case of the latter, if the goal is to reduce health inequalities, interventions that work best for the most disadvantaged groups might be more costly and could reduce the health gain achieved in the population as a whole. The following sets out some of the issues identified when league tables were first being discussed see https://www.sciencedirect.com/science/article/pii/S027795369390315U.</p> <p>Thank you for this comment. Mass media campaigns</p>

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			<p>2017.http://cochranelibrary-wiley.com/doi/10.1002/14651858.CD001006.pub3/full</p> <p>Mass media interventions for smoking cessation in adults. Cochrane Tobacco Addiction Group 2017.http://cochranelibrary-wiley.com/doi/10.1002/14651858.CD004704.pub4/full</p>	<p>for cessation are not included in the update of this guidance. They are already commonly used and there is little concern about variation in their use. Additionally, insufficient evidence has been identified through consultation to merit this new area.</p> <p>Please note that key issue 1.2 proposes to look at whether smoking cessation mass media campaigns using de-normalisation strategies aimed at adults are effective and cost effective in preventing the uptake of smoking among children and young people.</p>
Action on Smoking and Health	General	General	<p>The two headings 'prevention and promotion' and 'cessation and harm reduction' are overlapping and unclear. It would make better sense to split the two sections more clearly into non-treatment and treatment interventions. To make this clear, 'prevention and promotion' should be changed to 'preventing uptake and promoting quitting' and 'cessation and harm reduction' should be changed to 'treating tobacco dependency'.</p> <p>This would mean, for example, that mass media campaigns would be included in 'preventing uptake and promoting quitting' while clinical interventions such as stop smoking services and brief advice and prescribing would be included in 'treating tobacco dependency'.</p>	<p>Thank you for this comment. The subheading "prevention and promotion" has been amended to "preventing uptake". "Promoting quitting" does not form part of this update so it has been removed from the subheading. However, material from the original guidelines on promoting quitting will be retained and will form part of the final product.</p> <p>The subheading "cessation and harm reduction" has been amended to "treating tobacco dependence". This will continue to include review questions about quitting smoking and about reducing harm from smoking.</p> <p>We note that subheadings are intended to organise</p>

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			<p>Harm reduction and relapse prevention are not necessarily part of the treatment pathway. If smokers seek treatment for these purposes then they would be, but they are also part of 'preventing uptake and promoting quitting' if undertaken in the community. For example consumer e-cigarettes bought over the counter by smokers not engaging with healthcare professionals can deliver both relapse prevention and harm reduction. But if smokers seek help and advice for e-cigarettes or harm reduction then this would come under the treatment pathway.</p> <p>Furthermore measures 'preventing uptake and promoting quitting' apply to all age groups and the scope should not be limited to those aged 24 and under.</p>	<p>and provide an overview of what evidence will be updated, rather than reflecting the structure of the final published guidance. We also recognise the overlap between the two areas of preventing uptake and treating dependence. This is partly covered in key issue 1.2 (below) and will be considered by the committee when making recommendations.</p> <p><i>1.2 Are smoking cessation mass media campaigns using de-normalisation strategies aimed at adults effective and cost effective in preventing the uptake of smoking among children and young people?</i></p>
Action on Smoking and Health	2	20 - 21	<p>It is crucial to investigate the impact of e-cigarettes on smoking behaviour not just of those who do not currently smoke, but also those who do. (see also page 9 line 29-30)</p>	<p>Thank you for this comment. This area comes under prevention and as such the included population is people who do not currently smoke. However, in order to assess the impact of e-cigarettes on the future smoking behaviour of children and young people who do smoke, an additional key issue has been added to the 'treating tobacco dependency' section:</p> <p><i>What is the impact of e-cigarettes on the smoking</i></p>

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				<i>behaviour of children and young people who currently smoke?</i>
Action on Smoking and Health	2	4 to 5	Local authorities are making decisions about, for example, whether to fund stop smoking services versus school based interventions. They need to have the evidence about relative cost-effectiveness of different interventions in order to be able to make informed decisions.	<p>Thank you for your comment. NICE's preferred approach is to undertake a full incremental analysis where possible. However, this approach and likewise the development of a league table, may not be appropriate given the disparate nature of tobacco control measures that are likely to be covered by the guideline and difference in methods used to assess them. Take the following three interventions as an example:</p> <p>Intervention A: NRT + GP advice vs usual care (undefined) Intervention B: mass media campaign aimed at adults who smoke vs background quit rate Intervention C: school based prevention programme vs usual practice (undefined)</p> <p>A full incremental analysis would involve comparing interventions A, B and C sequentially in rank order of effectiveness (or cost). This assumes interventions A, B and C are mutually exclusive but there is nothing to say that is the case so a commissioning body could decide to fund all three.</p>

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				Although a league table of ICERs for these interventions could be created, differences in settings, population groups, comparators and in the case of smoking prevention – outcomes - would make it difficult to interpret in any meaningful way. There are other important considerations too such as the quality of evidence and uncertainty around the estimates, the size of the population likely to benefit and the impact on inequalities. In the case of the latter, if the goal is to reduce health inequalities, interventions that work best for the most disadvantaged groups might be more costly and could reduce the health gain achieved in the population as a whole. The following sets out some of the issues identified when league tables were first being discussed see https://www.sciencedirect.com/science/article/pii/S027795369390315U .
Action on Smoking and Health	2	17	There is evidence of a causal link between depictions of smoking in the entertainment media (TV and film in particular) smoking uptake among children and young people and this should be reviewed and covered by the guidance. References: The National Cancer Institute. The Role of the Media in	Thank you for this comment. Digital media for smoking cessation will not be covered as part of this update, however digital media interventions for prevention will be considered. Advertising restrictions and product placement are outside of NICE's remit and is therefore not something NICE would make recommendations on.

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			<p>Promoting and Reducing Tobacco Use. Tobacco Control Monograph No. 19. US Department of Health and Human Services National Institutes of Health, 2008.</p> <p>U.S. Department of Health and Human Services. Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012.</p> <p>U.S. Department of Health and Human Services. The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014</p>	
Action on Smoking and Health	2	24	The scope for opt out referrals should be wider than just pregnant women – there is precedent for this as in ng92 surgical patients were also recommended for opt out referral. (see also page 10 line 4)	Thank you for this comment. NG92 recommends an opt-out referral approach for people planning surgery. This recommendation will be carried forward into the new guidance. A surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified on opt-out referral pathways which would

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				change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence . Additionally, In addition, insufficient evidence has been identified through the consultation process to warrant a new review in this area. Therefore the scope of this update is limited to pregnant women. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.
Action on Smoking and Health	2	25	Use of e-cigarettes in pregnancy should also be included not just NRT – pregnant women are choosing to use e-cigarettes and clinicians and the women themselves need guidance on their use. The NCSCT already includes recommendations on this in their guidance on e-cigarettes. http://www.ncsct.co.uk/usr/pub/Electronic_cigarettes._A_briefing_for_stop_smoking_services.pdf	Thank you for this comment. The draft scope outlines draft review questions, one of which is a review question addressing the effectiveness, cost effectiveness, safety and acceptability of NRTs and e-cigarettes for pregnant women.
Action on Smoking and Health	3	13	There are some gaps in the legislation listed – for example the implementation of the display ban in shops and prohibition of smoking in private vehicles carrying children under 18, in addition to work vehicles.	Thank you for this comment. The list of legislative changes in the scope is not intended to be exhaustive, particularly as the area of tobacco is so large. However, some additions have been made to

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				<p>the list to include more of the key legislative changes, as follows:</p> <ul style="list-style-type: none"> • It was made illegal to display tobacco products at the point of sale. • Legislation was introduced to standardise packaging of tobacco products. • It was made illegal to smoke in private vehicles carrying anyone under the age of 18.
Action on Smoking and Health	4	19 - 20	<p>The comparison between trial of e-cigarettes and smoking in young people is not relevant as the evidence to date is that trial is not translating into regular use. If any comparison is made it should be about regular use.</p> <p>Reference: Bauld L et al Young People's Use of E-Cigarettes across the United Kingdom: Findings from Five Surveys 2015-2017, International Journal of Environmental Research and Public Health 2017, 14, 29 August 2017http://www.mdpi.com/1660-4601/14/9/973/pdf</p>	<p>Thank you for this comment. The scope aims to set out brief context only. These issues will be considered in more detail in the reviews and assessed. However, additional wording has been added to state:</p> <p>"However, regular use among young people is below 3% (Evidence review of e-cigarettes and heated tobacco products 2018 Public Health England)."</p>
Action on Smoking and Health	5	4 to 5	<p>'preventing uptake and promoting quitting' should not be limited to those aged 24 and under. These measures apply to any age group.</p>	<p>Thank you for this comment. The subheading "prevention and promotion" has been amended to "preventing uptake". "Promoting quitting" does not form part of this update so it has been removed from the subheading. However, material from the original guidelines on promoting quitting will be retained and</p>

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				will form part of the final product. Therefore the target population for the material included in this update for preventing uptake has been kept as people aged 24 and under, in line with evidence around age of smoking initiation.
Action on Smoking and Health	7	5	These recommendations should apply to all age groups not just 24 and under.	Thank you for this comment. The subheading "prevention and promotion" has been amended to "preventing uptake". "Promoting quitting" does not form part of this update so it has been removed from the subheading. However, material from the original guidelines on promoting quitting will be retained and will form part of the final product. Therefore the target population for the material included in this update for preventing uptake has been kept as people aged 24 and under, in line with evidence around age of smoking initiation.
Action on Smoking and Health	7	8; 21 - 22	The scope includes opt out referral for pregnant women so should cover all smokers not just those who ask for help to stop smoking.	Thank you for this comment. The phrase "who want to stop smoking" has been removed so the population is all women who are planning a pregnancy, are pregnant, or who have a child aged under 12 months.
Action on Smoking and Health	8	14 - 20	The scope should make clear that all healthcare settings are included – and then go on to specify as examples the list given.	Thank you for this comment. Healthcare settings, although they will be included in the final guidance in recommendations which are carried forward, are not among the settings for which recommendations are

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				being updated in relation to prevention. Therefore they are not included in this list.
Action on Smoking and Health	8	8	Adults aged 25 and over should not be excluded from the 'preventing uptake and promoting quitting' strand.	Thank you for this comment. The subheading "prevention and promotion" has been amended to "preventing uptake". "Promoting quitting" does not form part of this update so it has been removed from the subheading. However, material from the original guidelines on promoting quitting will be retained and will form part of the final product. Therefore the target population for the material included in this update for preventing uptake has been kept as people aged 24 and under, in line with evidence around age of smoking initiation.
Action on Smoking and Health	8	12	The scope should include entertainment media under 'preventing uptake and promoting quitting' see comment 6.	Thank you for this comment. Online and digital channels are listed as settings - these include social media, television, mobile apps and other settings which should cover 'entertainment media'.
Action on Smoking and Health	9	25 - 28	There has been a dramatic decline in smoking prevalence in school aged children in recent years which is likely to have a significant impact on how effective and cost-effective school based interventions are likely to be. For that reason all school-based interventions need to be updated. Reference: Smoking, Drinking and Drug Use among young people in	Thank you for this comment. A surveillance review was conducted for PH23 which searched for new evidence on all recommendations, including school-based interventions. No evidence was identified which would change current recommendations with the exception of smokefree class competitions. Insufficient additional evidence has been identified through surveillance or through consultation to update the recommendations on other types of

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			England 2016.NHS Digital, September 2017. Chapter 2 tables – smoking prevalence. Table 2.3	school-based prevention interventions. Despite a change in smoking prevalence in children, these interventions are likely to remain cost-effective and therefore the related recommendations will not be updated. Please see the surveillance report here: https://www.nice.org.uk/guidance/ph23/evidence/revi-ew-decision-2013-pdf-546068269 .
Action on Smoking and Health	10	19 - 20	See general comment 1 above that heated tobacco products should not be included in the scope.	Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include 'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.
Action on Smoking and Health	11	9 to 13	It is not clear why these interventions in schools are not being reviewed, when Smokefree class competitions are. (see also comment 18). It is essential that the cost-effectiveness of these interventions is assessed, and long term outcome data provided, since measures targeting children generally gain political support, and can often squeeze out more cost-effective options as a result. We therefore need to know whether these measures represent the best value	Thank you for your comment. A surveillance review was conducted for PH23 which searched for new evidence on all recommendations, including school-based interventions. No evidence was identified which would change current recommendations with the exception of smokefree class competitions. Please see the surveillance report here: https://www.nice.org.uk/guidance/ph23/evidence/revi-ew-decision-2013-pdf-546068269 .

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			<p>for money in comparison with other tobacco control measures, not just those involving schoolchildren.</p> <p>This issue comes up again on page 16 section 3.4 lines 9-16 on economic aspects and again in section 5 on key issues and draft questions.</p>	<p>Insufficient additional evidence has been identified to update the recommendations on other types of school-based prevention interventions.</p> <p>NICE's preferred approach is to undertake a full incremental analysis where possible. However, this approach and likewise the development of a league table, may not be appropriate given the disparate nature of tobacco control measures that are likely to be covered by the guideline and difference in methods used to assess them. Take the following three interventions as an example:</p> <p>Intervention A: NRT + GP advice vs usual care (undefined)</p> <p>Intervention B: mass media campaign aimed at adults who smoke vs background quit rate</p> <p>Intervention C: school based prevention programme vs usual practice (undefined)</p> <p>A full incremental analysis would involve comparing interventions A, B and C sequentially in rank order of effectiveness (or cost). This assumes interventions A, B and C are mutually exclusive but there is nothing to say that is the case so a commissioning body could decide to fund all three.</p>

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				<p>Although a league table of ICERs for these interventions could be created, differences in settings, population groups, comparators and in the case of smoking prevention – outcomes - would make it difficult to interpret in any meaningful way. There are other important considerations too such as the quality of evidence and uncertainty around the estimates, the size of the population likely to benefit and the impact on inequalities. In the case of the latter, if the goal is to reduce health inequalities, interventions that work best for the most disadvantaged groups might be more costly and could reduce the health gain achieved in the population as a whole. The following sets out some of the issues identified when league tables were first being discussed see https://www.sciencedirect.com/science/article/pii/S027795369390315U.</p>
Action on Smoking and Health	12	17 - 18	The scope needs to include reviewing the recommendation that smokers in acute, maternity and mental health services are referred to stop-smoking services. The UK model has been stand alone specialist stop-smoking services but there is growing evidence that provision of services within secondary care settings can be highly effective in promoting quitting (see Ottawa	Thank you for this comment. The design of service provision is outside of the scope of this referral and will not be covered by this guideline.

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NICE guideline on tobacco suite: prevention, cessation and harm reduction (update)

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			model http://tobaccocontrol.bmj.com/content/26/3/293) Furthermore there is no longer universal access to stand alone specialist services and therefore it is crucial that these recommendations are reviewed to ensure that smokers have access to the treatment they need.	
Action on Smoking and Health	13	14	It is not clear why shisha is excluded?	Thank you for this comment. Shisha will now be included in this update, and will be included in reviews which consider smoked tobacco.
Action on Smoking and Health	13	22	The scope currently needs to include reviewing service models (see also 21 above). The UK model has been for stand alone services but there is growing evidence that provision of services within secondary care settings can be highly effective in promoting quitting (see Ottawa model http://tobaccocontrol.bmj.com/content/26/3/293) Furthermore there is no longer universal access to such services and therefore it is crucial that these recommendations are reviewed to ensure that smokers have access to the treatment they need.	Thank you for this comment. The design of service provision is outside of the scope of this referral and will not be covered by this guideline.
Action on Smoking and Health	16	17 - 27	See comment 3 and 4	Thank you for this comment. Please see our response to the comment you reference.
Action on Smoking and Health	17	7 to 10	See comments 18 and 20.	Thank you for this comment. Please see our response to the comment you reference.

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Action on Smoking and Health	17	11 to 13	See comment 7.	Thank you for this comment. Please see our response to the comment you reference.
Allen Carr's Easyway to Stop Smoking	General	General	A fresh focus should be applied to alternative means of quitting smoking. The fact that the world's best-selling quit smoking book (of all time, in all countries) is ignored by NICE is strange. It would cost a few pounds per smoker to issue the book to smokers in the UK. It does no harm and is incredibly popular (15 million copies sold worldwide – mostly as a result of word of mouth recommendation).	Thank you for this comment. The guideline will consider in the first instance published trial evidence on effectiveness (and other outcomes) of interventions. A surveillance review was conducted for each guideline to be included in the final guidance. Areas for which evidence was identified which would change current recommendations are included in the scope. Other areas will be retained but not updated. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/evidence
Allen Carr's Easyway to Stop Smoking	10	Line 2 Cessation and harm reduction	Allen Carr's Easyway to Stop Smoking programme (group and one to one seminars) should be included as a means of cessation. There are 2 RCTs about to conclude which compare the method to the current best practise in the UK and Republic of Ireland	Thank you for this comment. Behavioural interventions for stopping smoking are covered in NG92 which was updated and published in 2018, and these recommendations will be retained. NG92 recommends that behavioural support (individual and group) are available for adults who smoke (recommendation 1.3.1). This would not be updated unless evidence which may change this recommendation emerges.
ASH Scotland	General	General	ASH Scotland opposes the inclusion of heated tobacco products (HTPs) in this guideline's scope.	Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat

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			<p>The tobacco industry has a long history of using smokeless tobacco (such as snus) to promote tobacco addiction, and has sold them as useful “for when you can’t smoke”. HTPs are a product category driven almost entirely by existing transnational tobacco companies which have substantial business interests in promoting the continued sale of tobacco. For these reasons, industry cannot be allowed to present itself as a stakeholder in discussions of public health.</p> <p>There is presently no independent evidence that HTPs can help smokers quit conventional tobacco products, and there is little evidence on their health effects. Other smokeless tobacco products (such as chewing tobacco and betel nut) have been shown to have serious negative effects on health.</p> <p>It should be noted that HTPs are tobacco products, not e-cigarettes, and that a clear distinction should be maintained between products which contain a suspension of nicotine and flavourings and those which contain tobacco in order to maintain clear public awareness of the harmfulness of tobacco products.</p>	<p>not burn’ products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include ‘heat not burn’ products in the final scope for the updates to the suite of Tobacco guidelines.</p>

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			We append our referenced briefing paper on this topic, which collates recent peer reviewed evidence.	
ASH Wales	10	8	<p>The draft scope currently excludes the use of financial incentives to help young disadvantaged smokers to quit, despite evidence existing to show that financial incentives may be very effective for this group of smokers and are likely to be cost-effective.</p> <p>ASH Wales ran a project for a year and half, which provided intensive smoking cessation programmes that lasted around 10 to 12 weeks, for groups of vulnerable young people from disadvantaged communities from August 2016 to February 2018.</p> <p>Given the lack of engagement and poor attendance exhibited by many of the young people targeted by the program, sessions included an incentive/competition element to enhance participation and encourage participants to quit. Participants competed within teams and/or individually to achieve reduced CO scores at the end of the programme relative to the scores recorded at the start. Successful teams/individuals were then offered a prize, such as a meal out or bowling as form of financial incentive for quitting. In addition, the quit smoking advice and support offered during the sessions were interspersed with fun, interactive, activities,</p>	<p>Thank you for this comment. A surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified on incentives for cessation which would change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence</p> <p>In addition, the majority of the evidence identified is related to pregnant women. Therefore the scope of this update is limited to pregnant women. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.</p>

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			<p>including cooking, film making, arts and crafts and elements of CBT were incorporated into each session to help young participants deal with outside stressors in a more positive way, thereby making it easier for them to focus on quitting smoking.</p> <p>The program was very successful. 494 smokers participated in the program, 96% (475) participants said that they increased their knowledge around the harms of smoking and 68% of these (337) made a quit attempt. 61% of those that made a quit attempt (205) quit smoking after 4 weeks, measured as CO score<7. 84% of those that made a quit attempt (284) quit after 4 weeks, when measures as CO score<10, which greatly surpassed an original target of 50%. For the purposes of this project, a successful quit was originally identified by a CO reading of 10ppm or less, which conforms with NICE guidelines and the CO validated quit level used by Stop Smoking Wales. However, it has been suggested that a lower CO score of 7ppm or less should be used to signify a successful quit among adolescents given their lower lung capacity relative to adults, which is what was used to assess the program.</p> <p>It may be useful to compare the results of this program to the latest figures for all services in Wales that help patients to stop smoking (pharmacy, GP, Stop Smoking</p>	

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			Wales and in-house hospital-based services). The latest figures show an average (CO <10) quit rate after 4-weeks of 42.1% in 2016-17 for Wales and estimates that 2.91% of smokers in Wales made a quit attempt via smoking cessation services where financial incentives are not used. Therefore, it is evident that the use of financial incentives may have had a strong positive effect on quit rates, with a 19% percentage point increase in the official quit rate for program compared to the average across services in Wales. It is also important to note that, deprived smokers generally have lower short-term quit rates than less deprived smokers, and are much more likely to smoke in the first place. These financial incentives are likely to be cost-effective. The core program cost £67,000 a year, which amounts to £489 per quit (when measuring a quit rate using a CO score <7ppm), and £352.60 per quit (when measuring a quit rate using a CO score <10ppm).	
ASH Wales	10	8	Discussions in the 2018 'stop smoking interventions and services' guidelines recommended by NICE, on the cost-effectiveness of various interventions state: 'The effectiveness evidence from 30 different interventions was modelled. Intervention costs ranged from £19 to £763 per person. Intervention effectiveness in terms of people who quit ranged from 9 to 47% and	Thank you for this comment. The intervention details you provide will be considered if they meet the criteria for the review questions. All evidence meeting the criteria will be presented to the committee.

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			<p>they were all highly cost effective at a threshold of £20,000 per quality-adjusted life year. Additionally, a 2-way scenario analysis that varied the quit rate associated with an intervention and the cost of the intervention showed that even when the lowest quit rate identified in the effectiveness studies (9%) is combined with the most expensive intervention cost (£763 per person), the intervention is still cost effective'.</p> <p>Given that each successful quit achieved by the ASH Wales project essentially cost £489 (or an intervention cost of £329 per person, with a quit rate of 61%), this easily surpasses the cost-effective threshold of £20,000 per quality-adjusted life year, or an intervention cost of £763 per person, with a quit rate of 9%, that these guidelines consider to be cost-effective. Therefore this program would be considered to be cost-effective when using these NICE guidelines.</p>	
Association of Directors of Public Health	General	General	<p>The scope should not include heat-not-burn products. Awareness and usage of heated tobacco products is low and this is likely to continue to be the case during the time the committee is reviewing the evidence. There is little evidence of these products effectiveness in supporting quitting, and what there is has been conducted by the tobacco industry and is not independent.</p>	<p>Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include</p>

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				'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.
Association of Directors of Public Health	General	General	The scope should include incentives for groups in addition to pregnant women, and needs to consider whether Nicotine Replacement Therapy (NRT) products should be free as part of specialist cessation services, means tested or available in keeping with "free prescriptions test".	<p>Thank you for this comment. NICE is concerned with working out what works - what is effective to improve or protect health. The free provision of NRTs is outside of the scope of this commission. The effectiveness, cost effectiveness, safety and acceptability of NRTs in pregnancy will be evaluated in this guideline and recommendations about their use made accordingly.</p> <p>A surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified on incentives for cessation which would change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence</p> <p>In addition, the majority of the evidence identified is related to pregnant women. Therefore the scope of</p>

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				this update is limited to pregnant women. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.
Association of Directors of Public Health	General	General	The scope could also include a review of the evidence of recommended timeframes for re-enrolment of clients in stop smoking services following a failed quit attempt; in particular, smokers experiencing social and economic disadvantage, long term conditions and / or comorbidities.	Thank you for this comment. However, insufficient evidence has been identified through consultation to merit this additional area.
British Thoracic Oncology Group	General	General	<p>The inclusion of heat not burn products:</p> <p>We feel that heat not burn products should be included in the scope of this review. These are new products that may cause considerable confusion to the public and healthcare professionals as to whether they will be of benefit and cause less harm than burnt tobacco. Their use in children all be especially important to understand and to make recommendations. Currently little if any data is collected from routine national surveys about the use of heat not burn products to be able to assess trends in usage in the UK. The recent review of e-cigarettes published in 2018 considered heat not burn products but as discussed in that review there is currently limited data available that has been produced independently from the manufacturers of these products.</p>	Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include 'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.

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			McNeill A, Brose LS, Calder R, Bauld L & Robson D (2018). Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England	
British Thoracic Oncology Group	General	General	<p>The inclusion of incentives:</p> <p>Financial incentives to aid in smoking cessation has been studied in the UK and therefore clear recommendations can now be made by NICE in this area. The question and study of incentives in other specific groups it is less clear however it would be useful to review the evidence on the use of incentives in hard to reach groups which could include those with mental health disorders, the homeless, the incarcerated and those who are the most socio-economically deprived who have a higher prevalence of smoking</p>	<p>Thank you for this comment. A surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified on incentives for cessation which would change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence</p> <p>In addition, the majority of the evidence identified is related to pregnant women. Therefore the scope of this update is limited to pregnant women. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.</p>
British Thoracic Oncology Group	General	General	<p>Cost saving recommendations:</p> <p>Pretty much any intervention that prevents smoking uptake or leads to smoking cessation will be cost saving</p>	<p>Thank you for this comment. NG92 recommends an opt-out referral approach for people planning surgery. This recommendation will be carried forward into the new guidance. A surveillance review was</p>

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			<p>if not in the short term (less than 1 year) will almost certainly be in the long-term and this has been demonstrated in numerous economic evaluations from NICE accompanying previous tobacco related guidelines.</p> <p>The glaring omission from the scope of this guideline is not reviewing the evidence opt-out referral for all patients accessing the NHS and instead only focussing on pregnancy related opt- out referral. Opt-out referral has been shown to double smoking quit rates in studies in the United Kingdom and the United States. It has also been shown to reduce hospital readmissions, emergency room attendances and visits to the general practitioners as well as reducing mortality at one year and two years in a study published in Canada(The Ottawa Model of Smoking Cessation). A report to be published by the Royal College of physicians in June 2018 called 'Hiding in plain sight: treating tobacco dependency in the NHS' has performed a detailed economic analysis on the costs of tobacco related disease in secondary care and estimated these to be in the region of £1 billion per year of avoidable costs in current smokers. In addition this same report has estimated the net cost saving of treating all smokers using secondary care to be £60 million assuming a 27% uptake on the offer of treatment.</p>	<p>conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified on opt-out referral pathways which would change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence. Additionally,</p> <p>In addition, insufficient evidence has been identified through the consultation process to warrant a new review in this area.</p>

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British Thoracic Society	General	General	The British Thoracic Society is grateful for the opportunity to comment on the scope of this important guideline. We welcome the amalgamation of the separate pieces of guidance into one document.	Thank you for this comment.
British Thoracic Society	General	General	Heat and burn products- these products should be not be recommended for the below reasons: · Given much of the harm caused by smoking is a result of the by-products of tobacco combustion it is possible that heat not burn products will be proved to be less harmful than smoked tobacco, as they do not possess the combustion element. At present however there is insufficient evidence to draw such conclusion. Almost all the research on heat not burn that currently exists has been undertaken by the tobacco industry, hence there will be an element of bias. In addition, there is some evidence to suggest the by-products of heat not burn contain elements that are the same as conventional tobacco cigarette smoke (Auer R, Concha-Lozano N, Jacot-Sadowski I, Cornuz J, Berthet A. Heat-Not-Burn Tobacco Cigarettes: Smoke by Any Other Name. JAMA Intern Med. 2017 Jul 1;177:1050-1052.). · Toxicology studies have shown that heat not burn products release measurable levels of carcinogenic compounds (carcinogenic aldehyde compounds, including formaldehyde, acetaldehyde, and acrolein), though at levels lower than conventional tobacco	Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include 'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.

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			<p>cigarettes, and therefore not completely risk free (Auer R, Concha-Lozano N, Jacot-Sadowski I, Cornuz J, Berthet A. Heat-Not-Burn Tobacco Cigarettes: Smoke by Any Other Name. JAMA Intern Med. 2017 Jul 1;177:1050-1052. Ruprecht AA, De Marco C, Saffari A et al. Environmental pollution and emission factors of electronic cigarettes, heat-not-burn tobacco products, and conventional cigarettes. Aerosol Sci Technol 2017; 51: 674-84).</p> <p>· Nicotine delivery to the smoker has been shown to play an important role in the ability to any harm reduction product to successfully substitute smoking. The heat not burn products have been shown to deliver significant levels of nicotine, the highly addictive component of smoking, therefore unlikely to lead to harm reduction (Farsalinos KE, Yannovits N, Sarri T, Voudris V, Poulas K. Nicotine delivery to the aerosol of a heat-not-burn tobacco product: comparison with a tobacco cigarette and e-cigarettes. Nicotine Tob Res. 2017 Jun 16).</p>	
British Thoracic Society	General	General	<p>· In terms of smoking prevention, heat not burns products may be a potential gateway to tobacco smoking as there is an increasing number people within the population has tried these products and many of them have never smoked cigarettes. Therefore these products are unlikely to lead to a reduction in risk taking behaviours and prevent smoking uptake (Liu X, Lugo A,</p>	<p>Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include</p>

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			Spizzichino L, Tabuchi T, Pacifici R, Gallus S. Heat-not-burn tobacco products: concerns from the Italian experience. Tob Control. 2018 Jan 26.).	'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.
British Thoracic Society	General	General	This paper suggests even at the lower temperature products of combustion can be found in this product [Davis B, Williams M, Talbot P iQOS: evidence of pyrolysis and release of a toxicant from plastic, Tobacco Control http://tobaccocontrol.bmj.com/content/early/2018/02/20/tobaccocontrol-2017-054104] Despite the evidence on falling use of eCig amongst teenagers and no overall increase in smoking rates – we are concerned about the effects on young adults. The Juul vape product is subtly different type of eCig in that it heats nicotine salt which can achieve high blood levels of nicotine.	Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include 'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.
British Thoracic Society	General	General	Apart from targeting pregnant women, it may be worth broadening the incentive to encompass patients with COPD that are current smokers with prior history of hospital admissions within the last 12 months. It is estimated each year the UK spends £1.9 billion in COPD care (Trueman, D. et al. Estimating the economic burden of respiratory illness in the UK. British Lung Foundation. 2017.). COPD admissions are also very costly. It has previously been shown that smoking cessation can lead to a significant (approximately 43%) reduction in COPD	Thank you for this comment. A surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified on incentives for cessation which would change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-

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			hospitalisations (Godtfredsen NS, et al. Risk of hospital admission for COPD following smoking cessation and reduction: a Danish population study. Thorax 2002;57(11):967-72.), reduction in disease progression (Fletcher C, Peto R. BrThe natural history of chronic airflow obstruction. Med J 1977; 1: 1645-8.) and mortality (Public Health England. Chronic smoking-related lung disease blights over 1 million lives in England. Available from: https://www.gov.uk/government/news/chronic-smoking-related-lung-disease-blights-over-1-million-lives-in-england . [Accessed June 2018]).	ph48-4424254962/chapter/Surveillance-decision?tab=evidence In addition, the majority of the evidence identified is related to pregnant women. Therefore the scope of this update is limited to pregnant women. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.
British Thoracic Society	General	General	There is also evidence to demonstrate that smoking cessation initiated during hospitalisation followed by post-discharge support can lead to a significant reduction in cumulative incidence of mortality and all cause re-hospitalisation. Therefore this can play a significant part in improving patients quality of life and reducing the economic burden exerted by the 'revolving door' patients (Kerri A Mullen, Douglas G Manuel, Steven J Hawken, Andrew L Pipe, Douglas Coyle, Laura A Hobler, Jaime Younger, George A Wells, and Robert D Reid. Effectiveness of a hospital-initiated smoking cessation programme: 2-year health and healthcare outcomes. Tob Control. 2017 May; 26(3): 293–299.).	Thank you for this comment. Recommendation 3 of PH48 includes advice about support post-discharge after hospitalisation. While this recommendation is not being updated, it will be retained in the final product: <i>"In addition, for people admitted to a secondary care setting:</i> <i>Provide immediate support if necessary, and otherwise within 24 hours of admission.</i> <i>Provide support (delivered in the setting) as often and for as long as needed during admission.</i>

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NICE guideline on tobacco suite: prevention, cessation and harm reduction (update)

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				<i>Offer weekly sessions, preferably face-to-face, for a minimum of 4 weeks after discharge. If it is not possible to provide this support after discharge, arrange a referral to a local stop smoking service."</i>
British Thoracic Society	General	General	We remain concerned about the dis-investment in smoking cessation services: e.g. the onward ref for cessation from Hospital to Community Smoking cessation service - after which a smoker might even need to attend primary care to be issued with a prescription (for champex etc). Keir Lewis' paper from 2009 showed v poor follow through from hospital initiated refs to community based services (7% in a group that got a lot more input than an average patient would). Lewis, K. Durgan, L. & Edwards, V. (2009). Can smokers pass from a hospital-based to a community-based stop-smoking service? An open-label, randomised trial comparing three referral schemes. J Tob Nicotine Res 11, 756-764. PH48 wants 30% of smokers referred but some areas don't have a cessation service to ref to currently. There have been reports from Primary care of GPs of letters from the CCG where they have attempted to initiate cessation products themselves as the funding for cessation services/public health comes from Local authority budgets. There are reports of similar occurrences in secondary care where there were	Thank you for this comment. NICE is concerned with working out what works - what is effective to improve or protect health. Changes to budgets and investment in cessation services are outside of NICE's remit and is therefore not something NICE would make recommendations on.

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			<p>concerns if we started issuing products before discharge the external smoking cessation service might not get the Quit money.</p> <p>The economic argument for smoking prevention and cessation should be clearly highlighted and the Ottawa data highlighting it as a treatment in terms of all cause mortality and preventing readmissions.</p>	
Cancer Research UK	General	General	<p>In response to question 1: Given the limited evidence on and usage of heated tobacco products, CRUK does not believe it is necessary for the revised NICE guidance to include them in its scope. If these tobacco products are mentioned, CRUK strongly recommends that it is only to note that they are not considered as a cessation or harm reduction tool, given that they include the use of tobacco and that there is no robust evidence for their effectiveness in helping people quit cigarettes. There is very little tobacco-industry independent research on heated tobacco products and it is still in the early stages of harm research.</p>	<p>Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include 'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.</p>
Cancer Research UK	General	General	<p>In response to question 3: Smoking cessation interventions are likely to be cost-saving, especially in the long-run. However, it may be more useful to assess an intervention based on its cost-effectiveness, especially in comparison to the cost-effectiveness of interventions used to treat common smoking-related diseases such as lung cancer, CVD and COPD.</p>	<p>Thank you for this comment. NICE's preferred approach is to undertake a full incremental analysis where possible. However, this approach and likewise the development of a league table, may not be appropriate given the disparate nature of tobacco control measures that are likely to be covered by the guideline and difference in methods used to assess</p>

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				<p>them. Take the following three interventions as an example:</p> <p>Intervention A: NRT + GP advice vs usual care (undefined)</p> <p>Intervention B: mass media campaign aimed at adults who smoke vs background quit rate</p> <p>Intervention C: school based prevention programme vs usual practice (undefined)</p> <p>A full incremental analysis would involve comparing interventions A, B and C sequentially in rank order of effectiveness (or cost). This assumes interventions A, B and C are mutually exclusive but there is nothing to say that is the case so a commissioning body could decide to fund all three.</p> <p>Although a league table of ICERs for these interventions could be created, differences in settings, population groups, comparators and in the case of smoking prevention – outcomes - would make it difficult to interpret in any meaningful way. There are other important considerations too such as the quality of evidence and uncertainty around the estimates, the size of the population likely to benefit and the impact on inequalities. In the case of the latter, if the goal is to reduce health inequalities, interventions that work best for the most</p>
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				disadvantaged groups might be more costly and could reduce the health gain achieved in the population as a whole. The following sets out some of the issues identified when league tables were first being discussed see https://www.sciencedirect.com/science/article/pii/S027795369390315U .
Cancer Research UK	General	General	The headings under which the information in this scoping document is presented could be clearer. We support ASH's suggestion to change these from 'prevention and promotion' / 'cessation and harm reduction' to 'preventing uptake and promoting quitting' / 'treating tobacco dependency'.	Thank you for this comment. The subheading "prevention and promotion" has been amended to "preventing uptake". "Promoting quitting" does not form part of this update so it has been removed from the subheading. However, material from the original guidelines on promoting quitting will be retained and will form part of the final product. The subheading "cessation and harm reduction" has been amended to "treating tobacco dependence". This will continue to include review questions about quitting smoking and about reducing harm from smoking.
Cancer Research UK	2	24	Reviewing evidence for opt-out referral pathways should go beyond those aimed at pregnant women only, for example for surgical or mental health patients.	Thank you for this comment. NG92 recommends an opt-out referral approach for people planning surgery. This recommendation will be carried forward into the new guidance. A surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was

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				<p>identified on opt-out referral pathways which would change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence. Additionally,</p> <p>In addition, insufficient evidence has been identified through the consultation process to warrant a new review in this area. Therefore the scope of this update is limited to pregnant women. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.</p>
Cancer Research UK	2	25	Evidence should be reviewed for the use of e-cigarettes (in addition to NRT) in helping women who are pregnant or planning a pregnancy etc. to quit. Clinicians and patients would benefit from further guidance as e-cigarettes are becoming an increasingly-used tool for quitting.	Thank you for this comment. The draft scope outlines draft review questions, one of which is a review question addressing the effectiveness, cost effectiveness, safety and acceptability of NRTs and e-cigarettes (licensed or consumer) at helping women who smoke to quit immediately before or during pregnancy, or following childbirth.
Cancer Research UK	5	4 to 6	Prevention and promotion interventions should not be limited to people aged 24 and under. Adults smokers have an influence on youth uptake of smoking, so	Thank you for this comment. The subheading "prevention and promotion" has been amended to "preventing uptake". "Promoting quitting" does not

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			promoting quitting to adult smokers is an important intervention for youth cessation.	<p>form part of this update so it has been removed from the subheading. However, material from the original guidelines on promoting quitting will be retained and will form part of the final product. Therefore the target population for the material included in this update for preventing uptake has been kept as people aged 24 and under, in line with evidence around age of smoking initiation.</p> <p>We recognise the interdependencies between cessation and prevention. A draft key issue looks specifically at mass media cessation interventions and their denormalising effects:</p> <p>"Are smoking cessation mass media campaigns aimed at adults effective and cost effective in preventing the uptake of smoking among children and young people?"</p> <p>Additionally, the areas of cessation which will be considered will, as you say, likely impact on prevention.</p>
Cancer Research UK	6	19 - 23	Evidence on cost-effectiveness will vary by area and study group, and so interventions may affect different social groups differently. It may not be that a one-size fits all approach will work.	Thank you for this comment. Sensitivity analyses are used to assess the impact of uncertainties in parameter values on the results produced by the economic model. They can also be used to explore

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				the impact of differential effectiveness and differences in costs. It is also usual practice that guidelines specify that local demographics and other contextual factors should be taken into account when implementing recommendations.
Cancer Research UK	7	9	An exclusion for pregnant women who might also be using maternity services may need to be made here, as they are captured by lines 21-23.	Thank you for this comment. As some review questions will have a whole population approach, pregnant women would also be considered for these questions. Separate questions will consider pregnant women only, which is why there are separate mentions here.
Cancer Research UK	7	5 to 6	See comment 6	Thank you for this comment. Please see our response to the comment you reference.
Cancer Research UK	7	22	Pregnant women are part of the opt-out referral system so they may not necessarily identify as women 'who want to quit smoking'. It could be clearer that these guidelines are for all pregnant women, not just those who actively want to quit.	Thank you for this comment. The phrase "who want to stop smoking" has been removed so the population is all women who are planning a pregnancy, are pregnant, or who have a child aged under 12 months.
Cancer Research UK	8	8	See comment 6	Thank you for this comment. Please see our response to the comment you reference.
Cancer Research UK	10	19 - 20	As outlined in comment 1, CRUK's view is that heated tobacco products should not be considered as a tool for harm reduction, given that they contain tobacco and that there is a lack of evidence on their effectiveness.	Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of

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				stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include 'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.
Cancer Research UK	11	9 to 13	All school-based interventions should be reviewed for cost-effectiveness (given changes to youth smoking rates in recent years) and compared with the cost-effectiveness of other interventions.	Thank you for this comment. A surveillance review was conducted for PH23 which searched for new evidence on all recommendations, including school-based interventions. No evidence was identified which would change current recommendations with the exception of smokefree class competitions. Insufficient additional evidence has been identified through surveillance or through consultation to update the recommendations on other types of school-based prevention interventions. Despite a change in smoking prevalence in children, these interventions are likely to remain cost-effective and therefore the related recommendations will not be updated. Please see the surveillance report here: https://www.nice.org.uk/guidance/ph23/evidence/review-decision-2013-pdf-546068269 .
Cancer Research UK	12	17 - 18	Given the decreasing availability of Stop Smoking Services offering universal access, evidence for specialist smoking cessation support offered within primary and secondary care settings should be reviewed and included within this scope of the guidance.	Thank you for this comment. The design of service provision is outside of the scope of this referral and will not be covered by this guideline.

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Cancer Research UK	13	14 - 15	CRUK is of the view that shisha should be included within the scope of this guidance, given the harms of shisha usage.	Thank you for this comment. Shisha will now be included in this update, and will be included in reviews which consider smoked tobacco.
Cancer Research UK	13	26 - 27	It is understandable that NHS Stop Smoking Services are not being included because they are now in the remit of local authorities. But it would be useful to review the ability of Stop Smoking Services to respond to fluctuations in demand, and (if possible) consider the impact that cuts have had on this ability.	Thank you for this comment. The recommendation on fluctuations in demand was made in advance of the smoking in public places ban, and so is out of date. The ability of stop smoking services to respond to fluctuations in demand was not part of the referral to NICE for this update, and the impact of cuts on services is outside of NICE's remit and is therefore not something NICE would make recommendations on.
Cancer Research UK	17	12 to 13	When looking at the prevalence of tobacco use among children and young people, there needs to be a clear differentiation in the evidence between trying/occasional vs regular use. In relation to e-cigarettes, any evidence must have a good control group.	Thank you for this comment. This will be taken into account when discussions with committee are had to decide definitions of smokers and non-smokers, and appropriate control groups.
Cancer Research UK	18	15	A range of interventions and quitting methods should be considered where possible, not just Stop Smoking Services.	Thank you for this comment. This draft review question has been amended to remove specific reference to quitting by stop smoking services only, and now includes quitting by any method. This may be amended based on input from the committee for this topic.

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Cancer Research UK	18	18	Both acceptability and awareness of different smoking cessation measures and interventions should be considered.	Thank you for this comment. Awareness of the interventions is outside of the scope of this referral. However, if this emerges as a factor in acceptability it will be recorded and discussed by the committee.
Central and North West London NHS Foundation Trust	General	General	The scope rightly includes 'heat not burn' products which are very new on the commercial market and I am aware of only one scientific and authoritative study which I believe was carried out in connection with the UK Tobacco Collaborating Centre so NICE will already be aware of it. However, this study was only able to provide general indications and not able to state what the comparative levels of harm were with reliable certainty, when compared with e-cigarettes. This information is urgently needed for health workers in order to advise patients on relative harm reduction approaches.	Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include 'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.
Central and North West London NHS Foundation Trust	General	General	It is very welcome news that NICE will be reviewing the impact of economic pressures on the delivery of smoking cessation services, and the responsibilities of councils – many of whom have had to withdraw funding from smoking cessation services.	Thank you for this comment. NICE is concerned with working out what works - what is effective to improve or protect health. The impact of budget changes is outside of NICE's remit and is therefore not something NICE would make recommendations on.
Central and North West London NHS Foundation Trust	General	General	Also, a positive factor is that users of secondary mental health services will feature as a priority group for smoking cessation.	Thank you for this comment.

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Central and North West London NHS Foundation Trust	General	General	If the guidelines also reinforce the standards required from hospital services with regard to smoking cessation and management of smoke free grounds, that would be advantageous as there is no evidence that this is being recognised as a responsibility for routine practice, despite the recent advice of PHE and the TCC.	Thank you for this comment. Recommendations on smoke-free policies and smoke free secondary care services are being retained but not updated (PH48).
Central and North West London NHS Foundation Trust	General	General	Whilst pleased that there seems to be more emphasis on prevention, I feel this needs to be stressed far more. Prevention should be aimed at all age groups, as although young people are of great concern, they are influenced by parents/older family members and celebrity role models.	Thank you for this comment. We recognise the interdependencies between cessation and prevention. A draft key issue looks specifically at mass media cessation interventions and their denormalising effects: "Are smoking cessation mass media campaigns aimed at adults effective and cost effective in preventing the uptake of smoking among children and young people?" Additionally, the areas of cessation which will be considered will likely impact on prevention. Prevention has been limited to those aged 24 and under in line with evidence around age of smoking initiation.
Central and North West London NHS	General	General	The extended family of a pregnant woman should be included (encouraging cessation/abstinence), with a routine opt-out consultation post delivery to encourage continued abstinence once the baby is born.	Thank you for this comment. The existing recommendations on partners of pregnant women and others in the household who smoke (PH26) and recommendations on providing information and

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Foundation Trust				advice for carers, family and other household members (PH48) will be retained but not updated due to a lack of new evidence to change these recommendations.
Central and North West London NHS Foundation Trust	General	General	SC should also be included as part of pre-conceptual care (family planning clinics?)	Thank you for this comment. Your comment mentions SC which we have assumed refers to smoking cessation. This update includes new questions on smoking cessation in pregnancy, in relation to opt-out referral pathways, incentives, NRT and e-cigarettes. The question on the effectiveness, cost effectiveness, safety and acceptability of NRT and e-cigarettes includes women 'immediately before' pregnancy, which includes those trying to conceive.
Central and North West London NHS Foundation Trust	General	General	Making Every Contact Count (MECC) interventions (including smoking/tobacco harm/nicotine addiction) should be routinely and opportunistically employed by ALL health professionals, as part of a holistic approach to improving health well-being.	Thank you for this comment. Making every contact count is a key approach which is implicit within the guidelines currently and will continue to be in the new guidance.
Central and North West London NHS Foundation Trust	General	General	PHSE lessons/social media campaigns should include the dangers of smoking /nicotine addiction (all types) along with education about other addictions. It is of concern that more young people claim to have tried e-cigarettes than there are smokers.	Thank you for this comment. Social media is included within the definition of mass media interventions, which will be considered for their effect on prevention in children and young people. Changes to curriculum are outside of the scope of this referral.

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Central and North West London NHS Foundation Trust	General	General	Youth workers should also be trained and expected to provide smoking cessation.	Thank you for this comment. Service delivery models are outside of the scope of this referral.
Central and North West London NHS Foundation Trust	General	General	Local authorities should be encouraged to establish smoke-free environments. In particular, remove smoking areas outside restaurants and pubs	Thank you for this comment. Smoking in public places and workplaces is covered by legislation and is outside of the scope of this referral.
Central and North West London NHS Foundation Trust	General	General	Offer incentives for reduced rates to local fitness facilities if manage to quit	Thank you for this comment. The effectiveness of financial and non-financial incentives for pregnant women will be considered in the reviews for this update.
Central and North West London NHS Foundation Trust	General	General	Also provision of more 'fitness parks' to encourage exercise as a diversionary activity	Thank you for this comment. Physical activity-related interventions for cessation are outside of the scope of this referral.
Central and North West London NHS Foundation Trust	General	General	Provision of local stop-smoking services should be mandatory, not a 'post-code lottery'. I feel Public Health should be within the auspices of the NHS – part of integrated working?	Thank you for this comment. Service delivery models are outside of the scope of this referral.

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Central and North West London NHS Foundation Trust	General	General	More emphasis should be given to the use of Varenicline to help smokers quit – particularly those chronically addicted to nicotine.	Thank you for this comment. The effectiveness of varenicline is outside of the scope of this referral with the exception of considering its effectiveness, cost effectiveness and safety in relation to e-cigarettes for cessation, and e-cigarettes and heat not burn products for harm reduction.
Central and North West London NHS Foundation Trust	General	General	If using e-cigarettes as a means of harm reduction quitting, advice on gradually reducing strength should be mandatory on packaging	Thank you for this comment. Packaging and information provided with e-cigarettes is outside of NICE's remit and is therefore not something NICE would make recommendations on.
Central and North West London NHS Foundation Trust	General	General	MHRA should be encouraged to finally licence approved e-cigarettes, or to say why not – do they have concerns about safety?	Thank you for this comment. Recommendations for the MHRA is outside of NICE's remit and is therefore not something NICE would make recommendations on.
Group for Research on Inequalities and Tobacco, University of Edinburgh	General	General	Heat Not Burn products- we think that these should be included in the scope of the guidance. While there is currently limited peer reviewed evidence on these products, this will increase over the next few years ie during the period that the guidance will be developed.	Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include 'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.

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Group for Research on Inequalities and Tobacco, University of Edinburgh	2	28	<p>We think that the scope of this should be expanded to include the use of incentives with other groups as well as pregnant women. In particular, their use with disadvantaged groups. Relevant recent references include:</p> <p>Halpern SD et al (2018) A pragmatic trial of e-cigarettes, incentives, and drugs for smoking cessation. NEJM, 23 May. Ormston R, van der Pol M, Ludbrook A, Amos A (2015) quit4u: the effectiveness of combining behavioural support, pharmacotherapy and financial incentives to support smoking cessation. Health Education Research, 30, 121-133. Cahill et al (2015) Incentives for smoking cessation. Cochrane Database Syst Rev.</p>	<p>Thank you for this comment. A surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified on incentives for cessation which would change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence</p> <p>In addition, the majority of the evidence identified is related to pregnant women. Therefore the scope of this update is limited to pregnant women. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.</p>
Group for Research on Inequalities and Tobacco, University of Edinburgh	4	1	<p>Should also highlight the national objective to reduce the inequality gap between those in routine and manual occupations and the general population. There have been four recent systematic reviews on the equity impact of tobacco control :</p> <p>Brown T, Platt S, Amos A (2014) Equity impact of interventions and policies to reduce smoking in youth: systematic review. Tobacco Control, 23, e98-e105. .</p>	<p>Thank you for this comment. The Equality Impact Assessment (EIA) document which sits alongside the scope and is updated throughout the development of the guideline looks in detail at issues related to equality. The disproportionate effect of smoking on routine and manual groups is detailed in that document, which was consulted on along with the scope.</p>

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NICE guideline on tobacco suite: prevention, cessation and harm reduction (update)

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			Brown T, Platt S, Amos A (2014) Equity impact of European individual-level smoking cessation interventions to reduce smoking in adults: a systematic review. <i>European Journal of Public Health</i> , 24, 551–556. Brown T, Platt S, Amos A (2014) Equity impact of population-level interventions and policies to reduce smoking in adults: a systematic review. <i>Drug and Alcohol Dependence</i> , 139, 7–16. Hill S, Amos A, Clifford D, Platt S (2014) Impact of tobacco control interventions on socioeconomic inequalities in smoking: review of the evidence. <i>Tobacco Control</i> , 23, e89–e97.	
Group for Research on Inequalities and Tobacco, University of Edinburgh	5	4 to 6	We welcome the extension of the prevention guidelines to include young people up to the age of 24 years, as national surveys show that smoking uptake in England continues up until this age.	Thank you for this comment.
Group for Research on Inequalities and Tobacco, University of Edinburgh	9	25 - 28	It is not clear why only adult led school interventions are included and why these are restricted to smoke-free class competitions. A recent Cochrane Review found that this approach was ineffective: · Hefler M, Liberato SC, Thomas DP. Incentives for preventing smoking in children and adolescents (2017) <i>Cochrane Database of Systematic Reviews</i> , Issue 6. Art. No.: CD008. http://onlinelibrary.wiley.com/doi/10.1002/146518	Thank you for this comment. Cochrane reviews are included in the types of evidence which NICE would consider in order to make recommendations which are based on the most recent evidence. Evidence which finds that interventions are not effective are equally as useful for decision-making as finding ones that are. A surveillance review was conducted for PH23 which

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			<p>58.CD008645.pub3/epdf</p> <p>· NICE (2013).School-based interventions to prevent the uptake of smoking among children and young people: Evidence Update 38.http://www.evidence.nhs.uk/evidence-update-38</p> <p>Thomas RE, McLellan J, Perera R (2013). School-based programmes for preventing smoking (Review). The Cochrane Database of Systematic Reviews, Issue 4. http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001293.pub3/pdf</p> <p>On peer-led approaches- a process evaluation of ASSIST was recently completed in Scotland, a report has been published and peer-reviewed papers will be published in the next year or so: Report: http://www.gov.scot/Publications/2017/03/6523 Research Findings: http://www.gov.scot/Publications/2017/03/4556</p>	<p>searched for new evidence on all recommendations, including school-based interventions. No evidence was identified which would change current recommendations with the exception of smokefree class competitions. Please see the surveillance report here: https://www.nice.org.uk/guidance/ph23/evidence/review-decision-2013-pdf-546068269.</p> <p>Insufficient additional evidence has been identified to update the recommendations on other types of school-based prevention interventions.</p>
Group for Research on Inequalities and Tobacco, University of Edinburgh	10	8 to 9	<p>See the point above about expanding incentives to consider other groups.</p>	<p>Thank you for this comment. Please see our response to the comment you reference.</p>

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Group for Research on Inequalities and Tobacco, University of Edinburgh	11	22 - 23	There have been several new studies on reducing children's exposure to secondhand smoke in the home eg Ratschen E, Thorley R, Jones L, Breton MO, Cook J, McNeill A, Britton J, Coleman T, Lewis S (2018) A randomised controlled trial of a complex intervention to reduce children's exposure to secondhand smoke in the home. Tobacco Control 27:155-162. Two papers from the Scottish First-Steps intervention using air quality measurements, led by Dr Sean Semple (Stirling University), are also currently under review.	Thank you for this comment. These references have been considered and discussed. There is insufficient evidence to change the existing recommendations made in PH26 about providing information about risks to the unborn child of smoking when pregnant; providing advice about the danger of other people's tobacco smoke; and offering partners who smoke help to stop using a multi-component intervention. Therefore this area has not been added to the scope for this update.
Hertfordshire County Council	General	General	It is our view that the scope for this review should not include Heat not Burn products, for several reasons: There is little evidence of these products effectiveness in supporting quitting, what there is has been conducted by the tobacco industry and is not independent, there seem to have been no RCT evidence or other good quality studies and this would mean there is not enough for the Committee to make a decision on. Awareness and usage of heated tobacco products is low and this is likely to continue to be the case during the time the committee is reviewing the evidence. At the same time, there is no consensus that heated tobacco being used instead of smoked tobacco is	Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include 'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.

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			<p>cessation of tobacco.</p> <p>As a local authority, our understanding is both we and NICE may be bound by the Framework convention for Tobacco Control, including Article 5.3. Accordingly, NICE would need in our view to review the Guidelines for implementation before considering how it handles data from the tobacco industry. This would make inclusion of heat not burn products problematic. We suggest that the current lack of independent evidence means further work would be premature at this point</p> <p>There will be intense controversy and possibly some reputational risk that would arise from considering heated tobacco products in this guidance given the situation above and this may well detract from the work which could usefully be done on the other aspects of the scope.</p> <p>We therefore recommend that heat not burn products are not included in the scope of this review</p>	
Hertfordshire County Council	General	General	<p>The scope should include incentives for groups in addition to pregnant women, and needs to consider whether Nicotine Replacement Therapy (NRT) products should be free as part of specialist cessation services, means tested or available in keeping with "free prescriptions test".</p>	<p>Thank you for this comment. NICE is concerned with working out what works - what is effective to improve or protect health. The free provision of NRTs is outside of the scope of this commission. The effectiveness, cost effectiveness, safety and acceptability of NRTs in pregnancy will be evaluated in this guideline and recommendations about their use made accordingly.</p>

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				<p>A surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified on incentives for cessation which would change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence</p> <p>In addition, the majority of the evidence identified is related to pregnant women. Therefore the scope of this update is limited to pregnant women. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.</p>
Improving Performance In Practice (IPIP) incorporating the Tobacco Control	General	General	<p>Question 1: consideration of inclusion of heated tobacco products in the scope.</p> <p>IPIP supports the view that heated tobacco products should not be included in the scope of this guidance because reports of their usage shows a low uptake and also there is a lack of independent (non-tobacco</p>	<p>Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include</p>

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Collaborating Centre			industry) evidence of the possible efficacy of these products in supporting quitting.	'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.
Improving Performance In Practice (IPIP) incorporating the Tobacco Control Collaborating Centre	2	20 - 21	The impact of e-cigarettes on smoking behaviour is important for those who do smoke as well as for those who do not.	Thank you for this comment. This area comes under prevention and as such the included population is people who do not currently smoke. However, in order to assess the impact of e-cigarettes on the future smoking behaviour of children and young people who do smoke, an additional key issue has been added to the 'treating tobacco dependency' section: <i>What is the impact of e-cigarettes on the smoking behaviour of children and young people who currently smoke?</i>
Improving Performance In Practice (IPIP) incorporating the Tobacco Control Collaborating Centre	2	17	Depictions of smoking in the entertainment media (TV and film in particular) has been shown to be causally linked to smoking uptake among children and young people. This link should be reviewed and covered by the guidance, including recommendations for action to prohibit or minimise impact.	Thank you for this comment. Digital media interventions for prevention will be considered. However, the removal of references to and images of smoking in entertainment media is related to broadcasting and media services regulations. These are outside of NICE's remit and therefore not something NICE would make recommendations on.
Improving Performance In Practice (IPIP) incorporating	2	24	The scope for opt out referrals should be widened to include all situations where smokers from vulnerable groups present as clients or patients for social and health services. The person is then free to choose to opt out	Thank you for this comment. NG92 recommends an opt-out referral approach for people planning surgery. This recommendation will be carried forward into the new guidance. A surveillance review was

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the Tobacco Control Collaborating Centre			after an approach by the stop smoking service has been made to them.	<p>conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified on opt-out referral pathways which would change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence. Additionally,</p> <p>In addition, insufficient evidence has been identified through the consultation process to warrant a new review in this area. Therefore the scope of this update is limited to pregnant women. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.</p>
Improving Performance In Practice (IPIP) incorporating the Tobacco Control Collaborating Centre	2	25	The NCSCT guidance recommends the use of e-cigarettes by pregnant women and could be extended to women considering pregnancy etc. http://www.ncsct.co.uk/usr/pub/Electronic_cigarettes._A_briefing_for_stop_smoking_services.pdf	<p>Thank you for this comment. The information will be considered when planning this review to inform the context. In addition, key issue 5.3 will consider how effective, cost effective, safe and acceptable e-cigarettes (licensed or consumer) are at helping women who smoke to quit immediately before or during pregnancy, or following childbirth.</p>

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Improving Performance In Practice (IPIP) incorporating the Tobacco Control Collaborating Centre	3	13	This is not a complete list of the newly introduced legislation. It should include the effects of the implementation of the prohibition of advertising and promotion of tobacco at the point of sale and the prohibition of smoking in private vehicles carrying children under 18. In the case of the both of which post implementation evaluation reports have been produced. There has also been a revision to the requirements for the display of no smoking signs.	<p>Thank you for this comment. The list of legislative changes in the scope is not intended to be exhaustive, particularly as the area of tobacco is so large. However, some additions have been made to the list to include more of the key legislative changes, as follows:</p> <ul style="list-style-type: none"> • It was made illegal to display tobacco products at the point of sale. • Legislation was introduced to standardise packaging of tobacco products. • It was made illegal to smoke in private vehicles carrying anyone under the age of 18.
Improving Performance In Practice (IPIP) incorporating the Tobacco Control Collaborating Centre	5	4 to 5	These measures apply to any age group because 'preventing uptake and promoting quitting' should not be limited to those aged 24 and under.	<p>Thank you for this comment. The subheading "prevention and promotion" has been amended to "preventing uptake". "Promoting quitting" does not form part of this update so it has been removed from the subheading. However, material from the original guidelines on promoting quitting will be retained and will form part of the final product. Therefore the target population for the material included in this update for preventing uptake has been kept as people aged 24 and under, in line with evidence around age of smoking initiation.</p>

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Improving Performance In Practice (IPIP) incorporating the Tobacco Control Collaborating Centre	7	8 - 14; 17 - 20; 21 - 23	The vocabulary used throughout should be adopted as standard vocabulary for all new guidance on this topic area.	Thank you for this suggestion.
Improving Performance In Practice (IPIP) incorporating the Tobacco Control Collaborating Centre	7	5	These recommendations should apply to any age group and should not be limited to those aged 24 and under.	Thank you for this comment. The subheading "prevention and promotion" has been amended to "preventing uptake". "Promoting quitting" does not form part of this update so it has been removed from the subheading. However, material from the original guidelines on promoting quitting will be retained and will form part of the final product. Therefore the target population for the material included in this update for preventing uptake has been kept as people aged 24 and under, in line with evidence around age of smoking initiation.
Improving Performance In Practice (IPIP) incorporating the Tobacco Control	8	14 - 20	All healthcare settings are included.	Thank you for this comment. Healthcare settings, although they will be included in the final guidance in recommendations which are carried forward, are not among the settings for which recommendations are being updated in relation to prevention. Therefore they are not included in this list.

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Collaborating Centre				
Improving Performance In Practice (IPIP) incorporating the Tobacco Control Collaborating Centre	8	8	Adults aged 25 and over should not be excluded from the 'preventing uptake and promoting quitting' strand.	Thank you for this comment. The subheading "prevention and promotion" has been amended to "preventing uptake". "Promoting quitting" does not form part of this update so it has been removed from the subheading. However, material from the original guidelines on promoting quitting will be retained and will form part of the final product. Therefore the target population for the material included in this update for preventing uptake has been kept as people aged 24 and under, in line with evidence around age of smoking initiation.
Improving Performance In Practice (IPIP) incorporating the Tobacco Control Collaborating Centre	8	12	The entertainment media should be included under 'preventing uptake and promoting quitting'	Thank you for this comment. Digital media interventions for prevention will be considered. However, the removal of references to and images of smoking in entertainment media is related to broadcasting and media services regulations. These are outside of NICE's remit and therefore not something NICE would make recommendations on.
Improving Performance In Practice (IPIP) incorporating the Tobacco	12	17 - 18	The scope needs to include reviewing the recommendation that smokers in acute, maternity and mental health services are referred to stop-smoking services. The UK model has been stand alone specialist stop-smoking services but there is growing evidence that	Thank you for this comment. The design of service provision is outside of the scope of this referral and will not be covered by this guideline.

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Control Collaborating Centre			provision of services within secondary care settings can be highly effective in promoting quitting (see Ottawa model http://tobaccocontrol.bmj.com/content/26/3/293) Furthermore there is no longer universal access to stand alone specialist services and therefore it is crucial that these recommendations are reviewed to ensure that smokers have access to the treatment they need.	
Improving Performance In Practice (IPIP) incorporating the Tobacco Control Collaborating Centre	13	14	The use of shisha should be included and considered as a specific topic area. The public health implications of shisha use have been well reported and require specific measures: http://www.adph.org.uk/wp-content/uploads/2017/03/PHE-ADPH-Shisha-Report-February-2017-.pdf	Thank you for this comment. Shisha will now be included in this update, and will be included in reviews which consider smoked tobacco.
Improving Performance In Practice (IPIP) incorporating the Tobacco Control Collaborating Centre	13	22	The scope currently needs to include reviewing service models. The UK model of universal access to services has broken down and become confusingly fragmented, inefficient, ineffective and even non-existent. This situation is unacceptable, may even worsen and can be expected to impact severely on projected stop smoking rates.	Thank you for this comment. The design of service provision is outside of the scope of this referral and will not be covered by this guideline.
Institute of Psychiatry	General	General	Question 1 Heat not burn products for harm reduction, the available evidence indicates that they are likely to be less harmful	Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who

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			<p>than cigarettes. However, it needs to be considered however that most of the evidence to date has been provided by manufacturers of heat not burn products, i.e. the tobacco industry. There is a small but growing body of independent evidence which also suggests reduced harm. However, more independent evidence is needed. To date, there is no evidence on using heat not burn products for smoking cessation and it would therefore be premature to include these products as options for smoking cessation.</p> <p>McNeill A., et al. (2018). Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London, Public Health England.</p> <p>https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review, specifically chapter 12.</p> <p>Simonavicius E, McNeill A, Shahab L, Brose LS. (Under review). Heat-not-burn tobacco products: a systematic literature review. Tobacco Control.</p>	commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include 'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.
Institute of Psychiatry	General	General	<p>Question 2</p> <p>We suggest the inclusion of the use of incentives for harm reduction and or cessation for people who smoke who have a mental health and/or substance misuse, examples of peer reviewed evidence include -</p>	<p>Thank you for this comment. A surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified on incentives for cessation which would change or add to current recommendations. Please find the surveillance report here:</p>

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			<p>Roll et al. Use of monetary reinforcement to reduce the cigarette smoking of persons with schizophrenia: A feasibility study. <i>Experimental and Clinical Psychopharmacology</i>, Vol 6(2), May 1998, 157-161</p> <p>Tidey et al. Effects of contingency management and bupropion on cigarette smoking in smokers with schizophrenia. <i>Psychopharmacology (Berl)</i>. 2011;217(2):279. Epub 2011 Apr 8.</p> <p>Gallagher et al. Patricia E. Penn, Eric Schindler & Wendy Layne (2011). A Comparison of Smoking Cessation Treatments for Persons with Schizophrenia and Other Serious Mental Illnesses, <i>Journal of Psychoactive Drugs</i>, 39:4, 487-497, DOI: 10.1080/02791072.2007.10399888</p> <p>Dunn, et al. 2010. A contingency-management intervention to promote initial smoking cessation among opioid-maintained patients. <i>Exp. Clin. Psychopharmacol.</i> 2010, 18, 37–50</p> <p>Ainscough et al. Contingency management for tobacco smoking during opioid addiction treatment: a randomised pilot study. <i>BMJ Open</i> 2017;7:e017467. doi: 10.1136/bmjopen-2017-017467.</p>	<p>https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence. The references you have supplied have been checked and are unlikely to match the inclusion criteria for a question on incentives in other groups.</p> <p>In addition, the majority of the evidence identified is related to pregnant women. Therefore the scope of this update is limited to pregnant women. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.</p>
Institute of Psychiatry	General	General	<p>Question 3</p> <p>We suggest including Peer support interventions for vulnerable/disadvantaged populations (in addition to pregnancy and school groups already proposed in the</p>	<p>Thank you for this comment. Peer support interventions are outside of the scope of this referral.</p>

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			scope) eg McKay CE, Dickerson F. Peer Supports for Tobacco Cessation for Adults with Serious Mental Illness: A Review of the Literature. Journal of dual diagnosis. 2012;8(2):104-112. doi:10.1080/15504263.2012.670847. Ford P, Clifford A, Gussy K, Gartner C. A Systematic Review of Peer-Support Programs for Smoking Cessation in Disadvantaged Groups. International Journal of Environmental Research and Public Health. 2013;10(11):5507-5522. doi:10.3390/ijerph10115507.	
Institute of Psychiatry	2	15 - 21	Prevention and promotion: In addition to the proposed areas, we suggest an additional area should include the licensing of tobacco retailers.	Thank you for this comment. The licensing of tobacco retailers is outside of NICE's remit and is therefore not something NICE would make recommendations on.
Institute of Psychiatry	3	13 - 20	Legislation and regulation also include changes to the point-of-sale display ban and standardised packaging for tobacco products	Thank you for this comment. The list of legislative changes in the scope is not intended to be exhaustive, particularly as the area of tobacco is so large. However, some additions have been made to the list to include more of the key legislative changes, as follows: <ul style="list-style-type: none"> • It was made illegal to display tobacco products at the point of sale. • Legislation was introduced to standardise packaging of tobacco products.

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NICE guideline on tobacco suite: prevention, cessation and harm reduction (update)

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				<ul style="list-style-type: none"> It was made illegal to smoke in private vehicles carrying anyone under the age of 18.
Institute of Psychiatry	4	12 - 15 16 - 20	<u>We suggest using more recent data published in https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/684963/Evidence_review_of_e-cigarettes_and_heated_tobacco_products_2018.pdf</u>	Thank you for this comment. We have checked the reference but have not found cause to amend this section. Where the reference cites a previous publication, the previous publication has been referenced in the scope.
Institute of Psychiatry	5	3 to 6	We suggest the evidence for the cut-off age of 24 years for prevention and promotion could be reviewed, particularly as promotion is likely to also be relevant for older age groups	Thank you for this comment. The subheading "prevention and promotion" has been amended to "preventing uptake". "Promoting quitting" does not form part of this update so it has been removed from the subheading. However, material from the original guidelines on promoting quitting will be retained and will form part of the final product. Therefore the target population for the material included in this update for preventing uptake has been kept as people aged 24 and under, in line with evidence around age of smoking initiation.
Institute of Psychiatry	7	2 to 25	Section 3.1. Who is the focus: Cessation and harm reduction: We suggest the inclusion of people who are <ul style="list-style-type: none"> - in prison - use non-licensed nicotine-containing products - living with children Smokers under the age of 12	Thank you for this comment. Custodial settings are covered in the section on settings, and is included. People who use e-cigarettes (a non-licensed nicotine-containing product) are included, but other non-licensed NCPs are not. Recommendations about people living with a pregnant woman or an infant are still relevant and will be retained but not updated. The age limit of 12 and over has been

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				retained due to the age at which nicotine replacement therapies (NRTs) can be prescribed, and also in part due to the scale of the problem (children under 12 looking to quit smoking) being comparatively small.
Institute of Psychiatry	8	8	As above, promotion (and prevention) may be relevant to those aged 25 and over	Thank you for this comment. The subheading "prevention and promotion" has been amended to "preventing uptake". "Promoting quitting" does not form part of this update so it has been removed from the subheading. However, material from the original guidelines on promoting quitting will be retained and will form part of the final product. Therefore the target population for the material included in this update for preventing uptake has been kept as people aged 24 and under, in line with evidence around age of smoking initiation.
Institute of Psychiatry	10	5 to 7	Consider including varenicline	Thank you for this comment. Varenicline is not licensed or recommended for use in pregnant and breastfeeding women so would not be considered in relation to this population
Institute of Psychiatry	10	10 to 18	We do not understand what this sentence is trying to say	Thank you for this comment. The material for this section has now been put in table format which we hope is clearer. In addition, the wording you were referring to has been removed.

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Institute of Psychiatry	5 to 6	all	Guidelines will also be relevant for prisons	Thank you for this comment. Under settings, or cessation and harm reduction, custodial settings are named as a relevant setting.
Institute of Psychiatry	5 6	3 - 15 1 - 10	Guidelines may also be relevant for researchers and policy-makers	Thank you for this comment. This change has been made.
Institute of Psychiatry	11 2	5 - 7 14- 29	“For the following areas, the evidence will not be reviewed but the recommendation may be 'refreshed'; that is, edited to ensure it meets current editorial standards, and reflects current policy and practice” We feel there is some discrepancy here with earlier sections, particularly 3.3. e.g. if the evidence for the recommendations in PH45 and 48 will not be reviewed, how will we know if the recommendations are still relevant or need changing?	Thank you for this comment. NICE's internal surveillance team regularly reviews all guidelines. The team considers new evidence in the area and whether the new evidence is sufficient to change recommendations. This decision is made with the input of experts and - if a decision is made not to recommend an update - a consultation is held with stakeholders as well. All the guidelines in this area have undergone this process. Those which will not be updated will still be 'refreshed' to bring in line with current NICE style, and may be amalgamated with other recommendations where sensible. This will be done through a committee composed of experts, lay members and core members.
Institute of Psychiatry	2 12	22 - 30 12 - 23	Cessation and harm reduction: In addition to cessation in pregnancy reviews, we also recommend including new evidence reviews in people with mental health and/or substance misuse conditions who smoke	Thank you for this comment. A surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified which would change current recommendations with the exception of changes to reflect other updates, for example updated recommendations on e-cigarettes. Please find the

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				surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence
Institute of Psychiatry	16	22 - 23	It is not clear what 'new media' are	Thank you for this comment. The scope will include mass media campaigns, including digital media. Digital media (which was previously phrased as 'digital channels' in the scope consultation) includes social media and online interventions. The mention of 'new media' referenced in your comment has been amended to read "mass media interventions, including those delivered through digital media...".
Institute of Psychiatry	16	9 to 16	Section 3.4. Economic aspects provides very little information, e.g. unclear what 'economic aspects' will be taken into account and what the criteria would be for prioritisation for economic modelling and analysis.	Thank you for this comment. By economic aspects we mean consideration of the costs relative to the benefits and disbenefits of the interventions being assessed. More information on the approaches that can be taken for different types of intervention, can be found in Chapter 7 of the NICE methods manual (https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/developing-NICE-guidelines-the-manual.pdf). The resource impact of

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				<p>recommendations is also considered.</p> <p>Prioritising areas for further economic evaluation is undertaken in discussion with the committee responsible for developing the guideline and depends on the information needed for decision making. For further information see Section 7.5 Prioritising questions for further economic analysis in Chapter 7 of the NICE methods manual.</p>
Institute of Psychiatry	8 to 9	11 to 5	<p>3.2 Settings: We suggest including smoke-free hospitals and prison/custodial settings in prevention and promotion.</p>	<p>Thank you for this comment. Smokefree hospitals were not identified among settings for which evidence was available which would change current recommendations. Although they are not a specific location for any of the proposed key issues for 'preventing uptake', recommendations on smokefree hospitals in PH48 will be carried forward. This does not preclude any studies which match the inclusion criteria and are set in or related to smokefree hospitals from being included, as this list of settings is not intended to be exhaustive.</p> <p>"Closed institutions such as custodial settings, secure mental health units and immigration detention centres" has been added to the settings for 'preventing uptake'.</p>

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Institute of Psychiatry	18	1 to 12	It is important that risks of e-cigarettes are compared with cigarettes. Also without this comparison this question is not relevant to tobacco guidance	Thank you for this comment. These proposed questions will form reviews, with literature searches to identify the studies to be included in these reviews. We will be considering the acceptability evidence for e-cigarettes. As e-cigarettes are currently used by many for harm reduction and may have an impact on cessation, they are relevant to a guideline about how to prevent uptake of tobacco and to help people quit.
Institute of Psychiatry	18	15 and footnote	<u>Someone who is not abstinent at the end of the 4-week period of the quit attempt should be defined as an unsuccessful quit attempt, not relapse. The Russell Standards (clinical) recommends:</u> 1) A smoker is counted as a 'self-reported 4-week quitter' (SR4WQ) if s/he is a 'treated smoker' (a smoker who undergoes at least one treatment session on or prior to the quit date and sets a firm quit date), is assessed 4 weeks after the designated quit date (minus 3 days or plus 14 days) and declares that s/he has not smoked even a single puff on a cigarette in the past 2 weeks. 2) A smoker is counted as a 'CO-verified 4-week quitter' (4WQ) if s/he is a self-reported 4-week quitter and his/her expired-air CO is assessed 4 weeks after the designated quit date (minus 3 days or plus 14 days) and found to be less than 10ppm. (http://www.ncsct.co.uk/usr/pub/assessing-smoking-	Thank you for this comment. The change you have suggested has been made.

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			cessation-performance-in-nhs-stop-smoking-services-the-russell-standard-clinical.pdf	
Institute of Psychiatry	2 16	16 25	We are unclear what is meant by 'de-normalisation strategies' and would appreciate a definition	Thank you for this comment. The draft key issue mentioning denormalisation has been amended as follows: "Are smoking cessation mass media campaigns aimed at adults effective and cost effective in preventing the uptake of smoking among children and young people?" This change has been made because denormalisation does not necessarily need to be a named or stated strategy of the intervention itself. Instead, denormalisation will be considered to be something which – to a greater or lesser extent – happens as a result of any campaign to increase cessation. Denormalisation would result in reduced uptake of smoking or qualitative measures of denormalisation.
Institute of Psychiatry	19	6	This seems to be the only instance where 'tobacco use' is used, not 'smoking'; suggest changing to smoking.	Thank you for this comment. This change has been made.
Institute of Psychiatry	23	n/a	'Make stop smoking pharmacotherapies available in hospital' – we suggest including e-cigarettes for visitors and staff	Thank you for this comment. Although e-cigarettes for visitors and staff in hospitals is not an area which will be reviewed specifically, the final product of this update process will be one coherent piece of

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				guidance. Areas which are being updated will by default update the things which cross refer to or reference them. The final guidance should be considered as a whole. Therefore where recommendations on e-cigarettes are updated based on new evidence, this will affect how existing related recommendations are read and implemented.
Institute of Psychiatry	24	n/a	'Advising on licensed nicotine-containing products' – we suggest including non-licensed nicotine-containing products	Thank you for this comment. Although e-cigarettes for visitors and staff in hospitals is not an area which will be reviewed specifically, the final product of this update process will be one coherent piece of guidance. Areas which are being updated will by default update the things which cross refer to or reference them. The final guidance should be considered as a whole. Therefore where recommendations on e-cigarettes are updated based on new evidence, this will affect how existing related recommendations are read and implemented.
Johnson & Johnson	3	3	Present wording is "e-cigarettes (licensed or consumer).....". We believe this could be confusing terminology as it is not clear whether "consumer" refers to consumer purchased products or e-cigarettes which do not hold a medicinal licence. Suggest changing to "e-cigarettes (licensed or unlicensed)" given that there are licensed products that can be purchased directly by consumers as OTC medicines with a GSL status.	Thank you for this comment. The wording has been amended to read: "manufacturers and retailers of licensed nicotine replacement therapies and e cigarettes (licensed or consumer)". The wording around licensing has not been changed due to a recognition that 'consumer' e-cigarettes are still regulated (although not as medicines).

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			Essentially the differentiator is whether the product has a medicinal license or is unlicensed. This change would need to be maintained throughout the document as this phrase is used multiple times throughout.	
Johnson & Johnson	6	9 to 10	Present wording is "manufacturers and retailers of licensed nicotine-containing products and e-cigarettes (licensed or consumer)". Suggest changing to "manufacturers and retailers of licensed nicotine replacement therapies (NRT) and e-cigarettes (licensed or unlicensed)" to reflect commonly used and recognized language and to be consistent with other areas in the draft scope (e.g. line 24 of page 7).	Thank you for this comment. The wording has been amended to read: "manufacturers and retailers of licensed nicotine replacement therapies and e cigarettes (licensed or consumer)". The wording around licensing has not been changed due to a recognition that 'consumer' e-cigarettes are still regulated (although not as medicines).
Johnson & Johnson	7	18	We suggest that the guidelines are not limited to those over the age of 12, but provide guidance for a child of any age who smokes.	Thank you for this comment. The age limit of 12 and over has been retained due to the age at which nicotine replacement therapies (NRTs) can be prescribed, and also in part due to the scale of the problem (children under 12 looking to quit smoking) being comparatively small.
Johnson & Johnson	8	11 to 20	Unclear as to why workplaces are not also included given the focus in on people age 24 and under.	Thank you for this comment. Workplaces are not a specific location for any of the proposed key issues for 'preventing uptake', so they have not been added to the list of settings. However, this does not preclude any studies which match the inclusion criteria and are set in or related to workplaces from

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				being included, as this list of settings is not intended to be exhaustive.
Johnson & Johnson	17	27 - 29	Present wording says "6.1 What are the most effective and cost-effective means of smoking cessation (including e-cigarettes) or harm reduction (including e-cigarettes and heat not burn products)?" As products can only be made available and positioned as a smoking cessation aid following medicinal licensing through the MHRA we believe this should be changed to state "6.1 What are the most effective and cost-effective means of smoking cessation (including licensed e-cigarettes) or harm reduction (including e-cigarettes and heat not burn products)?"	Thank you for this comment. NICE intends to consider the effect of both licensed and unlicensed e-cigarettes on cessation regardless of whether they can be positioned as a smoking cessation aid according to their licensing. This is because we are providing this information and the resulting recommendations to a variety of people approaching tobacco (prevention, cessation, harm reduction and so on) from various positions.
Johnson & Johnson	8 to 9	21 to 5	Unclear as to why "Schools and educational services" are not included.	Thank you for this comment. Schools and educational services are not a specific location for any of the proposed key issues for 'treating tobacco dependence', so they have not been added to the list of settings. However, this does not preclude any studies which match the inclusion criteria and are set in or related to schools and educational services from being included, as this list of settings is not intended to be exhaustive.
Lincolnshire County Council	2	19	Need to look wider than just smoke-free class competition. Need to look at best practice across the country on what is already being delivered with success.	Thank you for this comment. A surveillance review was conducted for PH23 which searched for new evidence on all recommendations, including school-based interventions. No evidence was identified

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				<p>which would change current recommendations with the exception of smokefree class competitions. Please see the surveillance report here: https://www.nice.org.uk/guidance/ph23/evidence/revi-ew-decision-2013-pdf-546068269.</p> <p>Insufficient additional evidence has been identified to update the recommendations on other types of school-based prevention interventions.</p>
Lincolnshire County Council	8	14	Community needs breaking down to include separate areas e.g. Uniformed and non-uniformed groups	Thank you for this comment. Community settings are commonly used in NICE guidance to encompass family and community level settings. Greater detail would not normally be provided at this stage in the guidance process.
Lincolnshire County Council	13	4	Disappointed that enforcement of legislation is not included. Believe that there should be the introduction of licensing scheme for Tobacco Retailers.	Thank you for this comment. The enforcement of legislation is outside of NICE's remit and is therefore not something NICE can make recommendations on.
Lincolnshire County Council	13	10	Disappointed that Tobacco pricing policies are not to be covered. A 'levy' on the Tobacco Industry is needed.	Thank you for this comment. Tobacco pricing policies are not something that NICE can make recommendations about as they are outside of remit.
Lincolnshire County Council	16	22	Best way is for adults to stop smoking and messages that encourage children to help their parents stop.	Thank you for this comment. The interdependence of cessation and prevention are acknowledged, and will be central to how this guidance is developed. A draft key issue looks specifically at mass media cessation interventions and their denormalising effects:

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				"Are smoking cessation mass media campaigns aimed at adults effective and cost effective in preventing the uptake of smoking among children and young people?"
Lincolnshire County Council	16	29	Introduction of a licensing scheme for Tobacco Retailers.	Thank you for this comment. The licensing of tobacco retailers is outside of NICE's remit and is therefore not something NICE would make recommendations on.
Lincolnshire County Council	17	4	Getting parents to ask questions like: where are your children getting their tobacco from? (fag houses / safeguarding issues), this is helping to fund serious and organised crime, Dangers of products that are not properly regulated.	Thank you for this comment. These proposed questions will form reviews, with literature searches to identify the studies to be included in these reviews. We will be considering the effectiveness evidence for a variety of interventions to engage and educate retailers for this question.
Lincolnshire County Council	17	8	Need to look at best practices county wide. Not just 'assist' programme. In Lincolnshire we offer BIIAB qualifications in Tobacco Control to vulnerable groups of young people, we have resource kits which can be lent to educational establishments etc...all free to user and young person. It operates on a train the trainer system.	Thank you for this comment. A surveillance review was conducted for PH23 which searched for new evidence on all recommendations, including school-based interventions. No evidence was identified which would change current recommendations with the exception of smokefree class competitions. Please see the surveillance report here: https://www.nice.org.uk/guidance/ph23/evidence/review-decision-2013-pdf-546068269 . Insufficient additional evidence has been identified to

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				update the recommendations on other types of school-based prevention interventions.
Lincolnshire County Council	17	16	It depends on how the message is delivered – needs to be made personal to the individual	Thank you for this comment. We will consider evidence on the details of interventions including how they are delivered.
Lincolnshire County Council	17	22	Very effective and should be widely promoted	Thank you for this comment. We will be considering effectiveness evidence for this intervention.
Lincolnshire County Council	17	27	Must be Behavioural support and prescribed/unprescribed medication as a combined approach.	Thank you for this comment. These proposed questions will form reviews, with literature searches to identify the studies to be included in these reviews. We will be considering the relative effectiveness evidence for a variety of cessation and harm reduction interventions for this question.
Lincolnshire County Council	18	1	What is needed is a clear, reliable and a consistent message e.g. currently messages are mixed with e cigs being called safe, then they are not.	Thank you for this comment. These proposed questions will form reviews, with literature searches to identify the studies to be included in these reviews. We will be considering the acceptability evidence for e-cigarettes.
Lincolnshire County Council	18	14	Having continued behavioural support possibly by peer led support groups in order to maintain quit, where people help and support each other. To continue to promote smoke free environments, celebrating anniversaries and keeping smoke free at the forefront of the public's mind.	Thank you for this comment. This information will be borne in mind. These proposed questions will form reviews, with literature searches to identify the studies to be included in these reviews. We will be considering data about preventing relapse from these studies.

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Middlesbrough Council	12	17	Scope should reference that those identified and initiate Quit attempt in secondary care settings can be transferred to community stop smoking services to avoid spontaneous quit limits	Thank you for this comment. The scope does not go into this level of detail for particular pathways as it is intended to be an overview document.
Middlesbrough Council	17	16	Reference – Bell, Glinianaia, Waal et al, Evaluation of a complex healthcare intervention to increase smoking cessation in pregnantwomen: Interrupted time series analysis with economic evaluation, Tobacco Control 2017 Routine CO Screening & Opt Out pathway increased referral of pregnant women twofold and 81% increased chance of quitting. Cost of intervention was £31 per delivery and £952 per quitter	Thank you for this comment. We will consider this reference when identifying studies for inclusion.
Middlesbrough Council	17	19	Reference – Tapping, Bauld et al, Financial incentives for smoking cessation inpregnancy: randomised controlled trial, BMJ 2015;350	Thank you for this comment. We will consider this reference when identifying studies for inclusion.
Middlesbrough Council	18	1	Attitudes to ecigarettes vary dependant on type of ecigarette and socio demographic of patients	Thank you for this comment. These proposed questions will form reviews, with literature searches to identify the studies to be included in these reviews. We will be considering the acceptability evidence for e-cigarettes.
National Pharmacy Association	4	6	In the year 2014-15, approximately 55,000 people registered to stop smoking in community pharmacy. Smoking cessation was by far the most frequently commissioned lifestyle modification service, in 133 (90%)	Thank you for this comment. The scope states that this update will be relevant to all providers of smoking cessation support, and community settings are included.

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			of LAs, and provided by 5660 pharmacies in England (48%). (Mackridge, Gray, Krska) BMJ 2017	
National Pharmacy Association	10	8	The NPA agrees that incentives for smoking cessation and harm reduction ought to be included in the guideline scope, as it is understood that incentives have had a positive impact as part of the smoking cessation scheme.ref. Tappin et al 2015. BMJ 2015;350:h134 doi: 10.1136/bmj.h134 (Published 27 January 2015)	Thank you for this comment.
National Pharmacy Association	10	21	The NPA notes, that the "review of evidence on e-cigarettes as a means of cutting down on smoking may lead to a update of previous recommendations....."is part of the guideline scope. There does not appear to be any evidence on the safety of e-cigarettes.	Thank you for this comment. We will consider evidence on e-cigarettes for cessation and harm reduction, which will include consideration of any evidence on risk, benefits, adverse events and safety. Any recommendations made, and the evidence used to make these recommendations, will be consulted on.
National Pharmacy Association	12	3	Point 9 explores the inclusion of brief interventions (including brief advice) by health and social care professionals including dental practitioners and GPs. The NPA suggests that Community pharmacists also be included, given that the sector currently plays an active role in identifying and supporting smokers with their smoking cessation.	Thank you for this comment, and this suggestion. Community pharmacists have been added to this point.
National Pharmacy Association	17	27	The NPA notes the guideline scope of looking at the most effective and cost effective means of smoking cessation (including e-cigarettes)....., and notes that e-	Thank you for this comment. The committee will consider the detail of review questions but it is intended that studies which consider the effect e-

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NICE guideline on tobacco suite: prevention, cessation and harm reduction (update)

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			cigarettes will be considered as monotherapy or in combination treatment with NRT or with behavioural support..... The NPA is not aware of any studies/ data where e-cigarettes could be used as part of the smoking cessation programme.	cigarette use has on cessation will be included, whether or not this is part of a formal cessation programme.
National Tobacco Focus Group (CTSI)	General	General	Enforcement of legislation is a critical aspect of comprehensive tobacco control; without enforcement there are no sanctions available to tackle those individuals and businesses that flout the law. This is particularly true in the prevention of uptake of smoking and E cigarettes by young people and the removal of illegal tobacco from our communities. This general observation underpins the submission of further comments made by the CTSI below.	Thank you for this comment. The enforcement of legislation for prevention is outside of NICE's remit and is therefore not something NICE would make recommendations on. This does not mean that enforcement action cannot or will not happen, or is not effective.
National Tobacco Focus Group (CTSI)	3	13	There are omissions in the legislation listed – for example the Tobacco Advertising and Display Regulations 2010, The Tobacco and Related Products Regulations 2016 (TRPRs) and the Standardised Packaging of Tobacco Regulations 2015. Also regulations prohibiting smoking in private vehicles carrying children under 18.	Thank you for this comment. The list of legislative changes in the scope is not intended to be exhaustive, particularly as the area of tobacco is so large. However, some additions have been made to the list to include more of the key legislative changes, as follows: <ul style="list-style-type: none"> • It was made illegal to display tobacco products at the point of sale. • Legislation was introduced to standardise packaging of tobacco products.

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				<ul style="list-style-type: none"> It was made illegal to smoke in private vehicles carrying anyone under the age of 18.
National Tobacco Focus Group (CTSI)	5	3	The Prevention and Promotion recommendations do not include those responsible for enforcing legislation specifically designed to prevent smoking uptake e.g. Local Authority Trading Standards Officers. This role supports the work of colleagues with a specific remit to improve the health and wellbeing of children and young people.	Thank you for this comment. The enforcement of legislation for prevention is outside of NICE's remit and is therefore not something NICE would make recommendations on.
National Tobacco Focus Group (CTSI)	9	22	CTSI has undertaken research with retailers and members of the public on proxy purchasing and potential interventions which may help them .	Thank you for this information. We will consider it when identifying research for inclusion.
National Tobacco Focus Group (CTSI)	13	4	We are concerned that the area of enforcement will not be considered when it has such an impact on tobacco use and uptake	Thank you for this comment. The enforcement of legislation is outside of NICE's remit and is therefore not something NICE can make recommendations on.
National Tobacco Focus Group (CTSI)	13	5	We are very concerned that recommendation 4 will be removed from PH14. This recommendation is absolutely vital to ensure that legislation designed to protect children from tobacco harm is effectively enforced. According to the "Statistics on Smoking, England 2016" report, nearly half of secondary school children who smoke reported buying cigarettes themselves from retailers. In the CTSI Annual Tobacco Survey for 2016/17, LAs carried out an estimated 3000 Test Purchases with young people, and the young volunteer	Thank you for this comment. Recommendation 4 of PH14 will be removed as part of this update. The enforcement of legislation is outside of NICE's remit and is therefore not something NICE can make recommendations on.

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			was sold tobacco on more than 10% of occasions. We are not at the stage where this recommendation is no longer needed. New data for 2017 -18 will be published by CTSI at the end of September 2018	
National Tobacco Focus Group (CTSI)	13	14	It is not clear why shisha and similar products are excluded. These are tobacco products and are covered by existing legislation including illegal sales to young people and the TRPRs 2016.	Thank you for this comment. Shisha will now be included in this update, and will be included in reviews which consider smoked tobacco.
National Tobacco Focus Group (CTSI)	16	29	Enforcement is effective and cost effective in engaging and educating retailers to reduce the illegal sale of tobacco to children and young people. Where contraventions occur, it is open to LAs to employ "alternative sanctions ". For example, a retailer may be offered the opportunity to attend an educational "Do You Pass" course as an alternative to prosecution. Removing enforcement from the scope of the guidelines effectively reduces opportunities to recommend these activities to reduce illegal sales.	Thank you for this comment. The enforcement of legislation for prevention is outside of NICE's remit and is therefore not something NICE would make recommendations on. This does not mean that enforcement action cannot or will not happen, or is not effective.
National Tobacco Focus Group (CTSI)	17	4	There is no alternative to enforcement to reduce the sale of illegal tobacco by retailers. Considering interventions whilst excluding enforcement is not taking a holistic approach.	Thank you for this comment. The enforcement of legislation for prevention is outside of NICE's remit and is therefore not something NICE would make recommendations on. This does not mean that enforcement action cannot or will not happen, or is not effective.

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National Tobacco Focus Group (CTSI)	18	3	<p>A general comment about the risks associated with Nicotine inhaling products (E cigs and Liquids). Unless the product is licensed by the MHRA , quality and effectiveness of the product cannot be guaranteed .</p> <p>Recent compliance monitoring carried out by Trading Standards across England revealed that almost 25% of products available in retail premises were found to be non-compliant with the law.The CTSI report on product compliance published May 2018 provides more information. Use of E cigarettes as an aid to quitting or within a harm reduction approach therefore requires careful consideration .</p>	Thank you for this comment. Safety of e-cigarettes will be considered alongside their effectiveness and cost effectiveness. Evidence about safety will be recorded and discussed by the committee.
New Nicotine Alliance (UK)	General	General	<p>Question 1</p> <p>There is a large amount of laboratory, short term clinical and some population and modelling evidence on heat not burn products, including that which would meet NICE standards. Much is inevitably from tobacco company R&D. It is important that NICE as an independent body scrutinises that evidence, especially so given the evidence from Japan that HNB is having a dramatic effect on reducing sales of cigarettes – down by 27% over the last two years. Euromonitor International (2018): Passport – Global Tobacco 2017: Key Findings Part 1 - New Insights and System Refresher; and as tracked in Japan Tobacco, Japanese Domestic Cigarette Sales</p>	Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include 'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.

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			Results https://www.jt.com/media/news/2018/pdf/20180413_02.pdf	
			Non Industry research to date includes the following:	
			Farsalinos et al., Nicotine Delivery to the Aerosol of a Heat-Not-Burn Tobacco Product: Comparison With a Tobacco Cigarette and E-Cigarettes, Nicotine & Tobacco Research, 16 June 2017	
			https://academic.oup.com/ntr/advance-article-abstract/doi/10.1093/ntr/ntx138/3868870?redirectedFrom=fulltext	
			Li et al., Chemical Analysis and Simulated Pyrolysis of Tobacco Heating System 2.2 Compared to Conventional Cigarettes, Nicotine & Tobacco Research, 8 January 2018	
			https://academic.oup.com/ntr/advance-article-abstract/doi/10.1093/ntr/nty005/4793230?redirectedFrom=fulltext	
			Bekki et al., Comparison of Chemicals in Mainstream Smoke in Heat-not-burn Tobacco and Combustion Cigarettes, National Institute of Public Health (Japan),	

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			<p>September 2017</p> <p>https://www.jstage.jst.go.jp/article/juoeh/39/3/39_201/_pdf</p> <p>Setyan, A., et al. (Swiss EMPA Institute), Physicochemical characterization of particles and volatile organic compounds emitted by electronic cigarettes and heat-not-burn products, compared to a reference tobacco cigarette, 2018</p> <p>https://www.researchgate.net/publication/322855531_Physico-Chemical_Characterization_of_Particles_and_Volatile_Organic_Compounds_Emitted_by_Electronic_Cigarettes_and_Heat-Not-Burn_Products_Compared_to_a_Reference_Tobacco_Cigarette</p> <p>Protano, C., et al., Second-hand smoke exposure generated by new electronic devices (IQOS and ecigs) and traditional cigarettes: submicron particle behavior in human respiratory system, Ann Ig, 2016</p> <p>http://www.seu-roma.it/riviste/annali_igiene/open_access/articoli/73492f</p>	

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			<p>053274d293f3db764cbfac1134.pdf</p> <p>Ruprecht, A.A., et al., Environmental pollution and emission factors of electronic cigarettes, heat-notburn tobacco products, and conventional cigarettes, Aerosol Science and Technology, 21 March 2017</p> <p>https://www.tandfonline.com/doi/abs/10.1080/02786826.2017.1300231</p> <p>Leigh et al., Cytotoxic Effects Of A Tobacco HeatNot-Burn System On Human Bronchial Epithelial Cells, Abstract presented at SRNT 2018</p> <p>https://c.ymcdn.com/sites/www.srnt.org/resource/resmgr/conferences/2018_Annual_Meeting/65388_SRNT_2018_Abstract_fin.pdf</p> <p>Tabuchi et al., Awareness and use of electronic cigarettes and heat-not-burn tobacco products in Japan, Addiction, 14 November 2015</p> <p>https://onlinelibrary.wiley.com/doi/abs/10.1111/add.13231</p>	
New Nicotine Alliance (UK)	General	General	<p>Question 2</p> <p>If incentives are effective and acceptable in helping</p>	<p>Thank you for this comment. A surveillance review was conducted for PH48 which includes acute,</p>

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			women quit smoking during and after pregnancy it is difficult to see why they wouldn't benefit other people who smoke, however it may only be cost effective where quitting immediately might produce some tangible benefit such as in people with chronic disease and mental health patients.	maternity, and mental health services. No evidence was identified on incentives for cessation which would change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence In addition, the majority of the evidence identified is related to pregnant women. Therefore the scope of this update is limited to pregnant women. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.
New Nicotine Alliance (UK)	General	General	Question 3 In this draft scope "cessation and harm reduction" is considered separately from "prevention and promotion" and is not included in mass media campaigns. However, we believe that mass media campaigns which focus on giving evidence based information on e-cigarettes would result in substantial cost savings. Many current smokers are deterred from switching because of misconceptions around nicotine and the relative risks of smoking and vaping. When smokers do switch to e-cigarettes it is at	Thank you for this comment. Investigating the effectiveness of e-cigarettes for harm reduction and cessation is within the scope of this referral. However, mass media campaigns to educate about them are not, and so NICE will not make recommendations on them in this update.

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			<p>no cost to the state.</p> <p>ASH welcomes new Public Health England Report on E-Cigarettes, press release 6 February 2018 http://ash.org.uk/media-and-news/press-releases-media-and-news/ash-welcomes-new-public-health-england-report-e-cigarettes/</p> <p>We would also like highlight that the tobacco control plan includes a commitment to communicate accurate information about the relative risks of harm reduced products (see page 15 of the Tobacco Control Plan). Furthermore, the tobacco control plan states that mass media campaigns will be used to promote smoking cessation (see page 21 of the Tobacco Control Plan).</p>	
New Nicotine Alliance (UK)	General	general	<p>In the last five years there has been a proliferation of additional sources of advice on safer nicotine products (mainly e-cigarettes) through e-cigarette manufacturers and retailers, and access to information on social media and through peers, which may be associated with the decline in the use of formal services such as stop smoking services. The landscape of smoking cessation has changed significantly and current NICE advice focusses too heavily on formal services. The draft scope fails to recognise that many of the drivers of smoking</p>	<p>Thank you for this comment. The issues you raise (advertising bans, limits on e-cigarette tank sizes and nicotine strength and prevalent bans on vaping in shared and public spaces) are legislative or related to advertising or manufacturing standards and so are outside of the scope of this referral.</p>

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			cessation are now outwith the NHS. NNA's view is that this scope should be altered to address some of the obstacles to smokers switching to harm reduced products: the advertising bans, the limits on e-cigarette tank sizes and nicotine strength and the prevalent bans on vaping in shared and public spaces.	
New Nicotine Alliance (UK)	General	General	The term "smokeless tobacco" is misleading as it covers a broad range of oral tobacco products encompassing a wide spectrum of risk profiles. The scope needs to be more specific about which smokeless tobacco products will be included. With respect to South Asian smokeless tobaccos (which have a variety of constituents in addition to tobacco consideration should be given to product standards as a harm reduction measure.	<p>Thank you for this comment. PH39 (Smokeless tobacco: South Asian communities), whilst not being updated based on new evidence, will be retained in the final product of this update. The recommendations will be refreshed to reflect current context and NICE style.</p> <p>In this scope, 'smoking', refers to the use of any smoked tobacco. This includes cigarettes and shisha. This has been clarified in a new footnote on p2 of the scope: "Throughout this scope, smoking refers to the use of all smoked tobacco products."</p> <p>Smokeless tobacco for people not of South Asian origin will not be included in any updated material apart from Key Issues 2.1 and 2.2 which are about the illicit supply of tobacco and proxy sales of tobacco to people under 18. Product standards for smokeless tobacco is outside of the scope of this update and so will not be considered.</p>

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New Nicotine Alliance (UK)	General	General	The division of "promotion and prevention" and "cessation and harm reduction" is not helpful as there is overlap between them.	Thank you for this comment. We note that subheadings are intended to organise and provide an overview of what evidence will be updated, rather than reflecting the structure of the final published guidance. We also recognise the overlap between the two areas of preventing uptake and treating dependence. This is partly covered in key issue 1.2 (below) and will be considered by the committee when making recommendations. <i>1.2 Are smoking cessation mass media campaigns using de-normalisation strategies aimed at adults effective and cost effective in preventing the uptake of smoking among children and young people?</i>
New Nicotine Alliance (UK)	2	16	It is limiting to consider mass media campaigns mainly in terms of denormalisation of smoking. The mass media campaign should include information about e-cigarettes, as around 40% of current smokers have never tried e-cigarettes and there are wide spread misperceptions about the relative risks from smoking and e-cigarette use. ASH welcomes new Public Health England Report on E-Cigarettes, press release 6 February 2018 http://ash.org.uk/media-and-news/press-releases-media-and-news/ash-welcomes-new-public-health-england-	Thank you for this comment. This update will pose review questions on what affects perceptions of appropriateness of e-cigarettes for smokers, data on absolute and relative benefits, risks, harms and adverse events associated with e-cigs will also be reported where available. Questions on mass media will also look at which mass media interventions are effective for prevention in children and young people. Advertising restrictions are outside of NICE's remit and is therefore not something NICE would make recommendations on.

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			report-e-cigarettes/ The tobacco control plan includes a commitment to communicate accurate information about the relative risks of harm reduced products (see page 15). The review should include assessment of the impact of current advertising restrictions on e-cigarettes, which shift the cost of information provision to the state.	
New Nicotine Alliance (UK)	2	21	This should include a review of the evidence on the impact of e-cigarettes on smoking behaviour in children and young people who do currently smoke. It is important to know whether uptake of vaping is preventing against uptake of smoking.	Thank you for this comment. This area comes under prevention and as such the included population is people who do not currently smoke. However, in order to assess the impact of e-cigarettes on the future smoking behaviour of children and young people who do smoke, an additional key issue has been added to the 'treating tobacco dependency' section: <i>What is the impact of e-cigarettes on the smoking behaviour of children and young people who currently smoke?</i>
New Nicotine Alliance (UK)	2	23	Why aren't e-cigarettes included here in "for cessation only"? We feel that this is inconsistent, as later in the scope e-cigarettes are classed as "smoking cessation interventions" (page 3, line 2).	Thank you for this comment. E-cigarettes will be explored as a method of smoking cessation. However, they are also considered in relation to harm reduction - on the path to cessation - as they

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				may have a significant role in temporary abstinence or attempts to cut down on the way to quitting.
New Nicotine Alliance (UK)	2	25	E-cigarettes should be included here. Please see the links in our comment for page 2, line 28.	Thank you for this comment. The draft scope outlines draft review questions, one of which is a review question addressing the effectiveness, cost effectiveness, safety and acceptability of NRTs and e-cigarettes for pregnant women.
New Nicotine Alliance (UK)	2	28	Consideration of e-cigarettes as incentives for woman who cannot otherwise stop smoking when pregnant should be included here. http://smokefreeaction.org.uk/wp-content/uploads/2017/06/eCigSIP.pdf http://smokefreeaction.org.uk/wp-content/uploads/2017/06/SIPe-cig-infographic.pdf http://www.ncsct.co.uk/user/pub/Electronic_cigarettes._A_briefing_for_stop_smoking_services.pdf	Thank you for this comment. The intention is that any form of incentive would be included in this review as long as it is classified as an incentive in any evidence. This also extends to e-cigarettes.
New Nicotine Alliance (UK)	3	13 - 20	Between 2007 and 2018 there were major legislative changes including the 2016 TRPD which contains provisions that the NNA consider have had a negative impact on consumer awareness of and access to some e-cigarette products, due to restrictions on advertising and limits on e-cigarette devices and the continuing ban on snus.	Thank you for this comment and your views on this legislation. The scope is not intended to comment on aspects of particular changes, simply to describe them.
New Nicotine Alliance (UK)	4	2	Should include: The tobacco control plan includes objectives "to support consumers in stopping smoking	Thank you for this comment. The wording you suggest has been added.

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			and adopting the use of less harmful nicotine products" (Tobacco Control Plan, page 15).	
New Nicotine Alliance (UK)	4	7	In the case of e-cigarettes and smoking cessation current practice needs to consider the changing landscape of provision of advice and information, which has shifted from formal services to the retail sector. Smokers wishing to try e-cigarettes currently visit vape shops for advice and to purchase the products.	Thank you for this comment. This section is intended as a very high level overview of current practice and cannot include this level of detail. Retail settings are included in the settings which will be considered (please see section on 'settings').
New Nicotine Alliance (UK)	5	7	Retailers – please define – does this include retailers of e-cigarettes and heat-not-burn products?	Thank you for this comment. This mention of retailers is in relation to preventing the uptake of smoking and so relates to retailers of all tobacco products. This has now been specified.
New Nicotine Alliance (UK)	6	2 to 10	The scope states that “People over the age of 12 who want to stop smoking” (page 7, line 8) are included in the scope for cessation and harm reduction. It is therefore inconsistent, and inappropriate, to not include the following: “The guidelines may also be relevant to children, young people and their parents and carers and other members of the public. “	Thank you for this comment. This change has been made.
New Nicotine Alliance (UK)	7	16	We are concerned that focussing on nicotine dependence misses the important point that some smokers are also highly dependent on smoking behaviour - “the non-nicotine, sensorimotor conditioned	Thank you for this comment. Wording has been amended to "...those who are highly dependent on tobacco".

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			effects" https://thepsychologist.bps.org.uk/volume-26/edition-5/why-it-so-hard-quit-smoking	
New Nicotine Alliance (UK)	7	17	This should be deleted: if someone is using e-cigarettes or another reduced risk nicotine product exclusively, and not using lit tobacco, then they should be considered to have stopped smoking.	Thank you for this comment. We agree that someone who is using, for example, e-cigarettes exclusively without lit tobacco would be considered to have stopped smoking. This bullet point and sub bullets (starting "people over the age of 12 who smoke and want to reduce harm from smoking") is not in relation to cessation. It refers exclusively to those who cannot stop using lit tobacco and are therefore still smoking - it covers harm reduction only. Cessation is covered in the bullet and sub-bullet previous to this one.
New Nicotine Alliance (UK)	8	5	Please see our general comment regarding the term "smokeless tobacco".	Thank you for this comment. Please see our response to the comment you reference.
New Nicotine Alliance (UK)	8	11	The last five years there has been a proliferation of additional sources of advice on safer nicotine products (mainly e-cigarettes) through e-cigarette manufacturers and retailers, and access to information on social media and through peers, which may be associated with the decline in the use of formal services such as stop smoking services. The guidance need to consider the role of vendors (giving advice at no costs to the NHS).	Thank you for this comment. This guidance will aim, in part, to evaluate the effectiveness, cost effectiveness, safety and acceptability of e-cigarettes. It does not aim to evaluate advice about e-cigarettes specifically, although this may prove to be a factor in their acceptability, in which case it will be considered.

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NICE guideline on tobacco suite: prevention, cessation and harm reduction (update)

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New Nicotine Alliance (UK)	8	27	Please see our general comment regarding the term "smokeless tobacco".	Thank you for this comment. Please see our response to the comment you reference.
New Nicotine Alliance (UK)	9	12	Please see our answer to Question 3, above, regarding mass media campaigns.	Thank you for this comment. Please see our response to the comment you reference.
New Nicotine Alliance (UK)	10	14	"raising awareness" – of what? And how will that differ from "choosing a harm reduction approach" (line 16)?	Thank you for this comment. The material for this section has now been put in table format which we hope is clearer. In addition, the wording you were referring to has been removed.
New Nicotine Alliance (UK)	11	22-27	Interventions should include discussions around tobacco harm reduction.	Thank you for this comment. The impact of e-cigarettes on indoor air quality will be considered in the indoor air guideline which is currently under development at NICE. Outcomes related to birth will be included.
New Nicotine Alliance (UK)	11	15	PH5 Smoking: workplace interventions was last updated in 2014. We believe that PH5 should be reviewed and the role of tobacco harm reduction in the workplace considered. PHE Use of e-cigarettes in public places and workplaces https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/534586/PHE-advice-on-use-of-e-cigarettes-in-public-places-and-workplaces.PDF	Thank you for this comment. Although for completeness we have listed items to be included but not updated by guideline number, the final product of this update process will be one coherent piece of guidance. Areas which are being updated will by default update the things which cross refer to or reference them. The final guidance should be considered as a whole. Therefore where recommendations on e-cigarettes are updated based on new evidence, this will affect how existing related recommendations are read and implemented.

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New Nicotine Alliance (UK)	11	17	Should be updated to include advice about tobacco harm reduction.	Thank you for this comment. Although for completeness we have listed items to be included but not updated by guideline number, the final product of this update process will be one coherent piece of guidance. Areas which are being updated will by default update the things which cross refer to or reference them. The final guidance should be considered as a whole. Therefore where recommendations on harm reduction are updated based on new evidence, this will affect how existing related recommendations are read and implemented.
New Nicotine Alliance (UK)	11	19	Should be updated to suggest gathering evidence on impact of provision of vaping areas	Thank you for this comment. NICE's role is to gather, appraise, and summarise the best available existing evidence. NICE does not itself commission evidence (please see the Guideline Manual for more detail). While research recommendations can be made where evidence is sought and not identified, it is not a sensible use of resources to produce a review to gather, appraise and summarise evidence in an area for which it is known that there is little or no available evidence.
New Nicotine Alliance (UK)	11	28	Please see our general comment regarding the term "smokeless tobacco".	Thank you for this comment. Please see our response to the comment you reference.
New Nicotine Alliance (UK)	12	8 & 9	Interventions should include discussions around tobacco harm reduction.	Thank you for this comment. This point outlines recommendations which are already published in PH39 which will not be updated but will be retained.

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				PH39 does not cover harm reduction and so it cannot be added here.
New Nicotine Alliance (UK)	12	26	"Behavioural support, counselling or advice for individuals or groups (unless it is in conjunction with or compared with e-cigarettes). " We hope this means that if is in conjunction with or compared with e-cigarettes it will be updated. .	Thank you for this comment. This statement refers to the fact that behavioural support is not being re-evaluated in its own right. However, where used in conjunction with or compared with e-cigarettes - which are within scope for this update - they will be included in that capacity.
New Nicotine Alliance (UK)	12	28	"Interventions (other than the use of e-cigarettes) to help people temporarily abstain from smoking. " We hope this means that if the intervention is the use of e-cigarettes it will be updated.	Thank you for this comment. This statement means that where e-cigarettes are used to help people temporarily abstain from smoking (a form of harm reduction), they will be included in this update.
New Nicotine Alliance (UK)	16	21	Please see our answer to Question 3, above, regarding mass media campaigns.	Thank you for this comment. Please see our response to the comment you reference.
New Nicotine Alliance (UK)	17	1	Deterring adults from proxy purchasing vaping products for under 18's who smoke encourages young people to smoke instead. We therefore hope the proxy purchasing interventions will concentrate on the proxy purchasing of lit tobacco products.	Thank you for this comment. Questions 2.1, 2.2 and 2.3 will not cover e-cigarettes, they are exclusively in relation to tobacco products.
New Nicotine Alliance (UK)	17	12	This should include a review of the evidence on the impact of e-cigarettes on smoking behaviour in children and young people who do currently smoke. It is important to know whether uptake of vaping is preventing against uptake of smoking.	Thank you for this comment. This area comes under prevention and as such the included population is people who do not currently smoke. However, in order to assess the impact of e-cigarettes on the future smoking behaviour of children and young people who do smoke, an additional key issue has

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				<p>been added to the 'treating tobacco dependency' section:</p> <p><i>What is the impact of e-cigarettes on the smoking behaviour of children and young people who currently smoke?</i></p>
New Nicotine Alliance (UK)	17	19	Please see our answer to Question 2 above.	Thank you for this comment. Please see our response to the comment you reference.
New Nicotine Alliance (UK)	17	22 & 27	Cost effective if e-cigarettes are handed out by practitioners? That doesn't currently happen.	Thank you for this comment. The assessment of cost effectiveness will follow the approach set out in the NICE methods manual and will be dependent on the data available and input from the committee. The method allows for different perspectives on costs to be taken into account.
Northumberland Tyne & Wear NHS Foundation Trust	General	General	<p>The draft scope states that the evidence for PH48 Smoking: acute, maternity and mental health services recommendations 1 to 16 will not be reviewed, but the recommendations may be refreshed.</p> <p>Whether or not there is new evidence is important but it is also a side-issue.</p> <p>The recommendations in PH48 cover mental health settings in general, although there were clear limitations in the evidence to support such generalisation. For example, evidence "Review 4: Effectiveness of Smoking cessation interventions in Mental health" identified no studies "which assessed the differential effectiveness of</p>	<p>Thank you for this comment. A surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified which would change current recommendations with the exception of changes to reflect other updates, for example updated recommendations on e-cigarettes. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/evidence</p> <p>Decisions about how to apply recommendations to different populations in different contexts should be</p>

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			<p>smoking cessation interventions by mental health diagnosis". Again, an evidence statement was not provided on the subsidiary question on whether variation in smoking cessation outcomes was affected by the setting in which the intervention was assessed, "for example, in-patients versus out-patient".</p> <p>NICE PH48 should be amended to reflect the evidence for a heterogeneous population with mental health conditions in heterogeneous mental healthcare settings. The mental health population should be de-homogenised and evidence statements should be amended to reflect the evidence for sub-groups defined by diagnosis, severity of illness, acute and chronic conditions, and the settings within which studies were conducted (i.e., in- and out-patient).</p> <p>New evidence has become available, e.g., Prochaska J, Hall S, Delucchi K, Hall S. Efficacy of initiating tobacco dependence treatment in inpatient psychiatry: a randomised controlled trial. Am J Public Health 2014.</p>	made locally by those with a knowledge of the demographics and situations of the population.
Northumberland Tyne & Wear NHS Foundation Trust	10	19	<p>Heat not burn products as a means of harm reduction – these certainly need to be reviewed and an evidence base established before further comment can be made. However initial thoughts are that any products containing tobacco do not fit well with tobacco control/smoking cessation interventions and the vision of making future generations tobacco free.</p>	Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include

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				'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.
Northumberland Tyne & Wear NHS Foundation Trust	12	22 - 23	New evidence has become available on the implementation of smoke-free strategies, e.g. Magor-Blatch, Lynne E., and A. R. Rugendyke. "Going smoke-free: attitudes of mental health professionals to policy change." Journal of psychiatric and mental health nursing 23.5 (2016): 290-302.	Thank you for this comment. Smoke-free strategies is not within the scope for any planned evidence reviews currently. Although there are some new studies which might meet the inclusion criteria for the previous review on smokefree strategies, the evidence is insufficient to change the current recommendations and will therefore not be reviewed.
Northumberland Tyne & Wear NHS Foundation Trust	18	1 to 2	In the evidence review on the factors influencing the acceptability of using e-cigarettes, please consider the aspect of voluntariness (e.g., considering the effect of settings where smoking bans have been introduced).	Thank you for this comment. These proposed questions will form reviews, with literature searches to identify the studies to be included in these reviews. We will be considering the acceptability evidence for e-cigarettes.
Primary Care Respiratory Society UK	General	General	<p>Question 1: consideration of inclusion of heated tobacco products in the scope.</p> <p>We support the stance ASH takes on this question: We do not believe that it would be appropriate to include heated tobacco products in the scope of this guidance.</p> <p>Awareness of heated tobacco products is low as is usage, and this is likely to continue to be the case during the time the committee is reviewing the evidence. Furthermore there is little evidence of these products effectiveness in supporting quitting, and what there is</p>	Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include 'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.

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			<p>Please insert each new comment in a new row</p> <p>has been conducted by the tobacco industry and is not independent.</p> <p>The UK is a party to the WHO Framework convention for Tobacco Control, and NICE and PHE are covered by its obligations, including those in Article 5.3 with respect to protecting public health policy with respect to tobacco control from the commercial and vested interests of the tobacco industry. NICE needs to review the Article 5.3 Guidelines carefully to help it consider how it will interpret data emanating from the tobacco industry. NICE has satisfied its public commitment to consult on whether heated tobacco products are in scope and the current lack of independent evidence means further work would be premature at this time.</p> <p>We support the development of independent evidence on the extent of harm these products may cause, and would welcome a NICE evidence review when such evidence is available.</p> <p>References: WHO FCTC Article 5.3 guidelines.http://www.who.int/entity/fctc/treaty_instruments/adopted/article_5_3/en/index.html</p>	<p>Please respond to each comment</p>

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			<p>McNeill A, Brose LS, Calder R, Bauld L & Robson D. Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England: https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review</p> <p>Committee on toxicity, carcinogenicity and mutagenicity of chemicals in food, consumer products and the environment. Statement on the toxicological evaluation of novel heat-not-burn tobacco products https://cot.food.gov.uk/sites/default/files/heat_not_burn_tobacco_statement.pdf</p>	
Primary Care Respiratory Society UK	General	General	<p>Question 2: draft scope position on use of incentives and whether this should be broadened out from pregnant women to other groups.</p> <p>The scope should be broadened out to look at groups other than pregnant women – in particular where there may be immediate benefit from quitting both to the smoker and to the NHS, for example patients with pre-existing smoking-related disease where quitting can improve outcomes (e.g. COPD, CVD and lung cancer) and other lung conditions which are exacerbated by smoking (e.g. asthma). Evidence should be gathered</p>	<p>Thank you for this comment. A surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified on incentives for cessation which would change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence</p>

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			both on effectiveness and cost-effectiveness of incentives under these conditions.	In addition, the majority of the evidence identified is related to pregnant women. Therefore the scope of this update is limited to pregnant women. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.
Primary Care Respiratory Society UK	General	General	<p>We support the following observation by ASH on the grouping of interventions in the guideline scope: The two headings 'prevention and promotion' and 'cessation and harm reduction' are overlapping and unclear. It would make better sense to split the two sections more clearly into non-treatment and treatment interventions. To make this clear, 'prevention and promotion' should be changed to 'preventing uptake and promoting quitting' and 'cessation and harm reduction' should be changed to 'treating tobacco dependency'.</p> <p>This would mean, for example, that mass media campaigns would be included in 'preventing uptake and promoting quitting' while clinical interventions such as stop smoking services and brief advice and prescribing would be included in 'treating tobacco dependency'.</p> <p>We believe it is very important to use the term 'treating tobacco dependency'. Tobacco dependency is a long term relapsing condition which usually starts in childhood.</p>	<p>Thank you for this comment. The subheading "cessation and harm reduction" has been amended to "treating tobacco dependence". This will continue to include review questions about quitting smoking and about reducing harm from smoking. We note that subheadings are intended to organise and provide an overview of what evidence will be updated, rather than reflecting the structure of the final published guidance.</p> <p>The subheading "prevention and promotion" has been amended to "preventing uptake". "Promoting quitting" does not form part of this update so it has been removed from the subheading. However, material from the original guidelines on promoting quitting will be retained and will form part of the final product.</p>

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			<p>Treating tobacco dependency is the single most cost effective intervention for the prevention of smoking-related disease and for smokers who have smoking-related disease(s). A range of evidence-based pharmacological treatments exist to support smokers facing the difficulty of behaviour change and breaking nicotine addiction.</p> <p>Smoking cessation treatment options, both pharmacological and advisory, are inexpensive and judged by NICE to be highly cost-effective in terms of life years gained. Providing a mixture of nicotine replacement therapy (NRT) and a stop smoking drug is the most effective pharmacological intervention when providing behavioural support. When using NRT, ensure you are prescribing enough to manage the nicotine withdrawal symptoms. The best way to do this is often by giving more than one delivery system so patients can fit it in to their daily life. As with choosing inhaler devices, use something that the patient would like to try and change if it isn't working. There is good evidence to show that combination NRT is more effective than single product use. NICE recommends that combination NRT should be considered as a viable option for smokers wanting to quit.</p>	

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			<p>We prefer the language 'treating tobacco dependency' to 'smoking cessation', as it make it clear that helping people to quit is the business of all healthcare professionals and requires an active intervention or interventions from them.</p> <p>Reference: https://www.pcrs-uk.org/sites/pcrs-uk.org/files/TobaccoDependencyFlierFINAL2018.pdf</p>	
Primary Care Respiratory Society UK	General	General	Carbon monoxide monitoring is not mentioned in the scope. It is an invaluable tool to demonstrate to patients that they are reducing harm from tobacco use. We promote a carbon monoxide monitor as a tool that should be on the desk of every healthcare practitioner to support the treatment of tobacco dependency.	Thank you for this comment. Carbon monoxide monitoring is mentioned in the existing guidelines in recommendations which will be retained in the new guidance.
Primary Care Respiratory Society UK	12	17 - 18	The scope needs to include reviewing the recommendation that smokers in acute, maternity and mental health services are referred to stop-smoking services. The UK model has been stand alone specialist stop-smoking services but there is growing evidence that provision of services within secondary care settings can be highly effective in promoting quitting (see Ottawa model http://tobaccocontrol.bmj.com/content/26/3/293) Furthermore there is no longer universal access to stand alone specialist services and therefore it is crucial that	Thank you for this comment. The design of service provision is outside of the scope of this referral and will not be covered by this guideline.

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			these recommendations are reviewed to ensure that smokers have access to the treatment they need.	
Primary Care Respiratory Society UK	17	General	<p><u>Providing a mixture of nicotine replacement therapy (NRT) and a stop smoking drug is the most effective pharmacological intervention when providing behavioural support</u></p> <p>Reference: https://www.pcrs-uk.org/sites/pcrs-uk.org/files/TobaccoDependencyFlierFINAL2018.pdf </p>	Thank you for this comment. The sources you provide will be considered if they meet the criteria for the review questions. All evidence meeting the criteria will be presented to the committee.
Primary Care Respiratory Society UK	17	General	<p>6.2 What influences the acceptability among smokers of using e-cigarettes as a smoking cessation or harm-reduction approach?</p> <p>Support from health professionals generally enhances the likelihood of people quitting successfully. This includes the prescribing of treatments rather than the individual buying them over the counter.</p>	Thank you for this comment. These proposed questions will form reviews, with literature searches to identify the studies to be included in these reviews. We will be considering the acceptability evidence for e-cigarettes.
Primary Care Respiratory Society UK	18	General	<p>Based on the current evidence, PCRS-UK supports e-cigarettes as a positive option to support people to quit tobacco smoking.</p> <ul style="list-style-type: none"> • E-cigarettes are marketed as consumer products and are proving much more popular than NRT as a substitute and competitor for tobacco cigarettes. • The hazard to health arising from long-term vapour inhalation from the e-cigarettes available today is unlikely 	Thank you for this comment and the information on your stance on e-cigarettes. The evidence on these devices will be evaluated as part of the update, and recommendations made accordingly.

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			<p>to exceed 5% of the harm from smoking tobacco.</p> <ul style="list-style-type: none"> • The available evidence to date indicates that e-cigarettes are being used almost exclusively as safer alternatives to smoked tobacco, by confirmed smokers who are trying to reduce harm to themselves or others from smoking, or to quit smoking completely. • Supported by Public Health England, RCP and RCGP – see their publications: <ul style="list-style-type: none"> · https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0 · RCGP Position Statement on the use of non-combustible inhaled tobacco products, November 2016 · PHE15 <p>www.gov.uk/government/uploads/system/uploads/attachment_data/file/454517/Ecigarettes_a_firm_foundation_for_evidence_based_policy_and_practice.pdf</p> <p>Reference: https://www.pcrs-uk.org/sites/pcrs-uk.org/files/TobaccoDependencyFlierFINAL2018.pdf</p>	
Primary Care Respiratory Society UK	18	General	Providing a mixture of nicotine replacement therapy (NRT) and a stop smoking drug is the most effective pharmacological intervention when providing behavioural support. When using NRT, clinicians must ensure they are prescribing enough to manage the nicotine withdrawal symptoms. The best way to do this is often by	Thank you for this comment and inclusion of your flyer. Recommendations on NRTs are not being updated except in relation to e-cigarettes, and for women are pregnant, planning a pregnancy or who have recently given birth.

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			<p>giving more than one delivery system so patients can fit it in to their daily life. As with choosing inhaler devices, use something that the patient would like to try and change if it isn't working.</p> <p>Reference: https://www.pcrs-uk.org/sites/pcrs-uk.org/files/TobaccoDependencyFlierFINAL2018.pdf</p>	
Primary Care Respiratory Society UK	18	General	<p>Support by healthcare professionals to stop smoking, across the board, has been shown to be a clinically and highly cost-effective long-term intervention for people with smoking-related long-term disease.</p> <p>Reference: https://www.pcrs-uk.org/sites/pcrs-uk.org/files/TobaccoDependencyFlierFINAL2018.pdf</p>	Thank you for this comment and inclusion of your flyer. Interventions for smoking-related long term disease are not included in the commission for this update, and are included in separate guidelines, for example those on COPD.
Public Health England	General	General	<p>It is our view that heat not burn products are out of scope for this review.</p> <p>Public Health England (PHE) recognise that NICE has committed to consult on whether heat not burn products for harm reduction or cessation should be in scope. However the lack of independent evidence noted in two reviews demonstrates that there will not be enough non-tobacco industry evidence to support an assertion of harm reduction. Furthermore, there is not a consensus</p>	Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include 'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.

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NICE guideline on tobacco suite: prevention, cessation and harm reduction (update)

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			<p>Please insert each new comment in a new row</p> <p>that substitution of heated tobacco for smoked tobacco can be considered 'cessation'.</p> <p>As an agency of the United Kingdom (UK) government, we understand that both PHE and NICE are bound by the Framework convention for Tobacco Control, including Article 5.3. PHE recommends that NICE review the Guidelines for implementation before considering how it will interpret data originating from the tobacco industry. We consider that NICE has satisfied its public commitment to consult on whether heated tobacco products are in scope and the current lack of independent evidence means further work would be premature at this point.</p> <p>Furthermore, the evidence that does exist is for a small number of products. Currently only two very different types of device have been notified for sale in the UK under Tobacco and Related Products Regulations. It is likely that more will be notified before this guidance is complete. A scan of the current and recent international market for these products suggests that it is highly unlikely that all these products will have sufficiently similar characteristics and health consequences to permit advice on them as a single general class of product. Any advice NICE were to provide on current</p>	<p>Please respond to each comment</p>

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			<p>products is unlikely to apply equally to future products. The heterogeneity of these products is much greater than for e-cigarettes.</p> <p>NICE should be aware of the likely intense controversy and avoidable reputational risk that would arise from considering heated tobacco products in this guidance.</p> <p>We therefore recommend that heat not burn products are not included in the scope of this review.</p> <p>References: McNeill A, Brose LS, Calder R, Bauld L & Robson D (2018). Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England:https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review</p>	
Public Health England	General	General	<p>Committee on toxicity, carcinogenicity and mutagenicity of chemicals in food, consumer products and the environment(COT, COC and COM) - Statement on the toxicological evaluation of novel heat-not-burn tobacco productshttps://cot.food.gov.uk/sites/default/files/heat_not_burn_tobacco_statement.pdf</p>	<p>Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include</p>

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				'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.
Public Health England	General	General	<p>On incentives for smoking cessation, PHE is aware of the growing body of good quality evidence to support the use of incentives to support women to stop smoking in pregnancy. Whilst it feels intuitive that this may be replicated in other contexts, particularly when looking to address health inequalities, we are not aware of any evidence to suggest this is the case.</p> <p>A Cochrane review on incentives for smoking cessation has found limited evidence for incentives to support longer term cessation, with most study contexts not transferrable to the situation in England. The review concluded: "Such an approach may only be feasible where independently-funded smoking cessation programmes are already available, and within a relatively affluent and educated population". The exception is for incentives to support smoking cessation in pregnancy, where most of the studies included in the review found improved cessations rates at the end of pregnancy and post-partum, including the largest study which was conducted in Scotland.</p> <p>It may be that further research is required in this area.</p>	<p>Thank you for this comment. As the majority of the evidence identified is related to pregnant women, the scope of this update is limited to that population. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.</p>

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			<p>References:</p> <p>Cahil, K., Hartmann-Boyce, J. & Perera, R. (2015). Incentives for smoking cessation.http://cochranelibrary-wiley.com/doi/10.1002/14651858.CD004307.pub5/abstract</p> <p>Tappin et al. (2015). Financial incentives for smoking cessation in pregnancy: randomised controlled trialhttps://www.bmj.com/content/350/bmj.h134</p> <p>Boyd et al (2016) Are financial incentives cost-effective to support smoking cessation during pregnancy?https://www.ncbi.nlm.nih.gov/pubmed/26370095</p>	
Public Health England	General	General	<p>Although mass media campaigns are referenced in sections 3.3 and 3.5, the focus of these references are on campaigns to prevent uptake of smoking. We know that evidence exists to demonstrate the effectiveness of national and regional mass media campaigns in helping smokers to quit. Greater focus should be put in the review of the role of mass media campaigns to promote quitting, and their cost effectiveness.</p>	<p>Thank you for this comment. Mass media campaigns for cessation are not included in the update of this guidance. They are already commonly used and there is little concern about variation in their use. Additionally, insufficient evidence has been identified through consultation to merit this new area.</p> <p>Please note that key issue 1.2 proposes to look at whether smoking cessation mass media campaigns using de-normalisation strategies aimed at adults are effective and cost effective in preventing the uptake of smoking among children and young people.</p>
Public Health England	1	5	<p>The title for this review is not clear. We suggest amending to:</p>	<p>Thank you for this comment. The title of the guideline (which incorporates the update and the material</p>

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			Smoking: preventing and treating tobacco dependence	which will not be updated but will be retained) has been amended to "Tobacco: preventing uptake, promoting quitting and treating dependence". The scope has been amended to reflect this change. While 'promoting quitting' does not form part of this update, material from the original guidelines on promoting quitting will be retained and will form part of the final product.
Public Health England	2	20 - 21	PHE maintains that it is important to consider evidence on young people who do and do not already smoke in relation to e-cigarettes in key areas for review. Suggest edit to: 'the impact of e-cigarettes on smoking behaviour in children and young people who do and do not currently smoke'	Thank you for this comment. This area comes under prevention and as such the included population is people who do not currently smoke. However, in order to assess the impact of e-cigarettes on the future smoking behaviour of children and young people who do smoke, an additional key issue has been added to the 'treating tobacco dependency' section: <i>What is the impact of e-cigarettes on the smoking behaviour of children and young people who currently smoke?</i>
Public Health England	2	14	Prevention and promotion is not clear. Suggest this heading is amended throughout to: 'Preventing uptake and promoting quitting'	Thank you for this comment. Subheadings are intended to organise and provide an overview of what evidence will be updated, rather than reflecting the structure of the final published guidance. The subheading "prevention and promotion" has been amended to "preventing uptake". "Promoting

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				quitting" does not form part of this update so it has been removed from the subheading. However, material from the original guidelines on promoting quitting will be retained and will form part of the final product.
Public Health England	4	16 - 22	<p>Also in relation to current practice, there is more up-to-date evidence relating to the use of e-cigarettes across the population in England. We suggest this section is edited to:</p> <p>There are around 2.9 million current adult e-cigarette users in Great Britain, approximately six percent of the adult population. The proportion of e-cigarette users who are ex-smokers has increased over time, and the majority of users are now ex-smokers who have switched completely to vaping. Prevalence of dual use (use and smoking) is similar for e-cigarette users and NRT users. Among young people, while experimentation with e-cigarettes is fairly common, regular use (at least weekly) is very low at three percent or less, and largely confined to regular smokers. Regular e-cigarette use among youth who have never smoked is very rare.</p> <p>Reference: McNeill A, Brose LS, Calder R, Bauld L & Robson D (2018). Evidence review of e-cigarettes and heated</p>	Thank you for this comment. We have updated the policy section where more up to date figures have been provided and identified in the reference.

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			tobacco products 2018. A report commissioned by Public Health England. London: Public Health England https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review	
Public Health England	4	8 to 9	In relation to current practice, PHE suggest the best reference for the statement on reductions in people attending stop smoking services would be the NHS Digital statistics. https://digital.nhs.uk/data-and-information/publications/statistical/statistics-on-nhs-stop-smoking-services-in-england/statistics-on-nhs-stop-smoking-services-england-april-2016-to-march-2017	Thank you for this comment. This change has been made.
Public Health England	5	2	As described in point 5 - Section heading unclear, suggest amending throughout to: 'Preventing uptake and promoting quitting'	Thank you for this comment. Subheadings are intended to organise and provide an overview of what evidence will be updated, rather than reflecting the structure of the final published guidance. The subheading "prevention and promotion" has been amended to "preventing uptake". "Promoting quitting" does not form part of this update so it has been removed from the subheading. However, material from the original guidelines on promoting quitting will be retained and will form part of the final product.
Public Health England	5	8	The term 'mass media services' is unclear. Suggest edit to:	Thank you for this comment. This change has been made.

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			`Mass media campaigns (or people developing mass media campaigns)`	
Public Health England	5	12	This should specify what is being commissioned and provided and be consistent with sections below. Suggest edit to: `Commissioners and providers of stop smoking interventions or services`	Thank you for this comment. For clarity, wording has been amended to: "commissioners and providers of interventions and services for preventing uptake".
Public Health England	5	18	This needs to be clearer on who the commissioners and providers are in this context. Suggest edit to: `Commissioners of stop smoking interventions or services and other services where practitioners engage with smokers`	Thank you for this comment. For clarity, wording has been amended to: "commissioners and providers of stop smoking interventions and services".
Public Health England	5	24	This point should be higher in the list. Suggest move up to line 19, following "commissioners".	Thank you for this comment. This change has been made.
Public Health England	6	23	We suggest that Lesbian Gay Bisexual Trans groups are included in this section as this group also experiences substantial smoking-related inequalities.	Thank you for this comment. This change has been made.
Public Health England	8	8	Where adults aged over 25 will not be covered, PHE maintains that a distinction should be made between 'prevention' and 'promotion'. Whilst guidance on preventing uptake in those aged over 25 should be out of	Thank you for this comment. The subheading "prevention and promotion" has been amended to "preventing uptake". "Promoting quitting" does not form part of this update so it has been removed from

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			scope, promotion of cessation should be focussed on all adults. It is the latter which will influence adults to quit and thereby indirectly impact on reductions in uptake amongst young people.	the subheading. However, material from the original guidelines on promoting quitting will be retained and will form part of the final product. Therefore the target population for the material included in this update for preventing uptake has been kept as people aged 24 and under, in line with evidence around age of smoking initiation.
Public Health England	8	19	Linked to the settings for prevention and promotion, we would suggest explicit reference to recommendations around the portrayal of smoking in the media, and the need for this to be minimised, given the correlation between youth uptake of smoking and its portrayal in the media.	Thank you for this comment. Digital media interventions for prevention will be considered. However, the removal of references to and images of smoking in entertainment media is related to broadcasting and media services regulations. These are outside of NICE's remit and therefore not something NICE would make recommendations on.
Public Health England	8	19	We recommend the inclusion of "healthcare settings" as part of the list of prevention and promotion settings.	Thank you for this comment. Healthcare settings, although they will be included in the final guidance in recommendations which are carried forward, are not among the settings for which recommendations are being updated in relation to prevention. Therefore they are not included in this list.
Public Health England	9	25 - 28	School-based interventions are currently out of scope for review. PHE would strongly recommend that they should be within scope, along with a review of cost-effectiveness relative to other interventions. Given falling youth smoking rates, and the strong correlation between youth uptake and parental smoking, this is an area that	Thank you for this comment. A surveillance review was conducted for PH23 which searched for new evidence on all recommendations, including school-based interventions. No evidence was identified which would change current recommendations with the exception of smokefree class competitions.

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			should be reviewed to ensure that current recommendations are still relevant, and that they represent an appropriate use of resources.	Please see the surveillance report here: https://www.nice.org.uk/guidance/ph23/evidence/review-decision-2013-pdf-546068269 . Insufficient additional evidence has been identified to update the recommendations on other types of school-based prevention interventions.
Public Health England	9	30	<p>As in point 2 - PHE maintains that it is important that the review considers evidence relating to young people who are already smoking, as well as those who are not.</p> <p>Evidence from national surveys indicates that in the UK regular use of e-cigarettes among young people remains very low, at three percent or less, and remains largely confined to regular smokers. Regular e-cigarette use among never smokers is very rare.</p> <p>Suggest edit this to:</p> <p>"E-cigarettes and their impact on smoking behaviour among children and young people who do and do not currently smoke".</p> <p>Reference: Bauld et al (2017). Young People's Use of E-Cigarettes across the United Kingdom: Findings from Five Surveys</p>	<p>Thank you for this comment. This area comes under prevention and as such the included population is people who do not currently smoke. However, in order to assess the impact of e-cigarettes on the future smoking behaviour of children and young people who do smoke, an additional key issue has been added to the 'treating tobacco dependency' section:</p> <p><i>What is the impact of e-cigarettes on the smoking behaviour of children and young people who currently smoke?</i></p>

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			2015–2017. http://www.mdpi.com/1660-4601/14/9/973/htm	
Public Health England	10	13 - 18	<p>It is unclear what the inclusion of these bullet points relates to.</p> <p>If these are for comparison with e-cigarettes as a means of cessation or harm reduction then “people living and working in closed institutions” does not fit.</p> <p>We suggest removing these bullet points as the text above in lines 10 – 13 is clear enough.</p>	Thank you for this comment. The material for this section has now been put in table format which we hope is clearer. In addition, the wording you were referring to has been removed.
Public Health England	10	5	The use of e-cigarettes in pregnancy should also be considered in this context and specified in addition to nicotine replacement therapy (NRT).	Thank you for this comment. E-cigarettes are being considered for pregnant women so wording has been amended to reflect this.
Public Health England	10	19	As described in point 1, we recommend that heat not burn products are NOT included in the scope of this review.	Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of ‘heat not burn’ products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include ‘heat not burn’ products in the final scope for the updates to the suite of Tobacco guidelines.
Public Health England	10	21	We suggest removing the word “cutting down” and replace with “stopping smoking” as this should be the	Thank you for this comment. E-cigarettes are being considered both as a means of quitting, and as harm

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			aim of any recommendation associated with use of e-cigarettes.	reduction (for temporary abstinence, cutting down etc.) as both are patterns of use seen. Wording has been amended to: "...as a means of cutting down on or quitting smoking".
Public Health England	13	20	As described in point 1, we recommend that heat not burn products are NOT included in the scope of this review.	Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include 'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.
Public Health England	17	28 - 29	As described in point 1, we recommend that heat not burn products are NOT included in the scope of this review.	Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include 'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.
Public Health England	17	13	As described in point 2 and 15: PHE maintain that it is important that the review considers evidence relating to young people who are already smoking, as well as those who are not.	Thank you for this comment. This area comes under prevention and as such the included population is people who do not currently smoke. However, in order to assess the impact of e-cigarettes on the

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			<p>Evidence from national surveys indicates that in the UK regular use of e-cigarettes among young people remains very low, at three percent or less, and remains largely confined to regular smokers. Regular e-cigarette use among never smokers is very rare.</p> <p>Suggest edit this to:</p> <p>"E-cigarettes and their impact on smoking behaviour among children and young people who currently do and do not smoke".</p> <p>Bauld et al (2017). Young People's Use of E-Cigarettes across the United Kingdom: Findings from Five Surveys 2015–2017. http://www.mdpi.com/1660-4601/14/9/973/htm</p>	<p>future smoking behaviour of children and young people who do smoke, an additional key issue has been added to the 'treating tobacco dependency' section:</p> <p><i>What is the impact of e-cigarettes on the smoking behaviour of children and young people who currently smoke?</i></p>
Public Health England	19	1 to 2	We suggest that mental wellbeing should also be included as an outcome here.	Thank you for this comment. Health Related Quality of Life (HRQoL) is NICE's preferred measure and will incorporate some aspects of mental wellbeing.
Royal College of General Practitioners	General	General	Smoking remains a massive public health problem and the RCGP welcomes the proposal to update guidance on smoking cessation whilst also reducing the number of sets of guidance on this subject. Fewer sets of more focussed guidance will be easier for clinicians to follow. The proposal to split guidance into that relevant for	Thank you for this comment. We are pleased to hear that fewer sets of guidance will be easier for clinicians to follow, and that the inclusion of e-cigarettes is supported.

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			<p>prevention of smoking uptake and for smoking cessation / harm reduction is welcomed; the latter should be particularly important for GPs and other primary care clinicians.</p> <p>The RCGP welcomes the proposal to produce evidence-based guidance about how e-cigarettes could be used to either assist smoking cessation or to reduce the harm patients incur from smoking tobacco. E-cigarettes have become very popular consumer products and GPs / primary care clinicians would welcome consensus guidance on how these can be best used by patients. ¶</p>	
Royal College of General Practitioners	General I	General	<p>What impact is loss of NHS funded cessation support having on uptake of attempts to quit for those less able to afford smoking cessation support? This concern applies particularly where there is low confidence that the measure will be a successful investment for that individual, such as in entrenched smokers who have recently had a significant smoking-related co-morbidity diagnosis. This group of patients require committed support in view of known benefits from quitting, rather than cost barriers.</p> <p>In view of the extensive slashing of smoking cessation funding in primary care it is important to understand the impact on the deprivation gap from costs being transferred directly to consumers. It is unlikely to be a</p>	<p>Thank you for this comment. The structure of service provision and service models is not within the scope of this referral. However we will be considering potential for inequalities in detail, as outlined in the Equality Impact Assessment. Recommendations will be made to attempt to reduce themse inequalities.</p>

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			safe assumption that all consumers would consider self-funded cessation support in the same way. There are concerns at how little consultation and wider debate there has been about this recent rationing process of what the NHS provides, particularly since the transfer of public health budgets across to local authorities. This guideline process could shed valuable understanding on particular aspects of the rationing process in relation to expectations of self-funded care on deprivation.	
Royal College of General Practitioners	Question 1	Question 1	<p>The RCGP does not believe it is appropriate to include 'heat not burn' tobacco products within the scope of this NICE guidance for the following reasons:</p> <p>There is very little research evidence on the toxicological profile of emissions from these products We are not aware of any clinical trials which could be used to determine efficacy / safety of such products Use of 'heat not burn' products is minimal in the UK so there is no pressing need to respond to consumer use patterns. The converse is true for e-cigarettes which are very widely used.</p> <p>We believe that until published safety / efficacy evidence becomes available it would not be a good use of NICE committee resources to spend time assessing 'heat not burn' products. Given that these products are not widely used and awareness of them is low, it seems likely that</p>	Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include 'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.

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NICE guideline on tobacco suite: prevention, cessation and harm reduction (update)

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			any NICE guidance regarding their use would become confused with those made for e-cigarettes; this could confuse clinicians and ultimately be counter-productive.	
Royal College of General Practitioners	Question 2	Question 2	<p>The RCGP welcomes the consideration of incentives for use to promote smoking cessation in pregnancy because the recently-published RCT of incentives used in this group suggested these could have a much bigger treatment effect than other recently-trialled interventions. See https://www.bmj.com/content/350/bmj.h134</p> <p>As smoking remains such an intractable issue, the RCGP welcomes an objective assessment of any harm-free method which could reduce the prevalence of this destructive behaviour and as such, welcomes an investigation of whether financial incentives, contingent on smoking cessation, might help non-pregnant smokers to stop.</p>	<p>Thank you for this comment. The reference you have supplied will be considered against the inclusion criteria of any review about incentives for pregnant women.</p> <p>In relation to incentives in other groups: a surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified on incentives for cessation which would change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence</p> <p>In addition, the majority of the evidence identified is related to pregnant women. Therefore the scope of this update is limited to pregnant women. However,</p>

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				NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.
Royal College of General Practitioners	Question 3	Question 3	<p>As smoking is so harmful and so costly to the NHS, even minimally-effective cessation interventions are likely to be cost-effective as assessed by standard metrics (see https://doi.org/10.1111/j.1360-0443.2007.01750.x).</p> <p>Consequently, any interventions which are particularly cheaply to disseminate (e.g. digital interventions) are likely to be cost-saving.</p> <p>For this reason we feel it is particularly important to include digital interventions used in pregnancy within the scope of the guidance update (see # 1 & # 5 below).</p>	Thank you for this comment. Please see our responses to the comments you reference about digital interventions.
Royal College of General Practitioners	16	10 to 16	<p>A dynamic, economic model to value smoking cessation in pregnancy has been developed at the University of Nottingham and this is being made available to others for academic and policy-orientated uses. A 'stripped' down version with instructions for accessing the 'full' model are found at: https://www.nottingham.ac.uk/research/groups/tobaccoandalcohol/smoking-in-pregnancy/esip/</p> <p>The current version of the model is extended from that described in this PhD thesis: http://eprints.nottingham.ac.uk/30604/</p>	Thank you for this comment. These references will be passed on to the team undertaking the economic analysis for this guideline update

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			<p>A manuscript describing the model is currently being evaluated for publication the 'Statistics and Methodology' section of Addiction; it is anticipated this will be published within 6 months.</p> <p>This model could be valuable in helping NICE to evaluate the cost-effectiveness of smoking cessation in pregnancy from either 'lifetime' or 'end of pregnancy' time-horizons and includes an assessment of 'Return on Investment' from smoking cessation interventions provided in pregnancy.</p>	
Royal College of General Practitioners	17	26 - 29	<p>It has also shown that pregnant women will initiate MiQuit after seeing online adverts (See doi:10.2196/jmir.8525, cost per quitter estimated as £735.86 [95% CI £227.66-£5223.93]) or after receiving information about it as part of their 'booking pack' information (See http://dx.doi.org/10.1136/bmjopen-2015-008871) .</p> <p>A third evaluative RCT is underway and has recruited 2/3 of target sample size in the last 5 months. A protocol has been submitted to 'Trials'; although this was not published at the time this response was compiled, by now it will probably be identifiable by searching online for 'MiQuit 3 Trial' and 'Trials'.</p>	<p>Thank you for this comment. Digital channels for smoking cessation is not currently an area covered in existing guidance or identified for new areas due to new evidence. However, NICE is updating its guidance on behaviour change which may look at evidence in this area.</p>

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			MiQuit would be easily and cheaply disseminated and economic analyses (further detail below) suggest it could be cost saving for the NHS. As a worked example in a paper describing a new economic model for smoking cessation in pregnancy, we have modelled the long-term cost-effectiveness of MiQuit (see #5 below). This manuscript, which we expect to be published within 6 months, demonstrates that MiQuit would likely be cost-saving to the NHS and highly cost-effective.	
Royal College of General Practitioners	17	26 - 29	Comments below highlight new research which will become available during the guideline development period and which could help answer questions posed in draft scope.	Thank you for this comment. Please see our responses to the comments you reference.
Royal College of General Practitioners	17	26 - 29	<p>This review summarises the literature on the determinants of nicotine replacement therapy (NRT) use in pregnancy would be relevant to answering question # 6.1 in Section 3.5. It provides information on the acceptability of NRT to pregnant women.</p> <p>Protocol: Tom Coleman-Haynes, Sophie Orton, Sue Cooper, Tim Coleman, Luis Vaz, Matthew Jones, Katharine Bowker, Katarzyna Campbell. A mixed-methods systematic review to identify the determinants of nicotine replacement therapy (NRT) use in pregnancy. PROSPERO 2017:CRD42017058347 Available</p>	Thank you for this comment. The sources you provide will be considered if they meet the criteria for the review questions. All evidence meeting the criteria will be presented to the committee.

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			<p>from http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42017058347</p> <p>Status: Unpublished - manuscript submitted to Nicotine & Tobacco Research in May 2018</p>	
Royal College of General Practitioners	17	26 - 29	<p>This review of observational studies will contribute to the literature on the safety of nicotine replacement therapy in pregnancy. (Question # 6.1 in Section 3.5)</p> <p>Protocol: Lauren Taylor, Tim Coleman, Tom Coleman-Haynes, Katarzyna Campbell, Sue Cooper, Anne Dickinson. Systematic review of observational studies to compare the safety of nicotine replacement therapy (NRT) use and smoking in pregnancy. https://www.crd.york.ac.uk/prospERO/display_record.php?RecordID=85834</p> <p>Status: Ongoing – completed manuscript expected by Autumn 2018</p>	Thank you for this comment. The sources you provide will be considered if they meet the criteria for the review questions. All evidence meeting the criteria will be presented to the committee.
Royal College of General Practitioners	17	26 - 29	<p>The comment below highlight new research of which would help answer questions posed in draft scope but which is unlikely to be fully published during the guideline development period</p> <p>Helping pregnant smokers quit: a multi-centre study of electronic cigarettes and nicotine patches http://www.isrctn.com/ISRCTN62025374</p>	Thank you for this comment. The sources you provide will be considered if they meet the criteria for the review questions. All evidence meeting the criteria will be presented to the committee.

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			This HTA funded RCT compares the effectiveness of e-cigarettes and nicotine patches for smoking cessation in pregnancy. It is led by Prof Peter Hajek (London, QMUL) but recruitment is led from Nottingham. We anticipate findings being available by the end of 2020.	
Royal College of General Practitioners	18	1 to 2	<p>Survey investigating attitudes to, and prevalence and determinants of e-cigarette use in pregnancy and postpartum. This ongoing study has recruited to target sample size at baseline and is following participants up at pregnancy and afterwards. (Question # 6.2 in Section 3.5)</p> <p>Findings will provide information on the acceptability of e-cigarettes for use in pregnancy and the feasibility of using them as a smoking cessation / harm reduction aid. We anticipate publication during 2019.</p>	Thank you for this comment. Literature searches will be undertaken to identify published evidence to answer the review questions. The source you provide is not yet published but will be considered if it is published in time for searches and meets the criteria for the review questions. All evidence meeting the criteria will be presented to the committee.
Royal College of General Practitioners	4	23 - 25	<p>The comment below deals with an omission from the draft scope. There is a strong likelihood that new research findings on an intervention described below will become available during the guideline development period and could inform guideline changesDigital interventions used for smoking cessation by pregnant women should be included in the scope.</p> <p>The scientific background to the scope says, "Digital</p>	Thank you for this comment. Digital channels for smoking cessation is not currently an area covered in existing guidance or identified for new areas due to new evidence. However, NICE is updating its guidance on behaviour change which may look at evidence in this area.

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	17	26 - 29	<p>channels, and in particular social media, offer opportunities to target messages to particular groups. Their effectiveness and cost effectiveness need to be determined".</p> <p>However, the draft scope only considers 'digital channels' for prevention of smoking uptake and not for harm reduction / cessation despite the fact that new evidence on this subject will become available during the guideline development period and this could inform the final guidance on how pregnant women who smoke should be helped to stop smoking.</p> <p>This omission means that question #6.1 in Section 3.5 will not be comprehensively-answered and so the updated guideline would be dated as soon as it is released.</p> <p>Specifically, a text-message programme which delivers self-help support to pregnant smokers (called 'MiQuit') has shown promising findings in published pilot trials. This is in the later stages of evaluation and definitive data regarding effectiveness should be available in summer /autumn 2019.</p> <p>Although various text message systems have been</p>	

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			<p>trialled for non-pregnant smokers, these should not be used by pregnant women because they give some advice which is inappropriate for this group (e.g. on how to avoid weight gain on stopping smoking and on using pharmacotherapies).</p> <p>Two smallish trials evaluating the text message intervention, MiQuit, have been published: https://doi.org/10.1093/ntr/ntr254 https://doi.org/10.1111/add.13802</p> <p>In the larger of these, a cost-per quitter, measured at the end of pregnancy was estimated as: The incremental cost-per-quitter was £133.53 (95% CI = -£395.78 to 843.62). This analysis has a short-term horizon and ignores any longer-term health gains from smoking cessation.</p> <p>CONTINUED BELOW.....</p>	
Royal College of General Practitioners	17 25	26 - 29 9 - 15	<p>This review contributes to the literature on the safety of nicotine replacement therapy (NRT) in pregnancy. It summarises the work on nicotine exposures from cigarettes and from using nicotine replacement therapy in pregnancy and quantifies these; a meta-analysis estimates the reduction in nicotine exposure from NRT compared to that from smoking. (Questions # 6.1 & 6.4</p>	<p>Thank you for this comment. The sources you provide will be considered if they meet the criteria for the review questions. All evidence meeting the criteria will be presented to the committee.</p>

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			<p>in Section 3.5).</p> <p>Protocol: Charlotte Hickson, Sarah Lewis, Tom Coleman-Haynes, Katarzyna Campbell, Sue Cooper, Tim Coleman. Systematic review and meta-analysis comparing nicotine concentrations generated by smoking and nicotine replacement therapy in pregnancy. PROSPERO 2017 CRD42017081914 Available from:http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017081914</p> <p>Status: Unpublished, manuscript submitted to Addiction in May 2018</p>	
Royal College of Paediatrics and Child Health	General	General	We are very happy with the document as it stands, assuming that outcomes will include effects on the foetus or proxy measures thereof such as Smoking Status At Time Of Delivery (SATOD)	Thank you for this comment. This will be borne in mind, and outcomes will be discussed with the committee during protocol development
Royal College of Physicians (RCP)	General	Cost-saving recommendations	It may be possible, through examining service provision models (not currently planned for this guidance), to identify more cost-effective ways to deliver smoking interventions. It is also important to identify those tobacco interventions that represent the best value, to ensure that tobacco control budgets are deployed as effectively as possible. It is particularly important to look	Thank you for this response to the consultation question on cost-saving. The design of service provision is outside of the scope of this referral and will not be covered by this guideline. Recommendations on school-based interventions were not identified by NICE's surveillance process as having the potential to be altered by any new

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			<p>at school-based interventions – ASSIST for example – for which cost-effectiveness data relate to periods when smoking uptake among young people was much higher than is the case today.</p> <p>However, since smoking prevention and cessation interventions are almost exclusively highly cost-effective, and more so than most other medical interventions, Our experts suggest that the question here should be aimed at those writing guidance on interventions that take precedence over smoking cessation and prevention, while also being less cost-effective.</p>	<p>evidence since publication of the original guideline, and so will not be included in the update for this guideline apart from as comparators to the Smokefree Class Competition.</p> <p>In terms of other interventions taking precedence over smoking cessation and prevention interventions: the guidelines developed by NICE are determined by the topics referred to NICE. To date there has not been a referral to compare the cost effectiveness of smoking cessation and prevention interventions with interventions in other topic areas.</p>
Royal College of Physicians (RCP)	General	General	The RCP is grateful for the opportunity to respond to the above consultation. We have liaised with UK Centre for Alcohol and Tobacco Studies (UKCTAS) and would like to make the following comments.	Thank you for this comment. Please see our individual responses to separate items.
Royal College of Physicians (RCP)	General	General	The use of the term 'prevention and promotion' for the first section of the new guidance is misleading. We suggest using the full phrase 'Preventing uptake, promoting quitting' as on line 16	Thank you for this comment. Subheadings are intended to organise and provide an overview of what evidence will be updated, rather than reflecting the structure of the final published guidance. The subheading "prevention and promotion" has been amended to "preventing uptake". "Promoting quitting" does not form part of this update so it has been removed from the subheading. However, material from the original guidelines on promoting

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				quitting will be retained and will form part of the final product.
Royal College of Physicians (RCP)	General	General	<p>The title of the second section, 'cessation and harm reduction' is fine but associates harm reduction with cessation services (as does PH45 guidance). In fact, harm reduction through consumer products is a means to help smokers quit without ever engaging in cessation services, and in this (much wider) application belongs in the preventing uptake and promoting cessation section.</p> <p>An alternative approach would be to call section one 'Preventing uptake, promoting quitting' and section two 'Treating tobacco dependency'.</p>	<p>Thank you for this comment. The subheading "cessation and harm reduction" has been amended to "treating tobacco dependence". This will continue to include review questions about quitting smoking and about reducing harm from smoking. We note that subheadings are intended to organise and provide an overview of what evidence will be updated, rather than reflecting the structure of the final published guidance.</p> <p>The subheading "prevention and promotion" has been amended to "preventing uptake". "Promoting quitting" does not form part of this update so it has been removed from the subheading. However, material from the original guidelines on promoting quitting will be retained and will form part of the final product.</p>
Royal College of Physicians (RCP)	General	Heat-not-burn products	Currently available evidence on Heat-not-burn (HNB) products originates almost entirely from the tobacco industry and is therefore unreliable; and these products are neither widely available, nor widely used, in the UK. Engagement with the tobacco industry on matters of health policy is also proscribed under Article 5.3 of the WHO Framework Convention on Tobacco Control. We	Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include

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			therefore strongly recommend that HNB products should be excluded from this guidance.	'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.
Royal College of Physicians (RCP)	General	Incentives	Incentives evidence is covered in a Cochrane Review: Cahill, K., Hartmann-Boyce, J., and Perera, R. Incentives for smoking cessation. Cochrane Database Syst Rev, 2015. 10.1002/14651858.CD004307.pub5: CD004307.	Thank you for this comment. A surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified on incentives for cessation which would change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence In addition, the majority of the evidence identified is related to pregnant women. Therefore the scope of this update is limited to pregnant women. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.
Royal College of Physicians (RCP)	16-17	17 - 21	Multiple comments made above apply where the relevant questions are repeated here.	Thank you for this comment. Please see our response to the comment you reference.
Royal College of Physicians (RCP)	2	20 - 21	Should be expanded to include impact of e-cigarettes on people who smoke (see general comment above)	Thank you for this comment. This area comes under prevention and as such the included population is people who do not currently smoke. However, in

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				<p>order to assess the impact of e-cigarettes on the future smoking behaviour of children and young people who do smoke, an additional key issue has been added to the 'treating tobacco dependency' section:</p> <p><i>What is the impact of e-cigarettes on the smoking behaviour of children and young people who currently smoke?</i></p>
Royal College of Physicians (RCP)	2	16	Should include harm reduction.	Thank you for this comment. Harm reduction is included in the material for update in the "cessation and harm reduction" sections.
Royal College of Physicians (RCP)	2	17	<p>It is not clear what is meant by 'digital channels, including social media' – but if the intention is that they are used only as a means to promote cessation, this section should also include minimising the pro-smoking effect of smoking imagery in these and in conventional media (such as TV and film).</p>	<p>Thank you for this comment. "Digital channels" has been amended to "digital media". Digital media includes websites and social media sites.</p> <p>Digital media for smoking cessation will not be covered as part of this update. Digital media interventions for prevention will be considered. However, the removal of references to and images of smoking in entertainment media is related to broadcasting and media services regulations. These are outside of NICE's remit and therefore not something NICE would make recommendations on.</p>

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Royal College of Physicians (RCP)	2	24	It is not clear why review of opt-out models is limited to pregnancy. It should include all cessation and harm reduction support provision.	<p>Thank you for this comment. NG92 recommends an opt-out referral approach for people planning surgery. This recommendation will be carried forward into the new guidance. A surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified on opt-out referral pathways which would change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence. Additionally,</p> <p>In addition, insufficient evidence has been identified through the consultation process to warrant a new review in this area. Therefore the scope of this update is limited to pregnant women. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.</p>
Royal College of Physicians (RCP)	2	28	It is not clear why review of the use of incentives is limited to pregnancy. Admittedly that is where most of the existing evidence is to be found, but the approach can be applied much more widely	Thank you for this comment. A surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified on incentives for cessation which

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				<p>would change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence</p> <p>In addition, the majority of the evidence identified is related to pregnant women. Therefore the scope of this update is limited to pregnant women. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.</p>
Royal College of Physicians (RCP)	4	16 - 18	Smokers who switch entirely to e-cigarettes rarely do so abruptly and irreversibly. That 2 of 5 e-cig users no longer smoke is therefore a good thing; and many of the 3 in 5 using them while still smoking may well migrate to exclusive e-cig use – and/or be open to encouragement to do so. The phrasing 'But 3 in 5 were using them as well as smoking ...' suggests that this is a bad thing, when in fact we should be encouraging smokers to try dual use.	Thank you for this comment. The sentence has been amended to emphasise the positive result of 2 in 5 e-cigarette users having switched completely.
Royal College of Physicians (RCP)	5	4 to 5	To say that prevention and promotion applies only to those aged 24 and under is wrong. While few people start smoking after age 25, measure to promote quitting	Thank you for this comment. The subheading "prevention and promotion" has been amended to "preventing uptake". "Promoting quitting" does not

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NICE guideline on tobacco suite: prevention, cessation and harm reduction (update)

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14/05/2018 to 11/06/2018

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			<p>should apply to all ages. The reference to an age limit should be removed.</p> <p>It is important to recognise that NICE guidance, while drafted with the intention of proactively recommending things to do to improve health outcomes, is often consumed (particularly in circumstances of tight finances) reactively with a view to identifying things that need not be done. This age limit is justification for anyone who does not have a remit for people aged 24 and under to ignore the rest of the prevention and promotion section.</p>	<p>form part of this update so it has been removed from the subheading. However, material from the original guidelines on promoting quitting will be retained and will form part of the final product. Therefore the target population for the material included in this update for preventing uptake has been kept as people aged 24 and under, in line with evidence around age of smoking initiation.</p>
Royal College of Physicians (RCP)	7	5 to 6	Same point as above regarding the age limit.	Thank you for this comment. Please see our response to the comment you reference.
Royal College of Physicians (RCP)	7	8 to 25	Could be replaced with the word 'Smokers' or, if brevity is not an aim, 'People who smoke'. If the current list of service user groups is retained, it should include smokers in primary care.	Thank you for this comment. The additional detail in this section of the scope has been retained and amended from previous scopes in order to match the current work. This has also been phrased to conform to the style of language that NICE uses. In terms of people who smoke in primary care, this would come under settings which is in a later section. Settings for cessation include primary care.
Royal College of Physicians (RCP)	8	14 - 20	Should include all healthcare settings and workplaces.	Thank you for this comment. Workplaces are not a specific location for any of the proposed key issues for 'preventing uptake', so they have not been added

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				to the list of settings. However, this does not preclude any studies which match the inclusion criteria and are set in or related to workplaces from being included, as this list of settings is not intended to be exhaustive. Healthcare settings, although included in recommendations which are carried forward in the final guidance, are not among the settings for which recommendations are being updated in relation to prevention. Therefore they are not included in this list.
Royal College of Physicians (RCP)	8	5	Our experts question whether this means that NICE will be updating guidance for users of smokeless tobacco who are not of south Asian origin.	Thank you for this comment. PH39 (Smokeless tobacco: South Asian communities), whilst not being updated based on new evidence, will be retained in the final product of this update. The recommendations will be refreshed to reflect current context and NICE style. Smokeless tobacco for people not of South Asian origin will not be included in any updated material apart from Key Issues 2.1 and 2.2 which are about the illicit supply of tobacco and proxy sales of tobacco to people under 18.
Royal College of Physicians (RCP)	8	8	Age limit point again.	Thank you for this comment. Please see our response to your previous comment.

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Royal College of Physicians (RCP)	9	20 - 25	It's not clear why these coercive measures are necessary when these activities are already illegal, but those laws are often unenforced because trading standards budgets have been reduced. The objective of this statement could be made clearer.	Thank you for this comment. Changes to budgets are outside of NICE's remit and is therefore not something NICE would make recommendations on. Please see the surveillance review for PH14 which details why the decision was made to update recommendations on illegal sales: https://www.nice.org.uk/guidance/ph14/evidence
Royal College of Physicians (RCP)	9	25 - 28	It is not clear why this small niche of school-based intervention is selected for updating when others are not. We are not aware of any major advance in evidence on this type of intervention.	Thank you for this comment. A surveillance review was conducted for PH23 which searched for new evidence on all recommendations, including school-based interventions. No evidence was identified which would change current recommendations with the exception of smokefree class competitions. Please see the surveillance report here: https://www.nice.org.uk/guidance/ph23/evidence/review-decision-2013-pdf-546068269 . Insufficient additional evidence has been identified to update the recommendations on other types of school-based prevention interventions.
Royal College of Physicians (RCP)	9	12 to 19	Here it becomes clear that the media focus is on health promotion. It is important to look at the other side of the same coin – preventing exposure to smoking imagery in these same media.	Thank you for this comment. Digital media interventions for prevention will be considered. However, the removal of references to and images of smoking in entertainment media is related to broadcasting and media services regulations. These

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				are outside of NICE's remit and therefore not something NICE would make recommendations on.
Royal College of Physicians (RCP)	10	4	Opt-out models are more effective than opt-in models. This is recognised in PH48, which advocates an opt-in approach. It is not clear why opt-out models are being considered only in relation to pregnant smokers.	<p>Thank you for this comment. NG92 recommends an opt-out referral approach for people planning surgery. This recommendation will be carried forward into the new guidance. A surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified on opt-out referral pathways which would change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence. Additionally,</p> <p>In addition, insufficient evidence has been identified through the consultation process to warrant a new review in this area. Therefore the scope of this update is limited to pregnant women. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.</p>

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Royal College of Physicians (RCP)	11	22 - 23	It is not clear why these interventions will not be reviewed. There are at least two new trials of relevance https://www.sciencedirect.com/science/article/pii/S0749379717306402 and http://tobaccocontrol.bmj.com/content/early/2017/04/21/tobaccocontrol-2016-053279?utm_source=trend_md&utm_medium=cpc&utm_campaign=jnnp&utm_content=trendmd4	Thank you for this comment. These references have been considered and discussed. There is insufficient evidence to change the existing recommendations made in PH26 about providing information about risks to the unborn child of smoking when pregnant; providing advice about the danger of other people's tobacco smoke; and offering partners who smoke help to stop using a multi-component intervention. Therefore this area has not been added to the scope for this update.
Royal College of Physicians (RCP)	11	10 to 13	It is not clear why these four intervention types in schools are not being revisited, when Smokefree class competitions are. It is essential that the cost-effectiveness of these interventions is assessed and long term outcome data provided, since measures targeting children generally gain political support, and can often eliminate more cost-effective options as a result. We therefore need to know whether these measures represent the best value for money in comparison with other tobacco control measures, not just those involving schoolchildren.	Thank you for your comment. A surveillance review was conducted for PH23 which searched for new evidence on all recommendations, including school-based interventions. No evidence was identified which would change current recommendations with the exception of smokefree class competitions. Please see the surveillance report here: https://www.nice.org.uk/guidance/ph23/evidence/review-decision-2013-pdf-546068269 . Insufficient additional evidence has been identified to update the recommendations on other types of school-based prevention interventions. NICE's preferred approach is to undertake a full incremental analysis where possible. However, this

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				<p>approach and likewise the development of a league table, may not be appropriate given the disparate nature of tobacco control measures that are likely to be covered by the guideline and difference in methods used to assess them. Take the following three interventions as an example:</p> <p>Intervention A: NRT + GP advice vs usual care (undefined)</p> <p>Intervention B: mass media campaign aimed at adults who smoke vs background quit rate</p> <p>Intervention C: school based prevention programme vs usual practice (undefined)</p> <p>A full incremental analysis would involve comparing interventions A, B and C sequentially in rank order of effectiveness (or cost). This assumes interventions A, B and C are mutually exclusive but there is nothing to say that is the case so a commissioning body could decide to fund all three.</p> <p>Although a league table of ICERs for these interventions could be created, differences in settings, population groups, comparators and in the case of smoking prevention – outcomes - would make it difficult to interpret in any meaningful way. There are other important considerations too such as the quality of evidence and uncertainty around the</p>
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				estimates, the size of the population likely to benefit and the impact on inequalities. In the case of the latter, if the goal is to reduce health inequalities, interventions that work best for the most disadvantaged groups might be more costly and could reduce the health gain achieved in the population as a whole. The following sets out some of the issues identified when league tables were first being discussed see https://www.sciencedirect.com/science/article/pii/S027795369390315U .
Royal College of Physicians (RCP)	12	17 - 18	It is not clear why this topic will not be reviewed. UK cessation services have evolved around a stand-alone service model, with referral to service being a default measure of intervention. Whilst there are good historical political reasons why this is the case, the evidence on opt-out systems indicates that it is far from ideal. The design of service provision models should be reviewed and the conventional wisdom that stand-alone is best questioned.	Thank you for this comment. The design of service provision is outside of the scope of this referral and will not be covered by this guideline.
Royal College of Physicians (RCP)	13	14	It is not clear why shisha is excluded. Shisha smoking is tobacco smoking. Our experts question why it is given special status.	Thank you for this comment. Shisha will now be included in this update, and will be included in reviews which consider smoked tobacco.
Royal College of Physicians (RCP)	13	8 to 9	Our experts do not understand this exclusion, which appears to undermine the intention to review digital and other media interventions.	Thank you for this comment. This exclusion has now been removed. Community interventions will be

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				included for some review questions, such as those on illicit supply of tobacco and proxy purchasing.
Royal College of Physicians (RCP)	13	22	See comment 21	Thank you for this comment. Please see our response to the comment you reference.
The National Centre for Smoking Cessation and Training	General	General	Thank you for the opportunity to comment on the scope of the NICE update on tobacco issues, including prevention, promotion, cessation and harm reduction. At the National Centre for Smoking Cessation and Training, we have read the scope, and we are pleased to see how comprehensive and forward-looking it is.	Thank you for this comment.
The National Centre for Smoking Cessation and Training	2	24	One query emerged: the scope talks about opt-out for pregnant smokers only. We believe that increasing this to include pre-surgical patients would make a considerable impact on patient health/outcomes, as well as overall NHS costs and bed-days.	Thank you for this comment. NG92 recommends an opt-out referral approach for people planning surgery. This recommendation will be carried forward into the new guidance. A surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified on opt-out referral pathways which would change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence . Additionally,

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				In addition, insufficient evidence has been identified through the consultation process to warrant a new review in this area. Therefore the scope of this update is limited to pregnant women. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.
UK Centre for Tobacco and Alcohol Studies	General	Cost-saving recommendations	<p>It may be possible, through examining service provision models (not currently planned for this guidance), to identify more cost-effective ways to deliver smoking interventions. It is also important to identify those tobacco interventions that represent the best value, to ensure that tobacco control budgets are deployed as effectively as possible. It is particularly important to look at school-based interventions – ASSIST for example – for which cost-effectiveness data relate to periods when smoking uptake among young people was much higher than is the case today.</p> <p>However, since smoking prevention and cessation interventions are almost exclusively highly cost-effective, and more so than most other medical interventions, the question here should surely be aimed at those writing guidance on interventions that take precedence over smoking cessation and prevention, while also being less cost-effective?</p>	<p>Thank you for this response to the consultation question on cost-saving. The design of service provision is outside of the scope of this referral and will not be covered by this guideline. Recommendations on school-based interventions were not identified by NICE's surveillance process as having the potential to be altered by any new evidence since publication of the original guideline, and so will not be included in the update for this guideline apart from as comparators to the Smokefree Class Competition.</p> <p>In terms of other interventions taking precedence over smoking cessation and prevention interventions: the guidelines developed by NICE are determined by the topics referred to NICE. To date there has not been a referral to compare the cost effectiveness of smoking cessation and prevention interventions with interventions in other topic areas.</p>

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UK Centre for Tobacco and Alcohol Studies	General	General	The use of the term 'prevention and promotion' for the first section of the new guidance is misleading. Promotion of what? Smoking? We suggest using the full phrase 'Preventing uptake, promoting quitting' as on line 16	Thank you for this comment. Subheadings are intended to organise and provide an overview of what evidence will be updated, rather than reflecting the structure of the final published guidance. The subheading "prevention and promotion" has been amended to "preventing uptake". "Promoting quitting" does not form part of this update so it has been removed from the subheading. However, material from the original guidelines on promoting quitting will be retained and will form part of the final product.
UK Centre for Tobacco and Alcohol Studies	General	General	<p>The title of the second section, 'cessation and harm reduction' is fine but lumps harm reduction with cessation services (as does PH45 guidance). In fact, harm reduction through consumer products is a means to help smokers quit without ever engaging in cessation services, and in this (much wider) application belongs in the preventing uptake and promoting cessation section.</p> <p>An alternative approach would be to call section one 'Preventing uptake, promoting quitting' and section two 'Treating tobacco dependency'.</p>	<p>Thank you for this comment. The subheading "cessation and harm reduction" has been amended to "treating tobacco dependence". This will continue to include review questions about quitting smoking and about reducing harm from smoking. We note that subheadings are intended to organise and provide an overview of what evidence will be updated, rather than reflecting the structure of the final published guidance.</p> <p>The subheading "prevention and promotion" has been amended to "preventing uptake". "Promoting quitting" does not form part of this update so it has been removed from the subheading. However, material from the original guidelines on promoting</p>

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				quitting will be retained and will form part of the final product.
UK Centre for Tobacco and Alcohol Studies	General	Heat-not-burn products	Currently available evidence on Heat-not-burn (HNB) products originates almost entirely from the tobacco industry and is therefore unreliable; and these products are neither widely available, nor widely used, in the UK. Engagement with the tobacco industry on matters of health policy is also proscribed under Article 5.3 of the WHO Framework Convention on Tobacco Control. We therefore argue that HNB products should be excluded from this guidance.	Thank you for your comment. Stakeholders were overwhelmingly in opposition to the inclusion of 'heat not burn' products in the final scope. Of the 18 who commented, 14 were against inclusion, 3 were in favour and 1 was unsure. Given the balance of stakeholder views and the strength of the arguments against inclusion, NICE has decided not to include 'heat not burn' products in the final scope for the updates to the suite of Tobacco guidelines.
UK Centre for Tobacco and Alcohol Studies	General	Incentives	Incentives evidence is covered in a Cochrane Review: Cahill, K., Hartmann-Boyce, J., and Perera, R. Incentives for smoking cessation. Cochrane Database Syst Rev, 2015. 10.1002/14651858.CD004307.pub5: CD004307.	Thank you for this comment. A surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified on incentives for cessation which would change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence In addition, the majority of the evidence identified is related to pregnant women. Therefore the scope of

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				this update is limited to pregnant women. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.
UK Centre for Tobacco and Alcohol Studies	16-17	17 - 21	Multiple comments made above apply where the relevant questions are repeated here.	Thank you for this comment. Please see our response to the comment you reference.
UK Centre for Tobacco and Alcohol Studies	2	20 - 21	Should be expanded to include impact of e-cigarettes on people who smoke (see general comment above)	Thank you for this comment. This area comes under prevention and as such the included population is people who do not currently smoke. However, in order to assess the impact of e-cigarettes on the future smoking behaviour of children and young people who do smoke, an additional key issue has been added to the 'treating tobacco dependency' section: <i>What is the impact of e-cigarettes on the smoking behaviour of children and young people who currently smoke?</i>
UK Centre for Tobacco and Alcohol Studies	2	16	Should include harm reduction	Thank you for this comment. Harm reduction is included in the material for update in the "cessation and harm reduction" sections.
UK Centre for Tobacco and Alcohol Studies	2	17	It is not clear what is meant by 'digital channels, including social media' – but if the intention is that they are used only as a means to promote cessation, this section should also include minimising the pro-smoking	Thank you for this comment. "Digital channels" has been amended to "digital media". Digital media includes websites and social media sites.

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			effect of smoking imagery in these and in conventional media (such as TV and film).	Digital media for smoking cessation will not be covered as part of this update. Digital media interventions for prevention will be considered. However, the removal of references to and images of smoking in entertainment media is related to broadcasting and media services regulations. These are outside of NICE's remit and therefore not something NICE would make recommendations on.
UK Centre for Tobacco and Alcohol Studies	2	24	It is not clear why review of opt-out models is limited to pregnancy. It should include all cessation and harm reduction support provision.	Thank you for this comment. NG92 recommends an opt-out referral approach for people planning surgery. This recommendation will be carried forward into the new guidance. A surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified on opt-out referral pathways which would change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence . Additionally, In addition, insufficient evidence has been identified through the consultation process to warrant a new

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				review in this area. Therefore the scope of this update is limited to pregnant women. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.
UK Centre for Tobacco and Alcohol Studies	2	28	It is not clear why review of the use of incentives is limited to pregnancy. Admittedly that is where most of the existing evidence is to be found, but the approach can be applied much more widely	<p>Thank you for this comment. A surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified on incentives for cessation which would change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence</p> <p>In addition, the majority of the evidence identified is related to pregnant women. Therefore the scope of this update is limited to pregnant women. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.</p>
UK Centre for Tobacco and Alcohol Studies	4	16 - 18	Smokers who switch entirely to e-cigarettes rarely do so abruptly and irreversibly. That 2 of 5 e-cig users no longer smoke is therefore a good thing; and many of the 3 in 5 using them while still smoking may well migrate to	Thank you for this comment. The sentence has been amended to emphasise the positive result of 2 in 5 e-cigarette users having switched completely.

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			exclusive e-cig use – and/or be open to encouragement to do so. The phrasing 'But 3 in 5 were using them as well as smoking ...' suggests that this is a bad thing, when in fact we should be encouraging smokers to try dual use.	
UK Centre for Tobacco and Alcohol Studies	5	4 to 5	<p>To say that prevention and promotion applies only to those aged 24 and under is wrong. While few people start smoking after age 25, measure to promote quitting should apply to all ages. The reference to an age limit should be removed.</p> <p>It is important to recognise that NICE guidance, while drafted with the intention of proactively recommending things to do to improve health outcomes, is often consumed (particularly in circumstances of tight finances) reactively with a view to identifying things that need not be done. This age limit is justification for anyone who does not have a remit for people aged 24 and under to ignore the rest of the prevention and promotion section.</p>	Thank you for this comment. The subheading "prevention and promotion" has been amended to "preventing uptake". "Promoting quitting" does not form part of this update so it has been removed from the subheading. However, material from the original guidelines on promoting quitting will be retained and will form part of the final product. Therefore the target population for the material included in this update for preventing uptake has been kept as people aged 24 and under, in line with evidence around age of smoking initiation.
UK Centre for Tobacco and Alcohol Studies	7	5 to 6	Same point as above regarding the age limit	Thank you for this comment. Please see our response to the comment you reference.
UK Centre for Tobacco and Alcohol Studies	7	8 to 25	Could be replaced with the word 'Smokers' or, if brevity is not an aim, 'People who smoke'. If the current list of	Thank you for this comment. Settings are included in a separate section, and 'primary care' is an included setting for 'treating tobacco dependence'.

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NICE guideline on tobacco suite: prevention, cessation and harm reduction (update)

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			service user groups is retained, it should include smokers in primary care.	
UK Centre for Tobacco and Alcohol Studies	8	14 - 20	Should include all healthcare settings and workplaces	Thank you for this comment. Workplaces are not a specific location for any of the proposed key issues for 'preventing uptake', so they have not been added to the list of settings. However, this does not preclude any studies which match the inclusion criteria and are set in or related to workplaces from being included, as this list of settings is not intended to be exhaustive. Healthcare settings, although included in recommendations which are carried forward in the final guidance, are not among the settings for which recommendations are being updated in relation to prevention. Therefore they are not included in this list.
UK Centre for Tobacco and Alcohol Studies	8	5	Does this mean that you will be updating guidance for users of smokeless tobacco who are not of south Asian origin?	Thank you for this comment. PH39 (Smokeless tobacco: South Asian communities), whilst not being updated based on new evidence, will be retained in the final product of this update. The recommendations will be refreshed to reflect current context and NICE style. Smokeless tobacco for people not of South Asian origin will not be included in any updated material apart from Key Issues 2.1 and 2.2 which are about

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				the illicit supply of tobacco and proxy sales of tobacco to people under 18.
UK Centre for Tobacco and Alcohol Studies	8	8	Age limit point again	Thank you for this comment. Please see our response to your previous comment.
UK Centre for Tobacco and Alcohol Studies	9	20 - 25	Its not clear why these coercive measures are necessary when these activities are already illegal, but those laws are often unenforced because trading standards budgets have been slashed. Perhaps the objective of this statement could be made more clear	Thank you for this comment. Changes to budgets are outside of NICE's remit and is therefore not something NICE would make recommendations on. Please see the surveillance review for PH14 which details why the decision was made to update recommendations on illegal sales: https://www.nice.org.uk/guidance/ph14/evidence
UK Centre for Tobacco and Alcohol Studies	9	25 - 28	It is not clear why this small niche of school-based intervention is selected for updating when others are not. We are not aware of any major advance in evidence on this type of intervention.	Thank you for this comment. A surveillance review was conducted for PH23 which searched for new evidence on all recommendations, including school-based interventions. No evidence was identified which would change current recommendations with the exception of smokefree class competitions. Please see the surveillance report here: https://www.nice.org.uk/guidance/ph23/evidence/review-decision-2013-pdf-546068269 . Insufficient additional evidence has been identified to update the recommendations on other types of school-based prevention interventions.

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UK Centre for Tobacco and Alcohol Studies	9	12 to 19	Here it becomes clear that the media focus is on health promotion. It is important to look at the other side of the same coin – preventing exposure to smoking imagery in these same media.	Thank you for this comment. Digital media interventions for prevention will be considered. However, the removal of references to and images of smoking in entertainment media is related to broadcasting and media services regulations. These are outside of NICE's remit and therefore not something NICE would make recommendations on.
UK Centre for Tobacco and Alcohol Studies	10	4	Opt-out models are more effective than opt-in models. This is recognised in PH48, which advocates an opt-in approach. It is not clear why opt-out models are being considered only in relation to pregnant smokers	Thank you for this comment. NG92 recommends an opt-out referral approach for people planning surgery. This recommendation will be carried forward into the new guidance. A surveillance review was conducted for PH48 which includes acute, maternity, and mental health services. No evidence was identified on opt-out referral pathways which would change or add to current recommendations. Please find the surveillance report here: https://www.nice.org.uk/guidance/ph48/resources/surveillance-report-2017-smoking-harm-reduction-2013-nice-guideline-ph45-and-smoking-acute-maternity-and-mental-health-services-2013-nice-guideline-ph48-4424254962/chapter/Surveillance-decision?tab=evidence . Additionally, In addition, insufficient evidence has been identified through the consultation process to warrant a new review in this area. Therefore the scope of this

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				update is limited to pregnant women. However, NICE's surveillance team have been made aware of this area for future monitoring of the evidence base.
UK Centre for Tobacco and Alcohol Studies	11	22 - 23	Not clear why these interventions will not be reviewed. There are at least two new trials of relevance https://www.sciencedirect.com/science/article/pii/S0749379717306402 and http://tobaccocontrol.bmj.com/content/early/2017/04/21/tobaccocontrol-2016-053279?utm_source=trend_md&utm_medium=cpc&utm_campaign=jnnp&utm_content=trendmd4	Thank you for this comment. These references have been considered and discussed. There is insufficient evidence to change the existing recommendations made in PH26 about providing information about risks to the unborn child of smoking when pregnant; providing advice about the danger of other people's tobacco smoke; and offering partners who smoke help to stop using a multi-component intervention. Therefore this area has not been added to the scope for this update.
UK Centre for Tobacco and Alcohol Studies	11	10 to 13	It is not clear why these four intervention types in schools are not being revisited, when Smokefree class competitions are. It is essential that the cost-effectiveness of these interventions is assessed, and long term outcome data provided, since measures targeting children generally gain political support, and can often squeeze out more cost-effective options as a result. We therefore need to know whether these measures represent the best value for money in comparison with other tobacco control measures, not just those involving schoolchildren.	Thank you for your comment. A surveillance review was conducted for PH23 which searched for new evidence on all recommendations, including school-based interventions. No evidence was identified which would change current recommendations with the exception of smokefree class competitions. Please see the surveillance report here: https://www.nice.org.uk/guidance/ph23/evidence/review-decision-2013-pdf-546068269 . Insufficient additional evidence has been identified to update the recommendations on other types of school-based prevention interventions.

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				<p>NICE's preferred approach is to undertake a full incremental analysis where possible. However, this approach and likewise the development of a league table, may not be appropriate given the disparate nature of tobacco control measures that are likely to be covered by the guideline and difference in methods used to assess them. Take the following three interventions as an example:</p> <p>Intervention A: NRT + GP advice vs usual care (undefined)</p> <p>Intervention B: mass media campaign aimed at adults who smoke vs background quit rate</p> <p>Intervention C: school based prevention programme vs usual practice (undefined)</p> <p>A full incremental analysis would involve comparing interventions A, B and C sequentially in rank order of effectiveness (or cost). This assumes interventions A, B and C are mutually exclusive but there is nothing to say that is the case so a commissioning body could decide to fund all three.</p> <p>Although a league table of ICERs for these interventions could be created, differences in settings, population groups, comparators and in the case of smoking prevention – outcomes - would</p>
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				make it difficult to interpret in any meaningful way. There are other important considerations too such as the quality of evidence and uncertainty around the estimates, the size of the population likely to benefit and the impact on inequalities. In the case of the latter, if the goal is to reduce health inequalities, interventions that work best for the most disadvantaged groups might be more costly and could reduce the health gain achieved in the population as a whole. The following sets out some of the issues identified when league tables were first being discussed see https://www.sciencedirect.com/science/article/pii/S027795369390315U .
UK Centre for Tobacco and Alcohol Studies	12	17 - 18	It is not clear why this topic will not be reviewed. UK cessation services have evolved around a stand-alone service model, with referral to service being a default measure of intervention. Whilst there are good historical political reasons why this is the case, the evidence on opt-out systems indicates that it is far from ideal. The design of service provision models should be reviewed and the conventional wisdom that stand-alone is best questioned.	Thank you for this comment. The design of service provision is outside of the scope of this referral and will not be covered by this guideline.
UK Centre for Tobacco and Alcohol Studies	13	14	It is not clear why shisha is excluded. Shisha smoking is tobacco smoking. Why give it special status?	Thank you for this comment. Shisha will now be included in this update, and will be included in reviews which consider smoked tobacco.

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UK Centre for Tobacco and Alcohol Studies	13	8 to 9	I don't understand this exclusion, which appears to undermine (for example) the intention to review digital and other media interventions.	Thank you for this comment. This exclusion has now been removed. Community interventions will be included for some review questions, such as those on illicit supply of tobacco and proxy purchasing.
UK Centre for Tobacco and Alcohol Studies	13	22	See comment 21	Thank you for this comment. Please see our response to the comment you reference.
Wendy Preston (RCN Head of Nursing Practice)	General	General	The Royal College of Nursing (RCN) and Association of Respiratory Nurse Specialists (ARNS) welcome proposals to update the suite of guidelines for prevention and promotion, cessation and harm reduction in tobacco use. The RCN and ARNS invited members who care for people with respiratory conditions to review the draft scope on its behalf. The comments below reflect the views of our reviewers.	Thank you for this comment. Please see our individual responses to separate items.
Wendy Preston (RCN Head of Nursing Practice)	General	General	The RCN attended the scoping workshop for the update of these guidelines and gave a comprehensive input at the meeting.	Thank you for this comment and for your attendance at the stakeholder workshop.
Wendy Preston (RCN Head of Nursing Practice)	General	General	We are supportive of the approach to update this suite of guidelines.	Thank you for this comment

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Wendy Preston (RCN Head of Nursing Practice)	General	General	We ask that the timescales of phases for the update should not be too long to ensure that once the update is completed the suite of guidelines would not be out of date.	Thank you for this comment. The scheduling and timeframes for this guideline will be according to the NICE guidelines manual and the resources of the NICE team and the committee involved. We recognise the need for timely updates and also the need for some in-progress studies to be included in the new guidance.
Wendy Preston (RCN Head of Nursing Practice)	General	General	The Royal College of Nursing (RCN) and Association of Respiratory Nurse Specialists (ARNS) welcome proposals to update the suite of guidelines for prevention and promotion, cessation and harm reduction in tobacco use. The RCN and ARNS invited members who care for people with respiratory conditions to review the draft scope on its behalf. The comments below reflect the views of our reviewers.	Thank you for this comment. Please see our individual responses to separate items.
Wendy Preston (RCN Head of Nursing Practice)	General	General	Smoking cessation should follow the pathway approach.	Thank you for this comment. NICE is moving more towards guidelines as pathways and that should be reflected in the final product for this update.
Wendy Preston (RCN Head of Nursing Practice)	General	General	The guidelines need to include all smoking cessation treatments including e-cigarettes.	Thank you for this comment. The new guidance will include all the treatments currently covered in the guidelines (some will have been updated, some carried forward) including e-cigarettes.

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Wendy Preston (RCN Head of Nursing Practice)	General	General	Recommended treatments should be provided with appropriate funding in place to enable effective implementation including making provision for resources needed for training and education of the workforce.	Thank you for this comment. Whilst funding for particular areas is not within the remit of NICE nor within the referral of this guideline, the information provided by the guideline in terms of cost effectiveness and effectiveness should inform the distribution of resources.
Wendy Preston (RCN Head of Nursing Practice)	5	1	We are pleased to see that the target population for tobacco prevention would include children and young people up to age 24 not 18.	Thank you for this comment.

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