

Tobacco: preventing uptake, promoting quitting and treating dependence (update)

**Consultation on draft guideline - Stakeholder comments table
25 June to 6 August 2021**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Action on Smoking and Health	Guideline	General	General	<p>The guidelines, quite rightly, make a range of recommendations for research (see page 72-76). Yet there is only one acknowledgement of the need to take into account the outcomes of any such research, in section 1.9.2 bullet 2 which recommends “Use the best available evidence of effectiveness, such as Cochrane reviews”.</p> <p>To our knowledge some, if not all, of the research recommendations are already being taken forward. For example, NIHR has funded 'Helping Pregnant Smokers Quit: A Multi-Centre RCT of Electronic Cigarette and Nicotine Patches'. Unfortunately, this important research won't be published in time to be taken into account in the guidelines, but it will be included in a Cochrane living systematic review of the evidence on electronic cigarettes for smoking cessation. NIHR is also funding research on smoking cessation in underserved groups such as prisoners and the homeless.</p> <p>The evidence continues to develop and evolve, and it is important therefore that in the overview section of the guidelines there is a generic recommendation that research outcomes are taken into account when</p>	<p>Thank you for your comment. The research recommendations developed by PHAC seek to address the gaps in the evidence identified during the guideline development process with the hope of stimulating research in these areas for consideration when this guideline or aspects of this guideline are considered for update.</p> <p>NICE routinely checks that published guidelines are current, accurate and up to date via our surveillance function which explores if there is any new evidence to contradict, reinforce or clarify guideline recommendations. Surveillance also identifies new interventions that may need to be considered within a guideline and explores changes in context that may mean modifications are needed, for example, changes in policy, infrastructure, legislation or costs. A proactive approach is taken that includes reacting to events at any time after guideline publication (for example, publication of a key study)..</p> <p>Thank you for the Greater Manchester Health and Social Care Partnership reference. We will pass this information to our local practice collection team. More information on local practice can be found here</p>

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				implementing any of the recommendations in the guidance. For example, Greater Manchester Health and Social Care Partnership are currently awaiting publication of a RCT evaluating at the impact of providing incentives for 1-year post-partum. We suggest wording along the lines: “When developing and implementing policies to prevent uptake, promote quitting and treat dependence it is essential to use the best available evidence of effectiveness, such as Cochrane reviews.	https://www.nice.org.uk/about/what-we-do/into-practice/shared-learning-case-studies
Action on Smoking and Health	Guideline	General	General	“Recommendations for research” (p.72-76) does not include any recommendations for population level policy interventions, such as smokefree outdoor places. Extending smokefree outdoor places is high on the list of policy interventions currently under consideration by local authorities, see for example, Greater Manchester and Oxfordshire County Council. However, PHE’s 2017 review of Smokefree outdoor public places and outdoor commercial places found that UK evidence is currently limited. The review did find that there is some evidence for positive effects on behaviour and associated harms when outdoor spaces are made smokefree, although in general the evidence for an effect was mixed.	Thank you for your comments. Population level policy interventions are outside the scope of this guideline. Please see the scope document on the NICE website.

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				<p>The Royal College of Physicians report "Smoking and Health 2021: A coming of age for tobacco control" has the following to say on smokefree outdoor policies; "Evaluation of such policies could include standardised, controlled studies on levels of exposure to ambient tobacco smoke; changes in attitudes for adult smokers, non-smokers and children; and assessing whether these policies have a positive effect. Investment in these policies by local areas should be considered as part of a comprehensive tobacco control strategy".</p> <p>We would suggest therefore that the research question should be framed as follows: 'Smokefree outdoor places: Do Smokefree outdoor policies reduce exposure to ambient tobacco smoke, and do they have a significant impact on attitudes to smoking among adult smokers, non-smokers and children.'</p>	
Action on Smoking and Health	Guideline	General	General	Financial incentives for quitting smoking are not highlighted as an effective intervention in the general population. They should be, as a Cochrane systematic review has concluded that there is high certainty evidence of their effectiveness in the general population of people who smoke (as well as in pregnancy, where they are currently highlighted).1 2	Thank you for your comment. Incentives were only considered in pregnant women. Incentives for other populations are outside the scope of this guideline. Please see the scope document on the NICE website.

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				<p>¹ Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD004307</p> <p>² Hartmann-Boyce J, Livingstone-Banks J, Ordóñez-Mena JM, Fanshawe TR, Lindson N, Freeman SC, Sutton AJ, Theodoulou A, Aveyard P. Behavioural interventions for smoking cessation: an overview and network meta-analysis. Cochrane Database of Systematic Reviews 2021, Issue 1. Art. No.: CD013229</p>	
Action on Smoking and Health	Guideline	046 - 047	General	<p>3 and 4ppm CO levels are both used in this section (p46 line 15 says 4ppm and p47 line 9 says 3ppm). The Smoking in Pregnancy Challenge Group recommends that women with a reading of 4ppm or above should be referred for smoking cessation support. Evidence suggests that 4ppm is the optimal cut-off for correctly identifying pregnant women who smoke and minimising the number of false positives.^{11 12}</p> <p>¹¹ Bailey BA. Using expired air carbon monoxide to determine smoking status during pregnancy: preliminary identification of an appropriately sensitive and specific cut-point. Addictive behaviors. 2013 Oct 1;38(10):2547-50.</p>	<p>Thank you for your comment. The different carbon monoxide levels refer to different groups of pregnant women: smokers and non-smokers and to different actions. The reference to 4 ppm in recommendation 1.18.2 is in the context of the provision of an opt-out referral to receive stop-smoking support for pregnant women. The reference to 3 ppm in recommendation 1.18.4 refers to women who do not smoke and to provide help to identify the source of the carbon monoxide level of 3 ppm.</p>

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				¹² Bauld L, Hackshaw L, Ferguson J, Coleman T, Taylor G, Salway R. Implementation of routine biochemical validation and an 'opt out' referral pathway for smoking cessation in pregnancy. <i>Addiction</i> . 2012 Dec;107:53- 60.	
Action on Smoking and Health	Guideline	013	005 - 007	<p>1.6.4 – While it is important to avoid inadvertently making e-cigarettes desirable to young people, it is just as important to avoid inadvertently reinforcing misperceptions that e-cigarettes are as harmful as smoking. Findings from the annual Smokefree GB survey commissioned by ASH show that the perception among 11–18-year-olds that cigarettes and e-cigarettes are equally harmful has increased since 2013. In 2021, only 43.8% of 11–18-year-olds knew that e-cigarettes were less harmful than cigarettes.³ Similarly, among adults, around a third (32%) believed e-cigarettes were more or equally as harmful as cigarettes in 2021, compared to 42% who thought they were less harmful.⁴ This is relevant because adults will be responsible for giving children advice about e-cigarettes.</p> <p>Therefore, an additional sentence should be added to recommendation 1.6.4 consistent with the wording on page 26 lines 1-4, that: "However, it is also important to make clear that although there is not currently enough</p>	Thank you for your comment. This is stated clearly elsewhere in the guideline and the committee were clear that they did not want to say anything that might promote the use of e-cigarettes in under 18s.

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				<p>evidence to know whether there are long-term harms from e-cigarettes, they are likely to be substantially less harmful than smoking.”</p> <p>³ASH. Use of e-cigarettes among young people in Great Britain. 2021</p> <p>⁴ASH. Use of e-cigarettes (vapes) among adults in Great Britain. 2021</p>	
Action on Smoking and Health	Guideline	017	001 - 003	<p>We welcome the recommendation to involve community pharmacies in local campaigns and maintain links with other professional groups such as dentists, fire services and voluntary groups.</p> <p>However, welfare and benefits officers/advisors should also be included in this list because they have a unique opportunity to screen for smoking, provide very brief advice and signpost to smoking cessation services as part of their interventions to help people manage their finances.</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.</p>
Action on Smoking and Health	Guideline	028	010 - 013	<p>1.14.1 –This section should also include a bullet point to highlight the mental health benefits of quitting smoking. A recent Cochrane systematic review found that smokers who stop have better mental health than those who continue to smoke and that the benefits to mental health were estimated to be equivalent to anti-depressants. Quitting can also help reduce the severity of psychotic</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.</p>

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				<p>symptoms and in some cases, contribute to reductions in prescribed medications and shorter hospital stays.⁶</p> <p>6 Taylor, D.M., Barnes, T.R.E., Young, A.H., (2021) The Maudsley Prescribing Guidelines in Psychiatry, 14th Edition, ISBN: 978-1-119-77223-1 July 2021 Wiley-Blackwell 976 Pages</p>	
Action on Smoking and Health	Guideline	029	011	<p>We welcome the recommendation that every smoker will be offered behavioural support in acute, maternity and mental health care settings but we are disappointed that this offer is only recommended “if the person agrees”. We recommend that behavioural support is provided on an opt-out basis – as recommended in the NHS Long Term Plan and by the RCP.^{7 8}</p> <p>Opt-out as opposed to opt-in referrals to NHS stop smoking services have been shown to increase engagement by pregnant smokers by 112 percent.⁹</p> <p>7 Royal College of Physicians. Hiding in plain sight: Treating tobacco dependency in the NHS. 2018</p> <p>8 NHS England. The NHS Long Term Plan: Smoking. January 2019</p> <p>9 Campbell, K. A., Cooper, S., Fahy, S. J., Bowker, K., Leonardi-Bee, J., McEwen, A., . . . Coleman, T. (2017). ‘Opt-out’ referrals after</p>	<p>Thank you for your comment. The evidence on opt-out referral schemes was in scope for pregnant women only. The committee has made recommendations on opt out referral schemes for pregnant women (see Recommendations 1.18.2 and 1.18.3). Opt-out referral schemes were not within scope for other population groups. Please see the scope document on the NICE website.</p>

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				identifying pregnant smokers using exhaled air carbon monoxide: impact on engagement with smoking cessation support. Tobacco control, 26(3), 300-306.	
Action on Smoking and Health	Guideline	030	014	The recommendation to provide support to smokers within 24 hours of admission does not go far enough to ensure patients comfort or ease their distress. The recommendation should require the provision of support within 30 minutes of arrival to hospital. For example, SLaM NHS Foundation Trust provide 'Tea and NRT' to smokers on arrival to hospital as an over the counter medication. This avoids the delays caused by getting a prescriber and is hugely beneficial since the half-life of nicotine is approximately 2 hours and longer delays will result in unnecessary discomfort.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Action on Smoking and Health	Guideline	032	004 - 009	1.14.20 - We welcome the recommendation to tell smokers about the different types of medicinally licensed nicotine containing products, how to use them and if possible, prescribe them. However, we are disappointed that e-cigarettes are not also recommended as a vital intervention for smokers who need to temporarily abstain. Failure to include e-cigarettes as a safe, valid and effective way to support temporary abstinence may discourage service providers from allowing the use of e-cigarettes for temporary abstinence, thus	Thank you for your comment. The evidence on the use of nicotine containing e-cigarettes to support temporary abstinence was not reviewed as part of this guideline update and therefore recommendations have not been made in this area. Regarding differing needs between people admitted to acute hospital settings and to mental health settings, these recommendations are greyed out as they are outside the scope for this update. Please see the scope document on the NICE website.

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				<p>losing a teachable moment to support stopping smoking and switching to an e-cigarette for those smokers for whom NRT is not effective.</p> <p>SLaM NHS Foundation Trust provide mental health care services from 4 large London based hospitals (50 wards). Typically, about half of adult patients admitted to hospital are current smokers, and it is rare to find a smoker at the point of admission who decides to make a quit attempt. For the overwhelming majority (95%) their decision at the point of admission is to use whatever support is available to temporarily abstain. Currently, the preferred option to support temporary abstinence for SLaM is an e-cigarette, because smokers feel that this more closely matches the experience of smoking compared with using NRT products. SLaM have used e-cigarettes in this way since 2012 and typically provide around 400 free e-cigarette starter packs each month. In about 30% of cases the smokers find that the provision of a free e-cigarette starter pack, given with the intention to support temporary abstinence on admission is so effective that they decide to continue using it, and do not return to smoking.</p>	

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				<p>In 2019 ASH conducted a survey of mental health trusts which found that 42% of mental health trusts in England provide free e-cigarettes to adult smokers on admission to hospital to support temporary abstinence, and we believe there is sufficient evidence to support this consensus practice.¹⁰ More generally in this section of the guidance, we think a distinction should be made between the needs of people admitted to an acute hospital setting and people admitted to a mental health setting. The needs of people in mental health crisis are very different and require a more bespoke response.</p> <p>¹⁰ ASH. Progress towards smokefree mental health services. Findings from a survey of mental health trusts in England. 2019</p>	
Action on Smoking and Health	Guideline	051	General	<p>1.20.12 – We are concerned that this guideline doesn't link to any guidance or information to support the implementation of incentive schemes. This could include case studies of existing schemes, key competencies for staff or dedicated training. The Smoking in Pregnancy Challenge Group has produced a briefing to support the commissioning and delivery of incentive schemes.¹⁹ The briefing summarises the evidence from previous incentive schemes, sets out lessons for practice and will be updated in line with</p>	<p>Thank you. The recommendations are based on the evidence of effectiveness, and the implementation of the recommendations is primarily a local commissioning decision.</p>

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				emerging evidence. The guidance should link to the Challenge Group briefing to ensure that commissioners have access to practice-focused information to support the delivery of incentive schemes. We also recommend that the guidance should link to case studies and guidance from previous incentive schemes. 19 Smoking in Pregnancy Challenge Group. Evidence into Practice: Supporting smokefree pregnancies through incentive schemesv. 2019	
Action on Smoking and Health	Guideline	051	015 - 016	1.20.12 – bullet 3 – This sentence should use the word “incentive” instead of “reward”. Incentive payments are not rewards; they are incentives to change behaviour and the terminology used should reflect that. This is particularly important given the sensitivity in the media and the public around the use of financial incentives in pregnancy. ¹⁵ 15 Hoddinott P, Morgan H, MacLennan G, Sewel K, Thomson G, Bauld L, Yi D, Ludbrook A, Campbell MK. Public acceptability of financial incentives for smoking cessation in pregnancy and breast feeding: a survey of the British public. <i>BMJ open</i> . 2014 Jul 1;4(7):e005524.	Thank you for your comment. PHAC considered your comment and the wording has been amended to reflect your comment.
Action on Smoking and Health	Guideline	051	015 - 016	1.20.12 – bullet 3 – The guideline should recommend that the offer of incentives be extended into the postnatal period for a	Thank you. The committee considered this. Please see the committee discussion section of evidence review J which says that “The

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				<p>minimum of 3 months to prevent women relapsing to smoking. Evidence suggests nearly half of women who quit smoking during pregnancy relapse within 1-year post-partum.¹⁶ This harms the health of the mother and makes it more likely that children will be exposed to secondhand smoke in the home, leading to higher rates of sudden infant death (SIDS), lower respiratory tract infection, middle ear disease, asthma and many other diseases.¹⁷ Consequently, supporting women and their partners to stay smokefree after their baby is born is key to helping them maintain a smokefree home and protecting them and their children from harmful tobacco smoke. Evidence from a 2019 Cochrane systematic review shows that providing incentives in the postnatal period is effective for supporting women to stay smokefree.¹⁸</p> <p>¹⁶ Jones, M., Lewis, S., Parrott, S., Wormall, S., & Coleman, T. Re-starting smoking in the postpartum period after receiving a smoking cessation intervention: A systematic review. <i>Addiction</i>, 2016, 111(6), 981–990</p> <p>¹⁷ Royal College of Physicians. <i>Passive smoking and children. A report by the Tobacco Advisory Group</i>. London: RCP, 2010</p> <p>¹⁸ Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J.</p>	<p>committee discussed the duration of incentive provision and agreed that this should occur at least until the end of pregnancy (including pregnancies that do not progress), however that it wasn't clear whether provision would be beneficial in the post-partum period “</p>

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				Incentives for smoking cessation (Review). Cochrane Database of Systematic Reviews. 2019. Issue 7. Art. No.: CD004307	
Action on Smoking and Health	Guideline	051	005	Research is underway on the effectiveness of e-cigarettes as a quitting aid for pregnant smokers and the impact of their use on birth outcomes,13 but will not be published in time to be taken into account in this guidance. Despite the lack of evidence specific to pregnancy at the current time, advice on the use of e-cigarettes in pregnancy should not be excluded from the guidance. E-cigarettes are already being used by some women as an aid to quit smoking during pregnancy, and midwifery and stop smoking practitioners are being asked for advice on their use. If they are unable to provide any advice, there is an increased risk that women may revert to smoking, which is a leading modifiable risk factor for many poor birth outcomes. That is why the Smoking in Pregnancy Challenge Group, an alliance of medical organisations such as the RCOG, RCM and RCGP, working together with charities such as the Lullaby Trust, Sands and Tommys, has produced peer reviewed resources for healthcare professionals and pregnant women on use of e-cigarettes.14 These resources are widely	Thank you. The committee did not see any evidence on the effectiveness of nicotine containing e-cigarettes during pregnancy and therefore is unable to make a recommendation in this area.

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				<p>used and are regularly updated in line with the evolving evidence base.</p> <p>Therefore, after the section on 'Nicotine replacement therapy and other pharmacological support' (pages 50 line 8 to 51 line 5) we recommend that a section should be added headed 'Use of e-cigarettes in pregnancy'. We suggest the following wording, that:</p> <p>"If a pregnant woman has chosen to use an e-cigarette to quit or to reduce the number of cigarettes that she smokes, she should not be discouraged from doing so, as any risks to the fetus is likely to be extremely small compared to continued smoking".</p> <p>Then go on to say that:</p> <p>"It is important to give pregnant smokers clear, consistent and up-to-date information about nicotine containing e-cigarettes (for example see the Smoking in Pregnancy Challenge Group resources on e-cigarettes). See also the section in the guideline on advice on nicotine-containing e-cigarettes."</p> <p>13 Griffiths et al. Project outline: Helping Pregnant Smokers Quit: A Multi-Centre RCT of Electronic Cigarette and Nicotine Patches. NIHR</p>	

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				14 Smoking in Pregnancy Challenge Group. Webpage: Using e-cigarettes before, during and after pregnancy.	
Action on Smoking and Health	Guideline	052	006	<p>We are concerned that the guideline 'Enabling all pregnant women to access stop-smoking support' does not explicitly recommend that stop smoking materials and support be provided in languages other than English. Although the NICE guideline on patient experience in adult NHS services recommends that healthcare services are accessible for non-English speakers, given high rates of smoking among some migrant communities, the guideline should explicitly highlight the need to provide stop smoking materials and advice in a range of languages.</p> <p>Migration Observatory analysis of the Annual Population Survey 2019, shows that women born in new EU accession countries, including Poland, Romania and Lithuania, have much higher rates of smoking than those born in the UK (22% compared to 13%).²⁰ Among men, those who are foreign-born are more likely to smoke than UK-born men, and men born in new EU accession countries more than twice as likely to smoke as UK-born men (34% compared to 15%). To ensure that these communities are not underserved by stop</p>	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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				<p>smoking support, we believe that the list starting on page 52, line 11, should include a point saying "Ensure resources and advice for stopping smoking are available in a range of different languages, taking into account local demographics."</p> <p>20 The Migration Observatory. The health of migrants in the UK. August 2020</p>	
Action on Smoking and Health	Guideline	059	010 - 011	<p>The statement "Include nicotine-containing products as options for sale in secondary settings (for example, in hospital shops.)" should be clarified. We assume, and would recommend, that this includes e-cigarettes as well as NRT, but this should be specified to avoid any confusion.</p>	<p>Thank you. Nicotine containing products is defined in the glossary section of the guideline. The definition of nicotine containing products has been amended to clarify that it includes nicotine containing e-cigarettes.</p>
Action on Smoking and Health	Guideline	062	General	<p>1.23 – [PH5] Smoking: workplace interventions - Recommendation 4: 'Ensure smoking cessation support and treatment is delivered only by staff who have received training that complies with the Standard for training in smoking cessation treatments' has been deleted. The reason given for deletion is that 'tailoring support and treatment is a general principle recommended in NICE's guideline on patient experience in adult NHS services.' We do not support this deletion.</p> <p>The National Training Standard was produced by the National Centre for Smoking Cessation</p>	<p>Thank you. Training is covered in recommendations 1.23.2 to 1.23.4. Additionally, 1.23.2 cross references to recommendations 1.12 which reference NCSCT training.</p>

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				<p>and Training (NCSCT) on behalf of the Department of Health and includes all behaviour change techniques (BCTs) for which there is evidence of effectiveness. It does not prevent tailoring support and treatment as appropriate, therefore the rationale for deletion is not justified. Practitioners trained to deliver interventions according to the standard have been proven to be effective in adding significant value to quit attempts.²¹ Removal of the Training Standard is likely to lead to a return to the situation prior to the establishment of the NCSCT where people provided training based on opinion, rather than the evidence, for what effective training should contain. This recommendation should therefore be reinstated.</p> <p>Related to this point, the National Training Standard is mentioned in 1.12 (in a rather non-specific manner) and again under Quitlines (1.12.20). However, section 1.23, line 12-26, 'Those who advise people to stop smoking' fails to include any mention of the Standard. While the subtitle may suggest this section is specific to those who identify smokers and prompt quit attempts (i.e. deliver VBA), there is nothing further in this section on training for those who deliver ongoing stop smoking</p>	

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				<p>support (i.e. behavioural support), as has been the case in previous versions of the document. At minimum this should be included for stop smoking services. The wording found in the 2018 NG92 recommendation on this subject served this purpose. The key being 1) stop smoking support is provided by trained staff and 2) that training be consistent with the National Training Standard. Given the level of depth the document goes into for maternity care and closed institutions, there should be at least the equivalent depth provided for all settings (stop smoking services, maternity care, closed institutions, primary care) who are delivering stop smoking support. This should consist of the National Training Standard as default, plus additional training for those working with specific population such as mental health and pregnancy.</p> <p>Overall, there is little said in the new NICE guidance on stop smoking services and stop smoking support delivered in other settings compared to previous guidance documents. There is also a level of specificity in some sections that is not consistently applied in the document (e.g. lots of detail in maternity care section and smokeless tobacco and only a few bullets on other important areas of practice).</p>	

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				This risks making the document less clear and less user friendly than previous NICE guidance. 21 Brose L, West R, Michie S, McEwen A. Changes in success rates of smoking cessation treatment associated with take up of a national evidence-based training programme. Preventive Medicine 2014;69C:1-4	
Action on Smoking and Health	Guideline	075	007 - 013	We suggest considering the addition of two further points regarding recommendations for further research into relapse prevention. Firstly, we see a clear need for more research on varenicline for relapse prevention, given the committee acknowledges its likelihood of increasing long-term abstinence and supporting Cochrane evidence. ²² Secondly, we suggest it would be a good idea to recommend more trials looking at relapse prevention interventions delivered to people who have been abstinent for 4+ weeks, as there is little evidence in this group. The committee's emphasis on the importance and paucity of this kind of longer-term evidence is reflected in evidence review N: "For this reason, the committee focussed on evidence where relapse was clearly additional to cessation and delivered at a later point (this included behavioural interventions for assisted	Thank you. Research recommendations in NICE guidelines are specifically to address gaps in the research that the committee considered while making their recommendations. They do not address general gaps in the evidence.

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				<p>abstainers [Figure 11, GRADE profile 5], and pharmacotherapy for assisted abstainers [Figure 13-16, GRADE profile 6]). There is a paucity of evidence on this type of longer term relapse prevention." (p.66 of evidence review N)</p> <p>22 Livingstone-Banks J, Norris E, Hartmann-Boyce J, West R, Jarvis M, Chubb E, Hajek P. Relapse prevention interventions for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 10. Art. No.: CD003999</p>	
Action on Smoking and Health	Guideline	078	027 - 029	<p>This states that nicotine e-cigarettes are of similar effectiveness to NRT. There is moderate certainty evidence that they are more effective than NRT (including in studies where participants are offered combined short and long-acting NRT) and this should be made clear.²³</p> <p>23 Hartmann-Boyce J, McRobbie H, Butler AR, Lindson N, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Fanshawe TR, Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2021, Issue 4. Art. No.: CD010216</p>	<p>Thank you. The pairwise meta-analysis found a pooled risk ratio of 1.47 (1.25 – 1.72) for nicotine e-cigs vs single NRT for abstinence at 3 months. The network meta-analysis uses the effectiveness data and NMA models from Thomas' (2020) review as well as results of NICE-conducted rerun searches. This NMA (based on 192 studies) showed no significant effect of e-cigarettes compared to NRT (RR of 1.23 [CrI: 0.73, 1.95]) or long + short NRT (RR: 0.84 [CrI 0.48, 1.40]). The discrepancy between pairwise and NMA effect estimates is likely to be due to the modifying effect of indirect treatment estimates within the network. Consistency checking did not identify any concerns with the model that was used for the NMA and the committee</p>

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					focussed their discussion on the results of this NMA.
Action on Smoking and Health	Guideline	079	008 - 013	<p>This section states the committee had low confidence in the finding of no difference in adverse events in people using nicotine e-cigarettes compared to NRT, e-cigarettes without nicotine, and no treatment, because the studies were powered to investigate effectiveness and not adverse events. Though this is an issue for serious adverse events, where events are rare, for non-serious adverse events, which this section appears to refer to at first glance, this is not an issue of underpowering because non-serious adverse events are more common than cessation (a study powered to detect a difference in cessation would also be powered to detect a difference in adverse events). If this section is on serious adverse events, it should be clarified that that is the case. If not, it should be reworded. The latest Cochrane review has moderate certainty evidence of no difference in rates of adverse events (non-serious) between nicotine and non-nicotine e-cigarettes. Error! Bookmark not defined.</p> <p>23 Hartmann-Boyce J, McRobbie H, Butler AR, Lindson N, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Fanshawe TR, Hajek P. Electronic</p>	<p>Thank you. Details of the adverse events reported are contained in evidence review K and are adverse events rather than serious adverse events.</p> <p>The rationale and impact section describes the committees consideration of the recommendations and their view is consistent with the findings in the systematic review that you reference.</p>

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				cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2021, Issue 4. Art. No.: CD010216	
Allen Carr's Easyway (International) Limited	Guideline	001	001	<p>The guideline states that it covers support to stop smoking for everyone aged 12 and over but there is a significant and serious omission from the proposed update to the guidance which needs immediate rectification. The update fails to include non-pharmacological solutions with at least two randomised controlled trials (RCTs).</p> <p>One such method is Allen Carr's Easyway to Stop Smoking Seminars (ACE) which has two published randomised controlled trials that have been conducted and now has a significant and robust evidence base to approve such non-pharmacological methods provided they are supported by at least two RCTs.</p> <p>There is now a non-pharmacological solution with at least two RCTs and as such is a proven pharmacological-free method of stopping smoking which has a lack of contraindicators reported, suggesting that there are minimal if any long-term health effects, and which is a one-off low cost treatment for smoking cessation.</p>	Thank you for your comment. A rapid review to examine the effectiveness of the Allen Carr method is currently in the commissioning process at NICE.

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				<p>In particular, ACE has helped an estimated 30 million smokers in over 50 countries worldwide during the past 37 years. It is a behavioural therapy (or more accurately a cognitive restructuring/retraining therapy).</p> <p>Some further background is that in 2017 ACE Informed NICE that two RCTs were underway as part of the consultation on NG92. The comments can be reviewed on https://www.nice.org.uk/guidance/ng92/documents/consultation-comments-and-responses-2. The feedback on NG92 from NICE was "The two ongoing RCTs (ISRCTN 23584477 and ISRCTN12951013) you cite may be considered in a future update of the guideline subject to i) the surveillance review deciding the guideline needs updating; and ii) the studies meeting the inclusion criteria for the review questions in the guideline update".</p> <p>In brief:</p> <ul style="list-style-type: none"> • NICE requested an RCT before they would update guidance on ACE NG92 (March 2018) & PH10 (February 2008) • NICE were aware of the RCTs before the draft scope was created for GID-NG10086 	

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				<ul style="list-style-type: none"> • NICE were aware of the RCTs during consultation of the scope for GID-NG10086 • NICE were aware of the RCTs once published for GID-NG10086 • NICE were aware of the RCTs during call for evidence for GID-NG10086 • NICE were kept up to date with the results of both RCTs at every stage • NICE knew that the RCTs were showing the strong performance of ACE • NICE knew that using the APEASE criteria that ACE passed all the criteria and should be recommended as an intervention • NICE knew that there is a lack of contraindicators reported which suggests that there is minimal if any long-term health effects. <p>It is very clear that a non-pharmacological solution with at least two RCTs should have been included in the scope of NICE guidance GID-NG10086. There was no reason for it to be excluded.</p> <p>It would appear highly negligent not to have included it given everything that NICE knew and were aware of. Instead the update was chosen to narrowly focus on a pharmacological product with unknown long-term health effects namely e-cigarettes as opposed to additionally</p>	

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				<p>including a non-pharmacological solution with at least two RCTs which is a pharmacological-free, cost-effective method with a lack of contraindicators reported.</p> <p>NICE state that their guidance is updated to take account of important new evidence yet they did not update the brief for this new guidance and furthermore NICE state that NICE can update some recommendations at any time if important new evidence is published which is clearly the case.</p> <p>NICE have clearly made an error and we request your immediate public update to the NICE guidance to expand it to recommend ACE as a method for smoking cessation to be used by stop smoking services as an alternative to pharmacological interventions.</p> <p>A non-pharmacological solution with at least two RCTs should therefore be included in this comprehensive review.</p>	
Allen Carr's Easyway (International) Limited	Guideline	003	008	The guideline states that "we have reviewed the on preventing uptake of smoking, promoting quitting, treating tobacco dependence, and policy, strategy and commissioning" but it does not include non-pharmacological solutions with	Thank you for your comment. A rapid review to examine the effectiveness of the Allen Carr method is currently in the commissioning process at NICE.

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				<p>at least two randomised controlled trials (RCTs).</p> <p>One such method is Allen Carr's Easyway to Stop Smoking Seminars (ACE) which has two published randomised controlled trials that have been conducted and now has a significant and robust evidence base to approve such non-pharmacological methods provided they are supported by at least two RCTs.</p> <p>There is now a non-pharmacological solution with at least two RCTs and as such is a proven pharmacological-free method of stopping smoking which has a lack of contraindicators reported, suggesting that there are minimal if any long-term health effects, and which is a one-off low cost treatment for smoking cessation.</p> <p>In particular, ACE has helped an estimated 30 million smokers in over 50 countries worldwide during the past 37 years. It is a behavioural therapy (or more accurately a cognitive restructuring/retraining therapy).</p> <p>Some further background is that in 2017 ACE Informed NICE that two RCTs were underway</p>	

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				<p>as part of the consultation on NG92. The comments can be reviewed on https://www.nice.org.uk/guidance/ng92/documents/consultation-comments-and-responses-2. The feedback on NG92 from NICE was “The two ongoing RCTs (ISRCTN 23584477 and ISRCTN12951013) you cite may be considered in a future update of the guideline subject to i) the surveillance review deciding the guideline needs updating; and ii) the studies meeting the inclusion criteria for the review questions in the guideline update”.</p> <p>In brief:</p> <ul style="list-style-type: none"> • NICE requested an RCT before they would update guidance on ACE NG92 (March 2018) & PH10 (February 2008) • NICE were aware of the RCTs before the draft scope was created for GID-NG10086 • NICE were aware of the RCTs during consultation of the scope for GID-NG10086 • NICE were aware of the RCTs once published for GID-NG10086 • NICE were aware of the RCTs during call for evidence for GID-NG10086 • NICE were kept up to date with the results of both RCTs at every stage • NICE knew that the RCTs were showing the strong performance of ACE 	

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				<ul style="list-style-type: none"> • NICE knew that using the APEASE criteria that ACE passed all the criteria and should be recommended as an intervention • NICE knew that there is a lack of contraindicators reported which suggests that there is minimal if any long-term health effects. <p>It is very clear that a non-pharmacological solution with at least two RCTs should have been included in the scope of NICE guidance GID-NG10086. There was no reason for it to be excluded.</p> <p>It would appear highly negligent not to have included it given everything that NICE knew and were aware of. Instead the update was chosen to narrowly focus on a pharmacological product with unknown long-term health effects namely e-cigarettes as opposed to additionally including a non-pharmacological solution with at least two RCTs which is a pharmacological-free, cost-effective method with a lack of contraindicators reported.</p> <p>NICE state that their guidance is updated to take account of important new evidence yet they did not update the brief for this new guidance and furthermore NICE state that NICE can update some recommendations at</p>	

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				<p>any time if important new evidence is published which is clearly the case.</p> <p>NICE have clearly made an error and we request your immediate public update to the NICE guidance to expand it to recommend ACE as a method for smoking cessation to be used by stop smoking services as an alternative to pharmacological interventions.</p> <p>A non-pharmacological solution with at least two RCTs should therefore be included in this comprehensive review.</p>	
Allen Carr's Easyway (International) Limited	Guideline	014	022	<p>Why is this section only focused on licensed nicotine-containing products? It contains a significant and serious omission in that it should also include non-pharmacological options that have been proven in at least two randomised controlled trials. These contain no nicotine and so are much safer. If it shouldn't go in this section then there should be a different section for non-pharmacological options that have been proven in at least two randomised controlled trials.</p>	<p>Thank you for your comment. A rapid review to examine the effectiveness of the Allen Carr method is currently in the commissioning process at NICE.</p>
Allen Carr's Easyway (International) Limited	Guideline	022	025	<p>There is a significant and serious omission in the behavioural interventions section that needs rectification namely that it should also include non-pharmacological options</p>	<p>Thank you for your comment. A rapid review to examine the effectiveness of the Allen Carr method is currently in the commissioning process at NICE.</p>

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				that have been proven in at least two randomised controlled trials	
Allen Carr's Easyway (International) Limited	Guideline	023	020	<p>There is a significant and serious omission in this section in that it should also include non-pharmacological options that have been proven in at least two randomised controlled trials where the success rates are the same or better than using NRT. For example:</p> <p>Published Trial Paper: Irish Study published in Tobacco Control: Keogan, Li and Clancy (2019)</p> <p>The objective of this trial was to determine if Allen Carr's Easyway to Stop Smoking (AC) was superior to Quit.ie in a randomised clinical trial (n=300) over a period of 12 months. Outcome measures were chemically verified.</p> <p>The conclusions were that (i) at 1, 3, 6 and 12 months Allen Carr's Easyway was superior to Quit.ie, and (ii) achieved outcomes were comparable with other established interventions.</p> <p>Published Trial paper: UK Study with Addiction: Frings et al., (2020)</p>	Thank you for your comment. A rapid review to examine the effectiveness of the Allen Carr method is currently in the commissioning process at NICE.

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				<p>The study comprised a randomised controlled trial (n = 620) which compared the efficacy of two psychological stop smoking interventions. Specifically, Allen Carr's Easyway smoking cessation programme comprising one 5/6 hour group session (plus one or two 3 hour booster sessions over the following 3 months for those who require them) and a 1-1 counselling service with funded pharmacotherapy available via the NHS (comprising one 30 minute session and four weekly follow ups of 10-15 minutes) were compared. Participants in the NHS arm were advised on e-cig use, but devices were not funded. The efficacy of both treatment arms were assessed at 4, 12 and 26 weeks after treatment. The evaluation was compliant with the Russell 6 Standard (which requires, amongst other things, a double blind, randomised design, chemical verification of quit outcomes, and the inclusion of all participants who received treatment in the final analysis). The study concluded that (i) with a well powered sample, no differences between ACE and a specialist stop smoking service with funded pharmacotherapy could be detected and (ii) both services performed at levels comparable to those observed elsewhere in the literature (i.e. in Cochrane reviews).</p>	

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				<p>The trial was pre-registered on the Open Science Framework (https://osf.io/9kj8d/). The osf site includes the trial registration, protocol, and data files (including syntax files registered before the data was unblinded) and related resources. Currently this is set to private but it will be made public upon the papers release. However, if there is a delay in publication beyond January 24th, the research team will open the site with the exception of the data and syntax files which will be made available on publication. The study protocol was also published in BMJOpen (Wood et al., 2017).</p> <p>The study concluded that Allen Carr's Easyway method appears to have similar effectiveness to specialist 1-1 NHS smoking cessation support.</p>	
Allen Carr's Easyway (International) Limited	Guideline	024	004	<p>The guideline says "For people aged 18 and over, prescribe or provide bupropion, varenicline 5 or NRT before they stop smoking". However, there is a significant and serious omission that needs rectification namely that it should also add unless the person is following a non-pharmacological option that has been proven in at least two randomised controlled trials. That option does not require any medication to achieve the</p>	

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				success rates and so should be clearly stated that medication is not needed / recommended for all people	
Allen Carr's Easyway (International) Limited	Guideline	029	011	The guideline says "Offer and, if the person agrees, arrange for them to receive behavioural support to stop smoking" However, there is a significant and serious omission that needs rectification namely that it should also include the offer of a non-pharmacological option that has been proven in at least two randomised controlled trials. That option does not require any medication to achieve the success rates and so should be included	Thank you for your comment. A rapid review to examine the effectiveness of the Allen Carr method is currently in the commissioning process at NICE
Allen Carr's Easyway (International) Limited	Guideline	030	001	The guideline says "Offer and arrange or supply prescriptions of stop-smoking options" However, there is a significant and serious omission that needs rectification namely that it should also include the offer of a non-pharmacological option that has been proven in at least two randomised controlled trials. That option does not require any medication to achieve the success rates and so should be included because otherwise is advising that the only option is pharmacological	Thank you for your comment. A rapid review to examine the effectiveness of the Allen Carr method is currently in the commissioning process at NICE
Allen Carr's Easyway (International) Limited	Guideline	031	006	The guideline says "If stop-smoking pharmacotherapy is accepted," However, there is a significant and serious omission that needs rectification namely that it should also	Thank you for your comment. A rapid review to examine the effectiveness of the Allen Carr method is currently in the commissioning process at NICE

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				include the offer of a non-pharmacological option that has been proven in at least two randomised controlled trials. That option does not require any medication to achieve the success rates and so should be included because otherwise is advising that the only option is pharmacological	
Allen Carr's Easyway (International) Limited	Guideline	032	006	The guideline says "tell them about the different types of medicinally licensed nicotine containing products" It should also include tell them about non-pharmacological options that have been proven in at least two randomised controlled trials because otherwise is advising that the only option is pharmacological	Thank you for your comment. A rapid review to examine the effectiveness of the Allen Carr method is currently in the commissioning process at NICE
Allen Carr's Easyway (International) Limited	Guideline	033	015	The guideline says "Ensure hospital pharmacies stock the medicinally licensed products" However, there is a significant and serious omission that needs rectification namely that it should also include tell them about non-pharmacological options that have been proven in at least two randomised controlled trials because otherwise is advising that the only option is pharmacological	Thank you for your comment. A rapid review to examine the effectiveness of the Allen Carr method is currently in the commissioning process at NICE
Allen Carr's Easyway (International) Limited	Guideline	034	015	The guideline says "Advise them to use medicinally licensed nicotine-containing products" However, there is a significant and serious omission that needs rectification namely that it should also include tell them about non-pharmacological options that have	Thank you for your comment. A rapid review to examine the effectiveness of the Allen Carr method is currently in the commissioning process at NICE

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				been proven in at least two randomised controlled trials because otherwise is advising that the only option is pharmacological.	
Allen Carr's Easyway (International) Limited	Guideline	034	026	This section discusses harm-reduction but the only offer is pharmacological. However, there is a significant and serious omission that needs rectification namely that it should also include tell them about non-pharmacological options that have been proven in at least two randomised controlled trials	Thank you for your comment. A rapid review to examine the effectiveness of the Allen Carr method is currently in the commissioning process at NICE
Allen Carr's Easyway (International) Limited	Guideline	036	021	This section discusses behavioural support. However, there is a significant and serious omission that needs rectification namely that it should also include non-pharmacological options that have been proven in at least two randomised controlled trials	Thank you for your comment. A rapid review to examine the effectiveness of the Allen Carr method is currently in the commissioning process at NICE
Allen Carr's Easyway (International) Limited	Guideline	044	018	The guideline says "Offer the opportunity for a further course of pharmacotherapy" However, there is a significant and serious omission that needs rectification namely that it should also include tell them about non-pharmacological options that have been proven in at least two randomised controlled trials because otherwise is advising that the only option is pharmacological	Thank you for your comment. A rapid review to examine the effectiveness of the Allen Carr method is currently in the commissioning process at NICE
Allen Carr's Easyway (International) Limited	Guideline	045	014	The guideline says "Offer medicinally licensed nicotine-containing products, as needed" However, there is a significant and serious omission that needs rectification namely that it	Thank you for your comment. A rapid review to examine the effectiveness of the Allen Carr method is currently in the commissioning process at NICE

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				should also say offer them about non-pharmacological options that have been proven in at least two randomised controlled trials because otherwise is advising that the only option is pharmacological	
Allen Carr's Easyway (International) Limited	Guideline	048	001	This section discusses pregnant women. However, there is a significant and serious omission that needs rectification namely that it should also include offering them non-pharmacological options that have been proven in at least two randomised controlled trials	Thank you for your comment. A rapid review to examine the effectiveness of the Allen Carr method is currently in the commissioning process at NICE
Allen Carr's Easyway (International) Limited	Guideline	049	007	This section discusses pregnant women. However, there is a significant and serious omission that needs rectification namely that it should also include offering them non-pharmacological options that have been proven in at least two randomised controlled trials	Thank you for your comment. A rapid review to examine the effectiveness of the Allen Carr method is currently in the commissioning process at NICE.
Allen Carr's Easyway (International) Limited	Guideline	050	008	This section discusses NRT for pregnant women. However, there is a significant and serious omission that needs rectification namely that it should also include offering them non-pharmacological options that have been proven in at least two randomised controlled trials	Thank you for your comment. A rapid review to examine the effectiveness of the Allen Carr method is currently in the commissioning process at NICE
Allen Carr's Easyway	Guideline	058	018	The guideline says "Ensure service specifications require providers of stop-smoking support to	Thank you for your comment. A rapid review to examine the effectiveness of the Allen Carr

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(International) Limited				offer medicinally licensed nicotine-containing products” However, there is a significant and serious omission that needs rectification namely that it should also ensure that they offer non-pharmacological options that have been proven in at least two randomised controlled trials because otherwise is advising that the only option is pharmacological	method is currently in the commissioning process at NICE
Allen Carr's Easyway (International) Limited	Guideline	059	008	The guideline says “Ensure stop-smoking medicinally licensed products are included in secondary care formularies” However, there is a significant and serious omission that needs rectification namely that it should also ensure that they offer 21 non-pharmacological options that have been proven in at least two randomised controlled trials because otherwise is advising that the only option is pharmacological	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Allen Carr's Easyway (International) Limited	Guideline	063	012	This section discusses Training on stopping smoking. However, there is a significant and serious omission that needs rectification namely that it should also include ensuring all frontline healthcare staff understand and can refer people to non-pharmacological options that have been proven in at least two randomised controlled trials	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Allen Carr's Easyway	Guideline	064	024	The guideline says “Midwives and others working with pregnant women should know about the treatments that can help people to	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update.

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(International) Limited				quit including NRT" However, there is a significant and serious omission that needs rectification namely that it should also ensure that they know about non-pharmacological options that have been proven in at least two randomised controlled trials because otherwise is advising that the only option is pharmacological	Please see the scope document on the NICE website.
Allen Carr's Easyway (International) Limited	Guideline	067	007	This section discusses Behavioural support but there is a significant and serious omission that needs rectification namely that it should also include non-pharmacological options that have been proven in at least two randomised controlled trials	Thank you for your comment. A rapid review to examine the effectiveness of the Allen Carr method is currently in the commissioning process at NICE.
Allen Carr's Easyway (International) Limited	Guideline	068	001	There is a section discussing E-cigarettes but there is a significant and serious omission that needs rectification namely that there is not one discussing non-pharmacological options that have been proven in at least two randomised controlled trials	Thank you. This section is to define terms used in this guideline.
Allen Carr's Easyway (International) Limited	Guideline	077	006	There is a section discussing Stop-smoking interventions after looking at a large amount of evidence but there is a significant and serious omission that needs rectification namely that it did not include non-pharmacological solutions with at least two randomised controlled trials (RCTs) despite being made aware before and during the review. This is a significant and serious omission that needs immediate	Thank you for your comment. A rapid review to examine the effectiveness of the Allen Carr method is currently in the commissioning process at NICE.

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				rectification given the results especially as the option is pharmacologically free.	
Allen Carr's Easyway (International) Limited	Guideline	082	010	There is a section discussing Supporting people trying to stop smoking and taking varenicline and bupropion for longer to improve their chances of success. However, there is a significant and serious omission that needs rectification namely that the committee did not include the RCTs from non-pharmacological solutions with at least two randomised controlled trials (RCTs) despite being made aware before and during the review. These showed that without any pharmacology the success rates were the same or better for the person and hence should have been considered and included here. Instead of recommended prescribing more pharmacotherapies an option should be to offer non-pharmacological solutions with at least two randomised controlled trials.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Allen Carr's Easyway (International) Limited	Guideline	085	005	There is a section discussing pregnant women and NRT and other pharmacological support. However, this section should also discuss non-pharmacological options that have been proven in at least two randomised controlled trials	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Allen Carr's Easyway	Guideline	087	009	There is a section discussing Commissioning and designing services. However, there is a significant and serious omission that needs	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update.

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(International) Limited				rectification and inclusion which is non-pharmacological options that have been proven in at least two randomised controlled trials	Please see the scope document on the NICE website.
Allen Carr's Easyway (International) Limited	Guideline	088	021	There is a section discussing Stop smoking in secondary care. However, there is a significant and serious omission that needs rectification and inclusion which is non-pharmacological options that have been proven in at least two randomised controlled trials	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
ASH Wales	Guideline	078	027 - 029	This section states that nicotine e-cigarettes are of similar effectiveness to NRT. There is some evidence that they are more effective than NRT 1 (including in studies where participants are offered combined short and long-acting NRT) and this should be stated. 8 Hartmann-Boyce J, McRobbie H, Butler AR, Lindson N, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Fanshawe TR, Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2021, Issue 4. Art. No.: CD010216	Thank you. The pairwise meta-analysis found a pooled risk ratio of 1.47 (1.25 – 1.72) for nicotine e-cigs vs single NRT for abstinence at 3 months. The network meta-analysis uses the effectiveness data and NMA models from Thomas' (2020) review as well as results of NICE-conducted rerun searches. This NMA (based on 192 studies) showed no significant effect of e-cigarettes compared to NRT (RR of 1.23 [CrI: 0.73, 1.95]) or long + short NRT (RR: 0.84 [CrI 0.48, 1.40]). The discrepancy between pairwise and NMA effect estimates is likely to be due to the modifying effect of indirect treatment estimates within the network. Consistency checking did not

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					identify any concerns with the model that was used for the NMA and the committee focussed their discussion on the results of this NMA.
Association of Respiratory Nurse Specialists	Guideline	010		Question 3. Some good initiative have been implemented in Scotland and other home nations which could be used as examples of good practice and support the implementation of for example smoke free schools.	Thank you for your response. Your comments will be considered by NICE where relevant support activity is being planned.
Association of Respiratory Nurse Specialists	Guideline	010	001	Question 1. Retailers – this will be challenging to enforce, cut backs in local authorities and council funding has meant a reduction in trading standards officers or their remit being extended. This means local authorities find it difficult to support the implementation of recommendations such as these. Also, having worked closely with young people shops are continuing to use tobacco products to gain the trust of young people which puts young people at risk of being taken advantage of in many ways. While local authorities and police are aware, unless they can catch the retailer (this is very difficult to do as retailers will often only sell to people they trust and young people they know making test purchasing harder as children out with the local area are used for safety reasons) in the act, very little can be done.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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Association of Respiratory Nurse Specialists	Guideline	010	001	1.3 Question 2. Retailers – Again local authorities would require greater funding in order to support this action.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Association of Respiratory Nurse Specialists	Guideline	011	025	1.5.1 Whole-School or organisation-wide smokefree policies – this can be challenging, having implemented a test of change approach within a local high school this required dedicated staff from the stop smoking service who are aware of how different schools in the local area are run but this also requires staff who are engaged within the school. You also need to make sure that ALL staff who enter the school premises are consulted and included in the process as often cleaning contracts are undertaken by different companies, making sure everyone adheres to the smokefree policy is helpful to the young people when taking this forward.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Association of Respiratory Nurse Specialists	Guideline	013	008	1.6.5 Booster activities are not required if you take a curriculum approach which would be better, booster activities are only required if you perform these discussions as a one-off tick box exercise. Being clear here would support the curriculum approach.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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Association of Respiratory Nurse Specialists	Guideline	017	026	Why would there be a recommendation for smoking breaks, rather than encourage smoke free working or only permitted within meal breaks.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Association of Respiratory Nurse Specialists	Guideline	019	003	Why would we change the wording to 'habit' this undermines all the work that has been done in shifting the populations views on smoking from being an acceptable activity to an addiction.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Association of Respiratory Nurse Specialists	Guideline	021	015	Adding in VBA, encourage training in VBA	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website
Association of Respiratory Nurse Specialists	Guideline	023	008	1.12.3 The benefits of behavioural support should be discussed alongside the use of pharmacotherapy otherwise people often try to stop on their own – for many this makes the process harder.	Thank you for your comment. Recommendation 1.12.5 (p.23; line 20 to 26) highlights the treatment options when combined with behavioural support that are likely to result in successful quit attempts. The rationale and impact section (p.77-78) highlights the discussion had by the Public Health Advisory Committee on the role of behaviour support in enhancing the effectiveness of treatments underpinning this recommendation. Based on the above the Public Health Advisory Committee (PHAC) have not made any changes in line with your comment

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Association of Respiratory Nurse Specialists	Guideline	023	027	1.12.6 While I understand wanting to set people up for success this section needs reworded, advising people that the options they have chosen after your consultation with them is less likely to result in a successful quit could undermine their attempt. Please consider rewording this.	Thank you for your comment. The Public Health Advisory Committee (PHAC) have considered your comment and outlined that patient informed choices in decision making regarding their health is a key element within this guideline and within NICE's work more broadly. Recommendations 1.12.4, 1.12.5 and 1.12.6 are intended to form part of the same discussion to support people to make an informed choice. Recommendation 1.12.6 outlines choices that based on the evidence considered PHAC has recommended as 'less likely to result in a successful quite attempt'. It is of their opinion based on the evidence considered that those providing stop-smoking support or advice should discuss all options and their possible outcomes with people when deciding which options to use to stop smoking. We would expect this information to be given to people before they made their choice.
Association of Respiratory Nurse Specialists	Guideline	051	006	Incentive Schemes – this money would need to be ring fenced. Also while this has type of initiative has helped short term abstinence, a lot of women return to smoking when the incentive stops – I'm sure this was the outcome of a similar incentive in Dundee	Thank you. The recommendations are based on the evidence of effectiveness and the implementation of the recommendations is primarily a local commissioning decision.

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				around 2008 ish. Also, you need to take into consideration gaming. Often the women who need this help and support the most are the hardest to reach even when an incentive is offered and how will this impact the inequalities gap in pregnant smokers.	As detailed in the rationale and impact section, the committee saw evidence that supported a staggered scheme of incentives up to and beyond birth. The committee were of the view that incentives may help to reduce inequalities.
Association of Respiratory Nurse Specialists	Guideline	052	018	1.20.17 Include family nurse partnership here	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Association of Respiratory Nurse Specialists	Guideline	054	006	Does this include the removal of smokeless smoking areas	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Association of Respiratory Nurse Specialists	Guideline	054	025	This is conflicting with advice stated in comment 1 above	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Association of Respiratory Nurse Specialists	Guideline	055	015	As per comment 3, concerned regarding mixed messaging	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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Association of Respiratory Nurse Specialists	Guideline	059	002	I would be concerned that this is not achievable although should be encouraged	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Association of Respiratory Nurse Specialists	Guideline	061	010	1.22.22 Monitoring stop smoking services while targets are necessary to make sure needs are met, it will be important to consider the implications on staff of the difficult groups who continue to smoke. Most people who wanted to stop smoking have stopped or will make a quit attempt, this leaves services with a difficult to reach population group making targets harder to reach despite best efforts made.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Association of Respiratory Nurse Specialists	Guideline	061	010	1.22.23 10ppm this is a long-established level however this is still high and could represent a social smoker, we measure this differently in pregnancy – could this be lowered for the rest of the population to more accurately reflect a quit.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Association of Respiratory Nurse Specialists	Guideline	063	013	Consider making this mandatory training	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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Association of Respiratory Nurse Specialists	Guideline	063	013	1.23.2 While I agree with this point completely how do you plan on training all frontline healthcare staff to offer VBA? Perhaps making training mandatory would help in this area.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Association of Respiratory Nurse Specialists	Guideline	065	001	1.23.10 Again I agree with this point however how do you plan on making sure this is achieved	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Asthma UK and the British Lung Foundation	Guideline	General	General	The guidelines, quite rightly, make a range of recommendations for research (see page 72-76). Yet there is only one acknowledgement of the need to take into account the outcomes of any such research, in section 1.9.2 bullet 2 which recommends "Use the best available evidence of effectiveness, such as Cochrane reviews". To our knowledge some, if not all, of the research recommendations are already being taken forward. For example, NIHR has funded 'Helping Pregnant Smokers Quit: A Multi-Centre RCT of Electronic Cigarette and Nicotine Patches', although unfortunately the research may not be available before the	Thank you for your comment. The research recommendations developed by PHAC seek to address the gaps in the evidence identified during the guideline development process with the hope of stimulating research in these areas for consideration when this guideline or aspects of this guideline are considered for update. NICE routinely checks that published guidelines are current, accurate and up to date via our surveillance function which explores if there is any new evidence to contradict, reinforce or clarify guideline recommendations. Surveillance also identifies new interventions that may need to be considered within a guideline and

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				<p>guidelines are published so is unlikely to be able to be taken into account during the consultation. NIHR is also funding research on smoking cessation in underserved groups such as prisoners and the homeless.</p> <p>As the evidence continues to develop and evolve, it is important that in the overview section of the guidelines there is a generic recommendation that research outcomes are taken into account. We suggest something along the lines, "When developing and implementing policies to prevent uptake, promote quitting and treat dependence it is essential to use the best available evidence of effectiveness, such as Cochrane reviews".</p>	<p>explores changes in context that may mean modifications are needed, for example, changes in policy, infrastructure, legislation or costs. A proactive approach is taken that includes reacting to events at any time after guideline publication (for example, publication of a key study) and a standard check every 5 years.</p>
Asthma UK and the British Lung Foundation	Guideline	General	General	<p>Financial incentives for quitting smoking are not highlighted as an effective intervention in the general population. They should be. There is high certainty evidence of their effectiveness in the general population of people who smoke (as well as in pregnancy, where they are currently highlighted).^{1 2}</p> <p>¹ Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD004307</p> <p>² Hartmann-Boyce J, Livingstone-Banks J, Ordóñez-Mena JM, Fanshawe TR, Lindson N,</p>	<p>Thank you for your comment. Incentives were only considered in pregnant women. Incentives for other populations is outside the scope of this update. Please see the scope document on the NICE website. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.</p>

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				Freeman SC, Sutton AJ, Theodoulou A, Aveyard P. Behavioural interventions for smoking cessation: an overview and network meta-analysis. <i>Cochrane Database of Systematic Reviews</i> 2021, Issue 1. Art. No.: CD013229	
Asthma UK and the British Lung Foundation	Guideline	046 - 047	General	<p>3 and 4ppm CO levels are both used in this section (p46 line 15 says 4ppm and p47 line 9 says 3ppm). The Smoking in Pregnancy Challenge Group recommends that women with a reading of 4ppm or above should be referred for smoking cessation support. Evidence suggests that 4ppm is the optimal cut-off for correctly identifying pregnant women who smoke and minimising the number of false positives.^{11 12}</p> <p>¹¹ Bailey BA. Using expired air carbon monoxide to determine smoking status during pregnancy: preliminary identification of an appropriately sensitive and specific cut-point. <i>Addictive behaviors</i>. 2013 Oct 1;38(10):2547-50.</p> <p>¹² Bauld L, Hackshaw L, Ferguson J, Coleman T, Taylor G, Salway R. Implementation of routine biochemical validation and an 'opt out' referral pathway for smoking cessation in pregnancy. <i>Addiction</i>. 2012 Dec;107:53- 60.</p>	Thank you for your comment. The different carbon monoxide levels refer to different groups of pregnant women: smokers and non-smokers and to different actions. The reference to 4 ppm in recommendation 1.18.2 is in the context of the provision of an opt-out referral to receive stop-smoking support for pregnant women. The reference to 3 ppm in recommendation 1.18.4 refers to women who do not smoke and to provide help to identify the source of the carbon monoxide level of 3 ppm.

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Asthma UK and the British Lung Foundation	Guideline	010	005	It would be more effective to recommend asking for proof of age from anyone who appears under the age of 25. 'Challenge 25' is a well established procedure within alcohol sales and recommended by the Retail of Alcohol Standards Group, who represent all the major supermarkets and alcohol retailers. While alcohol licensing guidance from the Home Office states that challenging those who appear to under 18 is the minimum requirement, it also highlights challenge 21 and challenge 25 schemes. It would be helpful if NICE guidance did likewise for tobacco sales. Retailers such as Tesco already operate a challenge 25 policy across both alcohol and tobacco, including vaping products.	Thank you for your comment. The Public Health Advisory Committee (PHAC) Have considered your comments and have decided not to change the recommendation. PHAC highlighted that Review C and D considered the evidence on proxy purchasing and based on the evidence, expert testimony and the contributions of co-optee members to the committee, the PHAC made the decision to carry forward the previous recommendations. Challenge 25 is specific to alcohol and the committee did not see any evidence to support its use in tobacco control. They were unclear about the provenance of Challenge 25, which is not a government policy.
Asthma UK and the British Lung Foundation	Guideline	013	005 - 007	1.6.4 – While it is important to avoid inadvertently making e-cigarettes desirable to young people, it is just as important to avoid inadvertently reinforcing misperceptions that e-cigarettes are as harmful as smoking. Findings from the annual Smokefree GB survey commissioned by ASH show that the perception among 11–18-year-olds that cigarettes and e-cigarettes are equally harmful has increased since 2013. In 2021, only 43.8% of 11–18-year-olds knew that e-cigarettes were less harmful than cigarettes. ³ Similarly, among adults, around a third (32%) believed e-	Thank you for your comment. This is stated clearly elsewhere in the guideline and the committee were clear that they did not want to say anything that might promote the use of e-cigarettes in under 18s.

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				<p>cigarettes were more or equally as harmful as cigarettes in 2021, compared to 42% who thought they were less harmful.⁴ This is relevant because adults will be responsible for giving children advice about e-cigarettes.</p> <p>An additional sentence should be added to recommendation 1.6.4 consistent with the wording on page 26 lines 1-4, that "However, it is also important to make clear that although there is not enough evidence to know whether there are long-term harms from e-cigarettes, they are likely to be substantially less harmful than smoking."</p> <p>³ ASH. Use of e-cigarettes among young people in Great Britain. 2021 ⁴ ASH. Use of e-cigarettes (vapes) among adults in Great Britain. 2021</p>	
Asthma UK and the British Lung Foundation	Guideline	017	001 - 003	<p>We welcome the recommendation to involve community pharmacies in local campaigns and maintain links with other professional groups such as dentists, fire services and voluntary groups.</p> <p>We would like to see children's services and welfare and benefits officers/advisors included in this list because they have a unique opportunity to screen for smoking, provide very brief advice and signpost to smoking cessation</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.</p>

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				services as part of their interventions to help people manage their financial situation.	
Asthma UK and the British Lung Foundation	Guideline	020	009	NICE already recommend Very Brief Advice (VBA) as an evidence based way of talking to smokers about quitting. It would be useful to refer to that here, linking to the guidance on delivering VBA, which would be more specific than saying 'at every opportunity ask people if they smoke or have recently stopped smoking.' The steps outlined in the draft guidance here are longer than the VBA process, so perhaps VBA could be recommended as the approach to take where time is short, with the more detailed steps outlined here recommended where more time is available.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website
Asthma UK and the British Lung Foundation	Guideline	023	006	It would be useful to add that patients should be told that they are three times more likely to quit with NHS support. ⁵ ⁵ NCSCT. Stop smoking services: increase the chance of quitting. 2019	Thank you for your comment. The Public Health Advisory Committee (PHAC) have considered your comment and agreed that based on the systematic reviews of the evidence and expert testimony considered, the guideline sufficiently covers the role of behaviour support in enhancing the effectiveness of treatments and makes sufficient references as to where this could occur. Based on this they have not changed the guideline.
Asthma UK and the	Guideline	028	010 - 013	1.14.1 – We would like to see this section include a bullet point to highlight the mental health benefits of quitting smoking. A recent	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update.

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British Lung Foundation				<p>Cochrane review found that smokers who stop have better mental health than those who continue to smoke and that the benefits to mental health were estimated to be equivalent to anti-depressants.⁶ Quitting can also help reduce the severity of psychotic symptoms and in some cases, contribute to reductions in prescribed medications and shorter hospital stays.⁷</p> <p>⁶ Taylor GM, Lindson N, Farley A, Leinberger-Jabari A, Sawyer K, te Water Naudé R, Theodoulou A, King N, Burke C, Aveyard P. Smoking cessation for improving mental health. Cochrane Database of Systematic Reviews. 2021(3).</p> <p>⁷ Taylor, D.M., Barnes, T.R.E., Young, A.H., (2021) The Maudsley Prescribing Guidelines in Psychiatry, 14th Edition, ISBN: 978-1-119-77223-1 July 2021 Wiley-Blackwell 976 Pages</p>	Please see the scope document on the NICE website.
Asthma UK and the British Lung Foundation	Guideline	029	011	<p>We are pleased to see the recommendation that every smoker will be offered behavioural support in acute, maternity and mental health care settings but we are disappointed that this offer is only recommended “if the person agrees”. We recommend that behavioural support is provided on an opt-out basis – as described in the Ottawa Model and in the RCPs Hiding in Plain Sight. ⁸ The Ottawa</p>	<p>Thank you for your comment. The evidence on opt-out referral schemes was in scope for pregnant women only. The committee has made recommendations on opt-out referral schemes for pregnant women (see Recommendations 1.18.2 and 1.18.3). Opt-out referral schemes were not within scope for other population groups. Please see the scope document on the NICE website.</p>

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				<p>model is also recommended in the NHS Long Term Plan.9</p> <p>It is often the case that at the point of screening for smoking and provision of Very Brief Advice at admission, people coming into mental health care settings are usually distressed and unlikely to be able to weigh up this decision. We recommend a more proactive approach which ensures those that need specialist support have access to it using an opt-out approach.</p> <p>8 Royal College of Physicians. Hiding in plain sight: Treating tobacco dependency in the NHS. 2018</p> <p>9 NHS England. The NHS Long Term Plan: Smoking. January 2019</p>	
Asthma UK and the British Lung Foundation	Guideline	030	014	<p>We do not believe that the recommendation to provide support to smokers within 24 hours of admission goes far enough to ensure patients comfort or ease their distress. We would welcome a recommendation to provide support within 30 minutes of arrival to hospital. For example, SLaM NHS Foundation Trust provide 'Tea and NRT' to smokers on arrival to hospital as an over the counter medication. This avoids the delays caused by getting a prescriber and is hugely beneficial since the half-life of</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.</p>

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				nicotine is approximately 2 hours and longer delays will result in unnecessary discomfort.	
Asthma UK and the British Lung Foundation	Guideline	032	004 - 009	<p>1.14.20 - We welcome the recommendation to tell smokers about the different types of medicinally licensed nicotine containing products, how to use them and if possible, prescribe them. However, we are disappointed that e-cigarettes are not also recommended as a vital intervention for smokers who are in a situation where they need to temporarily abstain. If this guideline only recommends the use of NRT to support tobacco abstinence, this represents an extremely challenging scenario for trusts that currently offer e-cigarettes to service users and risks further disadvantaging people with mental health ill health, who will be left behind. We would worry that failure to include e-cigarettes as a safe, valid and effective way to support temporary abstinence will enable some service providers to opt out of and we will find ourselves in a situation where the teachable moment to support stopping smoking and switching to an e-cigarette is lost.</p> <p>SLaM NHS Foundation Trust provide mental health care services from 4 large London based hospitals (50 wards). Typically, about half of the adult smokers admitted to hospital are current smokers, it is rare to find a smoker</p>	<p>Thank you for your comment. The evidence on the use of nicotine containing e-cigarettes to support temporary abstinence was not reviewed as part of this guideline update and therefore recommendations have not been made in this area.</p> <p>Regarding differing needs between people admitted to acute hospital settings and to mental health settings, these recommendations are greyed out as they are outside the scope for this update. Please see the scope document on the NICE website.</p>

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				<p>at the point of admission who decides to make a quit attempt. For the overwhelming majority (95%) their decision at the point of admission is to use whatever support is available to temporarily abstain. Currently, the preferred option to support temporary abstinence is an e-cigarette, because smokers feel that this more closely matches the experience of smoking compared with using NRT products. SLam have used e-cigarettes in this way since 2012 and typically provide around 400 free e-cigarette starter packs each month. In about 30% of cases the smokers find that the provision of a free e-cigarette starter pack, given with the intention to support temporary abstinence on admission is so effective that they decide to continue using it and do not return to smoking.</p> <p>In 2019 ASH conducted a survey of mental health trusts which found that 42% of mental health trusts in England provide free e-cigarettes to adult smokers on admission to hospital to support temporary abstinence, and as such we believe there is ample evidence to support this consensus practice.¹⁰ More generally in this section of the guidance, we think a distinction should be made between the needs of people admitted to an acute hospital</p>	

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				setting and people admitted to a mental health setting. The unique needs of people in mental health crisis is completely different and deserves a more bespoke response. 10 ASH. Progress towards smokefree mental health services. Findings from a survey of mental health trusts in England. 2019	
Asthma UK and the British Lung Foundation	Guideline	051	General	1.20.12 – We are concerned that this guideline doesn't link to any guidance or information to support the implementation of incentive schemes. This could include case studies of existing schemes, key competencies for staff or dedicated training. The Smoking in Pregnancy Challenge Group has produced a briefing to support the commissioning and delivery of incentive schemes. ¹⁸ The briefing summarises the evidence from previous incentive schemes, sets out lessons for practice and will be updated in line with emerging evidence. The guidance should link to the Challenge Group briefing to ensure that commissioners have access to practice-focused information to support the delivery of incentive schemes. We also recommend that the guidance should link to case studies and guidance from previous incentive schemes. ¹⁸ The Migration Observatory. The health of migrants in the UK. August 2020	Thank you. The recommendations are based on the evidence of effectiveness, and the implementation of the recommendations is primarily a local commissioning decision.

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Asthma UK and the British Lung Foundation	Guideline	051	015 - 016	1.20.12 – bullet 3 – This sentence should use the word “incentive” instead of “reward”. Incentive payments are not rewards; they are incentives to change behaviour and the terminology used should reflect that. This is particularly important given the sensitivity in the media around the use of financial incentives in pregnancy.	Thank you for your comment. PHAC considered your comment and the wording has been amended to reflect your comment.
Asthma UK and the British Lung Foundation	Guideline	051	015 - 016	1.20.12 – bullet 3 – The guideline should recommend that the offer of incentives be extended into the postnatal period for a minimum of 3 months to prevent women relapsing to smoking. Evidence suggests nearly half of women who quit smoking during pregnancy relapse within 1-year post-partum ¹⁵ This harms the health of the mother and makes it more likely that children will be exposed to secondhand smoke in the home, leading to higher rates of sudden infant death (SIDS), lower respiratory tract infection, middle ear disease, asthma and many other diseases ¹⁶ Consequently, supporting women and their partners to stay smokefree after their baby is born is key to helping them maintain a smokefree home and protecting them and their children from harmful tobacco smoke. Evidence from a 2019 Cochrane review shows that providing incentives into the postnatal period is effective for supporting women to	Thank you. The committee considered this. Please see the committee discussion section of evidence review J which says that “The committee discussed the duration of incentive provision and agreed that this should occur at least until the end of pregnancy (including pregnancies that do not progress), however that it wasn’t clear whether provision would be beneficial in the post-partum period “

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				<p>stay smokefree.¹⁷ Additionally, Greater Manchester Health and Social Care Partnership are currently awaiting publication of a RCT looking at the provision of incentives for 1-year post-partum.</p> <p>15 Royal College of Physicians. Passive smoking and children. A report by the Tobacco Advisory Group. London: RCP, 2010</p> <p>16 Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation (Review). Cochrane Database of Systematic Reviews. 2019. Issue 7. Art. No.: CD004307</p> <p>17 Smoking in Pregnancy Challenge Group. Evidence into Practice: Supporting smokefree pregnancies through incentive schemesv. 2019</p>	
Asthma UK and the British Lung Foundation	Guideline	051	005	<p>Research is underway on the effectiveness of e-cigarettes as a quitting aid for pregnant smokers and the impact of their use on birth outcomes, but will not be published in time to be taken into account in this guidance. Despite the lack of evidence specific to pregnancy at the current time, advice on the use of e-cigarettes in pregnancy should not be excluded from the guidance. E-cigarettes are already being used by some women as an aid to quit smoking during pregnancy, and midwifery and stop smoking practitioners are</p>	<p>Thank you. The committee did not see any evidence on the effectiveness of nicotine containing e-cigarettes during pregnancy and therefore is unable to make a recommendation in this area.</p>

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				<p>being asked for advice on their use. If they are unable to provide any advice, there is an increased risk that women may revert to smoking, which is a leading modifiable risk factor for many poor birth outcomes. That is why the Smoking in Pregnancy Challenge Group, an alliance of medical organisations such as the RCOG, RCM and RCGP, working together with charities such as the Lullaby Trust, Sands and Tommys, has produced peer reviewed resources for healthcare professionals and pregnant women on use of e-cigarettes.ii These resources are widely used and are regularly updated in line with the evolving evidence base.</p> <p>Therefore, after the section on 'Nicotine replacement therapy and other pharmacological support' (pages 50 line 8 to 51 line 5) a section should be added headed 'Use of e-cigarettes in pregnancy'. This should state that "If a pregnant woman has chosen to use an e-cigarette to quit or to reduce the number of cigarettes that she smokes, she should not be discouraged from doing so, as any risks to the fetus is likely to be extremely small compared to continued smoking". Then go on to say "It is important to give pregnant smokers clear, consistent and up-to-date information about nicotine containing e-</p>	

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				cigarettes (for example see the Smoking in Pregnancy Challenge Group resources on e-cigarettes). See also the section in the guideline on advice on nicotine-containing e-cigarettes."	
Asthma UK and the British Lung Foundation	Guideline	052	006	<p>We are concerned that the guideline 'Enabling all pregnant women to access stop-smoking support' does not explicitly recommend that stop smoking materials and support be provided in languages other than English. Although the NICE guideline on patient experience in adult NHS services recommends that healthcare services are accessible for non-English speakers, given high rates of smoking among some migrant communities, the guideline should explicitly highlight the need to provide stop smoking materials and advice in a range of languages.</p> <p>Migration Observatory analysis of the Annual Population Survey 2019, shows that women born in new EU accession countries, including Poland, Romania and Lithuania, have much higher rates of smoking than those born in the UK (22% compared to 13%).¹⁹ Among men, those who are foreign-born are more likely to smoke than UK-born men, and men born in new EU accession countries more than twice as likely to smoke as UK-born men (34%</p>	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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				<p>compared to 15%). To ensure that these communities are not underserved by stop smoking support, we believe that the list starting on page 52, line 11, should include a point saying "Ensure resources and advice for stopping smoking are available in a range of different languages, taking into account local demographics."</p> <p>19 Brose L, West R, Michie S, McEwen A. Changes in success rates of smoking cessation treatment associated with take up of a national evidence-based training programme. Preventive Medicine 2014;69C:1-4</p>	
Asthma UK and the British Lung Foundation	Guideline	059	010 - 011	<p>Clarify statement "Include nicotine-containing products as options for sale in secondary settings (for example, in hospital shops.)" The guideline should specify whether this refers to NRT and/or e-cigarettes to avoid any confusion. We would support the inclusion of e-cigarettes.</p>	<p>Thank you. Nicotine containing products is defined in the glossary section of the guideline. The definition of nicotine containing products has been amended to clarify that it includes nicotine containing e-cigarettes</p>
Asthma UK and the British Lung Foundation	Guideline	062	General	<p>1.23 – [PH5] Smoking: workplace interventions - Recommendation 4: 'Ensure smoking cessation support and treatment is delivered only by staff who have received training that complies with the 'Standard for training in smoking cessation treatments' has been deleted. The reason given for deletion is that 'tailoring support and treatment is a general</p>	<p>Thank you. Training is covered in recommendations 1.23.2 to 1.23.4. Additionally, 1.23.2 cross references to recommendations 1.12 which reference NCSCT training.</p>

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				<p>principle recommended in NICE's guideline on patient experience in adult NHS services.' We do not support this deletion.</p> <p>The National Training Standard was produced by the National Centre for Smoking Cessation and Training (NCSCT) on behalf of the Department of Health and includes all behaviour change techniques (BCTs) for which there is evidence of effectiveness. It does not prevent tailoring support and treatment as appropriate, therefore the rationale for deletion is not justified. Practitioners trained to deliver interventions according to the standard have been proven to be effective in adding significant value to quit attempts.iii Removal of the Training Standard is likely to lead to a return to the situation prior to the establishment of the NCSCT where people provided training based on opinion, rather than the evidence, for what effective training should contain. This recommendation should therefore be reinstated.</p> <p>Related to this point, the National Training Standard is mentioned in 1.12 (in a rather non-specific manner) and again under Quitlines (1.12.20). However, section 1.23, line 12-26, 'Those who advise people to stop smoking'</p>	

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				<p>fails to include any mention of the Standard. While the subtitle may suggest this section is specific to those who identify smokers and prompt quit attempts (i.e. deliver VBA), there is nothing further in this section on training for those who deliver ongoing stop smoking support (i.e. behavioural support), as has been the case in previous versions of the document. At minimum this should be included for stop smoking services. The wording found in the 2018 NG92 recommendation on this subject served this purpose. The key being 1) stop smoking support is provided by trained staff and 2) that training be consistent with the National Training Standard. Given the level of depth the document goes into for maternity care and closed institutions, there should be at least the equivalent depth provided for all settings (stop smoking services, maternity care, closed institutions, primary care) who are delivering stop smoking support. This should consist of the National Training Standard as default, plus additional training for those working with specific population such as mental health and pregnancy.</p> <p>Overall, there is little said in the new NICE guidance on stop smoking services and stop smoking support delivered in other settings</p>	

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				compared to previous guidance documents. There is also a level of specificity in some sections that is not consistently applied in the document (e.g. lots of detail in maternity care section and smokeless tobacco and only a few bullets on other important areas of practice). This risks making the document less clear and less user friendly than previous NICE guidance.	
Asthma UK and the British Lung Foundation	Guideline	063	012	There is a slight contradiction between the heading here ('Those who advise people how to stop smoking), and the comment below '(Train all frontline staff to offer very brief advice'). Perhaps the heading at line 12 should be 'Training for all front line staff'.	Thank you. We have amended this.
Asthma UK and the British Lung Foundation	Guideline	063	013	We welcome the fact that this guidance encourages the training of all frontline healthcare staff in VBA. However, our own research in VBA use by GPs shows that over half have had no VBA training and only 2% who have had training describe it as comprehensive ²⁰ It seems likely that the situation for all primary care staff is even worse than this, and so it would be worth adding to the recommendation the fact that VBA is known to be both effective and cost effective, as an incentive to encourage uptake. ²⁰ Asthma UK. A Breath of Fresh Air. 2021	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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Asthma UK and the British Lung Foundation	Guideline	075	007 - 013	<p>We suggest considering the addition of two further points regarding recommendations for further research into relapse prevention. Firstly, we see a clear need for more research on varenicline for relapse prevention, given the committee acknowledges its likelihood of increasing long-term abstinence and supporting Cochrane evidence.²¹ Secondly, we suggest it would be a good idea to recommend more trials looking at relapse prevention interventions delivered to people who have been abstinent for 4+ weeks, as there is little evidence in this group. The committee's emphasis on the importance and paucity of this kind of longer-term evidence is reflected in evidence review N: "For this reason, the committee focussed on evidence where relapse was clearly additional to cessation and delivered at a later point (this included behavioural interventions for assisted abstainers [Figure 11, GRADE profile 5], and pharmacotherapy for assisted abstainers [Figure 13-16, GRADE profile 6]). There is a paucity of evidence on this type of longer term relapse prevention." (p.66 of evidence review N)</p> <p>²¹ Livingstone-Banks J, Norris E, Hartmann-Boyce J, West R, Jarvis M, Chubb E, Hajek P. Relapse prevention interventions for</p>	<p>Thank you. Research recommendations in NICE guidelines are specifically to address gaps in the research that the committee considered while making their recommendations. They do not address general gaps in the evidence.</p>

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				smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 10. Art. No.: CD003999	
Asthma UK and the British Lung Foundation	Guideline	078	027 - 029	This states that nicotine e-cigarettes are of similar effectiveness to NRT. There is moderate certainty evidence that they are more effective than NRT (including in studies where participants are offered combined short and long-acting NRT) and this should be made clear. ²² 22 Hartmann-Boyce J, McRobbie H, Butler AR, Lindson N, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Fanshawe TR, Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2021, Issue 4. Art. No.: CD010216	Thank you. The pairwise meta-analysis found a pooled risk ratio of 1.47 (1.25 – 1.72) for nicotine e-cigs vs single NRT for abstinence at 3 months. The network meta-analysis uses the effectiveness data and NMA models from Thomas' (2020) review as well as results of NICE-conducted rerun searches. This NMA (based on 192 studies) showed no significant effect of e-cigarettes compared to NRT (RR of 1.23 [CrI: 0.73, 1.95]) or long + short NRT (RR: 0.84 [CrI 0.48, 1.40]). The discrepancy between pairwise and NMA effect estimates is likely to be due to the modifying effect of indirect treatment estimates within the network. Consistency checking did not identify any concerns with the model that was used for the NMA and the committee focussed their discussion on the results of this NMA.
Asthma UK and the British Lung Foundation	Guideline	079	008 - 013	This section states the committee had low confidence in the finding of no difference in adverse events in people using nicotine e-cigarettes compared to NRT, e-cigarettes without nicotine, and no treatment, because the studies were powered to investigate effectiveness and not adverse events. Though	Thank you. Details of the adverse events reported are contained in evidence review K and are adverse events rather than serious adverse events. The rationale and impact section describes the committees consideration of the recommendations and their view is consistent

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				<p>this is an issue for serious adverse events, where events are rare, for non-serious adverse events, which this section appears to refer to at first glance, this is not an issue of underpowering because non-serious adverse events are more common than cessation (a study powered to detect a difference in cessation would also be powered to detect a difference in adverse events). If this section is on serious adverse events, it should be clarified that that is the case. If not, it should be reworded. The latest Cochrane review has moderate certainty evidence of no difference in rates of adverse events (non-serious) between nicotine and non-nicotine e-cigarettes.²³ 23 Hartmann-Boyce J, McRobbie H, Butler AR, Lindson N, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Fanshawe TR, Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2021, Issue 4. Art. No.: CD010216</p>	<p>with the findings in the systematic review you reference.</p>
British Dental Association	Guideline	General	General	<p>Challenges and cost implications: due to the funding cuts to specialist cessation services over recent years, there are difficulties with referral in many areas.</p>	<p>Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned. Recommending increasing the number of smoking cessation services in the UK specifically is beyond the remit of this guideline. However, the guideline recognises</p>

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					the role of all services in supporting people to stop smoking and reduce people's harm from smoking, with recommendations focused on different sectors for example education, primary and secondary care, different high-risk groups and modes of tobacco consumption and treatments
British Dental Association	Guideline	025 - 026	General	We support the cautious approach to e-cigarettes given the unknown long-term health risks and potential gateway effect.	Thank you for your comment.
British Medical Association	Guideline	General	General	<p>The BMA welcomes this update guidance and development of the evidence base around effective interventions to help to reduce tobacco use. While smoking rates have been steadily declining over the past ten years, updated guidance that takes a pragmatic approach to reducing tobacco use and smoking related harm is valuable and will hopefully make improvements in the way tobacco use is treated in the UK.</p> <p>We are conscious however that this updated guidance asks more of clinicians in explaining new potential interventions i.e. e-cigarettes and recommending specific services for groups who disproportionately use tobacco and are less likely to access stop smoking services at present i.e. those who use mental health services. The BMA agrees</p>	Thank you for your comments. Your comments will be considered by NICE where relevant support activity is being planned. Recommending increasing the number of smoking cessation services in the UK specifically is beyond the remit of this guideline. However, the guideline recognises the role of all services in supporting people to stop smoking and reduce people's harm from smoking, with recommendations focused on different sectors for example education, primary and secondary care, different high-risk groups and modes of tobacco consumption and treatments.

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				<p>wholeheartedly with the need to look at the best ways to reduce ill health and chronic conditions caused by smoking and with targeting disadvantaged groups but this updated guidance comes in the context of cuts to local public health grants impacting Stop Smoking Services and in the context of an unprecedented demand of care currently being experience in Primary and Secondary care.</p> <p>Guidance that recommends clinicians take more time to explain different cessation options to patients needs to be supported with additional resources to facilitate this ask.</p>	
British Medical Association	Guideline	013	001	The BMA supports the addition of e-cigarettes to the curriculum around drug and tobacco misuse but equally the guidance that they are discussed as differently from tobacco products. Overall, the data suggests that regular e-cigarette use in among children and young people is low, but this remains a worthwhile intervention.	Thank you for your comment.
British Medical Association	Guideline	013	006	The BMA welcomes the proposed changed to guidance specifically the mention of taking a more targeted approach to communicating to groups in which there are higher rates of smoking. Tobacco use – along with other long term drivers of ill-health –follow a social gradient. As such we agree that tackling	Thank you for your comment

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				tobacco use among groups as having a higher than prevalence for smoking would help to reduce health inequalities in the UK.	
British Medical Association	Guideline	050	009	There is no convincing evidence from randomised placebo-controlled trials that nicotine replacement therapy (NRT) in pregnancy leads to smoking cessation in the third trimester. In the most recent Cochrane review, Claire R et al 2020 (see NICE Evidence Review J) the effect estimate was 1.21 (95%CI 0.95-1.55), moderate confidence.	<p>Thank you. The committee agreed that NRT is likely to be an effective method of stopping smoking in pregnancy but the evidence did not show this to be as effective as the committee would have expected.</p> <p>The committee discussed that doses of NRT was an area where there was a lack of clarity. While the studies tended to use low doses, the committee agreed that higher doses might deliver more benefits, particularly if paired with higher levels of adherence. Because of uncertainty about any potential harms of higher doses, the committee made a research recommendation in this area.</p> <p>The committee were concerned that the very low cessation rate would mean a large number of pregnant women would be needlessly taking NRT. They were also concerned about the risk of relapse to smoking as well as the resultant exposure to environmental tobacco smoke in the home and elsewhere. However, they were also mindful of the additional benefits of quitting</p>

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					during pregnancy that extend to the foetus and baby and the potential impact on the likelihood of the child taking up smoking if the mother succeeds in quitting. We have amended the recommendation to reflect the uncertainties in the evidence.
British Medical Association	Guideline	050	015	The encouragement to give pregnant women clear and consistent advice that NRT will help them stop smoking is not supported by evidence as referenced above.	<p>Thank you. The committee agreed that NRT is likely to be an effective method of stopping smoking in pregnancy but the evidence did not show this to be as effective as the committee would have expected.</p> <p>The committee discussed that doses of NRT was an area where there was a lack of clarity. While the studies tended to use low doses, the committee agreed that higher doses might deliver more benefits, particularly if paired with higher levels of adherence. Because of uncertainty about any potential harms of higher doses, the committee made a research recommendation in this area.</p> <p>The committee were concerned that the very low cessation rate would mean a large number of pregnant women would be needlessly taking NRT. They were also concerned about the risk of relapse to</p>

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					smoking as well as the resultant exposure to environmental tobacco smoke in the home and elsewhere. However, they were also mindful of the additional benefits of quitting during pregnancy that extend to the foetus and baby and the potential impact on the likelihood of the child taking up smoking if the mother succeeds in quitting. We have amended the recommendation to reflect the uncertainties in the evidence.
British Medical Association	Guideline	050	024	50/24/ Advice that "most smoking-related health problems are caused by other components in tobacco smoke, not by nicotine" is ambiguous at best when given to women who are pregnant, whose most important concern will be the health of their babies. There should be separate statements about the toxicology of nicotine to (1) women and to (2) babies. Investigations of the toxicology of nicotine administered during pregnancy in rhesus monkeys, which have lung development similar to humans demonstrate structural and functional abnormalities that mirror those of human offspring exposed to maternal smoking in pregnancy (decreased expiratory flows, increased pulmonary resistance, increased collagen deposition) and upregulation of alpha-7 nicotinic acetylcholine	Thank you. The committee carefully considered adverse event data in humans during the crafting of these recommendations. NICE does not routinely look at data from non-human studies. The committee agreed that while the statement is ambiguous, it is the most accurate reflection of our current knowledge on the subject. They were also clear that nicotine doses from NRT are much lower than those of smoking.

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				receptors. Investigations in sheep, rats and mice report similar findings. Evidence considered by NICE (Evidence Review J) does not include studies of experimental animals. It is noteworthy that the 2020 report on smoking cessation from the US Surgeon General (https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf) includes the statement "Nicotine is dangerous for pregnant women and their developing babies".	
British Medical Association	Guideline	050	026	The statement "any risks from using NRT are much lower than those from smoking" is not supported either by the evidence assembled by NICE (Evidence Review J) or by a recent report by the Cochrane Group (Taylor L, et al. Fetal safety of nicotine replacement therapy in pregnancy: systemic review and meta-analysis. <i>Addiction</i> 2021;116(2):239-77).	Thank you. The committee carefully considered adverse event data in humans during the crafting of these recommendations. NICE does not routinely look at data from non-human studies. The committee agreed that while the statement is ambiguous, it is the most accurate reflection of our current knowledge on the subject. They were also clear that nicotine doses from NRT are much lower than those of smoking. The evidence review you cite was unable to come to any conclusions because the findings from the meta-analyses were underpowered and inconsistent.
British Medical Association	Guideline	054	006	The BMA agrees with guidance on smoke free hospital sites and have long standing policy supporting this issue, it is important that healthcare workers and patients are able to use smoke free outdoor space.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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British Medical Association	Guideline	072	008	<p>The BMA agrees with NICE regarding the recommendation for further research into the short- and long-term impacts on e-cigarettes to develop a more comprehensive picture of the harm vs benefit of e-cigarettes over the longer term. In our 2017 report 'E-cigarettes: Balancing risks and opportunities' we highlighted the need for more evidence around the long term harm of e-cigarettes and their efficacy as a cessation method. As such we welcome the evidence presented that e-cigarettes have been found to be an effective tool for helping people quite smoking.</p> <p>Given the evidence supporting the use of e-cigarettes, we agree that it is important further research is conducted into the long-term health impacts of cigarettes. This will also give policy makers a better understanding of how to most effectively regulate e-cigarettes.</p>	Thank you for your comment.
British Medical Association	Guideline	073	001	<p>Agree that research into how smoking services can be modified to improve accessibility for under-served groups will be a useful piece of evidence moving forward, given the propensity for those who smoke and are in a more deprived social-demographic to be more likely to develop chronic non-communicable disease</p>	Thank you for your comment

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				both from tobacco use and from other drivers of ill health.	
British Society of Dental Hygiene and Therapy	Evidence Review N	General	General	As an observation, many studies related to interventions which included literature as an aid to prevent re-uptake and maintain cessation. Any guidance produced relating to prevention of re-uptake and maintaining cessation should consider the quality of the information in the literature used in these studies and replicate this within the guidance. This could be particularly relevant where an intervention is part of additional healthcare, and the smoker/patient has a lot of information to take in as part of the appointment. It is noted that cost of production of materials could be a concern/barrier.	Thank you for your comments. The guideline outlines several recommendations on promoting quitting including raising awareness (1.8.1 to 1.8.5), promoting stop-smoking support for developers of communication strategies (1.9.1 to 1.9.2) which includes coordinating communications strategies and signposts to evidence to underpin these strategies for example Cochrane reviews and advice regarding audience research and targeting and tailoring approaches. PHAC have considered the evidence presented and other testimony and developed the guideline that considers settings, smoking modality, high risk-groups, policy and commissioning amongst other things. Given the breadth of the evidence considered PHAC have synthesised the evidence to develop the guideline which is hyperlinked to the reviews within the guideline document for the purposes of transparency but to also allow the additional per study details for example the information in the literature regarding prevention of re-uptake or maintenance of cessation to be considered in more detail by a prospective user of the guideline.

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British Society of Dental Hygiene and Therapy	Evidence Review N	General	General	A role in prevention of re-uptake could be undertaken by all appropriately trained allied healthcare professionals, including medicine and dentistry	Thank you for your comment. The guideline acknowledges the role of allied healthcare professionals in the prevention of re-uptake of smoking (Recommendation 1.17 adherence and relapse prevention) and makes recommendations for them regarding supporting the prevention of re-uptake and maintenance of smoking cessation. Recommendation 1.17 refers to people providing 'stop-smoking support' which is defined in the glossary as interventions and support to stop smoking, regardless of how services are set up and may include allied healthcare professionals.
British Society of Dental Hygiene and Therapy	General	General	General	The absence of links in the document between oral health including oral cancer and smoking is disappointing. Smoking has detrimental effects on teeth and gums and is a known risk factor for periodontal disease (gum disease) and head and neck cancers that include squamous cell carcinomas of the lips, the hard and soft palate, the tongue, and floor of mouth, attributing to 85% of oral and pharyngeal cancers. The dental professional is the ONLY healthcare provider who performs a comprehensive head and neck examination that includes the face, skin, nose, mouth, tonsils, back of the throat and lymph as part of	Thank you for your comment. The Public Health Advisory Committee have considered your comments and are of the opinion that the guideline does not require an additional reference to the links between oral cancer and smoking specifically. Recommendation 1.8.1 refers to the risk posed by smoking in causing cancer more generally with specific reference to oropharyngeal cancers and periodontal disease (see recommendations 1.16.2 and 1.16.14). The Public Health Advisory Committee have considered your comments and are of the

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				<p>a routine dental appointment and apply psychological constructs to increase the likelihood of behaviour change. For these reasons not only dental hygienists and dental therapists, but the whole dental team should be considered to deliver brief interventions and appropriate signposting. Continued training is essential and wider availability in an online format and free to healthcare professionals at the point of delivery.</p>	<p>opinion that the guideline adequately covers the role of dentists within the line 'health and social care professionals and those providing stop-smoking support or advice' which is contained in the introduction to the guideline and in the introduction to several of the recommendations for example recommendation 1.10 (promoting support for people to stop using smokeless tobacco). There are several recommendations that allude to dentists. These include Recommendation 1.9 (promoting stop-smoking support) which refers to the involvement of community pharmacies in local campaigns and the need to maintain links with other professional groups such as dentists when developing and delivering communication strategies about stopping smoking. Recommendation 1.16 focuses on stopping the use of smokeless tobacco, and focuses on the roles of health professionals including dentists in identifying people who use smokeless tobacco and offering referral (recommendations 1.16.1 to 1.16.4), the role of dental health professionals as a source of data on the use of smokeless tobacco (1.16.12), the role of dental surgeries as a location for services for South Asian users of</p>

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					<p>smokeless tobacco (1.16.19) and the potential to use existing campaigns for example dental health campaigns (1.16.20) to embed approaches to smokeless tobacco cessation services as part of a wider approach to tobacco control prevention and cessation.</p> <p>PHAC considered your comments regarding training and agree that training is key and this has been adequately outlined in the guideline. For example, recommendation 1.23 focuses on training. Recommendation 1.23.10 highlights the need for training and skills to support women to stop smoking (especially pregnant women) in those working in dental facilities as part of a wider approach to ensuring all healthcare and other professionals have the same level of training as midwives. Recommendation 1.23.14 highlights the need for health, dental health, and allied health professionals to be adequately trained to advise people on how to use smokeless tobacco.</p>
British Society of Dental Hygiene and Therapy	General	General	General	As a profession we feel that long-term evidence is lacking on the effects of e-Cigarettes on the periodontal and oral tissues, as well as on systemic health. The profession supports and utilise the yellow card system to report adverse events, and dental	Thank you for your comments. The committee shared your views about e-cigarettes needing longer term research.

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				<p>examinations include medical and social history often reveals information that may otherwise go undetected.</p> <p>We support the recommendations to make e-Cigarettes accessible to individuals who may not otherwise have access to this intervention, especially if it is for a set period, with a definite endpoint of free supply, to help reduce the long-term use of e-Cigarettes.</p> <p>Finally, we support a call for reliable, evidence-based research into the long-term effects of e-Cigarettes.</p>	
British Society of Dental Hygiene and Therapy	Guideline	013	001 002 003 & 004	We welcome this recommendation however we feel that keep the conversation between the use of e-cigarettes and tobacco products separate is potentially difficult.	Thank you for your comment. Recommendation 1.6.3 highlights that discussions of e-cigarettes should occur as part of the curriculum on tobacco, alcohol, and drug misuse. The line 'Talk about e-cigarettes separately from tobacco products' is about discussing these two separate products (e-cigarettes and tobacco products) as distinct within this curriculum.
British Society of Dental Hygiene and Therapy	Guideline	013	005 006 & 007	Resources along with appropriate time to implement these interventions need to be made available along with training. Allied healthcare professions in medicine and dentistry such as dental hygienists and dental therapists are well placed to offer such	Thank you for your comment. The guideline introduction is clear that this guideline is for 'health and social care professionals' (p.2) amongst other key stakeholders which would include those in medicine and dentistry. Recommendation 1.6 is focused on preventing the uptake of tobacco and e-

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				interventions, seeing children, young people, and young adults on a regular basis.	cigarettes in non-smokers and are aimed at everyone working in and with primary and secondary schools and further education colleges. Treating tobacco dependence in schools, other educational services, universities, and other higher and further education organisations is outside the scope of this guideline. Please see the scope document on the NICE website. The PHAC agree that training is key and has made a series of training recommendations (1.23). Recommendation 1.23.1 outlines that those with responsibility for improving the health and wellbeing of children, young people and young adults who attend school, work in partnership with those involved in smoking prevention and stop smoking activities to design, deliver, monitor and evaluate smoking prevention training and interventions.
British Society of Dental Hygiene and Therapy	Guideline	022	024 – 029 001 - 005	We agree with the recommendation, the evidence to date shows that e-cigarettes do assist adults with giving up smoking, there does seem to be a lack of evidence of the long-term effects.	Thank you for your comment.
British Society of Dental	Guideline	023	006 – 007	We agree with this recommendation since dental hygienists and dental therapists seeing adult patients on a regular basis are able to	Thank you for your comment

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Hygiene and Therapy				signpost them to the appropriate intervention to increase enhance this support, access to continued online training would be beneficial for patients and healthcare professionals.	
British Society of Dental Hygiene and Therapy	Guideline	025	025 026	Lack of evidence on the long-term effects of e-cigarettes, as a profession we support and utilise the yellow card system to report adverse events.	Thank you for your comment
British Society of Dental Hygiene and Therapy	Guideline	056	026 027 028	Smoking cessation advice is within the scope of practice of a dental hygienist and dental therapist, educating, motivating, and supporting patients to achieve and maintain optimal oral health is one of our primary goals as healthcare professionals. With strong links between oral and systemic health, we take a holistic approach to patient care. Patients attending in a primary care setting 2, 3, 4 times each year, sometimes more allows for opportunistic advice and appropriate sign posting. BSDHT welcome this recommendation and ask that the directors, and commissioners look more broadly at the ensuring that dental professionals are considered in the commissioning and design of stop-smoking support services.	Thank you for your comment

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British Society of Dental Hygiene and Therapy	Guideline	059	010 011	Please consider enabling secondary care workers e.g., hospital shop staff to direct smokers' patients to a hospital pharmacy/local pharmacy by a recommendation of basic training for such staff to direct to an HCP in the event of a need for support.	Thank you. The committee did not consider this, nor did they see any evidence that highlighted it as an effective intervention.
British Thoracic Oncology Group	Guideline	016	019	NG 92 published in 2018 not 2008	Thank you for your comment. This has now been amended in line with your comment
British Thoracic Oncology Group	Guideline	017	008	NG 92 published in 2018 not 2008	Thank you for your comment. This has now been amended in line with your comment
British Thoracic Oncology Group	Guideline	025	005	<p>Section 1.12.14 Advice on nicotine containing e-cigarettes</p> <p>We welcome the recommendation to consider nicotine containing e-cigarettes in the treatment of tobacco addiction</p> <p>We would strongly encourage a separate bullet point at the start of the section such as :</p> <p>E-cigarettes are an effective option/ intervention to help people quit smoking that explicitly states the effectiveness of nicotine containing e-cigarettes in helping people to quit smoking. An explicit statement is</p>	<p>Thank you for your comment. The Public Health Advisory Committee (PHAC) have considered your comment and have outlined that the additional statement is not required as recommendation 1.12.1 already outlines that nicotine-containing e-cigarettes along with other stop-smoking interventions should be accessible to adults who smoke. Recommendation 1.12.5 highlights that nicotine-containing e-cigarettes when combined with behavioural support are more likely to result in successful stopping smoking, and recommendation 1.12.14 outlines that in advising people how to use nicotine-containing e-cigarettes that the use</p>

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				<p>supported by evidence review K, (page 59) where e-cigarettes have an RR of 2.25 in quit success (and supported by the cost-effectiveness estimates in table 14 on page 66 of evidence review K).</p> <p>The need for an explicit statement on the effectiveness of e-cigarettes in helping people quit is required to help overcome incorrect biases/assumptions/data interpretation that may be held by the public/health care professionals/public health practitioners/healthcare organisations in this highly polarised subject area, which has the impact of smokers continuing to smoke tobacco cigarettes rather than quitting successfully using an e-cigarette. More smokers would successfully stop smoking if they switched completely to e-cigarettes, reassured that they are an effective means to quit, yet the use of e-cigarettes has largely plateaued.</p> <p>https://ash.org.uk/wp-content/uploads/2021/06/Use-of-e-cigarettes-vapes-among-adults-in-Great-Britain-2021.pdf</p> <p>https://smokinginengland.info/graphs/e-cigarettes-latest-trends</p>	<p>of e-cigarettes is likely to be substantially less harmful than smoking. On this basis PHAC have not amended the guideline.</p>

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				<p>Such a bullet point would help counter balance the subsequent bullet points ie:</p> <ul style="list-style-type: none"> e-cigarettes are not licensed medicines but are regulated by the Tobacco and Related Products Regulations 2016 there is not enough evidence to know whether there are long-term harms from e-cigarette use 	
British Thoracic Oncology Group	Guideline	026		<p>An Opt-out approach for stop smoking treatment should be explicitly stated as the standard approach in Primary Care settings and Secondary Care settings (page 27 sections 1.13 and 1.14), as stated for pregnancy section (page 46 rec 1.18.2). The opt-out approach without delaying referral to another service, can double quit attempts and quit success and makes treatment more accessible for those patients who are ready to quit</p> <p>The Ottawa model has clearly demonstrated that an opt-out approach in these settings increases quit attempts and quit rates</p> <p>https://tobaccocontrol.bmj.com/content/26/3/293</p>	<p>Thank you for your comment. It is unclear what specific element on p.26 your comment refers to. Recommendation 1.12 focuses on stop-smoking interventions that should be accessible to adults and the advice that should be provided with these interventions as well as recommendations on stop-smoking quitlines. Recommendations 1.13 and 1.14 focus on support to stop smoking in primary and community care, and secondary care services (p.27 to 34) which are greyed-out area of the guideline and are outside of the scope for this update which only included opt out in pregnancy. Please see the scope document on the NICE website.</p>

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				<p>It could read:</p> <p>Provide an opt-out referral to receive stop-smoking support for all people attending Primary or Secondary care services who:</p> <ul style="list-style-type: none"> • say they smoke or have stopped smoking in the past 2 weeks or • have a carbon monoxide reading of 4 ppm or above or • have previously been provided with an opt-out referral but have not yet engaged with stop-smoking support 	
British Thoracic Oncology Group	Guideline	026	022	NG 92 published in 2018 not 2008	Thank you for your comment. This has been amended.
British Thoracic Oncology Group	Guideline	027	003	NG 92 published in 2018 not 2008	Thank you for your comment. This has been amended.
British Thoracic Oncology Group	Guideline	027	008	NG 92 published in 2018 not 2008	Thank you for your comment. This has been amended.
British Thoracic Society	Comments form	Q1		<i>Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why.</i>	Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned. There are a number of recommendations in

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				<p>Supporting staff to stop smoking will remain challenging in secondary/tertiary care. Whilst many organisations recognise it as a major wellbeing gain, the funding and infrastructure does not extend to include staff. This includes brief advice.</p> <p>Two consecutive BTS Audits have shown wide variation in smoke free policy on grounds and its policing. Specifically the banning of staff from helping people take smoking breaks for example. It is challenging and sometimes leads to confrontation and further guidance and support around this would be appreciated by NHS Organisations.</p> <p>Audits have also shown that most trusts are not fulfilling 1.22.19 (secondary care directors/managers for stop smoking support). This requires strong emphasis as it is a neglected area that is at the heart of any organisation building a robust stop smoking pathway.</p>	<p>the guideline that acknowledge the importance of support and seek to encourage it including recommendations 1.22.9, 1.9.6, 1.14.29, 1.21 and 1.22.10 to 14.</p>
British Thoracic Society	Comments form	Q3	Q3	<p><i>What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)</i></p> <p>The NHS Long Term Plan will provide organisations (including NHS Trusts) with the</p>	<p>Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned' and we will pass this information to our local practice collection team. More information on local practice can be found here</p>

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				financial resources required to build pathways and structures that allow smokers to quit when interacting with secondary care. Good examples of practice already exist e.g. Cure Project Manchester as well as the early implementer sites of the NHS Long Term Plan.	https://www.nice.org.uk/about/what-we-do/into-practice/shared-learning-case-studies .
British Thoracic Society	Guideline	General		<p>The British Thoracic Society welcomes the opportunity comment on this important document. We are broadly supportive of the guidance. It is carefully crafted and brings together multiple documents into one single repository of information. It is hoped that it will be more easy to navigate depending from which perspective you are wishing to use the resource (e.g. public health, primary care, tobacco lead in secondary care etc.) when this is available online.</p> <p>Specifically it provides clarity on what treatment options have the best evidence base and is aligned with the aims of the NHS England Long Term Plan, which is going to be implemented in trusts across the country over the coming months.</p>	Thank you for your comment.
Cancer Research UK	Guideline	General	General	The guidelines, quite rightly, make a range of recommendations for research (see page 72-76). Yet there is only one acknowledgement of the need to take into account the outcomes of any such research, in section 1.9.2 bullet 2	Thank you for your comment. The research recommendations developed by PHAC seek to address the gaps in the evidence identified during the guideline development process with the hope of stimulating research in these

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				<p>which recommends "Use the best available evidence of effectiveness, such as Cochrane reviews".</p> <p>As the evidence continues to develop and evolve, it is important that in the overview section of the guidelines there is a generic recommendation that research outcomes are taken into account. We suggest something along the lines, "When developing and implementing policies to prevent uptake, promote quitting and treat dependence it is essential to use the best available evidence of effectiveness, such as Cochrane reviews".</p>	<p>areas for consideration when this guideline or aspects of this guideline are considered for update.</p> <p>NICE routinely checks that published guidelines are current, accurate and up to date via our surveillance function which explores if there is any new evidence to contradict, reinforce or clarify guideline recommendations. Surveillance also identifies new interventions that may need to be considered within a guideline and explores changes in context that may mean modifications are needed, for example, changes in policy, infrastructure, legislation or costs. A proactive approach is taken that includes reacting to events at any time after guideline publication (for example, publication of a key study).</p>
Cancer Research UK	Guideline	General	General	<p>Guaranteed financial incentives for quitting smoking are not highlighted as an effective intervention in the general population, but we think NICE should consider the evidence on this. Some studies have suggested high certainty evidence of their effectiveness in the general population of people who smoke.[1,2]</p> <p><u>References</u></p>	<p>Thank you for your comment. Incentives were only considered in pregnant women. Incentives for other populations is outside the scope of this update. Please see the scope document on the NICE website.</p>

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				<ol style="list-style-type: none"> 1. Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD004307 2. Hartmann-Boyce J, Livingstone-Banks J, Ordóñez-Mena JM, Fanshawe TR, Lindson N, Freeman SC, Sutton AJ, Theodoulou A, Aveyard P. Behavioural interventions for smoking cessation: an overview and network meta-analysis. Cochrane Database of Systematic Reviews 2021, Issue 1. Art. No.: CD013229 	
Cancer Research UK	Guideline	General	General	<p>General - Given the removal of some recommendations because they are covered in NICE's guideline on patient experience in adult NHS services, these should be mentioned and linked to somewhere in the final guidelines.</p> <p>https://www.nice.org.uk/guidance/cg138/resources/patient-experience-in-adult-nhs-services-improving-the-experience-of-care-for-people-using-adult-nhs-services-pdf-35109517087429.</p>	Thank you for your comment. The Public Health Advisory Committee (PHAC) have discussed your comment. As there is a hyperlink to the guideline in question (CG138: Patient experience in adult NHS services) at every point where the deletion of previous recommendations is outlined, it was decided that this was sufficient.
Cancer Research UK	Guideline	038 - 044	General	Section 1.16 - Guidance should be included around preventing people from initiating	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update.

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				smoking or smoking more frequently as a way to give up smokeless tobacco.	Please see the scope document on the NICE website.
Cancer Research UK	Guideline	056 - 062	N/A	Section 1.22 - We think it would be helpful to make specific reference to the Targeted Lung Health Check programme in England and the opportunity this presents for smoking cessation, which must be adequately resourced and seen as a central tenet of the successful delivery of the Programme, with high quality, comprehensive smoking cessation across all TLHC sites.	Thank you for your comment. Recommendation 1.11 (Identifying and quantifying people's smoking) outlines recommendations for health and social care professionals and those providing stop-smoking support or advice. Recommendation 1.11.1 outlines that at every opportunity, 'ask people if they smoke or have recently stopped' which would include opportunities presented during the Targeted Lung Health Check programme.
Cancer Research UK	Guideline	022 - 027	General	Section 1.12 - This section should clearly direct users to the harm reduction approaches laid out in section 1.15 and box 1.	Thank you for your comment. Recommendation 1.12 refers to stop-smoking interventions for adults who smoke highlighting options that should be accessible and discussions and advice to be delivered when engaging with these options. Recommendation 1.15 is more specific, focusing on supporting people who don't want, or are not ready, to stop smoking. Recommendation 1.15 is a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website. The Public Health Advisory Committee (PHAC) discussed your comment and agreed not to make any further changes.

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Cancer Research UK	Guideline	067 - 072	General	Terms used in this guideline' section - Very brief advice should be included as a term in the guideline, and hyperlinked to the definition throughout the document.	Thank you for your comment. 'Very brief advice' is hyperlinked to the NICE glossary on the website. There is one instance where it has not been (recommendation 1.12.1) and this has been amended.
Cancer Research UK	Guideline	046 - 047	General	<p>Section 1.18 - although mentioned in guideline 1.11.1, we are concerned that given there is no specific mention about asking about and digitally recording smoking status in this section for pregnant women, it could be overlooked if healthcare professionals are short on time. The guideline should ideally include a recommendation similar to 1.11.1 in this section, or refer to recommendation 1.11.1 here.</p> <p>This would be similar to the mention in PH26, recommendation 2 bullet 1, and recommendation 4, bullet 1, first sentence - which have been deleted in place of recommendations in section 1.18 and 1.19.</p>	Thank you for your comment. Recommendation 1.20.1 states: 'Provide the pregnant woman with intensive and ongoing support...throughout pregnancy and beyond. This includes regularly monitoring her smoking status using carbon monoxide tests.' The recording of carbon monoxide levels and any feedback given is outlined in recommendation 1.18.6.
Cancer Research UK	Guideline	008	014 - 017	Recommendation 1.1.3 - given that the groups who are at high risk of tobacco-related harm are listed in 1.22.4, it would be useful to refer to this list here or repeat those who are at higher risk of tobacco-related harm.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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Cancer Research UK	Guideline	013	001 - 007	Recommendations 1.6.3 and 1.6.4 - Cancer Research UK agrees with the overall recommendation to discourage e-cigarette use in school children and the importance of differentiating e-cigarettes from tobacco products. However, there should be a greater emphasis in the guidelines on page 76 of the uncertainty of the relationship between vaping in young adults and later smoking. (Currently it cites on page 76 "The committee wanted to discourage e-cigarette use among young people and young adults who do not smoke because evidence shows that use of e-cigarettes is linked with a higher chance of ever smoking later in life.") However, NICE's evidence review recognises limitations in the studies included, for example insufficient adjustment for key confounding variables. In addition, the majority of studies looked at "ever smoking", so cannot give insight into the relationship between e-cigarette use and habitual smoking. The new guidelines also do not highlight the difficulty in assessing the gateway effect due to the "common liability hypothesis", whereby some young adults have characteristics that may make them more likely to engage in risky behaviours - like alcohol use, drug use, smoking and vaping. Therefore, studies examining smoking and vaping in	Thank you for your comment. The Public Health Advisory Committee (PHAC) considered your comment and feel that the current wording is sufficient in conveying the relationship between vaping in young adults and later smoking based on the evidence they have considered. Considering the effects of e-cigarettes as a gateway was outside the remit of this guideline, as was considering the illegal use of e-cigarettes by young people under 18.

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				<p>young people don't necessarily show that vaping leads them to start smoking, but that they may be likely to do both anyway. Overall, there's no strong evidence for a gateway effect in the UK. Although experimentation with e-cigarettes among young people has increased in recent years, regular vaping in young people in the UK remains very low. In a representative survey of 11 to 17 year-olds in Great Britain in 2021, out of 1,785 never smokers, only one person reported vaping daily.[1]</p> <p>The recommendations should instead be amended to focus on the need to protect young people from using e-cigarettes based on the fact that they are not risk free and their long-term effects are unknown. E-cigarettes should only be used as a smoking cessation tool, so should not be used by never-smokers, including young people. We would therefore suggest that recommendation 1.6.4 is more directive, and includes copy like the following: "When discussing e-cigarettes, make it clear why children, young people and young adults who do not smoke should avoid e-cigarettes (as they are not risk free and we don't know if there are long term effects of using them) to avoid inadvertently making them desirable." We would also suggest the copy on page 76 is</p>	

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				<p>amended to reflect the uncertainty of the evidence for a relationship between vaping in young adults and later smoking.</p> <p><u>Reference</u> 1. Action on Smoking and Health (ASH). Use of e-cigarettes among young people in Great Britain. 2021.</p>	
Cancer Research UK	Guideline	017	006 - 009	<p>Recommendation 1.9.2, sub bullet 6 - given that the groups who are at high risk of tobacco-related harm are listed in 1.22.4, it would be useful to refer to this list here or repeat those who are at higher risk of tobacco-related harm.</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.</p>
Cancer Research UK	Guideline	019	025 - 030	<p>Recommendations on treating tobacco dependence introduction section – clarification is needed on whether all of the recommendations in the section on treating tobacco dependence apply to those aged 12 or over.</p> <p>For example, the recommendations on e-cigarettes in section 1.12. E-cigarettes cannot be bought by or bought for people under the age of 18 legally, so NICE should be clearer here and in each section of the recommendation on who the recommendations apply to.</p>	<p>Thank you for your comment. We have clarified in the introduction to the recommendations on treating tobacco dependence that 'these recommendations aim to help people aged 12 or over unless otherwise stated to stop smoking'. The recommendations that refer to e-cigarettes specify 'adults' within the recommendation.</p>

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Cancer Research UK	Guideline	019	025 - 030	Recommendations on treating tobacco dependence introduction - vulnerable groups should be introduced as those 'who are more likely to start smoking, find smoking hard to stop or smoke a lot'.	Thank you for your comment. The Public Health Advisory Committee (PHAC) considered your comments but made no changes as the suggested addition did not fit with the overarching aim of these set of recommendation which focus on treating tobacco dependence, rather than preventing the uptake of smoking.
Cancer Research UK	Guideline	020	003	Section 1.11 - title ends abruptly, we presume this should read 'identifying and quantifying people's smoking status'.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website. We have reviewed the section header and it is correct.
Cancer Research UK	Guideline	020	026	Recommendation 1.11.5, sub bullet 1 - this sentence ends abruptly, we presume the end of the sentence should read '... - and how soon after waking they have their first cigarette'.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website
Cancer Research UK	Guideline	021	020 - 024	Recommendation 1.11.8 - As PH26 recommendation 4 bullet 1 has been merged into guideline 1.11.8, we believe this guideline should also be directed at stop smoking support advisers.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website
Cancer Research UK	Guideline	021	011 - 014	Recommendation 1.11.6 - we agree that all data regarding smoking status and all actions should be recorded. However, Cancer Research UK also believe that datasets should be shared across primary and secondary care,	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website

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				<p>and locally commissioned services (with due regard given to patient privacy, transparency and communication), to effectively identify people who smoke at all possible interaction points with health professionals. If information is shared between sources, this will enable better identification of patients who smoke and therefore practices may be able to better support patients from more deprived groups, who are disproportionately represented among people who smoke. This will also help continuity of care between different services. Cancer Research UK has recently published a report recommending this.[1]</p> <p>Accurate smoking status records in primary care are central to the successful delivery of the Targeted Lung Health Check Programme in England and to any future national targeted lung screening subject to recommendation of the UK National Screening Committee. Any 'no smoking status recorded' record should be accurately and promptly completed. The routine confirmation of smoking status records also warrants consideration given the proportion of people who have previously smoked that are incorrectly identified as people who have never smoked.</p>	

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				<p><u>Reference:</u></p> <p>1. Coker, T., Webber, L., Xu, M., Graff, H., Retat, L., Guzek, J., Courbould, E., Jain, R., Greenhill, T., Newberry Le Vay, J., Bullock, S., Cheek, O., Froguel, A., Vohra, J., Fitzgerald, K. 2021. Making Conversations Count for All: Benefits of improving delivery of smoking cessation interventions for different socioeconomic groups. Cancer Research UK.</p>	
Cancer Research UK	Guideline	022	007 - 014	<p>Recommendation 1.11.11 - As PH26 recommendation 7 has been merged into guideline 1.11.11 and 1.20.18, we believe this guideline should also be directed at stop smoking support advisers.</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website. For clarity the introduction to recommendations 1.11.8 to 1.11.11 (p.21, lines 17 to 19) and 1.20.18 (p.52, lines 1 to 3) outlines respectively that 'These recommendations are for anyone who is responsible for providing health and support services to people using acute, maternity or mental health services' and 'these recommendations are for providers of stop-smoking support' which the Public Health Advisory Committee (PHAC) agreed would include stop smoking support advisers.</p>
Cancer Research UK	Guideline	022	024 – 029	<p>Recommendation 1.12.1 - Cancer Research UK supports the addition of nicotine-containing e-cigarettes to the smoking cessation aids to</p>	<p>Thank you for your comment.</p>

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		023	001 - 005	<p>be made accessible to adults who smoke. E-cigarettes are the most popular smoking cessation aid for smokers in England.[1] Growing evidence shows that nicotine-containing e-cigarettes are an effective smoking cessation aid, including a 2020 Cochrane review [2] and a 2018 meta-analysis.[3] An English study showed that individuals using an e-cigarette are around 60% more likely to quit compared to going 'cold turkey' or using over-the-counter nicotine replacement therapy [4] and a 2019 CRUK-funded study showed that using e-cigarettes in combination with behavioural support was nearly twice as effective as NRT and behavioural support.[5]</p> <p><u>References</u></p> <p>1. Smoking Toolkit Study. (2021). Electronic cigarettes in England – latest trends. 2. Hartmann-Boyce J, McRobbie H, Lindson N, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Butler AR, Fanshawe TR, Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2020, Issue 10. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub4 3. Liu, X., Lu, W., Liao, S., Deng, Z., Zhang, Z.,</p>	

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				<p>Liu, Y., & Lu, W. (2018). Efficiency and adverse events of electronic cigarettes: A systematic review and meta-analysis (PRISMA-compliant article). <i>Medicine</i>, 97(19), e0324.</p> <p>4. Brown, J., Beard, E., Kotz, D., Michie, S., & West, R. (2014). Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study. <i>Addiction (Abingdon, England)</i>, 109(9), 1531-40.</p> <p>5. Hajek P, Phillips-Waller A, Przulj D, Pesola F, Myers Smith K, Bisal N, Li J, Parrott S, Sasieni P, Dawkins L, Ross L, Goniewicz M, Wu Q, McRobbie HJ. A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy. <i>N Engl J Med</i>. 2019 Feb 14;380(7):629-637.</p>	
Cancer Research UK	Guideline	023	020 - 026	<p>Recommendation 1.12.5 – it is important to note there is a disruption in supply of varenicline.[1] Moreover, as indicated by NICE on page 87, line 21 - 23, not all medically licensed products are available in stop smoking services.</p> <p>It is also important to acknowledge that not all pharmacotherapies are universally available in primary care settings. In some local health communities, GPs are restricted on what they</p>	<p>Thank you for your comment. The Public Health Advisory Committee (PHAC) discussed the current supply chain issues but concluded that this does not materially change the recommendations within the guideline. PHAC discussed the point raised regarding availability locally but highlighted that recommendation 1.12.1 outlines that those providing stop-smoking support or advice should ensure that medically licensed products bupropion, NRT and</p>

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				<p>can prescribe, as certain stop-smoking pharmacotherapies are excluded from local formularies.[2]</p> <p>NICE should encourage universal availability of stop-smoking interventions to make sure that everyone has access to the best support to stop smoking. Primary care professionals should be able to routinely prescribe everyone, including those from more deprived groups, with the most effective forms of pharmacotherapy (that is, varenicline) with behavioural support, to improve the chance of quitting successfully. Commissioners should also ensure that restrictions placed on clinicians prescribing these pharmacotherapies are repealed as a priority so that full the range of pharmacotherapy is available to prescribe.</p> <p><u>References</u></p> <ol style="list-style-type: none"> 1. Medicines & Healthcare products Regulatory Agency. Central Alerting System: Champix (varenicline) 0.5mg and 1mg tablets - Supply Disruption. Accessed 16 July 2021. 2. British Lung Foundation. Less help to quit: What's happening to stop smoking prescriptions across Britain. 2018. 	<p>varenicline are accessible to adults who smoke as well as behavioural interventions and nicotine-containing e-cigarettes. PHAC outlined that it is outside NICE's remit to make local commissioning decisions but emphasised that the recommendations regarding access to stop smoking interventions (1.12) are clear.</p>

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Cancer Research UK	Guideline	023	008 - 010	<p>Recommendation 1.12.3 - We would suggest explaining where and how this behavioural support would be accessed by the patient. It would also be helpful to recommend referral to stop smoking services if appropriate. Stop Smoking Services have been shown to be very effective in helping people successfully stop smoking. Compared with no support, people who use prescription medication and behavioural support from stop smoking services are around 3 times more likely to stop smoking. Those who use prescription medication with brief advice are around 1.6 times more likely to successfully stop compared with no support.[1]</p> <p><u>Reference</u> 1. Kotz D, Brown J, West R. 'Real-world' effectiveness of smoking cessation treatments: a population study. <i>Addiction</i>. 2014 Mar;109(3):491-9. doi: 10.1111/add.12429. Epub 2013 Dec 20. PMID: 24372901</p>	<p>Thank you for your comment. Recommendation 1.12 outlines that these recommendations are for people providing stop-smoking support or advice (p.22, lines 16 to 18). Recommendation 1.12.5 refers to the point you raise regarding the impact of behavioural support on the effectiveness of treatment options on successful quit attempts. The Public Health Advisory Committee (PHAC) has made its recommendations based on the best available evidence of effectiveness and costs-effectiveness and expert testimony. It is beyond NICE's remit to specify local commissioning decisions but provide guidance based on the evidence considered.</p>
Cancer Research UK	Guideline	023 024	027 - 029 001 - 003	<p>Recommendation 1.12.6 - Cancer Research UK advise altering wording of recommendation to 'If a person's stop smoking options are not limited by medication indication or other factors, advise that the options that are less likely...' so that people whose options</p>	<p>Thank you for your comment. The Public Health Advisory Committee (PHAC) discussed your comment. Central to the guideline was patient-led choice and informed decision making. Recommendation 1.12.5 and 1.12.6 reflect this element</p>

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				are limited, for example because they are contraindicated for varenicline, are not dissuaded from stopping smoking using another option.	allowing for all effective options, providing advice around these options and facilitating patient-led choices in their attempt to stop-smoking. Recommendation 1.12.4 recognises that for some people there may be contraindications for certain options, but encourages discussion around any medication they may be taking, contraindications and any potential for adverse effects, so that they are able to make an informed choice from the options that may be suitable for them.
Cancer Research UK	Guideline	024	002 and 003	Recommendation 1.12.6 - Cancer Research UK advise altering wording of last two bullet points to avoid confusion: '- short acting NRT used without long acting NRT - long acting NRT used without short acting NRT'	Thank you for your comment. The Public Health Advisory Committee (PHAC) have considered your comments and, in order to support clarity, have amended the guideline in line with them.
Cancer Research UK	Guideline	025 and 026	General	Advice on nicotine-containing e-cigarettes section – Given that e-cigarettes cannot be bought by or bought for people under the age of 18 legally, NICE should be clearer here that the recommendations in the 'advice on nicotine-containing e-cigarettes' section are for adult patients. Given that the recommendations on treating tobacco dependence introduction section	Thank you for your comment.. We have made this clearer by specifying 'adults' in recommendations 1.12.13 – 1.12.17.

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				encompasses this section, NICE should make sure that any recommendations that do not apply to all those aged 12 or over clearly state who they apply to.	
Cancer Research UK	Guideline	025 026	025 – 028 001 - 006	<p>Recommendation 1.12.14 - We would suggest adding a bullet point to say: "Evidence indicates that e-cigarettes are an effective smoking cessation tool and have helped many people who smoke to stop in the long-term".[1-3]</p> <p><u>References</u></p> <ol style="list-style-type: none"> 1. Malas M, van der Tempel J, Schwartz R, Minichiello A, Lightfoot C, Noormohamed A, Andrews J, Zawertailo L, Ferrence R. Electronic Cigarettes for Smoking Cessation: A Systematic Review. <i>Nicotine Tob Res.</i> 2016 Oct;18(10):1926-1936. doi: 10.1093/ntr/ntw119. 2. Beard Emma, West Robert, Michie Susan, Brown Jamie. Association between electronic cigarette use and changes in quit attempts, success of quit attempts, use of smoking cessation pharmacotherapy, and use of stop smoking services in England: time series analysis of population trends <i>BMJ</i> 2016; 354 :i4645 	<p>Thank you for your comment. The Public Health Advisory Committee (PHAC) have considered your comment and have outlined that the additional statement is not required as recommendation 1.12.1 already outlines that nicotine-containing e-cigarettes along with other stop-smoking interventions should be accessible to adults who smoke. Recommendation 1.12.5 highlights that nicotine-containing e-cigarettes when combined with behavioural support are more likely to result in successfully stopping smoking, and recommendation 1.12.14 outlines that in advising people how to use nicotine-containing e-cigarettes, that the use of e-cigarettes is likely to be substantially less harmful than smoking. On this basis PHAC have not amended the guideline.</p>

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				3. Hajek P, Phillips-Waller A, Przulj D et al. A randomised trial of e-cigarettes versus nicotine-replacement therapy. <i>New England Journal of medicine</i> . 2019.	
Cancer Research UK	Guideline	026	007 - 010	Recommendation 1.12.15 - Cancer Research UK believes that patients should be encouraged to use their nicotine-containing e-cigarette for as long as they feel is necessary to remain abstinent from smoking and calls for greater clarity in NICE guidelines on this issue. Use patterns of e-cigarettes varies by individuals, however evidence suggests that continued longer-term use of e-cigarettes is much higher than NRT. In a randomised control trial published in 2019 comparing e-cigarettes versus NRT for smoking cessation in Stop Smoking Services, e-cigarettes were nearly twice as effective as NRT when comparing 1-year quit rates. However, amongst those who successfully quit, continued use of the product was nearly 9x higher in the e-cigarette group compared with the NRT group.[1] Therefore, people who stop smoking using e-cigarettes may continue to use them for a longer period than NRT. As we currently do not have sufficient evidence on the optimum time period to continue e-cigarette use after cessation, we believe that patients should be encouraged to use their	Thank you for your comment. Recommendation 1.12.15 focuses on discussing the use of nicotine e-cigarettes for long enough to prevent a return to smoking. The recommendation is therefore consistent with the approach you suggest. It would not be possible to be more prescriptive, as this may vary among individuals.

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				<p>nicotine-containing e-cigarette for as long as they feel is necessary to remain abstinent from smoking.</p> <p>Reference</p> <p>1. Hajek P, Phillips-Waller A et al. (2019). A Randomized Trial of E-Cigarettes versus Nicotine Replacement Therapy. N Engl J Med; doi: 10.1056/NEJMoa1808779</p>	
Cancer Research UK	Guideline	026	015 - 017	<p>Recommendation 1.12.7 - We support the recommendation to discuss with patients how to get enough nicotine to overcome cravings. There is evidence to show that e-cigarette users may report greater nicotine withdrawal symptoms and "compensatory puffing" when using a lower nicotine concentration e-liquid compared to a higher nicotine concentration e-liquid.[1]</p> <p>Reference</p> <p>1. Dawkins L, Cox S, Goniewicz M, McRobbie H, Kimber C, Doig M, et al. 'Real-world' compensatory behaviour with low nicotine concentration e-liquid: subjective effects and nicotine, acrolein and formaldehyde exposure. Addiction (Abingdon, England). 2018;113(10):1874-82.</p>	Thank you for your comment

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Cancer Research UK	Guideline	026	003 and 004	<p>Recommendation 1.12.14, sub bullet 3- We would suggest changing the wording to "e-cigarettes do not contain tobacco and evidence indicates using them is substantially less harmful than smoking". There is significant evidence to show that e-cigarettes are less harmful than smoking. [1-6]</p> <p>References</p> <ol style="list-style-type: none"> 1. Stephens WE. Comparing the cancer potencies of emissions from vaporised nicotine products including e-cigarettes with those of tobacco smoke. Tobacco Control 2018;27:10-17. 2. Gualano MR, Passi S, Bert F, La Torre G, Scaiola G, Siliquini R. Electronic cigarettes: assessing the efficacy and the adverse effects through a systematic review of published studies. Journal of public health (Oxford, England). 2014:1–10. 3. Caponnetto P, Campagna D, Cibella F, et al. Efficiency and Safety of an eElectronic cigarette (ECLAT) as tobacco cigarettes substitute: a prospective 12-month randomized control design study. PloS one. 2013;8(6):e66317. 4. Burstyn I. Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells 	<p>Thank you for your comment. The committee are content that the recommendations they have made accurately reflect the evidence they have considered. They chose the wording specifically to convey the level of uncertainty about this.</p>

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				<p>us about health risks. BMC public health. 2014;14(1):18.</p> <p>5. Goniewicz M, Knysak J, Gawron M, et al. Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. Tob Control. 2013.</p> <p>6. McNeill A, Brose L, Calder R, Bauld L, Robson D. Evidence review of e-cigarettes and heated tobacco products 2018. Commissioned by Public Health England; 2018.</p>	
Cancer Research UK	Guideline	027	017 - 026	<p>Recommendation 1.13.1 – During the COVID-19 pandemic most consultations were remote, and it is likely remote consultations will be more common going forward. It is important to note that clinical assessment and intervention delivery may be more difficult in remote consultations. [1-7]</p> <p>This has affected the delivery of very brief advice (VBA). For example, a survey of UK GPs commissioned by Cancer Research UK found that during the pandemic where GP consultations have been delivered remotely, 29% of GPs surveyed agreed or strongly agreed with the statement that they do not currently have the time to deliver VBA to patients. 40% of GPs surveyed strongly agreed or agreed with the statement that it was</p>	<p>Thank you for your comment.</p> <p>The committee recognises the challenges to practice resulting from the Covid-19 pandemic and in the rationale and impact sections of the guidance has noted where the pandemic may have temporarily impacted on practice. However, the committee noted that it could not make recommendations based on such changes to practice as it has not reviewed evidence in this area.</p>

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				<p>more challenging to deliver VBA through remote consultation compared to face to face, and 31% of GPs surveyed agreed or strongly agreed that they would like training on how to deliver VBA in a remote consultation setting.[1] This highlights the need to tailor existing training, or provide extra guidance or training on how to deliver VBA in a remote setting.</p> <p>The delivery of VBA through remote consultations has also impacted the engagement with certain groups. For example, 80% of GPs surveyed found it significantly more or slightly more challenging to engage patients whose first language is not English in remote consultations. 57% of GPs surveyed found it significantly more or slightly more challenging to engage patients from a lower socioeconomic group.[1] This highlights that, if consultations continue to be delivered remotely, more needs to be done to engage people from these groups.</p> <p>Finally, pre-COVID-19, patients were often given information on smoking cessation to take away from face to face consultations. Given many consultations are currently remote, more thought may be needed on providing digital</p>	

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				<p>information to help patients quit smoking, for example through email or AccuRx.</p> <p>References</p> <ol style="list-style-type: none"> 1. Cancer Research UK GP Omnibus survey (2021) Unpublished findings. Data collected by medeConnect who interviewed 1000 regionally representative UK GPs online. medeConnect is a division of Doctors.net.uk. 2. Murphy M, Scott LJ, Salisbury C et al. Implementation of remote consulting in UK primary care following the COVID-19 pandemic: a mixed-methods longitudinal study. British Journal of General Practice. 2021; 71 (704): e166-e177. 3. McKinstry B, Campbell J, Salisbury C. Telephone first consultations in primary care. BMJ 2017; 358 :j4345 doi:10.1136/bmj.j4345 4. Hammersley V, Donaghy E, Parker R et al. Comparing the content and quality of video, telephone, and face-to-face consultations: a non-randomised, quasi-experimental, exploratory study in UK primary care. British Journal of General Practice. 2019; 69 (686): e595-e604. 5. McKinstry B, Watson P, Pinnock H, Heaney D, Sheikh A. Telephone consulting 	

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				<p>in primary care: a triangulated qualitative study of patients and providers. British Journal of General Practice. 2009. 59(563) e209–e218.</p> <p>6. Neve G, Fyfe M, Hayhoe B, Kumar S. Digital health in primary care: risks and recommendations. British Journal of General Practice. 2020; 70 (701): 609-610.</p> <p>7. Strategic Evidence Team, Cancer Research UK. Remote Consultations in Primary Care: A Summary of Evidence 2020/2021. Accessed 26 July 2021.</p>	
Cancer Research UK	Guideline	027	017 - 026	<p>Recommendation 1.13.1 –From Health Professional survey insights, it is important to acknowledge that some GPs do not recognise delivering stop-smoking interventions as their role. 19% of GPs disagreed that 'It's part of my role to encourage people who smoke to make a quit attempt'.[1]</p> <p>NICE should ensure that GPs role in smoking cessation is stressed so that health professionals understand the role they play in smoking cessation.</p> <p>Reference 1. Cancer Research UK. 2020. Survey of UK Healthcare Professionals. Unpublished, cited with permission.</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.</p>

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Cancer Research UK	Guideline	027	017 - 026	<p>Recommendation 1.13.1 –Cancer Research UK support this recommendation. However, we wanted to note that in some Local Authorities, some staff were redeployed from stop smoking services due to the COVID-19 pandemic, and some smoking cessation services are still not available.[1]</p> <p>Additionally, access to appropriate stop smoking services is difficult. Some GPs are unaware of local services available, or do not have local services available.[2,3] Therefore the 'ACT' part of VBA may be more challenging to implement.</p> <p>Taking both of these points into account, adherence to guidance asking primary care staff to refer patients to stop smoking services might be low.</p> <p>References</p> <ol style="list-style-type: none"> 1. Anecdotal feedback from local CRUK Facilitator teams. 2. Action on Smoking and Health and Cancer Research UK. Stepping Up: The response of stop smoking services in England to the COVID-19 pandemic. 2021. 3. Anecdotal insight from CRUK GPs. 	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.</p>

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Cancer Research UK	Guideline	027	022 - 023	<p>Recommendation 1.13.1 - We believe the role and efficacy of stop smoking services in achieving long term abstinence should be emphasised further in this recommendation. Compared with no support, people who use prescription medication and behavioural support from stop smoking are around 3 times more likely to stop smoking. Those who use prescription medication with brief advice are around 1.6 times more likely to successfully stop compared with no support. [1] We would suggest combining bullet 2 and 3 to say "provide stop-smoking interventions and advice and/or refer patients to local stop-smoking services if available". We have also suggested that referral to stop smoking services is referenced in guideline 1.12.3.</p> <p>Reference</p> <p>1. Kotz D, Brown J, West R. 'Real-world' effectiveness of smoking cessation treatments: a population study. <i>Addiction</i>. 2014 Mar;109(3):491-9.</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.</p>
Cancer Research UK	Guideline	028	010 - 014	<p>Recommendation 1.14.1 – We would like to see this section include a bullet point to highlight the mental health benefits of quitting smoking. A recent Cochrane review found that smokers who stop have better mental health than those who continue to smoke and that the</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.</p>

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				<p>benefits to mental health were estimated to be equivalent to anti-depressants.[1]</p> <p>Reference</p> <p>1. Taylor GM, Lindson N, Farley A, Leinberger-Jabari A, Sawyer K, te Water Naudé R, Theodoulou A, King N, Burke C, Aveyard P. Smoking cessation for improving mental health. Cochrane Database of Systematic Reviews. 2021(3).</p>	
Cancer Research UK	Guideline	031	019 - 023	<p>Recommendation 1.14.19 - It is important to stress that advisers are adequately trained, so reference to guideline 1.23.3 should be made here.</p>	<p>Thank you for your comment. The committee discussed training and agreed that throughout the guideline it is implicit that the professionals providing support and advice should be adequately trained to do so. While the recommendations in section 1.23 focus specifically on training, they are an integral part of the guideline and should be read alongside other sections.</p>
Cancer Research UK	Guideline	031	014 - 016	<p>Recommendation 1.14.18 - Cancer Research UK support the amended wording for this recommendation to remove mention of switching from e-cigarettes to a licensed product.</p> <p>Cancer Research UK supports the addition of nicotine-containing e-cigarettes to the smoking cessation aids to be made accessible to adults who smoke. E-cigarettes are the most popular</p>	<p>Thank you for your support of this recommendation.</p>

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				<p>smoking cessation aid for smokers in England.[1] Growing evidence shows that nicotine-containing e-cigarettes are an effective smoking cessation aid, including a 2020 Cochrane review [2] and a 2018 meta-analysis.[3] An English study showed that individuals using an e-cigarette are around 60% more likely to quit compared to going 'cold turkey' or using over-the-counter nicotine replacement therapy [4] and a 2019 CRUK-funded study showed that using e-cigarettes in combination with behavioural support was nearly twice as effective as NRT and behavioural support.[5]</p> <p>References</p> <ol style="list-style-type: none"> 1. Smoking Toolkit Study. (2021). Electronic cigarettes in England – latest trends. 2. Hartmann-Boyce J, McRobbie H, Lindson N, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Butler AR, Fanshawe TR, Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2020, Issue 10. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub4 3. Liu, X., Lu, W., Liao, S., Deng, Z., Zhang, Z., Liu, Y., & Lu, W. (2018). Efficiency and adverse events of electronic cigarettes: A systematic review and meta-analysis 	

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				(PRISMA-compliant article). <i>Medicine</i> , 97(19), e0324. 4. Brown, J., Beard, E., Kotz, D., Michie, S., & West, R. (2014). Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study. <i>Addiction</i> (Abingdon, England), 109(9), 1531-40. 5. Hajek P, Phillips-Waller A, Przulj D, Pesola F, Myers Smith K, Bisal N, Li J, Parrott S, Sasieni P, Dawkins L, Ross L, Goniewicz M, Wu Q, McRobbie HJ. A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy. <i>N Engl J Med</i> . 2019 Feb 14;380(7):629-637.	
Cancer Research UK	Guideline	031	017	Section on stop-smoking pharmacotherapies in acute and mental health services - line 17 is an important inclusion to make sure that the section on stop-smoking interventions are referred to alongside this guidance.	Thank you for your comment.
Cancer Research UK	Guideline	031	019	Recommendation 1.14.19 - Clarification is needed around what constitutes a severe mental health condition.	The rationale and impact section relating to this recommendation notes that there was a small amount of evidence about tailored smoking cessation interventions for people with mental health conditions. The evidence of effectiveness identified was in populations with severe mental health conditions such as bipolar disorder or schizophrenia. However,

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					the committee noted there was a lack of consensus of what constitutes a severe mental health condition. They heard from experts that people with other mental health conditions may need additional support as well. This applies both at an individual level and, for those in mental health settings, at a system level. The committee agreed that additional support should be offered to people with severe mental health conditions, but although it might be considered for other people with mental health conditions, there was insufficient evidence to make a wider recommendation.
Cancer Research UK	Guideline	032	004 - 010	<p>Recommendation 1.14.20 - We welcome the recommendation to inform people who smoke and are admitted to secondary care about the different types of medicinally licensed nicotine containing products, how to use them and if possible, prescribe them. We suggest that e-cigarettes are also recommended as an intervention, in both acute and mental health settings.</p> <p>Public Health England recommends the use of e-cigarettes as an alternative to smoking in mental health organisations.[1] In 2019, ASH conducted a survey of mental health trusts which found that 42% of trusts in England</p>	Thank you for your comment. The evidence on the use of nicotine containing e-cigarettes to support temporary abstinence not reviewed as part of this guideline update and therefore recommendations have not been made in this area.

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				<p>provide free e-cigarettes to adult smokers on admission to hospital to support temporary abstinence.[2] Therefore, the use of e-cigarettes in these settings is becoming increasingly well established.</p> <p>References</p> <ol style="list-style-type: none"> 1. Public Health England. Using electronic cigarettes in NHS mental health organisations. 2020. 2. Action on Smoking and Health (ASH). Progress towards smokefree mental health services. Findings from a survey of mental health trusts in England. 2019. 	
Cancer Research UK	Guideline	033	026 - 028	<p>Recommendation 1.14.27 - we are concerned that the amended wording from the previous guidelines suggests that a fully operating system for supporting staff in secondary care and closed institutions to stop smoking is not necessary, and instead advice and guidance alone should be provided. It is important that a system to support staff to stop smoking is in place, therefore we suggest adding back the previous wording, so the recommendation reads: 'Advise all staff who smoke to stop. Ensure systems are in place for staff who smoke to receive advice and guidance on how to stop in one go'.</p>	<p>Thank you for your comment. This recommendation was amalgamated from older recommendations and we agree that the amended wording does not reflect the spirit of the recommendation. We have amended the wording.</p>

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				Alternatively, recommendation 1.22.12 could include a mention that the on-site stop-smoking support is also open to staff.	
Cancer Research UK	Guideline	033	020	<p>Section on making stop-smoking options available in hospitals, line 20 - we agree to refer to Recommendation 1.22.14. Given the recommendations in section 1.12, we believe the wording of recommendation 1.22.14 should be changed to 'Include nicotine-containing products such as nicotine replacement therapy and nicotine-containing e-cigarettes as options for sale in secondary care settings (for example, in hospital shops).'</p> <p>This is assuming that the definition of nicotine-containing products includes e-cigarettes. If NICE does not include e-cigarettes in this definition, we believe nicotine-containing e-cigarettes should still be mentioned as an option for sale in secondary care settings.</p>	Thank you for your comment. The committee did not feel that examples of nicotine-containing products were necessary in this recommendation since they are defined in the glossary. The definition of nicotine containing products has been amended to clarify that it includes nicotine containing e-cigarettes.
Cancer Research UK	Guideline	037	022 - 029	Recommendation 1.15.13 - There are inconsistencies in the groups listed as being at higher risk of tobacco related harm in this recommendation, compared to recommendation 1.22.4. We suggest amending recommendation 1.22.4 to be inclusive of all groups, and signposting to 1.22.4 in 1.15.13.	Thank you for pointing out this inconsistency. We have addressed it in the final guideline and recommendation 1.15.13 now cross refers to recommendation 1.22.4.

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Cancer Research UK	Guideline	044	018 and 019	For recommendation 1.17.2, we ask for NICE to clarify whether "pharmacotherapy" includes medically licensed nicotine containing products. We understand that the NICE definition encapsulates both, however evidence on relapse prevention varies between NRT and stop smoking medications.	Thank you. Pharmacotherapy is defined in the glossary and includes stop-smoking medication such as varenicline or bupropion, as well a nicotine replacement therapy.
Cancer Research UK	Guideline	045	019 and 020	Recommendation 1.17.6 - Given PH45, recommendation 4 bullet 7 has been deleted, we would suggest updating wording to: 'For people attempting to stop smoking and those reducing their harm, offer follow-up appointments and review the approach taken at each contact.' The current wording is quite passive and relies on the person who smokes making contact again in order for there to be an opportunity to review the approach. The body of evidence as a whole suggests that there are multiple different effective ways of reducing the risk of relapse (as represented by NICE's evidence review N), so it makes sense to have touch points that aren't contingent on the person smoking to organise.	Thank you for your comment. We have made this clarification to the recommendation.
Cancer Research UK	Guideline	051	008 - 021	Recommendation 1.20.12 - As highlighted by NICE on page 87 of the guidelines, financial resources will need to be found to fund the voucher incentive scheme. It is important to acknowledge that increased	Thank you. The recommendations are based on the evidence of effectiveness, and the implementation of the recommendations is primarily a local commissioning decision.

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				<p>and sustainable funding is needed to support the recurring costs of tobacco control at a local, regional and national level. This could be achieved through a Smokefree 2030 Fund: making the tobacco industry pay for tobacco control but without letting them influence how the money is spent. A Smokefree Fund would pay for a comprehensive tobacco control strategy, and help free up budget for use in other important areas of public health.[1]</p> <p>Reference</p> <p>1. Delivering a Smokefree 2030: The All Party Parliamentary Group on Smoking and Health recommendations for the Tobacco Control Plan 2021. London: APPG on Smoking and Health. 2021.</p>	
Cancer Research UK	Guideline	051	015 - 016	<p>1.12.12– bullet 3 – This sentence should use the word “incentive” instead of “reward”. Incentive payments are not rewards; they are incentives to change behaviour and the terminology used should reflect that. This is particularly important given the sensitivity in the media around the use of financial incentives in pregnancy.</p>	<p>Thank you for your comment. PHAC considered your comment and the wording has been amended to reflect your comment.</p>
Cancer Research UK	Guideline	051	008 - 0	<p>Recommendation 1.20.12 - Within this recommendation suggested frequency and timings of rewards should be stated, and clarity is needed around what happens in the event of</p>	<p>Thank you. The voucher schemes differed in approach and in the absence of more evidence the committee were not more specific other than to recommend that</p>

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				<p>a relapse. Cancer Research UK agrees that those who relapse should not be excluded from continuing to take part in the incentive programme and try again. However, evidence suggests that rewards that are contingent on having stopped smoking are more effective than rewards given to those trying to stop smoking no matter the outcome [1, 2], so guidelines should reflect that those who relapse don't receive the full award.</p> <p>References</p> <ol style="list-style-type: none"> 1. Heil SH, Higgins ST, Bernstein IM, Solomon LJ, Rogers RE, Thomas CS, et al. Effects of voucher-based incentives on abstinence from cigarette smoking and fetal growth among pregnant women. <i>Addiction</i> 2008. 2. Higgins ST, Washio Y, Lopez AA, Heil SH, Solomon LJ, Lynch ME, et al. Examining two different schedules of financial incentives for smoking cessation among pregnant women. <i>Preventive Medicine</i> 2014. 	<p>vouchers be staggered on contingent on biochemically validated quit attempts.</p>
Cancer Research UK	Guideline	052	General	<p>Enabling all pregnant women to access stop-smoking support section - We are concerned that the guideline 'Enabling all pregnant women to access stop-smoking support' does not explicitly recommend that stop smoking</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.</p>

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				<p>materials and support be provided in languages other than English. Although the NICE guideline on patient experience in adult NHS services recommends that healthcare services are accessible for non-English speakers, given high rates of smoking among some migrant communities, the guideline should explicitly highlight the need to provide stop smoking materials and advice in a range of languages.</p> <p>We believe that the list starting on page 52, line 11, should include a point saying "Ensure resources and advice for stopping smoking are available in a range of different languages, taking into account local demographics."</p>	
Cancer Research UK	Guideline	057	012 - 030	<p>Recommendation 1.22.4, sub bullet 6 - we are concerned that some groups with a high smoking prevalence are not included here. We would recommend adding:</p> <ul style="list-style-type: none"> - unemployed people [1, 2] - people with lower levels of qualification, or no qualifications [1, 2] - people who are incarcerated [3] --looked after children [4] <p>References</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.</p>

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				<ol style="list-style-type: none"> 1. Office of National Statistics. Adult smoking habits in the UK: 2019. Published July 2020. 2. NHS Digital. Statistics on Smoking in England – 2019. Published 2 July 2019. Accessed 16 May 2021. 3. Public Health England. Reducing Smoking in Prisons: Management of tobacco use and nicotine withdrawal. 2015. 4. Office of National Statistics. The mental health of young people looked after by local authorities in England. 2003. 	
Cancer Research UK	Guideline	057	002 - 005	<p>Recommendation 1.22.1 - we are concerned that the use of the word 'range' could result in further restrictions of stop-smoking interventions on offer. Ideally all stop-smoking interventions, as listed in the section 1.12 on stop-smoking interventions, should be universally available.</p> <p>As indicated by NICE on page 87, line 21 - 23, not all medically licensed products are available in stop smoking services.</p> <p>It is also important to acknowledge that not all pharmacotherapies are universally available to be prescribed in primary care settings. In some local health communities, GPs are restricted on what they can prescribe, as certain stop-</p>	Thank you. The committee have changed this to 'the range' to make it clear that there is an expectation that they will provide all of the options rather than just some..

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				<p>smoking pharmacotherapies are excluded from local formularies.[1]</p> <p>NICE should encourage universal availability of stop-smoking interventions to make sure that everyone has access to the best support to stop smoking. Primary care professionals should be able to routinely prescribe everyone, including those from more deprived groups, with the most effective forms of pharmacotherapy (that is, varenicline) with behavioural support, to improve the chance of quitting successfully. Commissioners should also ensure that restrictions placed on clinicians prescribing these pharmacotherapies are repealed as a priority so that full the range of pharmacotherapy is available to prescribe.</p> <p>Reference 1. British Lung Foundation. Less help to quit: What's happening to stop smoking prescriptions across Britain. 2018.</p>	
Cancer Research UK	Guideline	057	002 - 005	<p>Recommendation 1.22.1 - given recommendation 1.22.1 has replaced recommendation 1.1.1 from NG92, we are concerned about the removal of the mention of 'services being available for everyone who smokes'. This stressed the importance of</p>	<p>Thank you. The committee believe this is adequately covered by 'adults who smoke'. It is not within NICE's remit to determine how these services should be commissioned.</p>

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				<p>smoking cessation services being accessible to all, which is unfortunately not the case.</p> <p>In 2020, only 77% of surveyed local authorities in England offered a specialist stop smoking service, and only 62% offered a specialist service to all those who smoked locally.[1] This is in part due to sustained reductions in local authority public health budgets.[2, 3] Given people who use prescription medication and behavioural support from stop smoking services are around three times more likely to stop smoking successfully than those attempting to quit unaided [4, 5], it is important for NICE to stress the importance of commissioning stop smoking services and protecting council budgets to commission stop smoking services wherever possible.</p> <p>It is also important to acknowledge that increased and sustainable funding is needed to support the recurring costs of tobacco control at a local, regional and national level. This could be achieved through a Smokefree 2030 Fund: making the tobacco industry pay for tobacco control but without letting them influence how the money is spent. A Smokefree 2030 Fund would pay a comprehensive tobacco control strategy, and</p>	

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				<p>help free up budget for use in other important areas of public health.[6]</p> <p>References</p> <ol style="list-style-type: none"> 1. Action on Smoking and Health and Cancer Research UK. Stepping Up: The response of stop smoking services in England to the COVID-19 pandemic. 2021. 2. The Health Foundation. Today's public health grant announcement provides some certainty, but more investment is needed over the longer-term. Published 17 March 2020. Accessed 18 May 2021. 3. The Health Foundation. Briefing: Taking our health for granted – plugging the public health grant funding gap. The Health Foundation; 2018. 4. Kotz D, Brown J, West R. 'Real-world' effectiveness of smoking cessation treatments: a population study. <i>Addiction</i>. 2014;109(3):491-9. doi: 10.1111/add.12429. 5. Kotz D, Brown J, West R. Prospective cohort study of the effectiveness of smoking cessation treatments used in the "Real World". <i>Mayo Clinic Proceedings</i>. 2014;89(10):1360-1367. 6. Delivering a Smokefree 2030: The All Party Parliamentary Group on Smoking 	

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				and Health recommendations for the Tobacco Control Plan 2021. London: APPG on Smoking and Health. 2021.	
Cancer Research UK	Guideline	059	010 and 011	<p>Recommendation 1.22.14 - Given the recommendations in section 1.12, we believe the wording of recommendation 1.22.14 should be changed to 'Include nicotine-containing products such as nicotine replacement therapy and nicotine-containing e-cigarettes as options for sale in secondary care settings (for example, in hospital shops).'</p> <p>This is assuming that the definition of nicotine-containing products includes nicotine-containing e-cigarettes. If NICE does not include e-cigarettes in this definition, we believe nicotine-containing e-cigarettes should still be mentioned as an option for sale in secondary care settings.</p>	Thank you. Nicotine containing products is defined in the glossary section of the guideline. The definition of nicotine containing products has been amended to clarify that it includes nicotine containing e-cigarettes.
Cancer Research UK	Guideline	060	013 - 027	<p>Recommendation 1.22.19 - although this recommendation has been copied across from recommendation 10 in PH48, certain sub bullets are missing (sub bullet 1, 4,5, 6 and 8). Although alluded to in the introduction of recommendation 1.22.19 that these should be provided alongside support for secondary care, the missing bullets should be added back here for clarity and completeness.</p>	<p>Thank you. Some bullet points were removed because they are covered immediately above as follows:</p> <p>An organisation wide smoke free policy – 1.22.10 and 11</p> <p>Referral and support pathways – 1.22.12, 13 and 15</p>

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				<p>Missing sub bullets:</p> <ul style="list-style-type: none"> – an organisation-wide smokefree policy is in place – referral and support pathways are part of the organisation's service plan – hospitals have an on-site stop smoking service – staff in secondary care services deliver stop smoking support to help people stop, or temporarily abstain, from smoking, in line with the recommendations in this guidance – progress and outcomes in each clinical area are monitored, for example, recording of individual smoking status (including at the time of giving birth), the number of referrals, uptake of interventions, prescribing of stop smoking pharmacotherapies, 4-week quit rates, training of staff 	<p>Onsite stop smoking service – 1.22.12</p> <p>Staff delivering stop smoking support – 1.22.15</p> <p>Monitoring progress – 1.22.16</p>
Cancer Research UK	Guideline	061	002 - 005	<p>Recommendation 1.22.20 - Although copied across from Recommendation 9 from PH48, the second sub bullet has been omitted. This stated: '– ensure smoking status is consistent in all patient records'. This should be added back in to ensure that records can clearly show a patient's smoking status.</p>	<p>Thank you. This is conveyed in the stem of the recommendation.</p>
Cancer Research UK	Guideline	062	023 and 024	<p>Section 1.23 on training - given the important role the National Centre for Smoking Cessation and Training play, we believe the</p>	<p>Thank you. Training is covered in recommendations 1.23.2 to 1.23.4. Additionally, 1.23.2 cross references to</p>

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				NCSCT should be mentioned in the upfront as a platform to access relevant training modules.	recommendations 1.13 which reference NCSCT training.
Cancer Research UK	Guideline	062 and 063	025 – 028 001 - 008	Recommendation 1.23.1 - In line with PH23, recommendation 2, bullet 5, which was incorporated into recommendation 1.23.1, we believe that local tobacco control alliances should be added back in as a partner. Also, given the prominent role integrated care systems will play in tobacco control, they should be mentioned here as well. Finally, from a health inequalities perspective, it may be worth adding in social care and community groups.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website. This recommendation is outside the scope of this update and has been editorially refreshed. We are unable to make significant changes to the groups in this recommendation but we have added tobacco control alliances under local authorities and social care and community groups are covered under local authorities and voluntary agencies.
Cancer Research UK	Guideline	063	013 - 019	Section 1.23 on training - we acknowledge that during the guideline update, NICE have deleted all recommendations on general training. However, we think it is important to highlight that many healthcare professionals across the NHS are not receiving adequate training in smoking cessation interventions.[1] Therefore, it is important to stress the need for training across all individuals who come into contact with people who smoke. For example, while NICE recommends all frontline staff in general practice should be trained in Very Brief Advice (VBA) in	Thank you. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website. Implementation of the recommendation is for local commissioners to manage. Recommendations state that both primary and secondary care staff should be trained in VBA (1.23.2).

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				<p>recommendation 1.23.2, research from Asthma UK and the British Lung Foundation shows that too few are given the training in VBA they need to make a difference to patients who smoke. This research found that over half of UK GPs have received no training in VBA. Of those GPs that received training, only 2% of respondents self-reported that VBA training was comprehensive and in total only 8% go on to deliver VBA daily.[2] A study by CRUK published in March 2019 found that just over half the GPs and practice nurses surveyed (53%) frequently completed all steps of VBA with people who smoke.[3]</p> <p>It is also likely that the changed delivery of primary care consultations due to the pandemic may have compounded the challenges of offering effective VBA, which should be addressed in training for healthcare professionals. A survey of UK GPs commissioned by Cancer Research UK found that during the pandemic where GP consultations have been being delivered remotely, 40% of GPs surveyed strongly agreed or agreed with the statement that it was more challenging to deliver VBA through remote consultation compared to face to face, and 31% of GPs agreed or strongly agreed</p>	

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				<p>that they would like training on how to deliver VBA in a remote consultation setting.[4] This highlights the need to tailor existing training, or provide extra guidance or training on how to deliver VBA in a remote setting.</p> <p>References</p> <ol style="list-style-type: none"> 1. Royal College of Physicians. Hiding in plain sight: Treating tobacco dependency in the NHS. June 2018. 2. Asthma UK, British Lung Foundation. A Breath of Fresh Air: research into the training needs of UK GPs on Very Brief Advice for smoking cessation. January 2021. 3. Cancer Research UK. Smoking Cessation in Primary Care: A cross-sectional survey of primary care health practitioners in the UK and the use of Very Brief Advice. 2019. 4. Cancer Research UK GP Omnibus survey (2021) Unpublished findings. Data collected by medeConnect who interviewed 1000 regionally representative UK GPs online. medeConnect is a division of Doctors.net.uk. 	
Cancer Research UK	Guideline	063	013 - 019	<p>Recommendation 1.23.2 – Delivery of VBA advice does not need to be limited to clinical staff. Therefore, it would be helpful if the term 'frontline healthcare staff' could be defined more clearly. The term 'staff from health and social care' may be more appropriate and</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.</p>

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				inclusive of Additional Roles Reimbursement Scheme (ARRS) and social prescriber roles as part of integrated care systems at Primary Care Network (PCN) level who can deliver VBA advice. There may be a training need at PCN level to support this, through peer support, shared learning and discussion.	
Cancer Research UK	Guideline	064	006 and 007	<p>Recommendation 1.23.6 - Cancer Research UK recommends NICE considers changing the wording of 1.23.6 to include prescribing or supplying stop smoking medication (varenicline/bupropion) and nicotine-containing e-cigarettes as well as medicinally licensed nicotine-containing products. It is important to ensure that people in closed institutions have access to all recommended smoking cessation aids previously outlined in NICE guidelines.</p> <p>Access to e-cigarettes in acute mental health settings is becoming more widespread. In a survey of mental health trusts in 2019, 42% provided e-cigarettes free of charge to their patients.[1]</p> <p>Reference 1. Action on Smoking and Health (ASH). Progress towards smokefree mental health services. Findings from a survey of mental health trusts in England. 2019.</p>	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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Cancer Research UK	Guideline	067	017 and 018	Terms used in this guideline' section, 'Behavioural support' definition - Given recommendations in section 1.12 also support the use of nicotine-containing e-cigarettes alongside behavioural support, Cancer Research UK believe that nicotine-containing e-cigarettes should be included here alongside pharmacotherapies in this definition.	Thank you. Cessation of e-cigarettes is outside the scope of this guideline. Please see the scope document on the NICE website.
Cancer Research UK	Guideline	068 and 069	028 - 030 001 - 006	Terms used in this guideline' section, 'nicotine-containing products' definition - Cancer Research UK asks for clarity on whether nicotine-containing e-cigarettes are considered "nicotine-containing products" as it is unclear from this definition. It may be necessary to future-proof this definition so that newer nicotine containing products are not considered as smoking cessation aids (e.g. nicotine pouches) prior to a full assessment. Cancer Research UK believe this definition should include nicotine-containing e-cigarettes.	Thank you. We have clarified the definition.
Cancer Research UK	Guideline	071	013 - 017	Terms used in this guideline' section, 'stop in one go' definition - The use of the word 'limited time afterwards' is quite vague. We want everyone who smokes to stop and not rely on pharmacotherapy or nicotine-containing e-cigarettes indefinitely, however use for an extended period of time is better than relapsing to smoking. Therefore CRUK suggest a	Thank you for your comments. PHAC have considered your comments and have amended the guideline in line with your suggested wording.

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				<p>wording change to '...and for a period of time afterwards, depending on the individual's needs'.</p> <p>Cancer Research UK believes that patients should be encouraged to use their nicotine-containing e-cigarette for as long as they feel is necessary to remain abstinent from smoking. Use patterns of e-cigarettes varies by individuals, however evidence suggests that continued longer-term use of e-cigarettes is much higher than NRT. In a randomised controlled trial published in 2019 comparing e-cigarettes versus NRT for smoking cessation in Stop Smoking Services, e-cigarettes were nearly twice as effective as NRT when comparing 1-year quit rates. However, amongst those who successfully quit, continued use of the product was nearly 9x higher in the e-cigarette group compared with the NRT group.[1] Therefore, people who stop smoking using e-cigarettes may continue to use them for a longer period than NRT. As we currently do not have sufficient evidence on the optimum time period to continue e-cigarette use after cessation, we believe that patients should be encouraged to use their e-cigarette for as long as they feel is necessary to remain abstinent from smoking.</p>	

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				Reference 1. Hajek P, Phillips-Waller A et al. (2019). A Randomized Trial of E-Cigarettes versus Nicotine Replacement Therapy. N Engl J Med; doi: 10.1056/NEJMoa1808779	
Cancer Research UK	Guideline	072	008 - 011	<p>Recommendations for research section, recommendation 1 - Cancer Research UK agrees with this research recommendation however believes the emphasis of research should be on the long-term, rather than short term effects of nicotine-containing e-cigarettes. Research so far shows that e-cigarettes are far less harmful than smoking. However, as they are a relatively new product, their long term effects are not known.[1-4] There is a need for long-term studies which combine biological and epidemiological methods.</p> <p>Relevant references: 1. Burstyn I. (2014) Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks. BMC public health. 2014;14(1):18. 2. Goniewicz M, Knysak J, Gawron M, et al. Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. Tob Control. 2013.</p>	Thank you. The committee agreed that both long and short term effects are important.

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				<p>3. McNeill A, Brose L, Calder R, Bauld L, Robson D. Evidence review of e-cigarettes and heated tobacco products 2018. Commissioned by Public Health England.; 2018.</p> <p>4. Tobacco Advisory Group of The Royal College of Physicians. Nicotine without Smoke; 2016.</p>	
Cancer Research UK	Guideline	073	001 - 004	<p>Recommendations for research section, recommendation 3 - Cancer Research UK agree that further research is needed on how to improve accessibility and engagement with underserved groups. We think it is equally important to research how we can best target and engage those from more deprived backgrounds and those groups with higher smoking rates (as alluded to in recommendation 1.22.4).</p> <p>Modelling by Cancer Research UK has indicated that improved delivery of stop smoking support for different socioeconomic groups would lead to more people stopping smoking, however it would not narrow the gap in smoking inequalities between the lower and higher socioeconomic groups.[1] This highlights the need for research into effective interventions for underserved groups.</p> <p>Reference</p>	Thank you. We believe this is covered in the wording of the research recommendation which talks about improving engagement and accessibility in under-served groups.

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				1. Coker, T., Webber, L., Xu, M., Graff, H., Retat, L., Guzek, J., Courbould, E., Jain, R., Greenhill, T., Newberry Le Vay, J., Bullock, S., Cheek, O., Froguel, A., Vohra, J., Fitzgerald, K. 2021. Making Conversations Count for All: Benefits of improving delivery of smoking cessation interventions for different socioeconomic groups. Cancer Research UK.	
Cancer Research UK	Guideline	073	014 - 016	<p>Recommendations for research section, recommendation 6 - Currently, research suggests that people who smoke need to switch completely to e-cigarettes to achieve the health benefits.[1] There is currently no good evidence that dual use of e-cigarettes/cigarettes is worse for health than exclusive smoking, so we agree that further high quality research in this area would be beneficial. Transitions from dual use of e-cigarettes/cigarettes to complete abstinence are also unclear, with some studies suggesting that dual use does not undermine smoking quit rates[2] The patterns of e-cigarette use alongside tobacco need to be understood more clearly in order to counsel patients on how best to use e-cigarettes to stop smoking.</p> <p>References 1. Shahab L, Goniewicz ML, Blount BC, et al.</p>	Thank you for your comment.

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				<p>Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users: A Cross-sectional Study. <i>Ann Intern Med.</i> 2017;166(6):390-400. doi:10.7326/M16-1107</p> <p>2. Jackson SE, Shahab L, West R, Brown J. Associations between dual use of e-cigarettes and smoking cessation: A prospective study of smokers in England. <i>Addict Behav.</i> 2020 Apr;103:106230. doi:10.1016/j.addbeh.2019.106230.</p>	
Cancer Research UK	Guideline	074	001 - 004	<p>Recommendations for research section, recommendation 7 - Cancer Research UK agree with this recommendation as research in this area is currently very limited. Further research is needed to determine optimum nicotine concentrations and use frequency for different people trying to stop smoking.</p> <p>Relevant references 1. Etter J-F, Farsalinos K, Hayek P, Le Houezec J, McRobbie H, Bullen C, Kozlowski L, Nides M, Kouretas D, Polosas R, Fagerstrom K, Jarvis M, Dawkins L, Caponnetto P, Foulds J (2014). "Scientific Errors in the Tobacco Products Directive: A letter sent by scientists to the European Union". http://www.ecigarette-research.org/research/index.php/whats-</p>	Thank you for your comment

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				new/whatsnew-2014/149-tpd-errors 2. Dawkins, L. et al. (2018). 'Real-world' compensatory behaviour with low nicotine concentration e-liquid: <i>Addiction</i> , 113: 1874-1882. doi: 10.1111/add.14271; https://rdcu.be/0LbY	
Cancer Research UK	Guideline	074	005 - 008	Recommendations for research section, recommendation 8 – We agree with this recommendation. Cancer Research UK recently completed a rapid review of e-cigarette flavours and smoking cessation, which highlighted the limited evidence addressing this topic specifically. Overall, there is some evidence that flavours play a role in promoting the appeal of e-cigarettes to adult smokers, but their role in smoking cessation is less clear.[1] Reference 1. Cancer Research UK (2020). The role of e-cigarette flavours in smoking cessation. Unpublished review.	Thank you for your comment
Cancer Research UK	Guideline	074	009 - 011	Recommendations for research section, recommendation 9 - Further research is needed to examine the link between e-cigarette use and future smoking. Current research in this area has several limitations. These include insufficient adjustment for confounders and difficulty in establishing	Thank you for your comment.

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				habitual smoking compared with ever smoking in surveys used. In addition, many studies do not consider the difficulty in assessing the gateway effect due to the "common liability hypothesis", whereby some young adults have characteristics that may make them more likely to engage in risky behaviours - like alcohol use, drug use, smoking and vaping. Therefore, studies examining smoking and vaping in young people don't necessarily show that vaping leads them to start smoking, but that they may be likely to do both anyway. Future research should attempt to overcome these limitations. Research in this area should also be interpreted with caution and population level rates of both e-cigarette use and smoking should be monitored closely to assess this relationship.	
Cancer Research UK	Guideline	075	010 - 013	<p>Recommendations for research, research recommendation 12 – Cancer Research UK agree with this recommendation for research.</p> <p>Smoking is unfortunately a relapsing condition, and therefore cannot be treated in an episodic manner. [1,2] So there needs to be a continuum of support across both primary and secondary care.</p>	Thank you for your comment

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				<p>It is important to acknowledge that communication between secondary care and primary care following discharge is not always timely, which could mean GPs are unaware of the stop smoking intervention / prescriptions that a patient has received.[3] Therefore there needs to be a more joined up approach following discharge and more follow up support in the community.</p> <p>More education and training is needed for GPs so that they are all aware of the relapsing nature of smoking, that often requires more than a one off intervention. [4,5]</p> <p>It is also important to acknowledge the likely impact of COVID-19. Patients may want to use local services rather than travel to secondary care during the COVID-19 pandemic.[3]</p> <p>References</p> <ol style="list-style-type: none"> 1. Joseph AM, Fu SS, Lindgren B, Rothman AJ, Kobl M, Lando H, Doyle B, Hatsukami, D. Chronic disease management for tobacco dependence: a randomized, controlled trial. Archives of internal medicine, 2011;171(21), 1894–1900. 2. Hughes JR, Keely J, Naud S. Shape of the relapse curve and long-term abstinence 	

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				<p>among untreated smokers. Society for the Study of Addiction. 2004; 99(1): 29-38.</p> <ol style="list-style-type: none"> 3. Anecdotal insight from CRUK GPs. 4. Anecdotal feedback from CRUK GP Trainer on smoking cessation 5. Anecdotal Feedback from local CRUK Facilitator teams. 	
Cancer Research UK	Guideline	085	006	Rationale and Impact, 'Nicotine replacement therapy and other pharmacological support' section - We believe line 6 should read 'Recommendations 1.20.6 to 1.20.8 and 1.20.10'.	Thank you. This has been amended
Cancer Research UK	Guideline	089	017 - 019	<p>Context section - we are thankful to NICE for referencing Cancer Research UK and Action on Smoking and Health's joint report in the context section, however we wanted to highlight that the hyperlink currently directs to CRUK's press release rather than the report. We would also be thankful if NICE referenced Cancer Research UK alongside Action on Smoking and Health, given this was a joint report.</p> <p>For reference, the full report can be found here: Cutting down: the reality of budget cuts to local tobacco control, Action on Smoking and Health, Cancer Research UK.</p>	Thank you for your comment. This has now been amended.

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				<p>We also wanted to note that there the latest version of this report was published in 2020 and can be found here:</p> <ul style="list-style-type: none"> Action on Smoking and Health and Cancer Research UK. Stepping Up: The response of stop smoking services in England to the COVID-19 pandemic. 2021. 	
Cancer Research UK	Guideline	092	N/A	<p>Table 1, PH5 Smoking: workplace interventions. Deleted recommendation 6 - we appreciated that smokefree legislation has already been implemented, however it is still important that services are able to respond to fluctuations in demand, particularly in relation to COVID-19. This need has also been brought into sharper focus since the disruption in supply of varenicline.[1]</p> <p>We would therefore urge NICE to include a recommendation similar to PH5 recommendation 6, but without mention of smokefree legislation and in relation to all services being able to deal with fluctuations in demand.</p> <p>Reference 1. Medicines & Healthcare products Regulatory Agency. Central Alerting System:</p>	Thank you. The recommendation was as you say specific to smokefree legislation. The ability of services to adapt and meet need is reflected throughout the current recommendations.

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				Champix (varenicline) 0.5mg and 1mg tablets - Supply Disruption. Accessed 16 July 2021.	
Cancer Research UK	Guideline	094	N/A	Table 1, PH26 Smoking: stopping in pregnancy and after childbirth. Deleted recommendation 1, bullet 6. We believe that the recommendations should still mention the NHS Smokefree Helpline to ensure all relevant stakeholders know the resource exists, as indicated on the following webpage: https://www.nhs.uk/pregnancy/keeping-well/stop-smoking/ .	Thank you. PHAC discussed this and agreed that the updated recommendations covered this adequately, for example 1.19.5 which refers to both telephone quitlines and online stop smoking support for pregnant women..
Cancer Research UK	Guideline	103	N/A	PH14 research recommendation 1 - we believe that there are still significant gaps in this area of research so question why this has been stood down and suggest that it is still prioritised.	Thank you. NICE research recommendations are designed to address gaps in the evidence base used for guidelines. A recent review of digital interventions for smoking behaviour for NICE guideline NG183 identified 19 studies.
Cancer Research UK	Guideline	106	N/A	PH45, research recommendation 4.3 - we believe that there are still significant gaps in this area of research so question why this has been stood down and suggest that it is still prioritised.	Thank you. NICE research recommendations highlight priority research areas that are needed to keep the guideline up to date and the committee did not identify this area as a priority because the contents of this deleted research recommendation are partly covered by research recommendations 6, 11 and 12 and in the recommendations in 1.15.
Cancer Research UK	Guideline	106	N/A	PH45, research recommendation 4.4 - we believe that there are still significant gaps in this area of research so question why this has	Thank you. NICE research recommendations highlight priority research areas that are needed to keep the guideline up to date and

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				been stood down and suggest that it is still prioritised.	the committee did not identify this area as a priority.
Cochrane Tobacco Addiction Group	Guideline	General	General	Financial incentives for quitting smoking are not highlighted as an effective intervention in the general population. They should be. There is high certainty evidence of their effectiveness in the general population of people who smoke (as well as in pregnancy, where they are currently highlighted). See: Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD004307. DOI: 10.1002/14651858.CD004307.pub6. Accessed 28 July 2021.; Hartmann-Boyce J, Livingstone-Banks J, Ordóñez-Mena JM, Fanshawe TR, Lindson N, Freeman SC, Sutton AJ, Theodoulou A, Aveyard P. Behavioural interventions for smoking cessation: an overview and network meta-analysis. Cochrane Database of Systematic Reviews 2021, Issue 1. Art. No.: CD013229. DOI: 10.1002/14651858.CD013229.pub2. Accessed 28 July 2021.	Thank you for your comment. Incentives were only considered in pregnant women. Incentives for other populations is outside the scope of this guideline. Please see the scope document on the NICE website.
Cochrane Tobacco Addiction Group	Guideline	General	General	We would like to see more of an emphasis on the role of the evidence in informing practice throughout. Relevant Cochrane reviews, for example, could be referred to by name. Evidence will continue to develop and evolve,	Thank you for your comment. The reference to Cochrane reviews (recommendation 1.9.2) relates to a greyed-out area of the guideline and is outside of the scope for this update.

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				particularly in key areas such as smoking cessation support in underserved groups and in pregnancy, it is important that in the overview section of the guidelines there is a generic recommendation that research outcomes are taken into account. We suggest something along the lines, "When developing and implementing policies to prevent uptake, promote quitting and treat dependence it is essential to use the best available evidence of effectiveness, such as Cochrane reviews".	Please see the scope document on the NICE website. The research recommendations developed by PHAC seek to address the gaps in the evidence identified during the guideline development process with the hope of stimulating research in these areas for consideration when this guideline or aspects of this guideline are considered for update. NICE routinely checks that published guidelines are current, accurate and up to date via our surveillance function which explores if there is any new evidence to contradict, reinforce or clarify guideline recommendations. Surveillance also identifies new interventions that may need to be considered within a guideline and explores changes in context that may mean modifications are needed, for example, changes in policy, infrastructure, legislation or costs. A proactive approach is taken that includes reacting to events at any time after guideline publication (for example, publication of a key study)
Cochrane Tobacco Addiction Group	Guideline	031	019 - 023	May be worth explicitly addressing the concern that quitting smoking will have negative impact on mental health. Cochrane review shows that that mental health does not worsen as a result of quitting smoking, and very low- to moderate-	Thank you for this reference. However this review would not have been eligible for inclusion in the evidence reviewed by the committee as it focuses on the benefits of stopping smoking on mental health, whereas

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				certainty evidence that smoking cessation is associated with small to moderate improvements in mental health. These improvements are seen in both unselected samples and in subpopulations, including people diagnosed with mental health conditions. (See: Taylor GMJ, Lindson N, Farley A, Leinberger-Jabari A, Sawyer K, Water Naudé R, Theodoulou A, King N, Burke C, Aveyard P. Smoking cessation for improving mental health. Cochrane Database of Systematic Reviews 2021, Issue 3. Art. No.: CD013522. DOI: 10.1002/14651858.CD013522.pub2.)	the focus of the evidence considered by the committee was on the effectiveness of smoking cessation interventions for people with mental health conditions.
Cochrane Tobacco Addiction Group	Guideline	059	010 - 011	Clarify statement "Include nicotine-containing products as options for sale in secondary settings (for example, in hospital shops.)" Cigarettes are nicotine containing products but this is not what is meant. I assume what is meant is NRT and nicotine containing e-cigarettes. This would benefit from being explicitly stated.	Thank you. Nicotine containing products is defined in the glossary section of the guideline. The definition of nicotine containing products has been amended to clarify that it includes nicotine containing e-cigarettes.
Cochrane Tobacco Addiction Group	Guideline	075	007 - 013	We suggest considering the addition of two further points regarding recommendations for further research into relapse prevention. Firstly, we see a clear need for more research on varenicline for relapse prevention, given the committee acknowledges its likelihood of increasing long-term abstinence and Cochrane	Thank you. Research recommendations in NICE guidelines are specifically to address gaps in the research that the committee considered while making their recommendations. They do not address general gaps in the evidence.

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				evidence suggests benefit (see: Livingstone-Banks J, Norris E, Hartmann-Boyce J, West R, Jarvis M, Chubb E, Hajek P. Relapse prevention interventions for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 10. Art. No.: CD003999. DOI: 10.1002/14651858.CD003999.pub6. Accessed 28 July 2021). Secondly, we suggest it would be a good idea to recommend more trials looking at relapse prevention interventions delivered to people who have been abstinent for 4+ weeks, as there is little evidence in this group. The committee's emphasis on the importance and paucity of this kind of longer-term evidence is reflected in evidence review N: "For this reason, the committee focussed on evidence where relapse was clearly additional to cessation and delivered at a later point (this included behavioural interventions for assisted abstainers [Figure 11, GRADE profile 5], and pharmacotherapy for assisted abstainers [Figure 13-16, GRADE profile 6]). There is a paucity of evidence on this type of longer term relapse prevention." (p.66 of evidence review N)	
Cochrane Tobacco Addiction Group	Guideline	078	027 - 029	Statement currently says that nicotine EC are of similar effectiveness to NRT. There is moderate certainty evidence that they are more effective than NRT (including in studies	Thank you. The pairwise meta-analysis found a pooled risk ratio of 1.47 (1.25 – 1.72) for nicotine e-cigs vs single NRT for abstinence at 3 months. The network meta-analysis uses

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				where participants are offered combined short and long-acting NRT) and this should be made clear. See: Hartmann-Boyce J, McRobbie H, Butler AR, Lindson N, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Fanshawe TR, Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2021, Issue 4. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub5	the effectiveness data and NMA models from Thomas' (2020) review as well as results of NICE-conducted rerun searches. This NMA (based on 192 studies) showed no significant effect of e-cigarettes compared to NRT (RR of 1.23 [CrI: 0.73, 1.95]) or long + short NRT (RR: 0.84 [CrI 0.48, 1.40]). The discrepancy between pairwise and NMA effect estimates is likely to be due to the modifying effect of indirect treatment estimates within the network. Consistency checking did not identify any concerns with the model that was used for the NMA and the committee focussed their discussion on the results of this NMA.
Cochrane Tobacco Addiction Group	Guideline	079	010 - 013	This section states the committee had low confidence in the finding of no difference in adverse events in people using nicotine EC compared to NRT, EC without nicotine, and no treatment, because the studies were powered to investigate effectiveness and not adverse events. Though this is an issue for serious adverse events, where events are rare, for non serious adverse events, which this section appears to refer to at first glance, this is not an issue of underpowering because non-serious adverse events are more common than cessation (a study powered to detect a difference in cessation would also be powered	Thank you. Details of the adverse events reported are contained in evidence review K and are adverse events rather than serious adverse events. The rationale and impact section describes the committees consideration of the recommendations and their view is consistent with the findings in the systematic review you reference.

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				to detect a difference in adverse events). If this section is on serious adverse events, it should be clarified that that is the case. If not, it should be reworded. The latest Cochrane review has moderate certainty evidence of no difference in rates of adverse events (non-serious) between nicotine and non-nicotine EC. See Hartmann-Boyce J, McRobbie H, Butler AR, Lindson N, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Fanshawe TR, Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2021, Issue 4. Art. No.: CD010216	
Cochrane Tobacco Addiction Group	Guideline	079	023 - 025	The committee may also want to consider whether to make recommendations related to possible impacts of EC device type on outcomes. List currently only includes amount of nicotine, frequency of use, and flavouring, but we know that device type can influence nicotine delivery.	Thank you for your comment. The committee's preference was to keep this research recommendation as it is currently worded rather than adding additional parameters but noted that it is for research funders to determine the specific areas that would be investigated in any future research.
Cuts Ice Limited	Comments form	Q1		<p>1. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why.</p> <p>The recommendations encouraging practitioners to explore the use of e-cigarettes will undoubtedly work towards improving perceptions of the devices as cessation tools and lead to more successful quits. However,</p>	Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned. The committee agreed that e-cigarettes are one of many tools to help individuals with quit attempts and the sustaining of non-smoking and non-tobacco use behaviour. However, the authorisation of new devices for prescription is beyond the remit of this

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				<p>the greatest challenge to implementing this guidance effectively will lie in the availability of e-cigarettes. The lack of a medically approved device on prescription is the greatest barrier. Without the option for practitioners to issue prescriptions for e-cigarettes in the presence of the potential quitter, a valuable point of intervention may be lost. The individual may conclude that sourcing their own device is too arduous or costly and consequently lose motivation to make a quit attempt with the most effective cessation tool.</p> <p>2. Would implementation of any of the draft recommendations have significant cost implications? We do not believe there would be significant cost implications to the recommendations that we concern ourselves with.</p> <p>3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)</p> <p>In order to overcome the challenge outlined in our answer to Q1, the relevant organisations must be prepared to approach solutions</p>	<p>guideline. The guideline highlights on p.2 that this guideline may be relevant for manufacturers and retailers of nicotine-containing e-cigarettes. Recommendation 1.11.4, 1.12.1, 1.12.4 - 5, 1.12.13 - 17, highlight the provision of advice regarding the use of e-cigarettes as a tool to aid quit attempts and sustaining non-smoking behaviour. The committee recognised the need for evidence about what factors may influence use of e-cigarettes and have made research recommendations relating to any possible impacts of amount of nicotine, frequency of use and flavourings.</p>

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				<p>dynamically. We believe that the following will be necessary:</p> <ul style="list-style-type: none"> - Greater collaboration between NICE, the MHRA and the Department for Health in creating a licensing process that is likely to result in an approved device that remains effective, safe and can be demonstrated feasibly. Supporting or funding baseline research that would be submitted in common to the licensing process and encouraging alterations to the licensing process will be necessary to achieve this. We would be keen to discuss this issue further through the contact details attached to this consultation. - Greater collaboration between practitioners, Stop Smoking Services, and the independent vaping industry. While the licensing process retains its significant barriers, it will be necessary for the relevant bodies to engage with independent (free from tobacco control or investment) companies. This could include bespoke deals for clients using local Stop Smoking Services or the provision of devices/e-liquid for trials or cessation research. We would be keen to discuss this issue further through the 	

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				<p>contact details attached to this consultation.</p> <p>4. The recommendations in this guideline were largely developed before the coronavirus pandemic. Please tell us if there are any particular issues relating to COVID-19 that we should take into account when finalising the guideline for publication.</p> <p>We do not believe that there are any particular issues relating to COVID-19 that are relevant to the sections we have concerned ourselves with.</p>	
Cuts Ice Limited	Guideline	072 - 075	All	We agree with desirability of more research. To ensure that the guideline's can realise their full potential, the guidelines should also issue recommendations for baseline research that could be used commonly as part of the medical licensing process, through discussions with the MHRA.	Thank you for your comment. It is not completely clear what you comment is referring to. Medical licensing is outside of NICE's remit. The research recommendations are based on the gaps in the evidence identified by the committee and therefore relate to the areas of the evidence which have been reviewed.
Cuts Ice Limited	Guideline	General		Where we have not commented on the areas pertaining to e-cigarettes this indicates agreement.	Thank you for your comment.
Cuts Ice Limited	Guideline	023	005	Practitioners are hindered in their ability to carry out the recommendation (1.12.1) to ensure e-cigarettes are accessible to adults	Thank you for your comment. E-cigarettes are one option recommended be accessible to adults amongst other options which

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				who smoke by the lack of a medically licensed device. While it would not be appropriate for NICE to issue guidance to the MHRA in this document, we seek reassurance that bilateral discussions between the organisations are taking place to ensure that the full benefits of the recommendation can be realised by making a licensed device available.	include medically licensed products, behavioural support, and brief advice. NICE does not engage with the MRHA regarding licensing decisions. NICE guidelines are developed by its Public Health Advisory Committee (PHAC) based on systematic reviews of the evidence and expert testimony. People have the right to be able to make informed decisions about their care. Our guidance should be considered when making decisions with them.
Cuts Ice Limited	Guideline	025	021 - 024	We believe that these are sensible sources of information about the safety of e-cigarettes.	Thank you for your comment
Cuts Ice Limited	Guideline	026	007 - 010	Rec 1.12.15 – The contents of this recommendation run the risk of creating a sense of failure if the user does not reduce the nicotine content of their e-cigarette to 0. This could lead to users reducing their nicotine content before they are ready and risk taking up cigarettes to achieve the desired strength again. The National Centre for Smoking Cessation and Training (https://elearning.ncsct.co.uk/e_cigarettes-stage_6) highlights the importance of achieving the sufficient dosage of nicotine. Conflating the issues of tobacco cessation and nicotine elimination risks confusing potential quitters and achieving neither outcome.	Thank you for your comment. The rationale and impact section of the guideline outline the Public Health Advisory Committees discussion regarding this recommendation. The committee used their knowledge and experience to supplement the very limited and uncertain evidence about harms. The committee agreed that with the limited data on effects of longer-term use, people should only use e-cigarettes for as long as they help prevent them going back to smoking. The committee discussed that it is more likely that people will not get enough nicotine to help them stop smoking, than get too much. They agreed that not getting enough nicotine is likely to increase the risk that the person will

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				Discussions with potential quitters should be on tobacco cessation solely.	return to smoking, so they recommended that people should be encouraged to use as much as they need (1.12.17) and told how to use the products effectively (1.12.14)
Cuts Ice Limited	Guideline	031	014 - 016	Rec 1.14.18: We do not oppose this recommendation but would request that NICE submit the relevant evidence to local consultations on indoor or outdoor smoking or vaping policies.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Cuts Ice Limited	Guideline	078	027 - 029	We disagree with the Committee's view that vaping provides similar efficacy to Nicotine Replacement Therapy. The long-awaited randomised control trial by Hayek, et al (https://www.nejm.org/doi/full/10.1056/NEJMoa1808779) confirmed that vaping products were twice as effective at helping smokers switch when compared to NRT products.	Thank you. The pairwise meta-analysis found a pooled risk ratio of 1.47 (1.25 – 1.72) for nicotine e-cigs vs single NRT for abstinence at 3 months. The network meta-analysis uses the effectiveness data and NMA models from Thomas' (2020) review as well as results of NICE-conducted rerun searches. This NMA (based on 192 studies) showed no significant effect of e-cigarettes compared to NRT (RR of 1.23 [CrI: 0.73, 1.95]) or long + short NRT (RR: 0.84 [CrI 0.48, 1.40]). The discrepancy between pairwise and NMA effect estimates is likely to be due to the modifying effect of indirect treatment estimates within the network. Consistency checking did not identify any concerns with the model that was used for the NMA and the committee focussed their discussion on the results of this NMA.

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East of England Priorities Advisory Committee	Guideline	General	General	Given the overall lack evidence on clinical and cost effectiveness and long term data on safety, we are concerned about the proposal to allow future prescribing of e-cigarettes if a licensed medicinal product becomes available particularly as these licensed products could have a higher nicotine content than currently specified and allowable under the UK Tobacco and Related Products Regulations 2016. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/962221/Vaping_in_England_evidence_update_February_2021.pdf and Licensing procedure for electronic cigarettes as medicines - GOV.UK (www.gov.uk) . As with all medicines and medical devices, these products would need to be assessed for clinical and cost effectiveness before they are commissioned and prescribing is permitted.	Thank you. The future medicinal licensing of e-cigarettes is for the MHRA and the decision about how these would need to be evaluated for that purpose would be theirs. If a manufacturer applied for a licence for a nicotine containing e-cigarette then the MHRA would need to authorise and license it as a medicine. As part of this process they would be assessed for clinical effectiveness and safety. Any products so licensed would fall under these recommendations.
East of England Priorities Advisory Committee	Guideline	022	024	What does 'accessible' mean? Clarity is needed on what is meant by 'Ensure the following are <i>accessible</i> to adults who smoke' with respect to unlicensed e-cigarettes.	Thank you for your comment. The committee was aware that local areas have very different commissioning arrangements for smoking cessation and agree that the most important thing was ensure that people had access to the range of interventions. The recommendation begins 'Ensure' and is therefore a strong recommendation.
East of England	Guideline	022	028	'Ensure medicinally licensed products are accessible'. Should an e-cigarette product be	Thank you. Nicotine containing e-cigarettes that applied for a licence would be assessed

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Priorities Advisory Committee				licensed in the future, its clinical and cost effectiveness would need to be evaluated before it was commissioned, and prescribing was permitted.	for clinical effectiveness and safety by the MHRA as part of the licensing process. At that point, NICE would consider reassessing the cost-effectiveness of the product.
East of England Priorities Advisory Committee	Guideline	023	005	The guideline suggests making e-cigarettes 'accessible' as a stopping smoking intervention. As there are currently no licensed e-cigarettes so they cannot be prescribed, does this mean making unlicensed e-cigarettes available free of charge from smoking cessation service as part of a quit attempt? If yes, how will this be funded?	Thank you for your comment. The committee was aware that local areas have very different commissioning arrangements for smoking cessation and agree that the most important thing was to ensure that people had access to the range of interventions.
East of England Priorities Advisory Committee	Guideline	026	001	The guideline states that there is not enough evidence to know whether there are long-term harms from e-cigarette use. We are concerned about the proposal to allow future prescribing of a medicinal product for which we have inadequate long term safety data, particularly as these licensed products could have a higher nicotine content than currently specified under the UK Tobacco and Related Products Regulations 2016. ; https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/962221/Vaping_in_England_evidence_update_February_2021.pdf and Licensing procedure for electronic cigarettes as medicines - GOV.UK (www.gov.uk).	Thank you for your comment. The guideline does not advocate that e-cigarettes are prescribed. The committee has recommended that nicotine containing e-cigarettes are one of a number of options to be made accessible to adults who smoke. As part of their discussions, they considered the potential long-term effects of using these products. The rationale and impact section relating to this recommendation outlines the issues the committee considered. These include the following: The extensive harms of smoking are well known, and the committee agreed it is unlikely that e-cigarettes could cause similar levels of harm

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					<p>There was a small amount of evidence about short-term adverse events of e-cigarettes that did not show that they caused any more adverse events than NRT, e-cigarettes without nicotine or no treatment. Experts from the MHRA described to the committee the monitoring process for both short- and long-term harms of using e-cigarettes, and that as of March 2020 no major concerns had been identified. Monitoring is ongoing and the evidence may change in the future. At this time the committee was unaware of any new evidence to change this.</p> <p>The committee agreed that with the limited data on effects of longer-term use, people should only use e-cigarettes for as long as they help prevent them going back to smoking</p> <p>E-cigarettes are relatively new devices, and it is important to understand whether they cause any health harms or benefits aside from their potential to reduce smoking-related harm (see research recommendation 1). If a nicotine containing e-cigarette were to become licensed, its effectiveness and safety would have been thoroughly assessed by the MHRA before the device became available.</p>

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East of England Priorities Advisory Committee	Guideline	032	009	This section states: 'encourage the use of medicinally licensed nicotine-containing products to help them abstain and, if possible, prescribe them'. Should an e-cigarette product be licensed in the future, its clinical and cost effectiveness would need to be evaluated before it was commissioned and prescribing was permitted.	Thank you. The future medicinal licensing of nicotine containing e-cigarettes is a task for the MHRA.. In order to license a product it would have to be assessed for clinical effectiveness as part of that process. At that point NICE would consider whether to assess the cost-effectiveness.
East of England Priorities Advisory Committee	Guideline	036	015	This section states: 'If possible, supply or prescribe medicinally licensed nicotine-containing products'. Should an e-cigarette product be licensed in the future, its clinical and cost effectiveness would need to be evaluated before it was commissioned, and prescribing was permitted.	Thank you. The future medicinal licensing of nicotine containing e-cigarettes is a task for the MHRA.. If the MHRA were to authorise the use of e-cigarettes and license them as a medicine for stopping smoking they would be assessed for clinical effectiveness as part of that process. At that point NICE would consider whether to assess the cost-effectiveness.
Faculty of Dental Surgery	Guideline	017	010	1.9.3: We would recommend making information on local stop-smoking support easily available to parents in addition to staff and students	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Faculty of Dental Surgery	Guideline	027	010	1.13: In addition to cancer and other ill effects of tobacco, in a primary dental setting, smoking increases complications following minor oral surgical procedures like dental extractions. A recommendation could be made to have a designated member of health care professional	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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				in the dental practice trained in stop-smoking counselling. This could also be an designated external health care professional in a local primary care. Such information should be easily available to staff and patients seeking dental treatment. Additionally, dentists should be actively encouraged to prescribe nicotine replacement therapy	
Faculty of Dental Surgery	Guideline	031	008	1.14.16: We are unaware of any human clinical trials about the effect of NRT on microvascular reconstruction and hence this recommendation should be omitted. Much of the evidence comes from unstimulated animal trials which have not be demonstrated in clinical and surgical practice	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website. We have passed your comment to the NICE surveillance team who will investigate further.
Faculty of Dental Surgery	Guideline	059	010	1.22.14: Whilst it is recommended to sell NRT in hospital shops, sale of ecigarettes in hospital shops could perhaps lead to poor public perception and should be discouraged.	Thank you for your comment. The Public Health Advisory Committee (PHAC) felt that the availability of nicotine containing e-cigarettes in hospitals would help stop smoking and to support temporary abstinence for patients, staff and visitors because hospital grounds are covered by smokefree legislation. This is outlined in the rationale and impact section of the guideline.
Fresh and Balance	Guideline	General	General	The guidelines, quite rightly, make a range of recommendations for research (see page 72-76). Yet there is only one acknowledgement of	Thank you for your comment. The research recommendations developed by PHAC seek to address the gaps in the evidence identified

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				<p>the need to take into account the outcomes of any such research, in section 1.9.2 bullet 2 which recommends "Use the best available evidence of effectiveness, such as Cochrane reviews".</p> <p>To our knowledge some, if not all, of the research recommendations are already being taken forward. For example, NIHR has funded 'Helping Pregnant Smokers Quit: A Multi-Centre RCT of Electronic Cigarette and Nicotine Patches', although unfortunately the research may not be available before the guidelines are published so is unlikely to be able to be taken into account during the consultation. NIHR is also funding research on smoking cessation in underserved groups such as prisoners and the homeless.</p> <p>As the evidence continues to develop and evolve, it is important that in the overview section of the guidelines there is a generic recommendation that research outcomes are taken into account. We suggest something along the lines, "When developing and implementing policies to prevent uptake, promote quitting and treat dependence it is essential to use the best available evidence of effectiveness, such as Cochrane reviews".</p>	<p>during the guideline development process with the hope of stimulating research in these areas for consideration when this guideline or aspects of this guideline are considered for update.</p> <p>NICE routinely checks that published guidelines are current, accurate and up to date via our surveillance function which explores if there is any new evidence to contradict, reinforce or clarify guideline recommendations. Surveillance also identifies new interventions that may need to be considered within a guideline and explores changes in context that may mean modifications are needed, for example, changes in policy, infrastructure, legislation or costs. A proactive approach is taken that includes reacting to events at any time after guideline publication (for example, publication of a key study) and a standard check every 5 years.</p>

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Fresh and Balance	Guideline	General	General	<p>Financial incentives for quitting smoking are not highlighted as an effective intervention in the general population. They should be. There is high certainty evidence of their effectiveness in the general population of people who smoke (as well as in pregnancy, where they are currently highlighted).^{1 2} A number of North East localities have now used such schemes adding additional value to maternal smoking approaches.</p> <p>¹ Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD004307</p> <p>² Hartmann-Boyce J, Livingstone-Banks J, Ordóñez-Mena JM, Fanshawe TR, Lindson N, Freeman SC, Sutton AJ, Theodoulou A, Aveyard P. Behavioural interventions for smoking cessation: an overview and network meta-analysis. Cochrane Database of Systematic Reviews 2021, Issue 1. Art. No.: CD013229</p>	<p>Thank you for your comment. Incentives were only considered in pregnant women. Incentives for other populations is outside the scope of this update. Please see the scope document on the NICE website.</p>
Fresh and Balance	Guideline	046 - 047	General	<p>3 and 4ppm CO levels are both used in this section (p46 line 15 says 4ppm and p47 line 9 says 3ppm). The Smoking in Pregnancy Challenge Group recommends that women with a reading of 4ppm or above should be referred for smoking cessation support.</p>	<p>The different carbon monoxide levels refer to different groups of pregnant women: smokers and non-smokers and to different actions. The reference to 4 ppm in recommendation 1.18.2 is in the context of the provision of an opt-out referral to receive stop-smoking</p>

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				<p>Evidence suggests that 4ppm is the optimal cut-off for correctly identifying pregnant women who smoke and minimising the number of false positives.^{10 11}</p> <p>¹⁰ Bailey BA. Using expired air carbon monoxide to determine smoking status during pregnancy: preliminary identification of an appropriately sensitive and specific cut-point. <i>Addictive behaviors</i>. 2013 Oct 1;38(10):2547-50.</p> <p>¹¹ Bauld L, Hackshaw L, Ferguson J, Coleman T, Taylor G, Salway R. Implementation of routine biochemical validation and an 'opt out' referral pathway for smoking cessation in pregnancy. <i>Addiction</i>. 2012 Dec;107:53- 60.</p>	<p>support for pregnant women. The reference to 3 ppm in recommendation 1.18.4 refers to women who do not smoke and to provide help to identify the source of the carbon monoxide level of 3 ppm.</p>
Fresh and Balance	Guideline	008	General	<p>We understand that previous guidelines have not been reviewed and simply rolled over into this document. We question the missed opportunity this has presented particularly in relation to these guidelines:</p> <p>1.1.1 Develop national, regional or local mass-media campaigns to prevent the uptake of smoking among young people under 18. Work in partnership with: the NHS, national, regional and local government and non governmental organisations, children and young people, media</p>	<p>Thank you for your comments. This guideline updates and replaces several of NICE's guidelines (PH5, PH23, PH26, PH39, PH45, PH48, NG92). The Public Health Advisory Committee (PHAC) drew on their expertise and considered the recommendations to see if they should be carried forward, deleted, or amended for clarification. The evidence for these recommendations was not reviewed - Please see the scope document on the NICE website and therefore the committee had no rationale for deleting them.</p>

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				<p>professionals, healthcare professionals, public relations agencies and local anti-tobacco activists. [2008 PH14 recommendation 1]-</p> <p>Our comment: There is scant evidence around running local mass media campaigns. The definition of mass media would include TV and it is not cost effective to run such campaigns at a local level.</p>	
Fresh and Balance	Guideline	010	General	<p>We understand that previous guidelines have not been reviewed and simply rolled over into this document. We question the missed opportunity this has presented particularly in relation to these guidelines:</p> <p>1.3.1 Provide retailers with training and guidance on how to avoid illegal sales. This includes encouraging them to: • ask for proof of age from anyone who appears younger than 18 who attempts to buy cigarettes, and get it verified (examples of proof include a passport or driving licence, or cards bearing the nationally-accredited 'PASS' hologram).</p> <p>Our comment: This could have been reviewed to include evidence around challenge 25 which</p>	<p>Thank you for your comment. The Public health Advisory Committee (PHAC) Have considered your comments and have decided not to change the recommendation. PHAC highlighted that Review C and D considered the evidence on proxy purchasing and based on the evidence, expert testimony and the contributions of co-optee members to the committee, the PHAC made the decision to carry forward the previous recommendations. Challenge 25 is specific to alcohol and the committee did not see any evidence to support its use in tobacco control. They were unclear about the provenance of Challenge 25, which is not a government policy.</p>

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				is now best practice approach around age of sale restricted products.	
Fresh and Balance	Guideline	013	005 - 007	<p>1.6.4 – While it is important to avoid inadvertently making e-cigarettes desirable to young people, it is just as important to avoid inadvertently reinforcing misperceptions that e-cigarettes are as harmful as smoking. Findings from the annual Smokefree GB survey commissioned by ASH show that the perception among 11–18-year-olds that cigarettes and e-cigarettes are equally harmful has increased since 2013. In 2021, only 43.8% of 11–18-year-olds knew that e-cigarettes were less harmful than cigarettes.³ Similarly, among adults, around a third (32%) believed e-cigarettes were more or equally as harmful as cigarettes in 2021, compared to 42% who thought they were less harmful.⁴ This is relevant because adults will be responsible for giving children advice about e-cigarettes.</p> <p>An additional sentence should be added to recommendation 1.6.4 consistent with the wording on page 26 lines 1-4, that “However, it is also important to make clear that although there is not enough evidence to know whether there are long-term harms from e-cigarettes, they are likely to be substantially less harmful than smoking.”</p>	Thank you for your comment. This is stated clearly elsewhere in the guideline and the committee were clear that they did not want to say anything that might promote the use of e-cigarettes in under 18s.

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				³ ASH. Use of e-cigarettes among young people in Great Britain. 2021 ⁴ ASH. Use of e-cigarettes (vapes) among adults in Great Britain. 2021	
Fresh and Balance	Guideline	017	001 - 003	We welcome the recommendation to involve community pharmacies in local campaigns and maintain links with other professional groups such as dentists, fire services and voluntary groups. We would like to see welfare and benefits officers/advisors included in this list because they have a unique opportunity to screen for smoking, provide very brief advice and signpost to stop smoking services as part of their interventions to help people manage their financial situation.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Fresh and Balance	Guideline	028	010 - 013	1.14.1 – We would like to see this section include a bullet point to highlight the mental health benefits of quitting smoking. A recent Cochrane review found that smokers who stop have better mental health than those who continue to smoke and that the benefits to mental health were estimated to be equivalent to anti-depressants. ⁵ Quitting can also help reduce the severity of psychotic symptoms and in some cases, contribute to reductions in prescribed medications and shorter hospital stays. ⁶ This has been reinforced here in the North East by consultant psychiatrist Dr Eilish	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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				<p>Gilvarry in this film: https://www.youtube.com/watch?v=PQsqjEO5NNk 5 Taylor GM, Lindson N, Farley A, Leinberger-Jabari A, Sawyer K, te Water Naudé R, Theodoulou A, King N, Burke C, Aveyard P. Smoking cessation for improving mental health. Cochrane Database of Systematic Reviews. 2021(3). 6 Taylor, D.M., Barnes, T.R.E., Young, A.H., (2021) The Maudsley Prescribing Guidelines in Psychiatry, 14th Edition, ISBN: 978-1-119-77223-1 July 2021 Wiley-Blackwell 976 Pages</p>	
Fresh and Balance	Guideline	029	011	<p>We are pleased to see the recommendation that every smoker will be offered behavioural support in acute, maternity and mental health care settings but we are disappointed that this offer is only recommended “if the person agrees”. We recommend that behavioural support is provided on an opt-out basis – as described in the Ottawa Model and in the RCPs Hiding in Plain Sight.⁷ The Ottawa model is also recommended in the NHS Long Term Plan.⁸ It is the approach that is being taken across the North East and North Cumbria ICS.</p> <p>It is often the case that at the point of screening for smoking and provision of Very</p>	<p>Thank you for your comment. The evidence on opt-out referral schemes was in scope for pregnant women only. The committee has made recommendations on opt out referral schemes for pregnant women (see Recommendations 1.18.2 and 1.18.3). Opt-out referral schemes were not within scope for other population groups. Please see the scope document on the NICE website.</p>

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				<p>Brief Advice at admission, people coming into mental health care settings are usually distressed and unlikely to be able to weigh up this decision. We recommend a more proactive approach which ensures those that need specialist support have access to it using an opt-out approach.</p> <p>7 Royal College of Physicians. Hiding in plain sight: Treating tobacco dependency in the NHS. 2018</p> <p>8 NHS England. The NHS Long Term Plan: Smoking. January 2019</p>	
Fresh and Balance	Guideline	030	014	<p>We do not believe that the recommendation to provide support to smokers within 24 hours of admission goes far enough to ensure patients comfort or ease their distress. We would welcome a recommendation to provide support around tobacco dependency within 30 minutes of arrival to hospital. For example, SLaM NHS Foundation Trust provide 'Tea and NRT' to smokers on arrival to hospital as an over the counter medication. This avoids the delays caused by getting a prescriber and is hugely beneficial since the half-life of nicotine is approximately 2 hours and longer delays will result in unnecessary discomfort.</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.</p>
Fresh and Balance	Guideline	032	004 - 009	<p>1.14.20 - We welcome the recommendation to tell smokers about the different types of medicinally licensed nicotine containing</p>	<p>Thank you for your comment. The evidence on the use of nicotine containing e-cigarettes to support temporary abstinence was not</p>

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				<p>products, how to use them and if possible, prescribe them. However, we are disappointed that e-cigarettes are not also recommended as a vital intervention for smokers who are in a situation where they need to temporarily abstain. If this guideline only recommends the use of NRT to support tobacco abstinence, this represents an extremely challenging scenario for trusts that currently offer e-cigarettes to service users and risks further disadvantaging people with mental health ill health, who will be left behind. We would worry that failure to include e-cigarettes as a safe, valid and effective way to support temporary abstinence will enable some service providers to opt out of and we will find ourselves in a situation where the teachable moment to support stopping smoking and switching to an e-cigarette is lost.</p> <p>SLaM NHS Foundation Trust provide mental health care services from 4 large London based hospitals (50 wards). Typically, about half of the adult smokers admitted to hospital are current smokers, it is rare to find a smoker at the point of admission who decides to make a quit attempt. For the overwhelming majority (95%) their decision at the point of admission is to use whatever support is available to temporarily abstain. Currently, the preferred</p>	<p>reviewed as part of this guideline update and therefore recommendations have not been made in this area.</p> <p>Regarding differing needs between people admitted to acute hospital settings and to mental health settings, these recommendations are greyed out as they are outside the scope for this update. Please see the scope document on the NICE website.</p>

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				<p>option to support temporary abstinence is an e-cigarette, because smokers feel that this more closely matches the experience of smoking compared with using NRT products. SLAM have used e-cigarettes in this way since 2012 and typically provide around 400 free e-cigarette starter packs each month. In about 30% of cases the smokers find that the provision of a free e-cigarette starter pack, given with the intention to support temporary abstinence on admission is so effective that they decide to continue using it and do not return to smoking.</p> <p>In 2019 ASH conducted a survey of mental health trusts which found that 42% of mental health trusts in England provide free e-cigarettes to adult smokers on admission to hospital to support temporary abstinence, and as such we believe there is ample evidence to support this consensus practice.⁹</p> <p>Here in the North East, both mental health trusts (Cumbria, Northumberland, Tyne and Wear and Tees, Esk Wear Valley) provide free e-cigarettes.</p> <p>More generally in this section of the guidance, we think a distinction should be made between</p>	

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				<p>the needs of people admitted to an acute hospital setting and people admitted to a mental health setting. The unique needs of people in mental health crisis is completely different and deserves a more bespoke response.</p> <p>9 ASH. Progress towards smokefree mental health services. Findings from a survey of mental health trusts in England. 2019</p>	
Fresh and Balance	Guideline	051	General	<p>1.20.12</p> <p>We are concerned that this guideline doesn't link to any guidance or information to support the implementation of incentive schemes. This could include case studies of existing schemes, key competencies for staff or dedicated training. The Smoking in Pregnancy Challenge Group has produced a briefing to support the commissioning and delivery of incentive schemes.16 The briefing summarises the evidence from previous incentive schemes, sets out lessons for practice and will be updated in line with emerging evidence. The guidance should link to the Challenge Group briefing to ensure that commissioners have access to practice-focused information to support the delivery of incentive schemes. We also recommend that the guidance should link to case studies and guidance from previous incentive schemes. The North East has</p>	<p>Thank you. The recommendations are based on the evidence of effectiveness, and the implementation of the recommendations is primarily a local commissioning decision.</p>

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				positively used incentives schemes in at least three of the 12 localities. 16 Smoking in Pregnancy Challenge Group. Evidence into Practice: Supporting smokefree pregnancies through incentive schemesv. 2019	
Fresh and Balance	Guideline	051	015 - 016	1.20.12 – bullet 3 – This sentence should use the word “incentive” instead of “reward”. Incentive payments are not rewards; they are incentives to change behaviour and the terminology used should reflect that. This is particularly important given the sensitivity in the media around the use of financial incentives in pregnancy.	Thank you for your comment. PHAC considered your comment and the wording has been amended to reflect your comment.
Fresh and Balance	Guideline	051	015 - 016	1.20.12 – bullet 3 – The guideline should recommend that the offer of incentives be extended into the postnatal period for a minimum of 3 months to prevent women relapsing to smoking. Evidence suggests nearly half of women who quit smoking during pregnancy relapse within 1-year post-partum.13 This harms the health of the mother and makes it more likely that children will be exposed to secondhand smoke in the home, leading to higher rates of sudden infant death (SIDS), lower respiratory tract infection, middle ear disease, asthma and many other diseases.14 Consequently, supporting women and their partners to stay smokefree after their	Thank you. The committee considered this. Please see the committee discussion section of evidence review J which says that “The committee discussed the duration of incentive provision and agreed that this should occur at least until the end of pregnancy (including pregnancies that do not progress), however that it wasn’t clear whether provision would be beneficial in the post-partum period “

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				<p>baby is born is key to helping them maintain a smokefree home and protecting them and their children from harmful tobacco smoke. Evidence from a 2019 Cochrane review shows that providing incentives into the postnatal period is effective for supporting women to stay smokefree. Additionally, Greater Manchester Health and Social Care Partnership are currently awaiting publication of a RCT looking at the provision of incentives for 1-year post-partum.</p> <p>13 Jones, M., Lewis, S., Parrott, S., Wormall, S., & Coleman, T. Re-starting smoking in the postpartum period after receiving a smoking cessation intervention: A systematic review. <i>Addiction</i>, 2016, 111(6), 981–990</p> <p>14 Royal College of Physicians. <i>Passive smoking and children. A report by the Tobacco Advisory Group</i>. London: RCP, 2010</p> <p>1 Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation (Review). <i>Cochrane Database of Systematic Reviews</i>. 2019. Issue 7. Art. No.: CD004307</p>	
Fresh and Balance	Guideline	051	005	<p>Research is underway on the effectiveness of e-cigarettes as a quitting aid for pregnant smokers and the impact of their use on birth outcomes, but will not be published in time to be taken into account in this guidance.</p>	<p>Thank you. The committee did not see any evidence on the effectiveness of e-cigarettes during pregnancy and therefore is unable to make a recommendation in this area.</p>

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				<p>Despite the lack of evidence specific to pregnancy at the current time, advice on the use of e-cigarettes in pregnancy should not be excluded from the guidance. E-cigarettes are already being used by some women as an aid to quit smoking during pregnancy, and midwifery and stop smoking practitioners are being asked for advice on their use. If they are unable to provide any advice, there is an increased risk that women may revert to smoking, which is a leading modifiable risk factor for many poor birth outcomes. That is why the Smoking in Pregnancy Challenge Group, an alliance of medical organisations such as the RCOG, RCM and RCGP, working together with charities such as the Lullaby Trust, Sands and Tommys and also with Fresh has produced peer reviewed resources for healthcare professionals and pregnant women on use of e-cigarettes.¹² These resources are widely used and are regularly updated in line with the evolving evidence base.</p> <p>Therefore, after the section on 'Nicotine replacement therapy and other pharmacological support' (pages 50 line 8 to 51 line 5) a section should be added headed 'Use of e-cigarettes in pregnancy'. This should state that "If a pregnant woman has chosen to use an e-cigarette to quit or to reduce the</p>	

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				<p>number of cigarettes that she smokes, she should not be discouraged from doing so, as any risks to the foetus is likely to be extremely small compared to continued smoking". Then go on to say "It is important to give pregnant smokers clear, consistent and up-to-date information about nicotine containing e-cigarettes (for example see the Smoking in Pregnancy Challenge Group resources on e-cigarettes). See also the section in the guideline on advice on nicotine-containing e-cigarettes."</p> <p>12 Smoking in Pregnancy Challenge Group. Webpage: Using e-cigarettes before, during and after pregnancy.</p>	
Fresh and Balance	Guideline	052	006	<p>We are concerned that the guideline 'Enabling all pregnant women to access stop-smoking support' does not explicitly recommend that stop smoking materials and support be provided in languages other than English. Although the NICE guideline on patient experience in adult NHS services recommends that healthcare services are accessible for non-English speakers, given high rates of smoking among some migrant communities, the guideline should explicitly highlight the need to provide stop smoking materials and advice in a range of languages.</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.</p>

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				<p>Migration Observatory analysis of the Annual Population Survey 2019, shows that women born in new EU accession countries, including Poland, Romania and Lithuania, have much higher rates of smoking than those born in the UK (22% compared to 13%).¹⁷ Among men, those who are foreign-born are more likely to smoke than UK-born men, and men born in new EU accession countries more than twice as likely to smoke as UK-born men (34% compared to 15%). To ensure that these communities are not underserved by stop smoking support, we believe that the list starting on page 52, line 11, should include a point saying "Ensure resources and advice for stopping smoking are available in a range of different languages, taking into account local demographics."</p> <p>¹⁷ The Migration Observatory. The health of migrants in the UK. August 2020</p>	
Fresh and Balance	Guideline	059	010 - 011	<p>Clarify statement "Include nicotine-containing products as options for sale in secondary settings (for example, in hospital shops.)" The guideline should specify whether this refers to NRT and/or e-cigarettes to avoid any confusion.</p>	<p>Thank you. Nicotine containing products is defined in the glossary section of the guideline. The definition of nicotine containing products has been amended to clarify that it includes nicotine containing e-cigarettes.</p>
Fresh and Balance	Guideline	062	General	<p>1.23 – [PH5] Smoking: workplace interventions - Recommendation 4: 'Ensure smoking cessation support and treatment is delivered</p>	<p>Thank you. Training is covered in recommendations 1.23.2 to 1.23.4. Additionally, 1.23.2 cross references to</p>

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				<p>only by staff who have received training that complies with the 'Standard for training in smoking cessation treatments' has been deleted. The reason given for deletion is that 'tailoring support and treatment is a general principle recommended in NICE's guideline on patient experience in adult NHS services.' We do not support this deletion.</p> <p>The National Training Standard was produced by the National Centre for Smoking Cessation and Training (NCSCT) on behalf of the Department of Health and includes all behaviour change techniques (BCTs) for which there is evidence of effectiveness. It does not prevent tailoring support and treatment as appropriate, therefore the rationale for deletion is not justified. Practitioners trained to deliver interventions according to the standard have been proven to be effective in adding significant value to quit attempts.¹⁸ Removal of the Training Standard is likely to lead to a return to the situation prior to the establishment of the NCSCT where people provided training based on opinion, rather than the evidence, for what effective training should contain. This recommendation should therefore be reinstated.</p>	<p>recommendations 1.13 which reference NCSCT training.</p>

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				<p>Related to this point, the National Training Standard is mentioned in 1.12 (in a rather non-specific manner) and again under Quitlines (1.12.20). However, section 1.23, line 12-26, 'Those who advise people to stop smoking' fails to include any mention of the Standard. While the subtitle may suggest this section is specific to those who identify smokers and prompt quit attempts (i.e. deliver VBA), there is nothing further in this section on training for those who deliver ongoing stop smoking support (i.e. behavioural support), as has been the case in previous versions of the document. At minimum this should be included for stop smoking services. The wording found in the 2018 NG92 recommendation on this subject served this purpose. The key being 1) stop smoking support is provided by trained staff and 2) that training be consistent with the National Training Standard. Given the level of depth the document goes into for maternity care and closed institutions, there should be at least the equivalent depth provided for all settings (stop smoking services, maternity care, closed institutions, primary care) who are delivering stop smoking support. This should consist of the National Training Standard as default, plus additional training for those</p>	

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				<p>working with specific population such as mental health and pregnancy.</p> <p>Overall, there is little said in the new NICE guidance on stop smoking services and stop smoking support delivered in other settings compared to previous guidance documents. There is also a level of specificity in some sections that is not consistently applied in the document (e.g. lots of detail in maternity care section and smokeless tobacco and only a few bullets on other important areas of practice). This risks making the document less clear and less user friendly than previous NICE guidance.</p> <p>18 Brose L, West R, Michie S, McEwen A. Changes in success rates of smoking cessation treatment associated with take up of a national evidence-based training programme. Preventive Medicine 2014;69C:1-4</p>	
Fresh and Balance	Guideline	075	007 - 013	<p>We suggest considering the addition of two further points regarding recommendations for further research into relapse prevention. Firstly, we see a clear need for more research on varenicline for relapse prevention, given the committee acknowledges its likelihood of increasing long-term abstinence and supporting Cochrane evidence.19 Secondly,</p>	<p>Thank you. Research recommendations in NICE guidelines are specifically to address gaps in the research that the committee considered while making their recommendations. They do not address general gaps in the evidence.</p>

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				<p>we suggest it would be a good idea to recommend more trials looking at relapse prevention interventions delivered to people who have been abstinent for 4+ weeks, as there is little evidence in this group. The committee's emphasis on the importance and paucity of this kind of longer-term evidence is reflected in evidence review N: "For this reason, the committee focussed on evidence where relapse was clearly additional to cessation and delivered at a later point (this included behavioural interventions for assisted abstainers [Figure 11, GRADE profile 5], and pharmacotherapy for assisted abstainers [Figure 13-16, GRADE profile 6]). There is a paucity of evidence on this type of longer term relapse prevention." (p.66 of evidence review N)</p> <p>19 Livingstone-Banks J, Norris E, Hartmann-Boyce J, West R, Jarvis M, Chubb E, Hajek P. Relapse prevention interventions for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 10. Art. No.: CD003999</p>	
Fresh and Balance	Guideline	078	027 - 029	<p>This states that nicotine e-cigarettes are of similar effectiveness to NRT. There is moderate certainty evidence that they are more effective than NRT (including in studies where participants are offered combined short</p>	<p>Thank you. The pairwise meta-analysis found a pooled risk ratio of 1.47 (1.25 – 1.72) for nicotine e-cigs vs single NRT for abstinence at 3 months. The network meta-analysis uses the effectiveness data and NMA models from</p>

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				and long-acting NRT) and this should be made clear. ²⁰ 20 Hartmann-Boyce J, McRobbie H, Butler AR, Lindson N, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Fanshawe TR, Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2021, Issue 4. Art. No.: CD010216	Thomas' (2020) review as well as results of NICE-conducted rerun searches. This NMA (based on 192 studies) showed no significant effect of e-cigarettes compared to NRT (RR of 1.23 [CrI: 0.73, 1.95]) or long + short NRT (RR: 0.84 [CrI 0.48, 1.40]). The discrepancy between pairwise and NMA effect estimates is likely to be due to the modifying effect of indirect treatment estimates within the network. Consistency checking did not identify any concerns with the model that was used for the NMA and the committee focussed their discussion on the results of this NMA.
Fresh and Balance	Guideline	079	008 - 013	This section states the committee had low confidence in the finding of no difference in adverse events in people using nicotine e-cigarettes compared to NRT, e-cigarettes without nicotine, and no treatment, because the studies were powered to investigate effectiveness and not adverse events. Though this is an issue for serious adverse events, where events are rare, for non-serious adverse events, which this section appears to refer to at first glance, this is not an issue of underpowering because non-serious adverse events are more common than cessation (a study powered to detect a difference in cessation would also be powered to detect a	Thank you. Details of the adverse events reported are contained in evidence review K and are adverse events rather than serious adverse events. The rationale and impact section describes the committees consideration of the recommendations and their view is consistent with the findings in the systematic review you reference.

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				difference in adverse events). If this section is on serious adverse events, it should be clarified that that is the case. If not, it should be reworded. The latest Cochrane review has moderate certainty evidence of no difference in rates of adverse events (non-serious) between nicotine and non-nicotine e-cigarettes ²¹ 21 Hartmann-Boyce J, McRobbie H, Butler AR, Lindson N, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Fanshawe TR, Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2021, Issue 4. Art. No.: CD010216	
Greater Manchester Health and Social Care Partnership	General	General	General	GMHSCP endorse the ASH response to this consultation	Thank you for your comments.
Greater Manchester Health and Social Care Partnership	Guideline	General	General	We welcome the guidance and the inclusion of everyone aged 12 and over, strengthening the continuous work within the school settings for both student and staff alike. Including additional support and updates for pregnant women, e-cigarettes and nicotine replacement therapies.	Thank you for your comments.
Greater Manchester Health and	Guideline	General	General	Whilst the guidance is important to support service develop and provide reassurance of best practice available, evidence continues to	Thank you for your comment. NICE routinely checks that published guidelines are current, accurate and up to date via our surveillance

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Social Care Partnership				advance and evolve, therefore it is important that within the guidelines there is a generic recommendation that research outcomes are considered.	function which explores if there is any new evidence to contradict, reinforce or clarify guideline recommendations. Surveillance also identifies new interventions that may need to be considered within a guideline and explores changes in context that may mean modifications are needed, for example, changes in policy, infrastructure, legislation or costs. A proactive approach is taken that includes reacting to events at any time after guideline publication (for example, publication of a key study).
Greater Manchester Health and Social Care Partnership	Guideline	General	General	There is a concern that the financial incentives for quitting smoking are not identified as an effective intervention within the general population. There is a level of evidence to support the effectiveness of the people which smoke as well as pregnant women which has been highlighted throughout.	Thank you for your comment. Incentives were only considered in pregnant women. Incentives for other populations is outside the scope of this update. Please see the scope document on the NICE website.
Greater Manchester Health and Social Care Partnership	Guideline	General	General	The draft guidance does not seem to outline what standard Stop Smoking support is without incentive scheme. It is support up to 12 weeks quit, NRT up to 12 weeks quit and that's it. The GM Incentive runs to 3 Months Post-Partum (3MPP) some only run to birth. This is key as evidence suggests women relapse in the third trimester.	Thank you for your comment. The committee did not see evidence as part of this update that enabled them to determine an appropriate length for stop smoking support. Evidence from new trials will be considered by the NICE surveillance team when they monitor the need for updating this guideline.

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				Evidence from a Cochrane review 2019, shows that providing incentives into the postnatal period is effective for supporting women to stay smoke free. In addition to this, we, the Greater Manchester Health and Social Care Partnership are currently awaiting publication of an RCT looking at provision of incentives for 1-year post-partum.	
Greater Manchester Health and Social Care Partnership	Guideline	General	General	<p>Incentives are not rewards so to change behaviour and reach a milestone we need to be careful about the terminology.</p> <p>Incentives should be given out at regulated intervals to ensure compliance remains with the quit attempt, identify those who relapse to ensure they are reverted back onto the high maternity risk pathway inc, scans to ensure the baby is observed for sign of foetal growth restriction and to also enable CO validating – we should not be taking self-reporting in pregnancy – no incentives should be given without CO validation as this is public funding.</p> <p>We endorse incentives in the post-partum period as a minimum for 3 months – to prevent relapse. Note that GMHSCP is awaiting the results for an RCT on post-partum incentives running up to 12 months being led by the University of Stirling.</p>	Thank you for your comment. The Public Health Advisory Committee (PHAC) has considered your comment and have changed the wording of the recommendation from rewards to incentives. Recommendation 1.20.12 highlights that incentives should be staggered until at least the end of pregnancy and are conditional on confirmation of abstinence validated by biochemical methods for example carbon monoxide test with a reading of less than 4 ppm.bv. This recommendation also outlines that women who have relapsed or where the pregnancy does not continue should not be excluded from continuing to take part in the scheme and try again. Recommendation 1.20.12 (bullet 3) specifies that incentives should be staggered until 'at least the end of pregnancy'.

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Greater Manchester Health and Social Care Partnership	Guideline	007	003 - 006	We feel this area would need to be reviewed as much of the PH guidance is from 2008 and therefore not necessarily meeting the needs of children, young people and young adults.	<p>Thank you for your comments. This guideline updates and replaces NICE's guidelines on:</p> <ul style="list-style-type: none"> smoking: workplace interventions (PH5, published April 2007) smoking: preventing uptake in children and young people (PH14, published July 2008) smoking prevention in schools (PH23, published 2010) smoking: stopping in pregnancy and after childbirth (PH26, published February 2010) smokeless tobacco: South Asian communities (PH39, published September 2012) smoking: harm reduction (PH45, published June 2013) smoking: acute, maternity and mental health services (PH48, published November 2013) stop-smoking interventions and services (NG92, published March 2018). <p>The areas you identify were reviewed as recommended by NICE's Surveillance Report but the recommendations were not updated due to a lack of evidence (see Evidence Reviews A and B, C and D, and E). NICE's surveillance team also identified several specific new areas for consideration in this guideline, and evidence was reviewed on preventing uptake of smoking, promoting</p>

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					quitting, treating tobacco dependence, and policy, strategy and commissioning.
Greater Manchester Health and Social Care Partnership	Guideline	007	001	Acknowledging that there are currently no nicotine-containing e-cigarettes licensed as a medicine and the availability of prescribed meds such as Champix are currently no longer readily available, is there now an opportunity to review the current position with regards to e-cigarettes being manufactured and licensed for the use of stop smoking?	Thank you for your comment. The review of nicotine-containing e-cigarettes UK licencing status as a medicine for stopping smoking is outside the scope of this guideline and outside NICE's remit. Please see the scope document on the NICE website
Greater Manchester Health and Social Care Partnership	Guideline	013	005 - 007	While it is important to avoid inadvertently making e-cigarettes desirable to young people, it is just as important to avoid inadvertently reinforcing misperceptions that e-cigarettes are as harmful as smoking. However, it is also important to make clear that although there is not currently enough evidence to know whether there are long-term harms from e-cigarettes, they are likely to be substantially less harmful than smoking.	Thank you for your comment. This is stated clearly elsewhere in the guideline and the committee were clear that they did not want to say anything that might promote the use of e-cigarettes in under 18s.
Greater Manchester Health and Social Care Partnership	Guideline	026	001 - 002	Opportunity to review the current position with regards to e-cigarettes and undertake further research into the long-term effects of use.	Thank you for your comment. Please see Research recommendation 1 which focuses on the short or long term health effects of e-cigarette use.
Greater Manchester Health and	Guideline	026	005 - 006	We agree with the comment as it would be an opportune moment if using e-cigarettes to quit using harmful tobacco. However, it is important to make clear that although there is not	Thank you for your comment. This point is addressed in the second bullet of recommendation 1.12.14

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Social Care Partnership				currently enough evidence to know whether there are long-term harms from e-cigarettes, they are likely to be substantially less harmful than smoking.	
Greater Manchester Health and Social Care Partnership	Guideline	029	003 - 005	<p>Encourage people who have been referred to elective surgery to stop smoking before their surgery, refer to local stop smoking support/service. For such cases this should be part of an opt-out process not an opt-in.</p> <p>This would be similar for patients who have poor mental health, there is evidence which supports the benefits of stop smoking, a recent Cochrane review cited smokers who had stopped smoking have better mental health than those who have continued to smoke. According to a Cochrane study, it can take just six weeks for quitting smoking to improve your mood and mental health. Reductions in anxiety and depression in those who quit smoking are found to be at least as effective as taking anti-depressants. The Cochrane study shows that quitting for at least six weeks may improve mental wellbeing, by reducing anxiety, depression and stress – compared to people who continued to smoke.</p>	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Greater Manchester Health and	Guideline	029	011 - 013	Similar to the last point raised, person agrees to receive behavioural support to stop smoking during their outpatients visit or inpatient stay,	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update.

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Social Care Partnership				we would suggest at this stage it should be an opt-out model, not opt-in. This would allow better access to patients through their discharge into local stop smoking support with a range of continued support and advice.	Please see the scope document on the NICE website.
Greater Manchester Health and Social Care Partnership	Guideline	046	010 - 013	We would concur with this recommendation as an example of good practice, as well as providing an Opt-out referral to receive stop smoking support.	Thank you for your comment.
Greater Manchester Health and Social Care Partnership	Guideline	050	015	Provide pregnant women clear and consistent information about NRT, however, should it not also include additional behavioural support programmes developed to support stop smoking? Despite a lack of evidence specific to pregnancy, advice on the use of e-cigarettes in addition to NRT should not be excluded from the guidance. E-cigarettes are already being used as an aid to quit smoking during pregnancy, midwifery and stop smoking advisers are being asked for advice on their use. The lack of advice may result in the pregnant women reverting back to smoking. If a pregnant woman chooses to engage with e-cigarettes she should 'not' be discouraged as any risk is likely to be less than if she continued to smoke cigarettes.	Thank you. Behavioural support is included in recommendation 1.20.6. The committee saw no evidence for the effectiveness of nicotine containing e-cigarettes during pregnancy and therefore was unable to recommend them.

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				As evidence continues to develop and evolve, it is important in the overview section of the guidelines there is recommendation that research outcomes are taken into account. For example, NHIR has funded 'Helping Pregnant Smokers Quit: A Multi-Centre RCT of Electronic Cigarette and Nicotine Patches'. However, it is my understanding that this research may not be available before the guidelines are published.	
Greater Manchester Health and Social Care Partnership	Guideline	051	015	Incentives are not rewards so to change behaviour and reach a milestone we need to consider the terminology. Keep the message consistent.	PHAC considered your comment and the wording has been amended to reflect your comment.
Greater Manchester Health and Social Care Partnership	Guideline	059	010 - 011	This statement needs to clarify whether this includes e-cigarettes as well as NRT	Thank you. Nicotine containing products is defined in the glossary section of the guideline. The definition of nicotine containing products has been amended to clarify that it includes nicotine containing e-cigarettes.
Haringey Council	Guideline	General	General	We felt that the guidelines were very comprehensive. With this level of extensive guidelines however, we did wonder about the resources that would be needed to fully implement all of the recommendations for practice.	Thank you for your comment. The committee considered the potential resource impact of the recommendations at every stage of development. Most of the recommendations in this guideline are pre-existing and therefore have no additional resource impact. The considerations of the resource impact of the new recommendations are discussed in

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					the rationale and impact sections of the guideline.
Haringey Council	Guideline	009	001	We felt that running a campaign for 3-5 years was a long time and would require dedicated resources to achieve this.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Haringey Council	Guideline	010	General	We felt that the term persistent offender in relation to counterfeit sales should be more clearly defined.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Haringey Council	Guideline	011	007	Schools would need examples of what activities they could deliver not to mention an understanding of any interventions that are evidence based to deliver this.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Haringey Council	Guideline	013	005	For schools to discuss e-cigarettes, they would need a briefing on this subject and the evidence available to understand why children and young people should be discouraged to use them.	Thank you for your comment. Recommendation 1.23.1 outlines that those with responsibility for improving the health and wellbeing of children, young people and young adults who attend school, work in partnership with those involved in smoking prevention and stop smoking activities to design, deliver, monitor and evaluate smoking prevention training and interventions. Partners include national and

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					local education agencies and training agencies amongst others who would provide the briefing you have suggested.
Haringey Council	Guideline	013	011	For teachers to be 'competent' in delivering interventions, they would need funded training.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Haringey Council	Guideline	014	004	Schools would again need to be provided examples of evidence-based peer-led interventions to enable them to deliver this. Again, this could be part of some training.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Haringey Council	Guideline	014	021	Pleased to see the inclusion of a harm reduction approach in the recommendation on promoting quitting.	Thank you for your comment
Haringey Council	Guideline	017	022	It is great to see the recommendation that staff should be given paid time off to attend smoking cessation. Would be good to have a list of benefits to employers of allowing this in order to encourage organisations to sign up to this.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Haringey Council	Guideline	020	005	Feel that instead of stating this applies to health and social care professionals that the word 'all' should be inserted. Otherwise, it is not clear that smokers should be asked about stopping smoking as a standard MECC/everyday conversation approach.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website. We have reviewed the wording and believe that the current wording is appropriate.

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Haringey Council	Guideline	022	007	Instead of acute, mental health and maternity settings, to normalise asking about smoking status, as above, should it not be across all settings.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Haringey Council	Guideline	023	005	Nice to see e-cigarettes now included following the Cochrane review.	Thank you for your comment
Haringey Council	Guideline	028	008	Would be good to specify which professional will give this information. For example, would it be the pre-operative clinic staff or the Practice Nurse?	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Haringey Council	Guideline	031	011	One week supply seems short, two weeks would be better to ensure that the person does not run out of medication/NRT and relapse.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Haringey Council	Guideline	039	024	Will additional resources be offered for cotinine testing? If not, this may be difficult to implement.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document
Haringey Council	Guideline	049	001	No mention of the need to make links with Health Visitors which would be important for post-partum women.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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Haringey Council	Guideline	049	015	Perhaps insisting on taking a urine sample would put pregnant woman off attending the service.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Haringey Council	Guideline	070	020	Could we add Shisha to the list please as it isn't clear if this is part of these products.	Thank you. Shisha is not smokeless tobacco.
Haringey Council	Guideline	071	005	We are fully supportive of the recommendations for research, especially in relation to the health impact of e-cigarette use.	Thank you for your comment
Haringey Council	Guideline	076	001	We liked the rationale and potential impact on practice section. We felt this was useful for making the case for change in local areas	Thank you for your comment.
Independent British Vape Trade Association (IBVTA)	Guideline	General	General	The IBVTA applauds the thorough and systematic review that has enabled this guideline to include nicotine-containing e-cigarettes. We also understand the reasons for limiting areas in which interventions involving e-cigarettes are encouraged, as the availability or quality of peer-reviewed clinical evidence is not seen as sufficient. However we believe that some opportunities to reduce smoking within specific groups may have been missed, and can be justified quite reasonably from existing evidence.	Thank you for your comments. The Public Health Advisory Committee (PHAC) have considered systematic reviews of the evidence, expert testimonies, and contributions from expert co-optees to the committee in the development of the guideline.
Independent British Vape Trade	Guideline	General	General	The biggest challenge smokers face in understanding e-cigarettes is a perception that they are harmful, and in many cases, they believe them to be as harmful as smoking.	Thank you for your comment. The guideline outlines several recommendations regarding advice on the use of nicotine-containing e-cigarettes (for example Recommendation

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Association (IBVTA)				While the inclusion of e-cigarettes as a recognised quit smoking intervention in a NICE guideline will go some way to redressing this misperception, that more needs to be done to educate both the UK public and health professionals cannot be overstated.	1.11.4) and recommends that those providing stop-smoking support or advice ensure that nicotine-containing e-cigarettes are an option accessible to adults who smoke (recommendation 1.12.1). Recommendations 1.12.13 to 1.12.17 outline advice to be provided on nicotine-containing e-cigarettes and is aimed at people providing stop-smoking support or advice and highlights that the use of e-cigarettes is likely to be substantially less harmful than smoking. The Public Health Advisory Committee (PHAC) acknowledge the lack of evidence regarding e-cigarettes and have developed seven research recommendations focused on e-cigarettes with the hope of stimulating further research in this area.
Independent British Vape Trade Association (IBVTA)	Guideline	029	025	The amendment of PH48 recommendation 3 is not specific that the options for recommendation have changed, which may go unnoticed. Suggest change to, "Provide information about the different types of stop-smoking options, including pharmacotherapies and e-cigarettes, and how to use them."	Thank you for your comment. At the beginning of section 1.12 'Stop smoking interventions' it is noted that the recommendations apply to people providing stop smoking support or advice. The recommendations in section 1.14 to which you refer are intended for health care professionals, stop smoking advisers and others trained to provide behavioural support to stop smoking. It is assumed that the audience will read all sections relevant to

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					their practice and that the recommendations will not be considered in isolation.
Independent British Vape Trade Association (IBVTA)	Guideline	032	006 - 010	It seems that those who have to stop smoking temporarily to use acute and mental health services are only recommended to use medicinally licensed products, and that 2013 PH48 recommendation 3 is implemented without the 2021 revision being applied, as in other instances. The absence of evidence that unlicensed nicotine replacement products such as e-cigarettes are effective in these circumstances potentially hides the "common sense" rationale that enables their recommendation. They have been shown to be at least as effective as medicinally licensed NRT in other scenarios, so there can be little doubt that they will be effective in this one.	Thank you for your comment. The evidence on the use of nicotine containing e-cigarettes to support temporary abstinence was not reviewed as part of this guideline update and therefore recommendations have not been made in this area.
Independent British Vape Trade Association (IBVTA)	Guideline	033	015 - 017	We are concerned that this recommendation may discourage hospital pharmacies from stocking unlicensed NRT products such as e-cigarettes and e-liquid before the next review of the guideline. In the absence of medicinally licensed products in this category, would it be possible to recommend that hospital pharmacies carry stocks of e-cigarettes and associated consumables if they are known to be effective and meet UK regulations?	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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Johnson & Johnson Limited	Guideline	General	General	<p>Johnson & Johnson Ltd welcomes the opportunity to comment on these draft guidelines. The health consequences of smoking tobacco have been extensively researched. Despite progress in recent years, smoking remains a leading cause of ill-health, early death and health inequalities. 7.2 million people in the UK still smoke. Smoking is linked to half a million hospital admissions annually and around 77,800 people die from smoking-related diseases in England every year (1). Smoking is also the attributed cause of 72% of the UK's lung cancer cases (2)</p> <p>Smoking is a major economic burden on the UK with smoking-related illnesses costing the NHS in England an estimated £2.5 billion (3) each year. The Covid-19 pandemic has put an even greater spotlight and urgency on the need for people to quit smoking, with Public Health England reporting that smokers are at greater risk of severe respiratory disease from Covid-19 (4).</p> <p>We therefore strongly welcome the Government's commitment – set out in the 2019 Prevention Green Paper - to go 'smoke-free' in England by 2030, and we support guidelines for healthcare professionals and</p>	Thank you for your comment.

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				<p>smoking cessation to help people quit tobacco and nicotine for good.</p> <p>1 Action on Smoking & Health (ASH) Facts at a Glance: Key Smoking Statistics, April 2020 2 Cancer Research UK (CRUK) Lung Cancer Risk, Accessed November 2020 3 Department of Health. Towards a Smoke free Generation: A Tobacco Control Plan for England. July 2017 4 Public Health England: Smokers at Greater Risk of Severe Respiratory Disease from Covid-19, April 2020</p>	
Johnson & Johnson Limited	Guideline	022 023	024 - 029 001 - 005	<p>We support that a wide range of stop smoking options should be accessible to adults who smoke. We suggest this should be updated to read: "Ensure the following are accessible to adults who smoke or that they are made aware of how to access them:"</p> <p>This takes into account that not all the options listed are licensed and can be prescribed.</p>	<p>Thank you for your comment. The Public Health Advisory Committee (PHAC) have considered your comments.</p> <p>Recommendation 1.12.1 outlines that the interventions outlined are accessible to adults who smoke and recommendation 1.12.2 outlines to "Tell people who smoke that a range of interventions is available to help them stop smoking and explain how to access them and refer them to stop smoking services where appropriate". On this basis no change has been made.</p>
Johnson & Johnson Limited	Guideline	023 024	020 – 029 001 - 003	<p>Evidence outlined in Evidence Review K [page 75, table 19] on the relative effectiveness of smoking cessation treatments indicates that, in effect, a difference was not detected for e-</p>	<p>Thank you. The guideline is about stopping tobacco use and therefore does not take into account the amount of time people use other forms of nicotine. This is because most</p>

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				<p>cigarette use compared with long- or short-acting NRT or bupropion, both of which are included in the Guideline as <i>“less likely to result in them successfully stopping smoking (when combined with behavioural support)”</i>.</p> <p>Similarly, the evidence summary for short-term follow-up (outcome in smoking cessation) [Evidence Review K, page 70 – 80, table 10] indicates that the only clinically important difference in smoking cessation between the e-cigarette group and NRT group can be seen at 0 – 3 months, with no clinically important difference between the two groups at 3 – 6 months. Furthermore, the Committee highlights [Evidence Review K, page 88, 1 – 4] <i>“low confidence in the results for the effectiveness of e-cigarettes at less than 6 month follow-up when compared with placebo e-cigarettes, NRT or no / minimal intervention..”</i></p> <p>In relation to intervention effectiveness [Evidence Review K, page 59, table 7], relative risks are based on a limited number of studies for e-cigarettes (4 studies) leading to a wider confidence interval (CI) than NRT (116 studies [Evidence Review K.]). page 11, table 3].</p>	<p>smoking related health problems are caused by other components in tobacco smoke, not by nicotine (see Recommendation 1.12.10). The committee considered the evidence from evidence review K alongside evidence from other reviews about the effectiveness and safety of e-cigarettes and alongside their own expertise and experience and they used this to contextualise the evidence into the recommendations in the guideline. The rationale and impact section explains how the committee contextualised the evidence to make the recommendations. More detail is provided in the committee discussion sections of the individual evidence reviews.</p>

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				<p>These should therefore be interpreted with caution.</p> <p>Considering the above, there is a lack of sufficient evidence to support e-cigarettes being listed as being as effective as combination NRT or varenicline or as more effective than long or short-acting NRT monotherapy.</p> <p>In addition, the evidence committee have highlighted that while most of the other recommended treatments are usually used for a defined period, and stopped within a number of months, people using e-cigarettes to stop smoking may be more likely to use them for longer [Evidence Review K, page 98, lines 25-27].</p> <p>In the study by Hajek et al (1), among participants with 1-year smoking abstinence, 80% (63 of 79) were still using e-cigarettes at 52 weeks in the e-cigarette group compared with 9% (4 of 44) who were continuing to use NRT in the NRT group. Both groups were matched for cigarette consumption at enrolment and therefore had similar levels of nicotine addiction.</p>	

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				<p>The elimination of nicotine use can be a challenging task for users. It is therefore likely that NRT, targeting a tobacco and nicotine free outcome, will have a lower success rate than interventions that do not seek to eliminate nicotine. Continuing to use nicotine may expose users to risks that those who eliminate it will not be exposed to. The Committee concluded [page 80, lines 15 – 17] <i>“with the limited data on effects of longer-term use, people should only use e-cigarettes for as long as they help prevent them going back to smoking.”</i></p> <p>Advising smokers that long or short acting NRT is “less likely to result in successfully stopping smoking” compared to e-cigarettes, does not take into account the very limited amount of evidence. Nor does it take into account that comparisons are made of data which use two different treatment strategies, with differing endpoints and differing residual risk.</p> <p>1 Hajek P et al. N Eng J Med 2019;380:629-636</p>	
Johnson & Johnson Limited	Guideline	026	010	We welcome inclusion in the guidance that those providing stop-smoking support or advice should also discuss how individuals	Thank you for your comment. Recommendation 1.12.13 includes a link to some resources which includes advice on

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				<p>should stop using nicotine-containing e-cigarettes when they are ready to do so, as is usually the case for licensed NRT products. Further guidance should be provided for those providing cessation advice on how people should stop using e-cigarettes. We would also recommend the guidance endorses follow-up sessions for those using nicotine-containing e-cigarettes at a defined point (e.g. after X months) with a stop-smoking advisor to review progress and discuss how to stop using the e-cigarette if the individual is ready to do so.</p>	<p>how to stop using nicotine containing e-cigarettes when the person is ready to do so.</p> <p>Regarding follow up sessions at a defined point, the committee has provided as much detail as it can given the evidence it has reviewed. The committee's discussion is summarised in the rationale and impact section relating to this recommendation.</p>
Johnson & Johnson Limited	Guideline	038	010 - 022	<p>The information specified in this section refers to the requirements for manufacturing information of medically licensed products. While there are no e-cigarettes currently licensed and marketed as medicines in the UK, similar guidance on informing about dosage, health risks and long-term use of e-cigarettes should be provided, to avoid gaps in the information being made available.</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.</p> <p>As is noted in the rationale and impact section under 'nicotine containing e-cigarettes for harm reduction', no evidence was found on the use of e-cigarettes specifically for harm reduction for people who do not want, or are not ready, to stop smoking in one go. So, the committee chose not to make recommendations on using e-cigarettes for harm reduction.</p>

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Johnson & Johnson Limited	Guideline	067	019 - 022	<p>“Cessation” definition should be updated to read “Tobacco Cessation”.</p> <p>Products such as e-cigarettes are only recommended for “stop in one go”, defined as an approach that “may or may not involve the use of pharmacotherapies or nicotine-containing cigarettes before the quit date and for a limited time afterwards” [page 71, lines 13 – 17], rather than a permanent alternative tobacco use.</p> <p>We believe it is important to ensure that tobacco cessation is not considered as an endpoint and that cessation should be reserved for being both tobacco and nicotine free.</p> <p>This is supported by the Committee’s conclusions [page 80, lines 15 – 17] “that with the limited data on effects of longer-term use, people should only use e-cigarettes for as long as they help prevent them going back to smoking.”</p> <p>Amending the definition to tobacco cessation is also in line with Guideline section 1.12.15 [page 26, lines 8 – 10] which outlines ‘nicotine</p>	<p>Thank you. This section defines terms that have been used in a particular way for this guideline. The definition clearly specifies that it refers to stopping tobacco, which is the remit of this guideline. The committee were not asked to make recommendations about quitting nicotine.</p>

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				<p>free' as the end point, recommending discussion on:</p> <ul style="list-style-type: none"> • How long the person intends to use nicotine-containing e-cigarettes for • Using them for long enough to prevent a return to smoking, and • How to stop using them when they are ready to do so <p>In addition to updating this definition, we recommend further guidance should be provided for those providing cessation advice on how people should stop using e-cigarettes. We would also recommend the guidance endorses follow-up sessions for those using nicotine-containing e-cigarettes at a defined point (e.g. after X months) with a stop-smoking advisor to review progress and discuss how to stop using the e-cigarette if the individual is ready to do so.</p>	
Johnson & Johnson Limited	Guideline	068	024 - 027	The current definition of "Medically licensed nicotine-containing products" should be updated to read "At the time of publication, no nicotine-containing e-cigarettes that have received a license from the MHRA have been commercialized. Any nicotine containing e-cigarette licensed and commercialized as a medicine would then be considered as a type	Thank you. We have updated the definition.

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				of Nicotine Replacement Therapy (NRT) product.”	
Johnson & Johnson Limited	Guideline	069	013 - 016	The current definition of “Nicotine Replacement Therapy” should be updated to note that mouth spray and lozenge formulations are also available.	Thank you for your comment. We have added mouth spray and lozenge to the definition.
Johnson & Johnson Limited	Guideline	078	026 - 029	<p>Evidence outlined in Evidence Review K [page 75, table 19] on the relative effectiveness of smoking cessation treatments indicates that, in effect, a difference was not detected for e-cigarette use compared with long- or short-acting NRT or bupropion, both of which are included in the Guideline as “less likely to result in them successfully stopping smoking (when combined with behavioural support)”.</p> <p>Similarly, the evidence summary for short-term follow-up (outcome in smoking cessation) [Evidence Review K, page 70 – 80, table 10] indicates that the only clinically important difference in smoking cessation between the e-cigarette group and NRT group can be seen at 0 – 3 months, with no clinically important difference between the two groups at 3 – 6 months. Furthermore, the Committee highlights [Evidence Review K, page 88, 1 – 4] “low confidence in the results for the effectiveness of e-cigarettes at less than 6</p>	<p>Thank you. The committee discussed the evidence at great length and agreed that, in their experience and expertise, since they were clear that most of the harm from smoked tobacco comes from other components of tobacco than nicotine. On this basis they agreed that e-cigs were a useful means of tobacco cessation, even if they contained nicotine (which currently no commercially available e-cigarettes do). The evidence for the longer term outcomes around nicotine dependency is beyond the remit of this guideline which is only about reducing or stopping tobacco use.</p> <p>We have highlighted the Hajek review to our surveillance team who will consider its potential impact on the guideline.</p>

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				<p>month follow-up when compared with placebo e-cigarettes, NRT or no / minimal intervention.”</p> <p>In relation to intervention effectiveness [Evidence Review K, page 59, table 7], relative risks are based on a limited number of studies for e-cigarettes (4 studies) leading to a wider confidence interval (CI) than NRT (116 studies [Evidence Review K.]). page 11, table 3]. These should therefore be interpreted with caution.</p> <p>Considering the above, there is a lack of sufficient evidence to support e-cigarettes being listed as being as effective as combination NRT or varenicline or as more effective than long or short-acting NRT monotherapy.</p> <p>In addition, the evidence committee have highlighted that while most of the other recommended treatments are usually used for a defined period, and stopped within a number of months, people using e-cigarettes to stop smoking may be more likely to use them for longer [Evidence Review K, page 98, lines 25-27].</p>	

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				<p>In the study by Hajek et al (1), among participants with 1-year smoking abstinence, 80% (63 of 79) were still using e-cigarettes at 52 weeks in the e-cigarette group compared with 9% (4 of 44) who were continuing to use NRT in the NRT group. Both groups were matched for cigarette consumption at enrolment and therefore had similar levels of nicotine addiction.</p> <p>The elimination of nicotine use can be a challenging task for users. It is therefore likely that NRT, targeting a tobacco and nicotine free outcome, will have a lower success rate than interventions that do not seek to eliminate nicotine. Continuing to use nicotine may expose users to risks that those who eliminate it will not be exposed to. The Committee concluded [page 80, lines 15 – 17] “with the limited data on effects of longer-term use, people should only use e-cigarettes for as long as they help prevent them going back to smoking”.</p> <p>Advising smokers that long or short acting NRT is “less likely to result in successfully stopping smoking” compared to e-cigarettes, does not take into account the very limited amount of evidence. Nor does it take into</p>	

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				<p>account that comparisons are made of data which use two different treatment strategies, with differing endpoints and differing residual risk.</p> <p>1 Hajek P et al. N Eng J Med 2019;380:629-636</p>	
Johnson & Johnson Limited	Guideline	081	001 - 023	<p>We recognise the importance of stop-smoking support being available to all, and that people with mental health conditions should not be treated differently. We suggest the guidance should also recognise that people with mental health conditions smoke significantly more on average and have higher levels of nicotine dependence than the population as a whole.¹ This may result in underdosing using nicotine replacement therapy. We suggest guidance should include "Advise how to use NRT correctly, including how to get a high enough dose of nicotine to control cravings, prevent compensatory smoking and stop successfully.</p> <p>1. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/779497/SF_MH_services_in_England_Guidance_for_Providers.pdf</p>	<p>Thank you. The guideline makes recommendations for those utilising mental health services and those with mental health conditions throughout, thus acknowledging this group as key. Recommendation 1.15.13 is quite specific in this regard referencing people with mental illness as a group where smoking is widespread, and many are possibly dependent on tobacco and recommendation 1.22.4 specifying the need to prioritise groups at high risk of tobacco-related harm which specifies people with mental health conditions. Further the committee developed a research recommendation regarding support for people with mental health conditions to stop smoking and the rationale and impact sections for recommendation 1.14.9 and others outline the points you raised regarding increased risk. In terms of advice to use stop-smoking interventions correctly and other advice this is covered specifically in this</p>

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					guideline for example recommendations 1.12.
Kent County Council	Guideline	General	General	We support the amalgamation of previous related tobacco guidance that culminates in a single comprehensive Guideline.	Thank you for your comment.
Kent County Council	Guideline	General	General	We support the recommendations which cover the breadth of tobacco dependency, in particular responding to latest e-cigarette evidence and to assist with the planning and delivery of the NHS Long Term plan Tobacco Dependency models.	Thank you for your comments.
Kent County Council	Guideline	013	001	Rec 1.6.3 – we welcome the recommendation to discourage those who do not smoke from experimenting with smoking or vaping.	Thank you for your comment
Kent County Council	Guideline	025	021	Rec 1.12.13 – we support stop smoking advisers giving advice on e-cigarettes which will require training from an effective (ideally approved) non-biased provider.	Thank you for your comment. Recommendation 1.23 provides further specific recommendations on training and the introduction to recommendation 1.12 outlines and hyperlinks to training requirements.
Kent County Council	Guideline	025	025	Rec 1.12.14 – we welcome the guideline explaining the TRPD 2016 regulations and MHRA Yellow card Scheme (Rec 1.12.16)	Thank you for your comment
Kent County Council	Guideline	044	018	Rec 1.17.2 – we welcome the new recommendation to offer further pharmacotherapy to prevent relapse.	Thank you for your comment
Kent County Council	Guideline	051	008	Rec. 1.20.12 – We accept the review's successful outcomes of incentive schemes but would be concerned that some smokers may defer their quit attempt to meet the scheme's	Thank you. The committee discussed this but overall thought that the benefits outweighed the risks of this scenario because of the

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				criteria in order to access the incentives. This would require careful monitoring of SATOB rates and trends.	overwhelming risks to the foetus of smoking during pregnancy.
King's College London – Nicotine Research Group	General	General	General	We welcome the opportunity to submit a response to this consultation and congratulate the Committee and reviewers on updating this substantial body of work.	Thank you for your comment.
King's College London – Nicotine Research Group	Guideline	013	001	We agree that 'As part of the curriculum on tobacco, alcohol and drug misuse, discourage children, young people....who do not smoke from experimenting with or regularly using e-cigarettes'. Regarding 'young adults' (18-24) this may imply NICE are recommending 'as part of the curriculum' includes the higher education curriculum, such as universities. Clarity and guidance would be welcome, given that many higher education organisations (with a high proportion of 18-24 year olds) allow vaping in their grounds. This recommendation will therefore be challenging to implement for this age group.	Thank you for your comment. Recommendations 1.6 (1.6.1 to 1.6.8) focus on primary and secondary schools and further education colleges (see p.12, line 14 to 15) and are not aimed at universities. Universities and other higher education organisations are outside the scope of this update. Please see the scope document on the NICE website.
King's College London – Nicotine Research Group	Guideline	013	003	We are concerned that not educating <18s about e-cigarettes <i>relative</i> to tobacco cigarette smoking and the recommendation to 'talk about e-cigarettes separately from tobacco products', may contribute to the inaccurate	Thank you for your comment. Recommendation 1.6.3 highlights that discussions of e-cigarettes should occur as part of the curriculum on tobacco, alcohol, and drug misuse. The line 'Talk about e-cigarettes separately from tobacco products'

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				misperceptions about the relative harm of e-cigarettes.	is about discussing these two separate products (e-cigarettes and tobacco products) as distinct within this curriculum.
King's College London – Nicotine Research Group	Guideline	013	005	We support the goal to make e-cigarettes undesirable to children, and young people. The recommendation that <i>'everyone working in and with primary and secondary schools and further education collegesWhen discussing e-cigarettes, make it clear why children, young peoplewho do not smoke should avoid e-cigarettes to avoid inadvertently making them desirable,</i> requires a skilled and competent workforce otherwise it may actually have the effect of making them desirable. We have seen the approach taken by countries such as the US towards informing children and young people about the 'dangers' of vaping has made them inadvertently more attractive.	Thank you for your comment. The committee agree with your comment and the rationale and impact section (p.76, lines 5 to 22) specify that the committee wanted to discourage e-cigarette use among young people and young adults who do not smoke because evidence shows that use of e-cigarettes is linked with a higher chance of ever smoking later in life. Further the committee agreed that school-based interventions could help to discourage e-cigarette use among those who do not smoke and noted the need to not inadvertently make e-cigarettes desirable. Recommendation 1.6.6 outlines that smoking prevention interventions should be delivered by teachers and higher-level teaching assistants who are both credible and competent in the subject, or by external experts. The guideline acknowledges the importance of training and it makes a number of training specific recommendations (1.23). Recommendation 1.23.1 outlines that those with responsibility for improving the health and wellbeing of children, young people and young adults who attend school, work in

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					partnership with those involved in smoking prevention and stop smoking activities to design, deliver, monitor and evaluate smoking prevention training and interventions.
King's College London – Nicotine Research Group	Guideline	013	013	The recommendations for who should provide smoking prevention interventions and how the interventions should be delivered should also apply to e-cigarettes. New resources should be developed /provided by experts in collaboration with young people and teachers. This will have cost and resource implications over and above smoking prevention materials.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
King's College London – Nicotine Research Group	Guideline	016	001 - 005	Under <i>Recommendations on promoting quitting</i> : This advice on NRT is welcome. Re 'provide information on long term use to prevent relapse' – signposting/providing new education materials for practitioners and NRT users about what 'long term use' means is needed, to ensure this recommendation is widely implemented.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
King's College London – Nicotine Research Group	Guideline	016	024	It is helpful that practitioners are advised to 'Use the best available evidence of effectiveness, such as Cochrane reviews'. As the evidence base is continually evolving, and NICE are unlikely to review/update this guidance regularly, we would welcome suggesting that research outcomes are taken	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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				into account when implementing any of the recommendations in the guidance and the most up to date evidence is used (eg Cochrane reviews) to guide policy and practice. The Cochrane living systematic review on e-cigarettes [1] is a good example of where to find the most up to date evidence on e-cigarettes for cessation and harm reduction. 1, Hartmann-Boyce J, et al (2021) Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2021, Issue 4. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub5.	
King's College London – Nicotine Research Group	Guideline	023	005 026 026	It's encouraging to see that the recommendation that as well as licensed smoking cessation aids, nicotine containing e-cigarettes should also be accessible, and can help people successfully stop smoking. We believe there will be a cost implication to truly making e-cigarettes accessible by stop smoking services and also within secondary care mental health settings. For example, only 11% of community stop smoking services provide e-cigarettes as part of their cessation offer. [2] 2.Action on Smoking and Health (ASH), Progress towards smokefree mental health services: findings from a survey of mental	Thank you for your comment. E-cigarettes are one option recommended be accessible to adults amongst other options which include medicinally licensed products, behavioural support, and brief advice. NICE guidelines are developed by its Public Health Advisory Committee (PHAC) based on systematic reviews of the evidence and expert testimony. They set out the care and services suitable for most people with a specific condition or need, and people in particular circumstances or settings. People have the right to be able to make informed decisions about their care. Our guidance should be considered when making decisions with them. It is beyond NICE's remit to make

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				health trusts in England. 2019, Action on Smoking and Health (ASH): London	commissioning or funding decisions and these should rightly occur at the local commissioning level.
King's College London – Nicotine Research Group	Guideline	026	008 - 010	These recommendations – ‘to discuss.....using (e-cigarettes) for long enough to prevent a return to smoking, and how to stop using them when they are ready to do so’ are important but lack an evidence base to guide practitioners to recommend how long is ‘long enough’ and how to stop vaping without relapsing back to smoking. New education materials/resources are needed for practitioners and e-cigarette users.	Thank you for your comment. The committee agreed with your comment and have outlined research recommendations to stimulate research in these areas specifically: Research recommendation 7 (Use of e-cigarettes (amount and frequency)); 11 Relapse prevention. Recommendation 1.12.13 provides examples of education materials and resources regarding e-cigarettes to facilitate people providing stop-smoking support or advice to give clear, consistent, and up-to-date information about nicotine- containing e-cigarettes.
King's College London – Nicotine Research Group	Guideline	026	015 - 017	Explain to people who choose to use nicotine-containing e-cigarettes the importance of getting enough nicotine to overcome withdrawal symptoms, and explain how to get enough nicotine. Again, these are helpful recommendations in order to maximise the benefit of e-cigarettes but require new education materials/resources to be developed for practitioners and e-cigarette users.	Thank you for your comment. Recommendation 1.12.13 provides examples of education materials and resources regarding e-cigarettes to facilitate people providing stop-smoking support or advice to give clear, consistent, and up-to-date information about nicotine- containing e-cigarettes.
King's College London –	Guideline	028	010	In this section (Info on stopping smoking for those using acute, maternity and mental health services) there is an opportunity to add	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update.

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Nicotine Research Group				another example to the benefits of quitting (currently it has a surgery example) eg stopping smoking can improve one's mental health (Taylor et al 2021, Smoking cessation for improving mental health – Cochrane review). [3] 3.Taylor GMJ et al. Smoking cessation for improving mental health. Cochrane Database of Systematic Reviews 2021, Issue 3. Art. No.: CD013522. DOI: 10.1002/14651858.CD013522.pub2.	Please see the scope document on the NICE website.
King's College London – Nicotine Research Group	Guideline	030	018	Given that most stop smoking support has occurred over the telephone or online in the last 18 months, perhaps rather than stating offer weekly sessions post discharge, preferably face to face, add in the additional option of telephone/online support.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
King's College London – Nicotine Research Group	Guideline	031	018	We are pleased to see the new addition of support for people with severe mental health conditions in that support should be delivered by a specialist adviser with mental health expertise and tailored to the persons needs. Clarity would be welcome about what the Committee define as 'mental health expertise'.	Thank you for your comment. This will be for local systems to agree. However, in the studies which underpin this recommendation, structured smoking cessation interventions were delivered by trained mental health smoking cessation practitioners. These were generally experienced mental health nurses who worked in conjunction with the participant and the participant's primary care physician or mental health specialist to

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					provide an individually tailored smoking cessation service.
King's College London – Nicotine Research Group	Guideline	032	001 - 021	Re 'Supporting people who have to stop smoking temporarily....for those who need to abstain temporarily to use acute and mental health services' which is a substantial number of people, the lack of mention of the use of nicotine containing e-cigarettes is a concern. E-cigarettes are allowed in the majority of mental health Trusts in England and just under half of Trusts supply them for free. [4] The majority of people in inpt mental health services do not want to quit completely but are open to using e-cigarettes for temporary abstinence. Often using an e-cigarette product for temporary abstinence is a springboard for future cessation. 4.ASH (2019) Progress towards smokefree mental health services. ASH London	Thank you for your comment. The evidence on the use of nicotine containing e-cigarettes to support temporary abstinence was not reviewed as part of this guideline update and therefore recommendations have not been made in this area.
King's College London – Nicotine Research Group	Guideline	033	005	An additional and most up to date resource for interactions with smoking and stopping smoking and psychotropic medication are the Maudsley Prescribing Guidelines.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
King's College London – Nicotine	Guideline	035	Box 1	Under the recommendations -Supporting people who do not want, or are not ready, to stop smoking in one go to reduce their harm from smoking	Thank you for your comment. As is noted in the rationale and impact section under 'nicotine containing e-cigarettes for harm reduction', no evidence was found on the use

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Research Group		045	001 - 014	<p>Box 1 lists harm reducing approaches, identified as cutting down before stopping, smoking reduction and temporarily not smoking, for which NRT is recommended.</p> <p>Under the recommendations -Supporting people cutting down or stopping temporarily- only NRT is recommended</p> <p>We believe the lack of recommendation for nicotine containing e-cigarettes is unwarranted and will be a barrier to tobacco harm reduction, particularly those with the highest smoking prevalence – people with mental illness, substance use disorders, those accessing homeless services and those in prison.</p>	<p>of e-cigarettes specifically for harm reduction for people who do not want, or are not ready, to stop smoking in one go. So the committee chose not to make recommendations on using e-cigarettes for harm reduction. The evidence on the use of nicotine containing e-cigarettes for temporary abstinence was not reviewed as part of this guideline update and therefore recommendations have not been made in this area. .</p>
King's College London – Nicotine Research Group	Guideline	054	017	<p>Since smokefree policies have been introduced following publication of PH48, the storage of tobacco has become a contentious issue in many Trusts. Many Trusts circumvent the spirit of the PH48 and get around the recommendation to 'ban staff from supervising or helping people to take smoking breaks' (53, 25) by storing tobacco on the ward and handing it back and forward several times a day to service users who are given section 17 leave to smoke. Alternatively, Trusts have invested in lockers for patients to store their</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.</p>

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				tobacco off the ward. Other Trusts turn a blind eye to patients hiding tobacco in hospital grounds to use during their 'fresh air breaks' We would welcome a stronger steer from NICE about this major barrier to fully implementing PH48.	
King's College London – Nicotine Research Group	Guideline	057	001	Recommendation re Commissioning and designing services In addition to the existing recommendations, it is a good opportunity to make reference to the NHS Long Term plan and recommendations for hospitals (and eventually community services) to provide 'tobacco dependence treatment services and for long-term users of specialist mental health, and in learning disability services this should include the option to switch to e-cigarettes while in inpt services'.	Thank you. Section 1.14 of the guideline covers mental health settings.
King's College London – Nicotine Research Group	Guideline	059	021	As all Trusts are about to be funded to provide tobacco dependence treatment support for smokers whilst in hospital, we would welcome that the recommendations for recording of data in secondary care matches the metrics proposed by NHSE.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
King's College London – Nicotine	Guideline	082	001 - 006	No evidence was found on the use of e-cigarettes specifically for harm reduction for people who do not want, or are not ready, to stop smoking in one go. So the committee chose not to make recommendations on using	Thank you. This evidence will form part of the ongoing surveillance of this guideline and will be used to update it in the future.

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Research Group	Evidence review K for cessation and harm	086	011	<p>e-cigarettes for harm reduction. They did discuss that e-cigarettes may be used in this way and that there may be substantial dual use</p> <p>The final search date for identifying this evidence was November 2019. Between Nov and June 2021 there has been further evidence published to support using e-cigarettes for harm reduction (as defined by the Committee) for people who do not want, or are not ready, to stop smoking in one go. Whilst we agree dual use has been common, its prevalence is reducing. Concurrent use is often necessary when transitioning from smoking to vaping, and there some evidence it reduces harm (eg Shahab et al, 2017) [5]. NICE's new recommendations for informing people who smoke who switch to e-cigarettes, how to use them, getting sufficient nicotine, switching completely etc should mitigate any potential problems.</p> <p>5. Shahab L, et al (2017) Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users: A Cross-sectional Study. <i>Ann Intern Med</i>;166(6):390-400. doi: 10.7326/M16-1107. Epub 2017 Feb 7. PMID: 28166548; PMCID: PMC5362067.</p>	

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				<p>The Cochrane living systematic review on e-cigarettes [1] includes several studies that recruited people who do not want, or are not ready, to stop smoking in one go and have been followed up for 6 months and provide cessation, reduction data and effect on health. Also, McNeill et al [6] in our most recent evidence review commissioned by PHE also includes such studies.</p> <p>6.McNeill, A., Brose, L.S., Calder, R., Simonavicius, E. and Robson, D. (2021). Vaping in England: An evidence update including vaping for smoking cessation, February 2021: a report commissioned by Public Health England. London: Public Health England</p> <p>Although not meeting the inclusion criteria of 6 month follow up, it is of note that in a systematic review for our PHE commissioned evidence review of Vaping in England in 2020, [7] we identified five studies of vaping interventions in people with severe mental health problems, four of which recruited people who did not intend to quit smoking. There has been a further vaping intervention study published this year of 40 people with schizophreniform illness in which people with</p>	

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				<p>schizophrenia significantly reduced their tobacco use. [8]</p> <p>7.McNeill, A., Brose, L.S., Calder, R., Bauld, L., and Robson, D. (2020). Vaping in England: an evidence update including mental health and pregnancy, March 2020: a report commissioned by Public Health England. London: Public Health England.</p> <p>8.Caponnetto, P et al (2021). A Single-Arm, Open-Label, Pilot, and Feasibility Study of a High Nicotine Strength E-Cigarette Intervention for Smoking Cessation or Reduction for People With Schizophrenia Spectrum Disorders Who Smoke Cigarettes, <i>Nicotine & Tobacco Research</i>, 23 (7) 1113–1122, https://doi.org/10.1093/ntr/ntab005</p> <p>The Cochrane review for interventions to reduce harm from continued tobacco use [9] last updated in 2016, found evidence that NRT was effective for reducing smoking but overall, the quality of the evidence was low or very low. None of the trials included in the review directly tested whether harm reduction strategies actually reduced the harms to health caused by smoking. Therefore one could question the Committee's decision in that - if the evidence base for medicinally licenced products for smoking reduction is of low quality</p>	

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				<p>and there is lack of evidence for reducing harms to health, why is nicotine replacement therapy and behavioural support recommended for harm reduction and nicotine containing e-cigarettes not recommended? References</p> <p>9.Lindson-Hawley N, et al. Interventions to reduce harm from continued tobacco use. Cochrane Database of Systematic Reviews 2016, Issue 10. Art. No.: CD005231. DOI: 10.1002/14651858.CD005231.pub3</p>	
Leeds and York Partnership NHS Foundation Trust	General	General	General	It is helpful to have one updated guideline amalgamating previous versions of tobacco guidance. This encourages an holistic approach.	Thank you for your comment.
Leeds and York Partnership NHS Foundation Trust	Guideline	013	001 - 004	Expansion of the section on prevention in school children and young people through education is a welcome addition to the guidance and formalises this as a key part of the curriculum.	Thank you for your comment
Leeds and York Partnership NHS	Guideline	023	005	Inclusion of nicotine containing e-cigarettes as a stop smoking intervention is a welcome addition to the guidance.	Thank you for your comment

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Foundation Trust					
Leeds and York Partnership NHS Foundation Trust	Guideline	025 026	019 - 028 001 - 006	This section is helpful in informing policies for the use of nicotine-containing e-cigarettes	Thank you for your comment
Leeds and York Partnership NHS Foundation Trust	Guideline	026	011 - 014	Reinforcement of the availability of the MHRA yellow card scheme is a helpful addition	Thank you for your comment.
Leeds and York Partnership NHS Foundation Trust	Guideline	026	015 - 017	Inclusion of explaining to people how to receive enough nicotine to prevent withdrawal when using e-cigarettes is a helpful inclusion in the guidance	Thank you for your comment
Leeds and York Partnership NHS Foundation Trust	Guideline	028	008	People are very rarely admitted to a mental health setting electively and therefore will have not been given the opportunity to consider a reduction in smoking or stopping smoking altogether.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Leeds and York Partnership	Guideline	031 and	018 – 023 and	recommendations for supporting people who have to stop smoking temporarily	Thank you for your comment. The evidence on the use of nicotine containing e-cigarettes to support temporary abstinence was not

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NHS Foundation Trust		032	001 - 021	<p>For those who have to abstain temporarily to use acute and mental health services</p> <p>There is an omission of the use of e-cigarettes to address the needs of people who need to stop smoking temporarily during a hospital admission. This does not reflect the needs of people admitted to a mental health inpatient unit, who must abstain from smoking during lengthy admission periods. E-cigarettes are an important component of managing dependency in those being cared for in mental health environments. In this respect the guidance does not reflect the experiential learning of mental health Trusts in relation to the use of e-cigarettes, widely used as a key part of managing nicotine dependence.</p> <p>We are concerned that the omission of e-cigarettes as a recognised aid to support abstinence in an inpatient mental health setting will exacerbate the existing inequalities that people with SMI experience. This will happen by reducing the options for products to support individuals and therefore reducing the likelihood that they will engage with the idea of stopping smoking.</p> <p>A further consequence would be the likely failure of mental health Trusts to achieve</p>	reviewed as part of this guideline update and therefore recommendations have not been made in this area. e.

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				smoke free status for all patients and employees.	
Leeds and York Partnership NHS Foundation Trust	Guideline	053	025	<p>Recommendations on Policy: ban staff from supervising or helping people to take smoking breaks.</p> <p>The guidance could provide more clarity on whether storage of smoking paraphernalia constitutes 'help' as this is a problematic area causing friction between staff and service users.</p> <p>Clarity on the use of Section 17 leave would also be helpful including the balance of health promotion/risk and additional removal of liberty from service users beyond the boundaries of NHS grounds. The storage of smoking paraphernalia is at the centre of this, straddling discussions on "helping" unhealthy behaviours, restrictive procedures and supporting long term voluntary behaviour change.</p>	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Leeds and York Partnership NHS Foundation Trust	Guideline	059	010 - 011	<p>Recommendation: smoking support in secondary care to 'Include nicotine-containing products as option for sale in secondary care settings (for example, in hospital shops':</p> <p>Unless access to e-cigarettes is freely available in mental health Trusts this will further disadvantage patients due to the high prevalence of smoking in those with serious mental illness and also the levels of financial hardship experienced by many. There is also</p>	Thank you for your comment. This is a matter for local commissioning arrangements. The committee did not look at any evidence to support free provision of e-cigarettes to people with serious mental illness.

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				the potential that attaching a monetary value will create a 'market' in the devices. We feel strongly that e-cigarettes should be freely available to inpatients to address dependence. We would not expect an inpatient to buy their NRT supply.	
Leeds and York Partnership NHS Foundation Trust	Guideline	063	027	Recommendation: 'People who work in closed institutions' this would also apply to those who work in mental health inpatient settings.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Leicester City Council	Guideline	009	007 - 011	Rec. 1.2 – we felt that NHS Trusts should be included in who this recommendation was aimed towards	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Leicester City Council	Guideline	010	011 - 014	Rec 1.3.2 – Specific reference to proxy purchasing seems to be missing from this recommendation	Thank you for your comment. The Public health Advisory Committee (PHAC) Have considered your comments and have decided not to change the recommendation. PHAC highlighted that Review C and D considered the evidence on proxy purchasing but there was insufficient evidence, to make new recommendations. The PHAC therefore made the decision to carry forward the previous recommendations.

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Leicester City Council	Guideline	010	005 - 006	Rec 1.4 – This recommendation could be difficult to implement as the Academy status of schools means that many schools are able to create their own smoke free policies so across a single local authority there could be a number of differing smoke free policies, which may not be consistent with local public health policy advice.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Leicester City Council	Guideline	010	016	Rec 1.5 – there is an opportunity here to include guidance on supporting young people who do breach smokefree rules within their school to access advice and support to become smoke free.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Leicester City Council	Guideline	010	016	Rec 1.5 – It would be helpful to include guidance on where staff training and development can be accessed so that this comes from a reputable and nationally accredited source, and avoids misinformation being delivered.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Leicester City Council	Guideline	012	013	Rec 1.6 – we could not see any reference to second-hand smoke and felt that this should be included in any teaching on smoking and tobacco use.	Thank you for your comment. The guideline does acknowledge the risk posed by second hand smoke with recommendations outlining the need to raise public awareness of the harm of second hand smoke in the context of using medicinally licensed nicotine-containing products (1.8.1); the provision of clear advice regarding the danger of second hand smoke for those using acute, maternity and mental health services (1.14.1) and during contact

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					with partners, parents and other household members of people using acute, maternity and mental health services when identifying smoking (1.11.11); and in the context of the development of policy for smokefree grounds (1.21.2); and when training those who advise people how to stop smoking (1.23.4 and 1.23.11).
Leicester City Council	Guideline	013	005 - 007	Rec 1.6.4 – we agree with the content of this recommendation but would also like to see an addition to reflect that, for those who do smoke, e-cigarettes can be a valuable harm-reduced quitting aid. We feel it is important that young people, who may have parents and carers who smoke, are equipped with the knowledge that (in the circumstance of being used as a quitting aid) they are less harmful than tobacco smoking.	Thank you for your comment. Recommendations in 1.6 are focused on preventing children, young people, and young adults from taking up smoking. The committee were clear that they did not want to say anything that might promote the use of e-cigarettes in under 18s.
Leicester City Council	Guideline	044	015 - 017	Rec 1.17.1 – although the service delivery model has changed due to COVID restrictions (and the new service delivery model looks likely to remain longer term) this recommendation does feel achievable with 'tweaks' to how advisors deliver their relapse prevention session. It may for example involve provision of a specific "what ifs" type resource to highlight high risk situations and how they can be managed, tailored to individual service users situations.	Thank you for your comment. The committee recognises the challenges to practice resulting from the Covid-19 pandemic. The rationale and impact sections of the guidance has noted where the pandemic may have temporarily impacted on practice. However, the committee noted that it could not make recommendations based on such changes to practice as it has not reviewed evidence in this area.

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Leicester City Council	Guideline	044	018 - 019	Rec 1.17.2 – we felt that some clarity is needed around how individual services should manage this due to potential cost implications, i.e. after the initial 12 week supply should clients be provided with a further course of medication via their GP on prescription, or entered back into the service as a new episode?	The committee has made recommendations based on evidence of effectiveness and cost-effectiveness. Resourcing the implementation of the recommendations is outside of the committee's remit and is for local commissioners.
Leicester City Council	Guideline	049	009 - 010	Rec 1.20.6 – we felt that e-cigarettes should be included alongside NRT here as a first line of treatment option. Many pregnant women struggle to use the oral NRT products and find vaping devices are the key to quitting, but without clear guidance that this is a viable first line of treatment it could (and does) put women off trying them.	Thank you. The committee did not find any evidence to support the use of nicotine containing e-cigarettes during pregnancy as described in the rationale and impact section for these recommendations, and did not make any recommendations regarding this. The committee have made a series of research recommendation regarding nicotine containing e-cigarettes and pregnancy to stimulate research in this area.
Leicester City Council	Guideline	050	015 - 020	Rec 1.20.8 – this could be elaborated to include "Give clear, consistent and updated information on safety/handling of e-cigarettes"	Thank you. As described in the rationale and impact section for these recommendations, the committee found no evidence to support the use of nicotine containing e-cigarettes during pregnancy and therefore was unable to recommend them. The committee have made a series of research recommendation regarding nicotine containing e-cigarettes and pregnancy to stimulate research in this area.

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Leicester City Council	Guideline	051	008 - 021	Rec 1.20.12 – Could provision of an e-cigarette starter pack/e-liquids be included here as an incentive?	Thank you. The committee did not see any evidence that an e-cigarette starter pack/e-liquids was an effective incentive.
Leicester City Council	Guideline	057	006 - 008	Rec 1.22.2 – Clarity is needed on whether this recommendation is referring to community services or referrals back to primary care as there are cost implications to longer term service provision for community providers with limited budgets. Should a cut off point be recommended whereby if a client has not quit/made improvements to their smoking behaviours by e.g. 4 weeks they may need to take a break and return when they are able to commit more fully?	Thank you. The committee did not see any evidence for an effective cut off point and agreed this would vary from person to person. They were clear that support should be provided for as long as a person needs it.
Leicester City Council	Guideline	059	010 - 011	Red 1.22.14 – this is working well in many areas – clarity needed on whether this recommendation includes e-cigarettes or is it referring only to NRT products?	Thank you. Nicotine containing products is defined in the glossary section of the guideline. The definition of nicotine containing products has been amended to clarify that it includes nicotine containing e-cigarettes.
London Borough of Barnet	Evidence Review F	076	008 - 010	This link is tenuous looking at the evidence and studies with low confidence and certainty intervals (see studies quoted in appendix). It will drive educational settings and practitioners to give the message “ e-cigarettes are bad”.	Thank you for your comment. The evidence utilised in the development of this guideline has been identified and appraised in line with NICE's methods and process manual. The evidence along with expert testimony and the contributions of co-opted expert members to the committee has been utilised by the public health advisory

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					committee (PHAC) to develop the NICE tobacco guideline. The guideline specifies in recommendation 1.6.3 and 1.6.4 that in children, young people and young adults who do not smoke experimenting with or regularly using e-cigarettes should be discouraged, and e-cigarettes should be avoided to avoid making them inadvertently desirable. The committee wanted to discourage e-cigarette use among young people and young adults who do not smoke because evidence shows that use of e-cigarettes is linked with a higher chance of ever smoking later in life. Although there was no evidence about children, committee members agreed that ideas about smoking and what is normal can start from a young age so the recommendation should also apply to this age group. Recommendation 1.12.1 includes nicotine-containing e-cigarettes among the options that should be accessible to adults who smoke.
London Borough of Barnet	Evidence Review J	019	Table 5	1.20.6 Evidence review suggests the there is moderate evidence that NRT+ Behavioural support gives good outcome- why are we using the work "consider" – broadly should this be "discuss NRT and behavioural support"	Thank you for your comment. NICE uses 'consider' to reflect a recommendation for which the evidence of benefit is less certain (rather than an 'offer' recommendation which would reflect a strong recommendation, usually where there is clear evidence of

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					benefit) and reflects the PHAC's deliberations and the consideration of the moderate evidence identified and other expert testimony in line with the NICE methods and process manual.
London Borough of Barnet	Guideline	013	001 - 007	1.6.4 We agree that discussion around e-cigarettes in this setting need to be separate, but surely we must recognise that e-cigarette awareness will support CYP knowledge that this is a route out of smoking, both for themselves, their peers and families. The risk here is that making it so far removed from smoking means it ceases to become a cognitive link to stopping smoking, should be discussed in context of "if smoking regularly, offers route out of smoking".	Thank you for your comment. The preceding recommendation 1.6.3 highlights that "as part of the curriculum on tobacco, alcohol and drug misuse, discourage children, young people and young adults who do not smoke from experimenting with or regularly using e-cigarettes." The recommendation goes on to state that e-cigarettes be spoken about separately from tobacco products. So e-cigarettes will be discussed in the context of a tobacco, alcohol and drug misuse but as something separate from tobacco so that e-cigarettes could not be confused with tobacco. The rational and impact section outlines the committee discussion regarding this recommendation and they wanted to discourage e-cigarette use among young people and young adults who do not smoke because evidence shows that use of e-cigarettes is linked with a higher chance of ever smoking later in life. Although there was no evidence about children, committee members agreed that ideas about smoking and what is normal can start from a young

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					age so the recommendation should also apply to this age group. The committee agreed that school-based interventions could help to discourage e-cigarette use among those who do not smoke and noted the need to not inadvertently make e-cigarettes desirable.
London Borough of Barnet	Guideline	023	017 - 019	1.12.4 This guidance is in direct conflict with the legal position and the scope of this documents use. Legally under 18yr olds cannot buy E-cigarettes, and medicolegally to advise an under 18yr old in e-cigarette may cause consternation/concern in many people. How do we align that we KNOW e-cigarette use would be less harmful than continuing to smoke, and CONVEY this to a under 18 year old without breaching legal parameters? The scope of the NICE guidance is to support smokers to stop, prevent them starting, reduce harm from "aged 12 and up" and yet here, there is a disparity.	Thank you for your comment. The guideline is not in conflict with the legal position and does not recommend the sale or use of e-cigarettes by young people under the age of 18. The Public Health Advisory Committee (PHAC) discussed your comment and outlined that all the recommendations apply to those aged 12 or over unless otherwise specified. E-cigarettes cannot be purchased by people under the age of 18 and recommendation 1.12.1 specifies "ensure the following are accessible to adults who smoke with reference to interventions outlined including 'nicotine-containing e-cigarettes'". On this basis the PHAC considered the recommendations sufficiently clear and made no changes. Despite the above, we have amended the statement prefatory to recommendations 1.12.13-1.12.17 to clarify that these recommendations are for people providing stop-smoking support or advice relating to the use of e-cigarettes by adults.

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London Borough of Barnet	Guideline	023	005	1.12.1 The barriers to offering the nicotine-containing e-cigarettes are many, and well documented. How will the NICE guidance and implementation of them, support the roll out? How will the clinical reticence from HCP in a variety of settings be addressed and worries assuaged? A public facing and HCP facing campaign will be integral. In line with this advice many LA Stop Smoking Services will be looking for ways to include this into their offer, how will they do this without PHE support/guidance given risk averse nature, political sway and concerns re breaching article 5.3 of WHO FCTC?	Thank you for your comment. It is beyond NICE's remit to make commissioning decisions and these should occur at the local commissioning level. As noted in the guideline, there are currently no licensed nicotine containing e-cigarettes.
London Borough of Barnet	Guideline	023	026	1.12.5 The barriers to offering the nicotine-containing e-cigarettes are many, and well documented. How will the NICE guidance and implementation of them, support the roll out? How will the clinical reticence from HCP in a variety of settings be addressed and worries assuaged? A public facing and HCP facing campaign will be integral. In line with this advice many LA Stop Smoking Services will be looking for ways to include this into their offer, how will they do this without PHE support/guidance given risk averse nature, political sway and concerns re breaching article 5.3 of WHO FCTC?	Thank you for your comment NICE guidelines are evidence-based recommendations for health and care in England. They set out the care and services suitable for most people with a specific condition or need, and people in particular circumstances or settings. People have the right to be able to make informed decisions about their care. Our guidance should be considered when making decisions with them. It is beyond NICE's remit to make commissioning decisions and these should rightly occur at the local commissioning level.

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London Borough of Barnet	Guideline	025	021 - 024	1.12.13 This will require a concerted information campaign for Public, HCP, stakeholders- without that, this message will be lost and we will continue to have smokers needlessly dying.	Thank you for your comment. Recommendations 1.9 focuses on promoting stop-smoking support and makes recommendations regarding co-ordinating communication strategies to support the delivery of stop-smoking support, stop-smoking Quitlines and other activities designed to help people stop smoking. It includes developing and delivering communications strategies about stopping smoking in partnership with the NHS, national, regional, and local government and non-governmental organisations and specific recommendations to employers and others to raise awareness to help people stop smoking which would raise awareness in the groups you outlined. Coupled with this are recommendations on policy (1.21), commissioning (1.22) and training (1.23) directing those with responsibility for developing smokefree policy, and for commissioning and training services to take action with opportunities to raise awareness through these processes.
London Borough of Barnet	Guideline	046	012 - 017	1.18.2 We think another bullet point needs to be added – to cover SecondHand Smoke exposure	Thank you. The committee did not consider the evidence for second hand smoke exposure and therefore were unable to make recommendations about it.

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London Borough of Barnet	Guideline	050	009 - 010	1.20.6 Evidence review suggests the there is moderate evidence that NRT+ Behavioural support gives good outcome- why are we using the work “consider” – broadly should this be “discuss NRT and behavioural support”	Thank you. The committee discussion section of the evidence review explains that the committee found the evidence to be unconvincing in this area and expected a larger effect than they saw. Much of the evidence was of low quality or not statistically significant. The committee discussed the evidence alongside their own experience and expertise and agreed that a recommendation to consider adding NRT to behavioural support was an appropriate recommendation.
London Borough of Barnet	Guideline	051	008 - 021	1.20.12 We assume there will be a overarching piece of funding available for LA? This is not part if NHS LTP funding and as such this offering of incentives will create an inequity of service for those offered support via Hospital as opposed to those supported in community.	Thank you. The recommendations are based on the evidence of effectiveness, and the implementation of the recommendations is primarily a local commissioning decision.
London Borough of Barnet	Guideline	057	006 - 008	1.22.2 Whilst the 12 week model is gold standard, it would be useful to know how this and providing NRT and support beyond (“for as long as is needed”) will be achieved in the context of ever shrinking public purse and non ring fenced budgets.....	Thank you. The committee did not see any evidence for an effective cut off point and agreed this would vary from person to person. They were clear that support should be provided for as long as a person needs it.
Medicines and Prescribing Team	Guideline	General	General	I found that navigating back and for the through the guideline with the internal links didn't always bring me back to the page I was reading, which could be a bit confusing. Please double check all these when it goes to	Internal comment – Editors check all hyperlinks before publication.

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				publication so it is as user friendly as possible. Thanks	
Medicines and Prescribing Team	Guideline	023	009	1.12.3 I had to read this a few times because I found the wording confusing. Does 'it' in '...and how they will access it?' refer to <i>behavioural support</i> or <i>the option they choose to help them stop smoking</i> ?	internal comment. We have amended this recommendation to "Offer behavioural support to people who smoke regardless of which intervention they choose to help them stop smoking. Explain how to access it" so it is clearer that 'it' refers to the behavioural support.
Medicines and Prescribing Team	Guideline	023	022	Varenicline – There is currently a supply issue with varenicline https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103160 Please keep an eye on this closer to guideline publication	The committee were aware of this issue but noted that this should not affect the recommendations.
Medicines and Prescribing Team	Guideline	069	015	For the link to the British National Formulary, it would be worth linking to the NICE BNF as you have for all other BNF links, rather than the BNF website homepage so users can easily find the relevant information they need on NRT. This might be a better link for this https://bnf.nice.org.uk/drug/nicotine.html	Thank you for your comment. The link has now been updated.
Medicines and Prescribing Team	Guideline	069	016	Lozenges and oromucosal spray are the only 2 types of NRT that haven't been included in this list. Suggest adding these, especially as p25 1.12.12 line 15 mentions lozenges. They can be found on the relevant page of the BNF here: https://bnf.nice.org.uk/drug/nicotine.html	Thank you for your comment. We have added mouth spray and lozenge to the definition.

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Modern Health Group /Evapo	Guideline	025 - 026	025 -	1.12.14 – 1.12.17 Clinicians should understand the role nicotine plays in ensuring a successful switch attempt. Offering clear guidance on nicotine strength will prevent relapse and help adult smokers find the right nicotine concentration to mirror the nicotine levels delivered through their use of combustible cigarettes. It is often better to start on a higher strength to first ensure all cravings are satisfied and reduce the risk of falling back to smoking.	Thank you for your comment. Recommendation 1.12.13 to 1.12.17 are for people providing stop-smoking advice which would include clinicians. Recommendation 1.12.17 outlines that those providing advice should “explain to people who choose to use nicotine-containing e-cigarettes the importance of getting enough nicotine to overcome withdrawal symptoms and explain how to get enough nicotine”. This is discussed further in the ‘Rationale and Impact’ section of the guideline (p.80) where committee discussion on the role of nicotine and the impacts of not getting enough nicotine on quit attempts are outlined and that “people should be encouraged to use as much as they need and told how to use the products effectively”
Modern Health Group /Evapo	Guideline	022 - 023	024	We support new guidance which would add e-cigarettes to the list of possible interventions that are to be made accessible to smokers. An ASH survey of tobacco control leads found that only 11% of local authority stop smoking services offered e-cigarettes to some or all people making a quit attempt (PHE, Vaping in England: 2021 evidence update summary, February 2021 Link). Nearly two thirds (68%) of vapers say that they never thought they would quit smoking until	Thank you for your comments. The committee agreed that e-cigarettes are one of many tools to help individuals with quit attempts.

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				<p>vaping came along (OnePoll, 2019 Link) and in one year alone, PHE identified that over 50,000 smokers quit cigarettes with the help of a vaping (STS Survey, PHE, 2021 evidence update summary, February 2021 Link). There are now approximately 2m smokers who have successfully quit in the UK using e-cigarettes. For this number to continue to increase however, stop-smoking interventions must be able to deliver consistent and effective guidance on attempts to quit combustible tobacco. This must include offering a range of options to those looking to quit and should include e-cigarettes as the most effective, less harmful alternative.</p> <p>We note with concern the recent comments by the World Health Organisation (WHO) which described e-cigarettes as 'harmful'. Whilst we agree that regulation concerning e-cigarettes could be enhanced, this should be evidence-based, fair and proportionate. The fundamental difference between the UK and the WHO is that the UK has taken a science and evidence-led approach towards tobacco harm reduction. The evidence clearly shows the enormous role vaping products play in helping smokers to quit and move away from smoking for good. Public Health England confirms that</p>	

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				<p>vaping is at least 95% less harmful than smoking.</p> <p>Misinformation about vaping continues to deter smokers from switching to a less harmful alternative. Clinicians should use their position to challenge increasing misperceptions about the relative harm from e-cigarettes when offering advice and guidance to patients in their care. The latest PHE report has found that:</p> <p><i>'Perceptions of the harm caused by vaping compared with smoking are increasingly out of line with the evidence, with just 29% of current smokers believing that vaping is less harmful than smoking, 38% believing vaping to be as harmful as smoking, 18% not knowing whether vaping or smoking is more harmful and 15% of smokers believing vaping to be more harmful than smoking.'</i> (PHE, <i>Vaping in England: 2021 evidence update summary, February 2021</i> Link p147)</p> <p>ASH data also suggests that millions of smokers – more than half of the 6.9 million remaining smokers – could now be dissuaded from exploring switching to e-cigarettes because of incorrect views or confusion about the relative harms of e-cigarettes versus combustible cigarettes:</p>	

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				<p><i>'Since 2013 there has been a significant increase in misperception of the relative risks of vaping compared to smoking among the adult population... The proportion of the adult population thinking that e-cigarettes are more or equally harmful as smoking is five times higher than in 2013, increasing from 7% in 2013 to 37% in 2020.'</i> (Action on Smoking Health, 2020 Link, p8)</p> <p>We agree that all inhalable nicotine e-liquids, including non-nicotine containing e-liquids, should be notified to the MHRA and subject to the same packaging, ingredients, emissions, and toxicological testing requirements. Regulating all e-liquids in this way will ensure that manufacturers are deterred from adding unregulated ingredients into their e-liquids and that consumers are better protected if they choose to mix their own products (e.g. shortfill/shake n'vape).</p>	
Modern Health Group /Evapo	Guideline	020	General	<p>1.11.1 – 1.11.5 Clinicians must work with patients looking to switch to less harmful alternatives to understand their current smoking habits, previous quit attempts (if any) and which of these was the most effective. Any advice should be based on this information. That advice may include using a combination of</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.</p>

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				behavioural support and alternative nicotine delivery products, including e-cigarettes. We follow the suggestion from the recent APPG on Smoking and Health report that smokers should automatically be opt in to join a stop smoking consultation. This would encourage smokers to seek a consultation and help the UK reach its Smokefree 2030 target.	
Modern Health Group /Evapo	Guideline	023	General	<p>1.12.5</p> <p>While we recognise there exists a range of reduced harm alternatives to smoking, vaping has been scientifically proven and continues to be the most effective tool in supporting adult smokers to quit in the UK.</p> <p>The independent Cochrane Collaboration recently published a systematic review finding that e-cigarettes were more effective for smoking cessation than nicotine replacement therapy (Cochrane, 2021 Link). In addition, a recent UK-based trial of e-cigarettes found them twice as effective as best combination nicotine replacement therapy at one fifth of the price (Li, Hajek et al. 2019 Link). There is also evidence that e-cigarette use in the community is contributing at least 70,000 additional quits per year in England (Beard, West, Michie, Brown 2019 Link).</p> <p>A recent trial in a stop smoking clinic in Birmingham achieved a 174% higher number</p>	<p>Thank you for your comment. The recommendations in this guideline reflect your comments highlighting the need to ensure access to a range of stop-smoking interventions to adults who smoke which includes e-cigarettes (recommendation 1.12.1), informing them of the range of interventions available and how to access them (recommendation 1.12.2), discussing with people who smoke which options to use to stop smoking taking into account a number of person centred factors in that decision making process (recommendation 1.12.4) and advising people who smoke of the evidence-based options that result in more successful quit attempts (recommendation 1.12.5) amongst other things.</p>

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				<p>of quits by using an e-cigarette as part of the treatment formulary whilst reducing the cost per quit by more than £150 (Soar, LSBU 2021 Link).</p> <p>Clinicians must work with patients looking to switch to less harmful alternatives to understand their current smoking habits, previous quit attempts (if any) and which of these was the most effective. Any advice should be based on this information. That advice may include using a combination of behavioural support and alternative nicotine delivery products, including e-cigarettes.</p>	
Modern Health Group /Evapo	Guideline	025	General	<p>1.12.13 Misinformation about vaping continues to deter smokers from switching to less harmful alternatives. Clinicians should use their position to challenge increasing misperceptions about the relative harm from e-cigarettes when offering advice and guidance to patients in their care.</p> <p>Cancer Research produced a cross-sectional survey of nurses and GPs across the UK in October 2019 and found that:</p> <ul style="list-style-type: none"> Over 1 in 3 clinicians are unsure if e-cigarettes are safe enough to recommend as a quit tool to patients who smoke. 	<p>Thank you for your comments. The committee agreed that e-cigarettes are one of many tools to help individuals with quit attempts. NICE guidelines are evidence-based recommendations for health and care that set out the care and services suitable for most people with a specific condition or need, and people in particular circumstances or settings. People have the right to be able to make informed decisions about their care and NICE guidance should be taken into account when making decisions with them. The introduction to recommendation 12.1 outlines and provides a hyperlink for training requirements. Further recommendations 1.12.13 to 1.12.17 outline the advice on</p>

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				<ul style="list-style-type: none"> 2 in 5 said that they would feel uncomfortable recommending e-cigarettes to their patients who smoke. 1 in 6 clinicians said they would never recommend using e-cigarettes to patients who smoke. Fewer than 3 in 10 clinicians agree that current knowledge is sufficient for advising patients about e-cigarettes. With 3 in 5 clinicians citing news, media and advertising as their source of information (Cancer Research UK, E-cigarettes and primary care, October 2019 Link). <p>ASH data also suggests that millions of smokers – more than half of the 6.9 million remaining smokers – could now be dissuaded from exploring switching to e-cigarettes because of incorrect views or confusion about the relative harms of e-cigarettes versus combustible cigarettes: <i>'Since 2013 there has been a significant increase in misperception of the relative risks of vaping compared to smoking among the adult population... The proportion of the adult</i></p>	<p>nicotine-containing e-cigarettes to be provided by people providing stop-smoking support or advice, with recommendations highlighting the giving of clear, consistent and up-to-date information on e-cigarettes and how to use them, including hyperlinks to examples of where to access this information.</p> <p>The Public Health Advisory Committee (PHAC) discussed the limited evidence and recognise the need for evidence and have developed research recommendations that seek to stimulate research regarding the health effects of e-cigarettes, the effectiveness of e-cigarettes in pregnant women, the effectiveness and safety of e-cigarettes for harm reduction when used alongside tobacco products to cut down on smoking, the impact of amount and frequency of e-cigarette use on their effectiveness to stop smoking, the impact of e-cigarette flavouring on effectiveness as an aid to stop smoking, the role of e-cigarettes on establishing future smoking, and understanding the factors that may influence the use of e-cigarettes.</p>

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				<p><i>population thinking that e-cigarettes are more or equally harmful as smoking is five times higher than in 2013, increasing from 7% in 2013 to 37% in 2020.'</i> (Action on Smoking Health, 2020 Link, p8)</p> <p>The Government should support the health service by firstly signposting clinicians to the latest clinical guidance on e-cigarettes. In addition, it is also hoped that both medical professionals and local stop smoking practices adopt a consistent approach to supporting patients attempting to quit smoking by recommending e-cigarettes as the most effective and least harmful alternative.</p> <p>The latest PHE report (2021) has found that: <i>'Perceptions of the harm caused by vaping compared with smoking are increasingly out of line with the evidence, with just 29% of current smokers believing that vaping is less harmful than smoking, 38% believing vaping to be as harmful as smoking, 18% not knowing whether vaping or smoking is more harmful and 15% of smokers believing vaping to be more harmful than smoking.'</i> (PHE, Vaping in England: 2021 evidence update summary, February 2021 Link p147)</p> <p>We also suggest that there is a gap in education on e-cigarettes in the healthcare community which needs to be addressed.</p>	

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				Surveys show that many GPs still believe that nicotine is causing cancer which is of course incorrect. The combustion of tobacco is causing all the smoking related diseases. Smokers smoke for the nicotine but die from the tar. E-cigarettes are sidestepping the combustion, but still satisfy the nicotine cravings. There should be mandatory courses for GPs and health care professionals on offer to help with education around e-cigarettes.	
Modern Health Group /Evapo	Guideline	074	001 - 004	There are several factors that determine nicotine delivery to the user. These include the nicotine concentration of the e-liquid; the e-liquid formulation; the heating temperature; and the user behaviour (how many puffs; how deep, how often etc). The delivery of nicotine is therefore the result of the interplay of these factors and regulating nicotine delivery based on one factor alone may shift the dynamics of the other factors. For e-cigarettes to compete with combustible cigarettes and provide a satisfactory alternative to those looking to switching, they must provide a comparably satisfying nicotine effect and experience. Regulating e-cigarettes to ensure they can deliver nicotine competitively with a combustible cigarette will involve achieving the right balance between	Thank you for your comment

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				these factors while minimising modifiable risks from e-cigarettes.	
Modern Health Group /Evapo	Guideline	074	005 - 008	Academics and tobacco harm reduction experts have rightly highlighted the critical role that flavours play in supporting those switching from smoking to vaping and preventing relapse. Adult smokers should have access to a full range of flavours to ensure that they do not turn to illegal products or relapse to smoking, as evidence suggests. (ASH, Use of e-cigarettes (vapes) among adults in Great Britain, 2020 Link p8). This is a conclusion which is supported by a vast body of scientific evidence. Furthermore, steps can be taken to ensure products are not youth-appealing. Through explicitly banning cartoons and youth-appealing iconography, and restricting flavour names/descriptors that may disproportionately appeal to underage users. These steps should help promote the responsible manufacturing and sale of e-liquids, whilst not limiting brand creativity.	Thank you for your comment
Modern Health Group /Evapo	Guideline	074	009 - 011	The latest PHE data has found that 'most young people who had never smoked had also never vaped. Between 0.8% and 1.3% of young people who had never smoked were current vapers' and that 'most current vapers were either former or current smokers.' (PHE,	Thank you for your comment

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				<p>Vaping in England: 2021 evidence update summary, February 2021 Link p13/14)</p> <p>In response to a Parliamentary Question in February 2021, Public Health Minister Jo Churchill stated there was 'no evidence that vaping amongst adults leads them to start smoking and little evidence that increases in vaping among young people leads to increases in smoking' (Written Parliamentary Question, 15 February 2021, Link).</p> <p>According to ASH, a large majority of 11-18 year-olds have never tried or are unaware of e-cigarettes (83%) (ASH, Use of e-cigarettes among young people in Great Britain, January 2021 Link p1). Of young people aged 11-18 years old who have never smoked, 5.5% have ever tried electronic cigarettes, 0.8% are current vapers, only 0.1% vape more than once a week, and not a single never smoker reported vaping daily (ASH, 2019 Link).</p>	
Modern Health Group /Evapo	Guideline	075	001 - 006	<p>In this country, there are vast inequalities attributable to or associated with smoking and reviewing restrictions bottle sizes and commissioning a review on effective nicotine delivery will be critical to reaching under-served groups.</p> <ul style="list-style-type: none"> - Smoking prevalence is around 12% higher amongst the unemployed compared to those in employment, and 	<p>Thank you for your comment. The committee thought including e-cigs as an additional intervention for cessation increases the available options. The regulation of non nicotine containing products is outside NICE's remit.</p>

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				<p>roughly 2.5 times higher among those in manual labour when compared to managerial and professional employment (Data in this section from: ONS, Adult Smoking habits in the UK: 2019 Link)</p> <ul style="list-style-type: none"> - Those with no educational qualifications are more likely to smoke (28.3%) compared to those with degree level qualifications 7.8% (Data in this section from: ONS, Adult Smoking habits in the UK: 2019 Link) - Around 40% of smokers reported suffering from some form of mental illness compared to 16.5% of all adults (Mental health data: GP Patient Surveys 2014-15 cited at: Public Health England, Health Matters, Smoking and Mental Health, 26 February 2020 Link) <p>Effective nicotine delivery Cigarette smoke contains thousands of distinct constituents, many of which are toxic or carcinogenic. It is these toxic by-products of combustion, not the nicotine, that are responsible for smoking-related death and disease. E-cigarettes do not burn tobacco</p>	

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				<p>leaves but use electronic heat sources to aerosolise a nicotine-containing liquid that is then inhaled by the user. This provides nicotine without burning tobacco, thus significantly reducing exposure to the harmful chemicals found in tobacco smoke.</p> <p>This is the same rationale the committee (NICE committee) have concluded on P80 – Line 7-14</p> <p>“They [the committee] agreed that because many of the harmful components of cigarettes are not present in e-cigarettes, switching to nicotine containing e-cigarettes was likely to be significantly less harmful than continuing smoking. So the committee agreed that people should be able to access them as part of the range of interventions they can choose to use (see the section on stop smoking interventions). They also agreed that people should be given up-to-date information on what is known about e-cigarettes to help them make an informed decision about whether to use them.”</p> <p>Reduced toxicant exposure is the primary benefit of switching to an e-cigarette, but delivery of nicotine must be competitive with that of a combustible cigarette. This is an important factor in determining whether adult smokers are likely to continue to use an e-</p>	

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				<p>cigarette in place of their regular cigarettes – a critical component of harm reduction and reducing smoking prevalence.</p> <p>There are several factors that determine nicotine delivery to the user. These include the nicotine concentration of the e-liquid; the e-liquid formulation; the heating temperature; and the user behaviour (how many puffs; how deep, how often etc). The delivery of nicotine is therefore the result of the interplay of these factors and regulating nicotine delivery based on one factor alone may shift the dynamics of the other factors.</p> <p>For e-cigarettes to compete with combustible cigarettes and provide a satisfactory alternative to those looking to switching, they must provide a comparably satisfying nicotine effect and experience. Regulating e-cigarettes to ensure they can deliver nicotine competitively with a combustible cigarette will involve achieving the right balance between these factors while minimising modifiable risks from e-cigarettes.</p> <p>Bottle size limitations and nicotine strength There is a significant opportunity for the industry to increase convenience for the consumer by allowing larger bottle sizes, without increasing the risk profile of e-liquids.</p>	

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				<p>This can be achieved by replacing the existing limit on bottle size (currently set at 10ml) in favour of a limit on total nicotine quantity per bottle, set at 200mg (equivalent to the current limit of 20mg/ml nicotine in a 10ml bottle). To illustrate the point, the implementation of this change would allow an e-cigarette user currently vaping at a nicotine strength of 3mg/ml and restricted to buying 10ml bottles, to instead purchase a single 60ml bottle, rather than six 10ml bottles.</p> <p>As nicotine is a key component to satisfaction and is delivered by the use of bottled e-liquids and pods, I/we support a government review is commissioned to examine the role in which nicotine plays in allowing e-cigarettes to be a satisfying alternative to adult smokers wishing to make the switch away from smoking.</p> <p>Following review, should the limit on nicotine concentration be increased, the maximum nicotine content limit should be increased proportionately. This may further maximise the benefits to consumers and the environment.</p> <p>Should non-nicotine containing e-liquids be brought under the scope of the TRPR when the government publishes its response to the post-implementation review, these products should not be subject to the existing limitations</p>	

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				in bottle size as those which do contain nicotine.	
Modern Health Group /Evapo	Guideline	075	007 - 009	<p>For e-cigarettes to compete with combustible cigarettes and provide a satisfactory alternative to those looking to switching, they must provide a comparably satisfying nicotine effect and experience. Regulating e-cigarettes to ensure they can deliver nicotine competitively with a combustible cigarette will involve achieving the right balance between several factors while minimising modifiable risks from e-cigarettes.</p> <p>As nicotine is a key component to satisfaction and is delivered by the use of bottled e-liquids and pods, I/we support a government review is commissioned to examine the role in which nicotine plays in allowing e-cigarettes to be a satisfying alternative to adult smokers wishing to make the switch away from smoking. Evidence from ASH on the current satisfaction level of vaping compared to smoking suggests that 80% of former e-cigarette users who are current smokers found vaping to be less satisfying than cigarette smoking. Although at a lower rate (61%) those who currently use an e-cigarette in conjunction with combustible cigarettes, are also less satisfied (Action on Smoking Health, October 2020 Link). The main reason given for discontinuation vaping was</p>	Thank you for your comment. The regulation of e-cigarettes is beyond NICE's remit.

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				<p>that e-cigarettes did not help users with their cravings due to insufficient nicotine delivery. This is the same rationale the committee have concluded on P80 – Line 20-24</p> <p>“The committee discussed that it is more likely that people will not get enough nicotine to help them stop smoking, than get too much. They agreed that not getting enough nicotine is likely to increase the risk that the person will return to smoking, so they recommended that people should be encouraged to use as much as they need and told how to use the products effectively.”</p> <p>Academics and tobacco harm reduction experts have rightly highlighted the critical role that flavours play in supporting those switching from smoking to vaping and preventing relapse as well. Adult smokers should have access to a full range of flavours to ensure that they do not turn to illegal products or relapse to smoking, as evidence suggests. (ASH, Use of e-cigarettes (vapes) among adults in Great Britain, 2020 Link p8). This is a conclusion which is supported by a vast body of scientific evidence.</p> <p>Should non-nicotine containing e-liquids be brought under the scope of the TRPR, when the government publishes its response to the</p>	

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				post-implementation review, these products should not be subject to the existing limitations in bottle size as those which do contain nicotine.	
National Centre for Smoking Cessation and Training	Guideline	General	General	<p>The NCSCT is pleased to see increased confidence in the guideline in recommending that stakeholders routinely include e-cigarettes (EC) in the toolkit of what works for people who smoke and who either want to stop smoking or who are not ready to stop in one go.</p> <p>The NCSCT notes that the guidance recommends talking about EC separately from tobacco products. This is an important distinction to make and will help stakeholders, clinicians and patients understand relative harms.</p> <p>Certain sections (32.1, 33.13, 36) would have benefited from including EC along with licensed nicotine-containing products. This would strengthen the guidance.</p> <p>In some sections which state licensed nicotine containing products, it would seem that they could include non-nicotine containing first line stop smoking medications (i.e. varenicline and</p>	<p>Thank you for your comment. The Public Health Advisory Committee (PHAC) considered your comment and are of the opinion that the glossary defines what is meant by 'nicotine-containing products'. The definition has been amended to make it clearer that this includes nicotine containing e-cigarettes.</p> <p>The references to 'licensed nicotine-containing products' are in carried forward recommendations (greyed-out recommendations) for which the evidence underpinning them has not been considered and thus these recommendations cannot be amended.</p> <p>The Public Health Advisory Committee (PHAC) considered evidence of effectiveness, cost-effectiveness, barriers and facilitators as well as expert testimony in their deliberations when developing NICE guidelines and the recommendations. Some of the recommendations have been carried</p>

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				<p>to a lesser extent to bupropion). As is stated in the document combination NRT, varenicline, and emerging evidence suggest EC offer the greatest efficacy.</p> <p>There is less guidance on stop smoking services and stop smoking support delivered in other settings compared to previous guidance documents. This could be disconcerting for stop smoking services and lead to more variability in interventions offered, and result in a decrease in the quality of services.</p> <p>There is a level of specificity in some sections not consistently applied in the document (e.g. a level of detail on maternity care and smokeless tobacco not replicated in other important areas of practice).</p> <p>Behavioural support ('stop smoking support') is only effective if delivered by someone trained in behavioural support for smoking cessation. This should be emphasised or it risks serious quit attempts being undermined by inadequate behavioural support resulting in higher rates of relapse than could be achieved by a trained practitioner, and lives being lost.</p>	<p>over and the evidence underpinning them have not been considered.</p> <p>The PHAC agree with your comment that behaviour support is only effective if delivered by someone trained in behavioural support for smoking cessation and PHAC have specified (with hyperlinks) the National Centre for Smoking Cessation and Training for training requirements in the introduction to recommendation 1.12 and this is further clarified in the glossary definition for 'behavioural support' which is hyperlinked throughout the guideline document and makes specific reference to 'a counsellor trained to provide stop-smoking support'.</p>
National Centre for	Guideline	063 - 066	011 - 026	1.23 Training	Thank you for your comment. This comment relates to a greyed-out area of the guideline

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Smoking Cessation and Training				<p>Sub-section 1.23.2 Training on stopping smoking</p> <p>This section includes three sub-sections with recommendation as follows:</p> <ul style="list-style-type: none"> ▪ Those who advise people on how to stop smoking ▪ People working in closed institutions ▪ Midwives and others working with healthcare professions <p>This section has omitted very important recommendations that were included in previous NICE Guidance documents on training for those who provide stop smoking support (referred to in bullet one as 'Those who advise people on how to stop smoking'). Specifically, training recommendations for staff in local stop smoking services, but also staff delivering behavioural support programmes for smoking cessation in a variety of settings (including acute care, primary care, pharmacy, maternity care settings etc).</p> <p>Additionally, the wording 'Ensure smoking cessation support and treatment is delivered only by staff who have received training that complies with the 'Standard for training in smoking cessation treatments' has been</p>	<p>and is outside of the scope for this update. Please see the scope document on the NICE website. It should also be noted that in the introduction to recommendation 1.12 there is a sentence that hyperlinks to the NCST training standards as the reference point for training requirements.</p>

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				<p>deleted. The reason given for deletion is that 'tailoring support and treatment is a general principle recommended in NICE's guideline on patient experience in adult NHS services.' We do not support this deletion.</p> <p>The National Training Standard was produced by the NCST on behalf of DH and includes all behaviour change techniques (BCTs) for which there is evidence of effectiveness. It does not prevent tailoring support and treatment as appropriate, therefore the rationale for deletion is not justified. "Practitioners trained to deliver interventions according to the standard have been proven to be effective in adding significant value to quit attempts (Brose L, West R, Michie S, McEwen A. Changes in success rates of smoking cessation treatment associated with take up of a national evidence-based training programme. Preventive Medicine 2014;69C:1-4). Removal of the Training Standard is likely to lead to a return to the situation prior to the establishment of the NCST where people provided training based on opinion, rather than the evidence, for what effective training should contain. This recommendation should therefore be reinstated.</p>	

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				<p>We would recommend an amendment to the wording used in 2018 NG92 NICE Guidance (see below) should be included in section 1.23.</p> <p>'All staff who deliver stop support/tobacco use treatment should be trained in the core competencies for stop smoking support and ideally be certified as a stop smoking practitioner (include hyperlink). Training should comply with the Standard for training in smoking cessation treatments or its updates (include hyperlink).'</p> <p>Supporting Reference:</p> <ul style="list-style-type: none"> ▪ Brose L, West R, Michie S, McEwen A. Changes in success rates of smoking cessation treatment associated with take up of a national evidence-based training programme. Preventive Medicine 2014;69C:1-4. 	
National Centre for Smoking Cessation and Training	Guideline	020	013 - 014	1.11.2 should say that: "...stopping smoking in one go with a combination of medication and behavioural support is the best approach."	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
National Centre for	Guideline	022	015	The statement seems to wish to reference the NCSCT Training Standard. The hyperlink	Thank you for your comment. The hyperlink has been updated.

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Smoking Cessation and Training				takes you to the NCSCT training page, where you are able to access online training is stop smoking support. Suggested edit: "These recommendations are for people providing stop-smoking support or advice. For training requirements see the National Centre for Smoking Cessation and Training (NCSCT) Training Standard. Hyperlink should be corrected to link directly to the Training Standard document: https://www.ncsct.co.uk/pub_training-resources.php "	
National Centre for Smoking Cessation and Training	Guideline	023	006 - 007	1.12.2 There is an opportunity here to be more specific about what very brief advice on smoking (VBA) involves: Ask, Advise and Act. This is supported by meta-analysis (Aveyard et al 2012).	Thank you for your comment. 1.12.2 is a recommendation about making sure that people are aware of the range of interventions that they can access (and how to access them). VBA is covered in 1.12.1. The Public Health Advisory Committee (PHAC) outlined that the introduction to recommendation 1.12 outlines and provides a hyperlink to training requirements (National Centre for Smoking Cessation and Training) where further details regarding very brief advice are available. PHAC noted that as these recommendations are aimed at people providing stop-smoking support or advice they would be aware of these interventions and as outlined training requirements are hyperlinked.

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National Centre for Smoking Cessation and Training	Guideline	023	008 - 009	1.12.3 Behavioural support is only effective if delivered by someone trained in behavioural support and this guideline should reflect this: "Offer behavioural support from a trained practitioner to people"	Thank you for your comment. The introduction to recommendation 1.12 outlines and provides a hyperlink to training requirements (National Centre for Smoking Cessation and Training) where further details regarding requirements are outlined.
National Centre for Smoking Cessation and Training	Guideline	023	025	Better wording suggested: "a combination of longer-acting with shorter-acting NRT."	Thank you for your comments. This guideline has been through NICE's editorial process and conforms to its standards. The Public Health Advisory Committee (PHAC) considered your comments and have not made the suggested change on this basis.
National Centre for Smoking Cessation and Training	Guideline	025	014 - 018	For more dependent smokers, replacing 'each cigarette with the product they are using' could exceed recommended daily doses. It may be useful to provide examples of using combination NRT given that this is the recommendation made in 1.12.5	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
National Centre for Smoking Cessation and Training	Guideline	025	010	Should say: "manage urges to smoke."	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
National Centre for Smoking Cessation	Guideline	026	008	It may not be helpful to ask an individual how long they intend to vape for. Many people when they start a quit attempt think that they should stop all nicotine use as soon as	Thank you for your comment. The rationale and impact section of the guideline outline the Public Health Advisory Committees discussion regarding this recommendation.

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and Training				possible, and only continue once they find it helps them stay smokefree. Some weeks after their initial quit date, they may see things in a different light once their confidence about not smoking grows.	The committee used their knowledge and experience to supplement the very limited and uncertain evidence about harms. The committee agreed that with the limited data on effects of longer-term use, people should only use e-cigarettes for as long as they help prevent them going back to smoking. They also agreed that people should be discouraged from continuing to smoke when using e-cigarettes, even if they are smoking less, because there is no information on whether this will reduce their harm from smoking. The committee discussed that it is more likely that people will not get enough nicotine to help them stop smoking, than get too much. They agreed that not getting enough nicotine is likely to increase the risk that the person will return to smoking, so they recommended that people should be encouraged to use as much as they need (1.12.17) and told how to use the products effectively (1.12.14)
National Centre for Smoking Cessation and Training	Guideline	026	010	If the practitioner does not know how an individual can stop vaping, this may not be helpful. The NCSCT is producing guidance on this, but in real life situations we know from clients that reducing the dose of nicotine is fairly commonplace, indicating that if an individual wants to stop vaping, it is well within	Thank you for your comment. Recommendation 1.12.13 links to NCSCT resources which includes advice on how to stop using nicotine containing e-cigarettes when the person is ready to do so.

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				their control to do this. Stopping too early increases the risk of relapse to smoking, and longer term vaping may help to avoid this.	The second bullet point of recommendation 1.12.15 recognises your concern about the risk of relapse and recommends that nicotine containing e-cigarettes are used for long enough to prevent a return to smoking.
National Centre for Smoking Cessation and Training	Guideline	026	015	We are pleased to see the emphasis on using enough nicotine, a point which is often missed by users and healthcare workers alike.	Thank you for your comment
National Centre for Smoking Cessation and Training	Guideline	027	018 - 026	1.13.1 This section is somewhat confusing and could benefit from stressing that the best chance of quitting is with a combination of behavioural support and medication; people should be directed/referred towards wherever this is available. If a practitioner has not been trained in delivering behavioural support and stop smoking medications, then they should refer to someone who has. It is also unclear (line 24-5) why someone who opts out of wanting support to quit would be referred for pharmacotherapy and very brief advice. A note should be made in their records that they have received VBA, declined to make a quit attempt and informed that they will be asked about their smoking at the next appointment as it is a matter of concern.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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National Centre for Smoking Cessation and Training	Guideline (Note: error in greyed text)	027	001 - 009	These sections are specific to quitline staff. There is an opportunity to use clearer wording in this statement and/or ensure that this guideline is applied beyond quit line staff. Specific training in behavioural support for smoking cessation up to the national Training Standard may be more relevant than a counselling qualification as it contains the necessary behaviour change techniques to add value to quit attempts.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
National Centre for Smoking Cessation and Training	Guideline	028	027	Add "or local stop smoking service". It is stated below in 1.14.3 but there should be consistency in message.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
National Centre for Smoking Cessation and Training	Guideline	032	006 - 010	There is an opportunity to include EC here as one of the options to support people achieving temporary abstinence.	Thank you for your comment. The evidence on the use of nicotine containing e-cigarettes to support temporary abstinence was not reviewed as part of this guideline update and therefore recommendations have not been made in this area.
National Centre for Smoking Cessation	Guideline	035	010	Box 1. There is an opportunity to include EC here as one of the options to support people achieving temporary abstinence, cut down to stop and smoking reduction.	Thank you for your comment. As is noted in the rationale and impact section under 'nicotine containing e-cigarettes for harm reduction', no evidence was found on the use of e-cigarettes specifically for harm reduction

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and Training					for people who do not want, or are not ready, to stop smoking in one go. So, the committee chose not to make recommendations on using e-cigarettes for harm reduction. The evidence on the use of nicotine containing e-cigarettes for temporary abstinence was as part of this guideline update and therefore recommendations have not been made in this area.
National Centre for Smoking Cessation and Training	Guideline	044	018	We think advice on EC should also be offered here.	Thank you for your comment. No evidence was identified on the effectiveness of nicotine containing e-cigarettes for relapse prevention and so the committee did not make recommendations on their use for this purpose (please see Review N).
National Centre for Smoking Cessation and Training	Guideline	053	016	Recommendations on policy, commissioning and training. This section on policy would benefit from a statement along the lines of: "Be open to the use of vaping products." Some NHS trusts and local authorities are still highly resistant to the use of vaping products, leading to inequality of approach and outcomes.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
National Centre for Smoking Cessation and Training	Guideline	061	018	Thought could be given to an alternative to CO-verification of quit attempts (e.g. self-report) given the challenges that COVID has presented, and will continue to present, for face-to-face consultations.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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National Centre for Smoking Cessation and Training	Guideline greyed	064	019	Comment: This hyperlink connects to the NCSCT specialty module, it would be best replaced with the NCSCT module on VBA in pregnancy (https://elearning.ncsct.co.uk/vba_pregnancy-launch). There should be text added for those who are delivering stop smoking support with a link to the specialist training and training qualifications (https://www.ncsct.co.uk/publication_pregnancy_and_the_post_partum_period.php).	Thank you for your comment. The Public Health Advisory Committee (PHAC) have considered your comment and have changed this as you suggest.
National Centre for Smoking Cessation and Training	Guideline	068	020	It is inaccurate to state that “the benefits of harm reduction are uncertain” when literature exists showing just that. Harm reduction is a proven method, as shown by its historical use in other fields.	Thank you for your comment which the committee have carefully considered, however they agreed that the current definition accurately reflects their discussions.
National Centre for Smoking Cessation and Training	Guideline	072	009	We suggest changing to: “What are the short or long term effects of e-cigarette use compared to cigarettes? Many short-term beneficial effects appear to have already been proven; “long term” needs further definition – is it 10, 20, 30 years?	Thank you. The committee specified no tobacco comparator as they were interested in absolute effects. Full PICO protocols for the research recommendations can be found in the relevant evidence review. Long term is funding dependent, which means it is unlikely to be 20 or 30 years.
National Centre for Smoking Cessation	Guideline	074	007	We suggest this addition (in red): “Does the effectiveness of nicotine-containing e-cigarettes as an aid to stopping smoking and to prevent relapse vary according to the	Thank you. The committee agreed that in the first instance it was more important to establish the optimal dose for quitting.

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and Training				amount of nicotine they contain or the frequency of use?"	
National Centre for Smoking Cessation and Training	Guideline (Note: error in greyed text)	020	018 - 026	1.11.2 This title speaks to asking and the assessment but 1.11.2 to 1.11.5 are about advising and there is no mention of referral to stop smoking support. Medications are mentioned in 1.11.3. and 1.11.4 however behavioural support is not mentioned. Recommended edit: "Explain the best way of stopping smoking is with a combination of behavioural support and a stop smoking medication or an e-cigarette."	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
New Nicotine Alliance (UK)	Guideline	General	General	<p>The New Nicotine Alliance is pleased to see the leadership shown in 'Tobacco: preventing uptake, promoting quitting and treating tobacco dependence (Draft for consultation June 2021)' in terms of recommending that stakeholders routinely include e-cigarettes (EC) in the toolkit of what works for people who smoke who either want to stop smoking or who are not ready to stop in one go.</p> <p>The NNA particularly appreciates that the guidance recommends talking about EC separately from tobacco products. This distinction is lost on many health organisations worldwide.</p>	<p>Thank you for your comment. The Public Health Advisory Committee (PHAC) considered your comment and are of the opinion that the glossary defines what is meant by 'nicotine-containing products'. The definition has been amended to clarify it.</p> <p>The references to 'licensed nicotine-containing products' are in carried forward recommendations (greyed-out recommendations) which were not part of this update and thus these recommendations cannot be amended.</p>

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				<p>There are a number of areas in which it would have been useful to include EC along with licensed nicotine-containing products (32.1, 33.13, 36). This would have strengthened the guidance.</p> <p>We are aware that evidence is slow to accumulate and applaud the work of researchers (Hajek, Britton, West, Brown, Hartman-Boyce, Notley, Cox, Dawkins, McNeill, Robson and others) in gathering evidence to demonstrate the benefits of EC to help people who smoke to quit, especially in the face of contrary evidence funded by investors who have an openly anti-vaping agenda, and who in fact merely protect the cigarette industry by opposing harm-reduced products.</p>	
New Nicotine Alliance (UK)	Guideline	013	005 - 007	<p>We feel the guidelines should be more prescriptive in advising on what should be said to make it clear why vaping should be avoided by non-smokers. We are concerned that the people providing this support and advice are unlikely to be sufficiently well informed about the relative risks of EC to convey this accurately, given that misperceptions about vaping and nicotine are so widespread. We think that an additional sentence should be added here, to explain that although using EC</p>	<p>Thank you for your comment. This is stated clearly elsewhere in the guideline and the committee were clear that they did not want to say anything that might promote the use of e-cigarettes in under 18s.</p>

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				is far less harmful than smoking, the long term risks are not yet known and so non smokers should avoid using them.	
New Nicotine Alliance (UK)	Guideline	013	003 - 004	“Combustible” should be inserted here: “ <i>Talk about e-cigarettes separately from combustible tobacco products.</i> ” Not all tobacco products are harmful – Swedish snus is far less harmful to health than combustible tobacco products, and heated tobacco products are also likely to be much less harmful. The people providing the support and advice need to be aware and to convey that the harms come from combustion.	Thank you for your comments. The committee discussed your comment and agreed that the addition of ‘combustible’ was not necessary as the introduction to the guideline (p.1) is quite clear regarding what the guideline covers.
New Nicotine Alliance (UK)	Guideline	025	022	We suggest this change: “ <i>Give clear, consistent and up-to-date information about nicotine-containing e-cigarettes so people who are become interested in using them to stop</i> ”	Thank you for your comment. This recommendation is focused on the provision of advice to adults who smoke and have shown an interest in using them to stop smoking. Based on this, the Public Health Advisory Committee (PHAC) did not amend the guideline.
New Nicotine Alliance (UK)	Guideline	026	008	It may not be helpful to ask an individual how long they intend to vape for. Many people, when they start a quit attempt, think they should stop all nicotine use as soon as possible, and only continue once they find it helps them stay smokefree. Some weeks after their initial quit date, they may see things in a different light, once their confidence about not smoking grows.	Thank you for your comment. The rationale and impact section of the guideline outline the Public Health Advisory Committees discussion regarding this recommendation. The committee used their knowledge and experience to supplement the very limited and uncertain evidence about harms. The committee agreed that with the limited data on effects of longer-term use, people should

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					only use e-cigarettes for as long as they help prevent them going back to smoking. They also agreed that people should be discouraged from continuing to smoke when using e-cigarettes, even if they are smoking less, because there is no information on whether this will reduce their harm from smoking. The committee discussed that it is more likely that people will not get enough nicotine to help them stop smoking, than get too much. They agreed that not getting enough nicotine is likely to increase the risk that the person will return to smoking, so they recommended that people should be encouraged to use as much as they need (1.12.17) and told how to use the products effectively (1.12.14)
New Nicotine Alliance (UK)	Guideline	026	010	If the practitioner does not know how an individual can stop vaping, this may not be helpful. The NCSCT is producing guidance on this, but in real life situations we know from consumers that reducing the dose of nicotine is fairly commonplace, indicating that if an individual wants to stop vaping, it is well within their control to do this. Stopping too early increases the risk of relapse to smoking, and longer term vaping may help to avoid this	<p>Thank you for your comment. Thank you for your comment. Recommendation 1.12.13 links to NCSCT resources which includes advice on how to stop using nicotine containing e-cigarettes when the person is ready to do so.</p> <p>The second bullet point of recommendation 1.12.15 recognises your concern about the risk of relapse and recommends that nicotine containing e-cigarettes are used for long enough to prevent a return to smoking.</p>

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New Nicotine Alliance (UK)	Guideline	026	015	We are pleased to see the emphasis on using enough nicotine, a point which is often missed by users and healthcare workers alike.	Thank you for your comment
New Nicotine Alliance (UK)	Guideline	044	018	We think advice on EC should also be offered here.	Thank you for your comment. No evidence was identified on the effectiveness of nicotine containing e-cigarettes for relapse prevention and so the committee did not make recommendations on their use for this purpose (please see Review N).
New Nicotine Alliance (UK)	Guideline	053	016	(Recommendations on policy, commissioning and training) – this needs, in our opinion, something like 'Be open to the use of vaping products.' Some NHS trusts and local authorities are still highly resistant to the use of vaping products, leading to a postcode lottery for people who smoke.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
New Nicotine Alliance (UK)	Guideline	059	010	It might be helpful to give examples of the types of nicotine products which could be sold in hospital shops. This guidance is written for a diverse group of stakeholders and some will not know what is referred to here. We are aware that a fuller explanation is given in the "Terms used in this guideline" section but still think that adding examples here would be helpful.	Thank you. Nicotine containing products is defined in the glossary section of the guideline. The definition of nicotine containing products has been amended to clarify that it includes nicotine containing e-cigarettes.
New Nicotine	Guideline	068	001 - 005	This definition is inaccurate because rechargeable devices are also commonly used with tanks, not solely with single use	Thank you. The definition is clear that e-cigarettes can be disposable or refillable.

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Alliance (UK)				cartridges. The definition is misleading, because it gives prominence to disposables. Whilst disposables are gaining in popularity, most vapers – especially those with less money – use open tank systems. This definition seems to cover pod devices, not open tank systems. The definition seems to suggest that there are disposable refillable devices. To our knowledge, those do not exist (it would be pointless to have a device which could be recharged but not refilled).	
New Nicotine Alliance (UK)	Guideline	068	001	We suggest that the guidance refers to “vapes” or “vaping products” rather than to “e-cigarettes”.	Thank you. The committee and editors agreed that e-cigarettes is the most understandable term. The definition in the ‘terms used in this guideline’ section clarifies that this is also called vaping.
New Nicotine Alliance (UK)	Guideline	068	003	It is inaccurate to use “consumption” in conjunction with vaping. Vapour is inhaled - not consumed - as it is then exhaled. Only partial amounts are consumed as a proportion is also exhaled	Thank you for your comment. The Public Health Advisory Committee (PHAC) have considered your comment and this has been updated to say ‘inhaled’.
New Nicotine Alliance (UK)	Guideline	068	020	We feel it is inaccurate to state that “the benefits of harm reduction are uncertain”: harm reduction is a proven method, as shown by its historical use in other fields.	Thank you for your comment which the committee have carefully considered, however they agreed that the current definition accurately reflects their discussions.
New Nicotine	Guideline	072	009	We suggest this change (“or” to “and” and add “compared to cigarettes”:	Thank you. The committee specified no tobacco comparator as they were interested in absolute effects. Full PICO protocols for

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Alliance (UK)				<p>“What are the short or long term effects of e-cigarette use compared to cigarettes? We think that short term effects are already proven. What think that “long term” needs further definition – is it 10 years, 20, 30, 50?</p>	<p>the research recommendations can be found in the relevant evidence review. Long term is funding dependent, which means it is unlikely to be 20 or 30 years.</p>
New Nicotine Alliance (UK)	Guideline	074	007	<p>We suggest this addition (in red): Does the effectiveness of nicotine-containing e-cigarettes as an aid to stopping smoking and to prevent relapse vary according to the amount of nicotine they contain or the frequency of use?</p>	<p>Thank you. The committee agreed that in the first instance it was more important to establish the optimal dose for quitting.</p>
New Nicotine Alliance (UK)	Guideline	076	017	<p>We suggest “combustible” is added here, i.e.: “They also emphasised that e-cigarettes should not be confused with combustible tobacco products, so talking about them separately is important.” As also stated in our comment at page 13 line 3, above: Not all tobacco products are harmful – Swedish snus is far less harmful to health than combustible tobacco products, and heated tobacco products are also likely to be much less harmful. The people providing the support and advice need to be aware and to convey that the harms come from combustion.</p>	<p>Thank you for your comment. The Public Health Advisory Committee (PHAC) did not add the word combustible because they were making a distinction between e-cigs and all tobacco products.</p>
NHS England and NHS	Evidence Review	079	030	<p>A significant period has elapsed from the reported date of 30 March 2020 when the MHRA reported that no short- and long-term harms of using e-cigarettes had been identified</p>	<p>Thank you. The report was made to NICE as part of expert testimony by the MHRA at that point in time. The expert testimony is included in the evidence review. The</p>

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Improvement				<p>through the yellow card system. Other MHRA updates on licensing have been included.</p> <p>Can an addendum be added bearing in mind publication will nearly be 2 year post the reported period?</p>	<p>committee were unable to ascertain whether any harms had been identified since the time of the expert testimony, but were unaware of any.</p>
NHS England and NHS Improvement	Guideline	General	General	<p>Main comments relate to the inclusion of e-cigarettes containing nicotine. Many GPs would be reluctant to advise use as a non-medical product, and the guideline is lacking in clarity about what primary care should be specifically advising. For this to work there would need to be some specific guidance around this for GPs to follow – as there is for the medical products. Primary care would be subject to complaints about incorrect advice and the default may then be just to not include advice as outside of expertise. Smoking Cessation Services are more likely to be better placed to advise on it, so a distinction between specific services and general primary care services would be helpful.</p>	<p>Thank you for your comments. Recommendation 1.12.4 outlines that people providing stop-smoking support (which would include primary care professionals) discuss options to use to stop smoking in the context of individuals preferences and circumstances, current medication, contraindications and previous experiences of stop-smoking aids. Recommendation 1.12.5 highlights that those providing stop-smoking advice should advise that nicotine-containing e-cigarettes (as well as varenicline and a combination of short-acting and long acting NRT) can result in successful quit attempts when combined with behavioural support). Recommendations 1.12.13 to 1.12.17 provide specific advice for those delivering stop-smoking support or advice regarding nicotine-containing e-cigarettes which cross refers to (with hyperlinks) NCSCCT e-cigarette guide and Public Health England's information on e-cigarettes and vaping. Recommendation 1.23.2 to 1.23.15</p>

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					acknowledges that training may be required for those advising people on how to stop smoking, people working in closed institutions, those working with pregnant women and those advising people how to stop using smokeless tobacco.
NHS England and NHS Improvement	Guideline			There is some inconsistent use of language between the amalgamated guidance (out of scope). For example, some recommendations shift from the term "pharmacotherapies" to "options" (presumably to include e-cigarettes). For example, pharmacotherapies is updated to "options" in recommendation 1.14.8, but its use is continued in the recommendations 1.14.1 and 1.14.15.	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.</p> <p>In 1.14.8 'pharmacotherapies' was deliberately changed to 'options' as this section is focusing on behavioural support which recommendations in section 1.12 state should be offered alongside all options.</p> <p>In recommendation 1.14.1 the focus is on temporary abstinence and the evidence for e cigarettes was not reviewed in this area. In 1.14.15 the focus is specifically about pharmacotherapies, not e- cigarettes. and so in these cases 'pharmacotherapies' has not been changed to 'options'.</p>
NHS England	Guideline	010	020	1.3.3 Please clarify what other agencies do you mean?	Thank you for your comment. This comment relates to a greyed-out area of the guideline

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and NHS Improvement					and is outside of the scope for this update. Please see the scope document on the NICE website.
NHS England and NHS Improvement	Guideline	010	024	1.3.4 Please clarify who will run the campaigns?	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
NHS England and NHS Improvement	Guideline	015	005	Recommendation 1.8.2 (section technically not in scope) – does this contradict other elements of guidance that recommend the use on alternative non-medically licensed nicotine-containing products i.e. e-cigarettes as a substitute for tobacco (acknowledging the gap in evidence for their use as a partial substitute)?	Thank you for your comment. This recommendation has been carried forward and the evidence underpinning this recommendation has not been reviewed. Please see the scope document on the NICE website. Recommendation 1.8.2 focuses on directing those working in public health and those with tobacco control as part of their remit to raise awareness to people who smoke and the use of 1 or more medically licensed nicotine-containing products to reduce the risk of illness and death. It does not suggest that medically licensed nicotine-containing products are the only way to reduce the risk of illness and death and further down in this recommendation (p.16, line 6-7) recommendations on what information to provide about nicotine-containing e-cigarettes are hyperlinked.
NHS England	Guideline	016	019	NG 92 published in 2018 not 2008	Thank you for your comment. This has now been amended in line with your comment

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and NHS Improvement					
NHS England and NHS Improvement	Guideline	017	008	NG 92 published in 2018 not 2008	Thank you for your comment. This has now been amended in line with your comment
NHS England and NHS Improvement	Guideline	022	024	1.12.1 Have you considered using "Allen Carr's Easy Way to stop smoking" methodology? Much the same way that tackling obesity now uses Weight Watchers and Slimming World.	Thank you for your comment. A rapid review to examine the effectiveness of the Allen Carr method is currently in the commissioning process at NICE.
NHS England and NHS Improvement	Guideline	025	005	The section on makes a requirement on NHS staff to be able to appraise patients on the pros and cons of using e-cigarettes. The current wording in section 1.12.14 focuses on risks, but could be clearer on the evidence base and effectiveness of e-cigarettes (as presented in evidence review K; page 59).	Thank you for your comment. The format of the recommendations is in line with the NICE editorial style and the NICE methods and process guide. The recommendation (1.12.14) provides the advice based on the underpinning evidence base. The consideration and discussion of the evidence by the Public Health Advisory Committee (PHAC) is outlined in the rational and impact section (p.78 to 79) and the evidence review both of which are hyperlinked for ease of access on page 26 underneath recommendation 1.12.17.
NHS England and NHS	Guideline	025	025	1.12.14 What about the risks of battery overheating on charging e-cigarettes and is there any evidence of allergies to vapour?	Thank you for your comment. No evidence was identified regarding the risks of battery overheating or allergies to vapour.

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Improvement					Recommendation 1.12.13 refers to the provision of consistent and up-to-date information about nicotine-containing e-cigarettes and provides examples which includes the NCSCT e-cigarette guide which has a section within it regarding use, charging and batteries. Recommendation 1.12.16 highlights that people providing stop-smoking support or advice, should ask people using nicotine-containing e-cigarettes about any side effects or safety concerns that they may experience: 'Report these to the MHRA Yellow Card scheme, and let people know they can report side effects directly'.
NHS England and NHS Improvement	Guideline	026		<p>The NHS in secondary care is adopting an opt-out approach to the delivery of smoking cessation interventions (evidence for effectiveness based on the Ottawa Model for Smoking Cessation https://tobaccocontrol.bmj.com/content/26/3/293).</p> <p>Should an opt-out approach for stop smoking treatment should be explicitly stated as the recommended approach across all care settings including Primary and Secondary Care?</p>	<p>Thank you for your comment. It is unclear what specific element on p.26 your comment refers to. Recommendation 1.12 focuses on stop-smoking interventions that should be accessible to adults and the advice that should be provided with these interventions as well as recommendations on stop-smoking quitlines. Recommendations 1.13 and 1.14 focus on support to stop smoking in primary and community care, and secondary care services (p.27 to 34) which are a greyed-out area of the guideline and are outside of the scope for this update which only included opt out in pregnancy. Please</p>

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					see the scope document on the NICE website.
NHS England and NHS Improvement	Guideline	026	022	NG 92 published in 2018 not 2008	Thank you for your comment. This has been amended.
NHS England and NHS Improvement	Guideline	027	001	1.12.19 Suggest consideration as to how do you ensure that organisations allow and enable staff delivering the advice to have additional time within the appointment to accommodate these messages of stop smoking effectively?	Thank you for your response. Your comments will be considered by NICE where relevant support activity is being planned.
NHS England and NHS Improvement	Guideline	027	003	NG 92 published in 2018 not 2008	Thank you for your comment. This has been amended.
NHS England and NHS Improvement	Guideline	027	004	Recommendation 1.12.7 (section technically not in scope) – have NICE considered recommending the dual use of varenicline/bupropion and NRT where people are in a smokefree environment (such as hospital) or wish proceed immediately with a quit attempt.	Thank you for your comment. As you have noted, this comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website. This means that the committee did not consider this recommendation or any evidence relating to it.

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NHS England and NHS Improvement	Guideline	027	008	NG 92 published in 2018 not 2008	Thank you for your comment. This has been amended.
NHS England and NHS Improvement	Guideline	028	008	1.14.1 Does this include exploring with the individual their motive for stopping? Aren't they more likely to stop smoking for good when they have decided for themselves the reason?	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
NHS England and NHS Improvement	Guideline	030	005	1.14.11 Could you also provide a list of the other benefits here to health the longer people stop smoking?	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
NHS England and NHS Improvement	Guideline	033	001	1.14.23 Should also include that the person's primary prescriber needs to be informed of any prescribing and involved in any changes to medications needed.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
NHS England and NHS Improvement	Guideline	035	001	1.15.2 Would this be a good opportunity to ask them to consider what would make them stop smoking in the future?	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
NHS England	Guideline	039	019	1.16.5 Please clarify who will provide this information?	Thank you for your comment. As is noted in the guideline, these recommendations are for

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and NHS Improvement					people providing support or advice as part of a comprehensive specialist tobacco cessation service.
NHS England and NHS Improvement	Guideline	040	001	1.16.8 Suggest a translator be used in these circumstances.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
NHS England and NHS Improvement	Guideline	040	023	1.16.12 Please clarify where and how is this data used and published?	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
NHS England and NHS Improvement	Guideline	044	020	Is this checked against local/area formulary advice?	Thank you. 'Off label' means that it is not licensed by MHRA for this use.
NHS England and NHS Improvement	Guideline	046	007	Recommendation 1.18. There is no mention of e-cigarettes in relation to the support of pregnant women within the recommendations. They are clearly recommended as a stop smoking intervention in other sections, but are not referenced at all in section 1.18. A stated position, even if it is to state that there is insufficient evidence to confirm either way will reduce the risk of inferred support based on earlier recommendations.	Thank you. Please see the Rationale and Impact section which makes the explicit statement that the committee found no evidence about the effectiveness or safety of using nicotine-containing e-cigarettes to help women stop smoking in pregnancy. The committee have made a series of research recommendation regarding nicotine containing e-cigarettes and pregnancy to stimulate research in this area. We will pass this information to our local practice collection

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				<p>We suggest signposting NICE to the smoking in pregnancy challenge group shared key messages which says:</p> <p>'Licensed NRT is the recommended option, however if a pregnant smoker has chosen to use an e-cigarette to help her quit she should not be discouraged from doing so if it helps her stop smoking and a referral should be made to the local stop smoking service, or a smoking in pregnancy specialist if available, for advice and support'.</p>	<p>team. More information on local practice can be found here (www.nice.org.uk/about/what-we-do/into-practice)</p>
NHS England and NHS Improvement	Guideline	046	015	<p>Carbon Monoxide testing levels of 4ppm and above for identification of smokers are listed on page 46 line 15, but the guidance later states 3ppm and above for action to be taken for those who say they do not smoke on page 47 line 9. There is not identifiable rationale and differential cut offs will be confusing for health care practitioners.</p> <p>Is there any reason why 3 ppm rather than 4ppm has been stipulated in page 47?</p>	<p>Thank you for your comment. The different carbon monoxide levels refer to different groups of pregnant women: smokers and non-smokers and to different actions. The reference to 4 ppm in recommendation 1.18.2 is in the context of the provision of an opt-out referral to receive stop-smoking support for pregnant women. The reference to 3 ppm in recommendation 1.18.4 refers to women who do not smoke and to provide help to identify the source of the carbon monoxide level of 3 ppm.</p>
NHS England and NHS	Guideline	047	009	<p>There is a discrepancy between the cut offs for action on CO testing levels of 4ppm and above for identification of smokers (page 46 p15), and 3ppm and above for action to be taken for</p>	<p>Thank you for your comment. The different carbon monoxide levels refer to different groups of pregnant women: smokers and non-smokers and to different actions. The</p>

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Improvement				those who say they do not smoke (p47 line 9). Unclear of the rationale as to why the lower level of 3ppm is made on page 47 and the different cut offs are a confusing method for HCPs. Is there any reason why 3 ppm rather than 4ppm has been stipulated in page 47?	reference to 4 ppm in recommendation 1.18.2 is in the context of the provision of an opt-out referral to receive stop-smoking support for pregnant women. The reference to 3 ppm in recommendation 1.18.4 refers to women who do not smoke and to provide help to identify the source of the carbon monoxide level of 3 ppm.
NHS England and NHS Improvement	Guideline	059	010	<p>Recommendation 1.22.14 is recommending that NHS providers make nicotine-containing products commercially available in hospital shops; which therefore includes e-cigarettes. Bearing in mind the acknowledged unknown risks associated with the long term use of e-cigarettes should this recommendation be inclusive of these products?</p> <p>Additionally, if so, would it be appropriate for NICE to advise on stocking of products that are or are not associated with the tobacco industry?</p>	Thank you for your comment. The committee recommend e-cigarettes throughout the guideline and it is unclear why this circumstance would be different. It is not within NICEs remit to advise on which specific products shops should stock. Any nicotine containing e-cigarettes that were awarded a license by MHRA would have been assessed for their clinical effectiveness and safety as part of the licensing process. This would include any long-term risks.
NHS England and NHS Improvement	Guideline	090	005 and 006	<p>The current guideline states that "In the current guideline, switching completely from smoking to any nicotine-containing product is considered to be stopping smoking rather than harm reduction".</p> <p>It was difficult to identify this in the recommendations; is it clearly stated?</p>	Thank you. The term cessation is used throughout the guideline and is defined in the 'terms used in this guideline' section.

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Pfizer	Comments form	Q1	Q1	<p>Which areas will have the biggest impact on practice and be challenging to implement?</p> <p>We welcome the UK Government ambition for England to be smoke-free by 2030¹ and the 2022 smoking prevalence target of 12%, established as a critical milestone on the path to this ambition¹. However, due to the significant decline in smoking cessation services across the UK, we believe that this will be extremely challenging to achieve without a specific action plan and focus on the critical activities most likely to deliver change.</p> <p>To achieve this initial smoking prevalence milestone, an additional 900,000 smokers must successfully quit by the end of 2022, reducing the number of adult smokers from 6.4m (14.4%) to 5.5m (12%).^{1,2}</p> <p>As part of the NHS operational planning 2021/2022 guidance³ we recognise the NHS are taking further steps to improve population health and tackle health inequalities by asking systems to develop focused plans for the prevention of ill health as outlined in the Long Term Plan (LTP). However, we can and must do more. At Pfizer, we believe that the 2030 target is still achievable through the use of</p>	<p>Thank you for your comments. Your comments will be considered by NICE where relevant support activity is being planned. Recommending increasing the number of smoking cessation services in the UK specifically is beyond the remit of this guideline. However, the guideline recognises the role of all services in supporting people to stop smoking and reduce people's harm from smoking, with recommendations focused on different sectors for example education, primary and secondary care, different high-risk groups and modes of tobacco consumption and treatments.</p> <p>The committee agreed with the points raised regarding the on-going health service reconfiguration and the opportunities it presents. Recommendation 1.22 focuses on commissioning and designing services and speaks specifically about the utilisation of integrated care system plans, health and wellbeing strategies and other relevant local strategies and plans to make interventions specified in the guideline document accessible to adults who smoke. Further it highlights the provision of support for employers acknowledging that demand may exceed resource and outlining where resources may be best placed. The</p>

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				<p>evidence-based support and interventions, all of which are available today.</p> <p>We also believe this is a moment of extraordinary opportunity for the UK, with the establishment of designated Integrated Care Systems (ICS) across England. Led by the nominated Senior Responsible Officer (SRO), local place-based joint working could better deliver against the NHS Long Term Plan's objectives, prioritising leading causes of ill-health, and improve outcomes for patients.</p> <p>These developments could be particularly significant for smoking, with collective focus and action especially in areas with higher smoking prevalence. The expansion of smoking cessation services and a standardised, evidence-based approach would deliver an increase in supported quit attempts and help towards reducing those health inequalities felt in many communities in England. Furthermore, the ICS structure should enable better integration of services and pathways across primary and secondary care, and the setting of clear local priorities.</p> <p>Below we lay out the critical areas we consider essential over the next nine years to meet the</p>	<p>committee discussed expert testimony provided regarding under-served groups and their lack of access to services and acknowledged the lack of evidence in this particular area by developing a research recommendation for stop-smoking interventions in under-served communities.</p> <p>This guideline recommends (1.21.10) local stop-smoking care pathway and referral process to ensure continuity of care between primary, community and secondary care with additional recommendations focused on support to stop smoking in primary and community settings (1.13) and secondary care services (1.14), as well as recommendations to prevent uptake (1.1 to 1.7), promoting quitting (1.8 to 1.10) and the identification and quantifying people's smoking (1.11).</p> <p>The recommending of a national varenicline patient group direction is beyond the remit of this guideline but the guideline does emphasise the need to ensure access to stop-smoking interventions to adults who smoke which includes varenicline (1.12.1).</p> <p>This guideline makes recommendations that seek to address the points raised regarding a</p>

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				<p>2030 smoke-free target, reduce the health impact and level the inequalities associated in areas of higher smoking prevalence.</p> <p>Critical actions and areas of focus towards achieving the 2030 smoke-free vision:</p> <ol style="list-style-type: none"> 1. To further reduce disease and the health impact and inequalities of smoking, we believe any plan must critically focus on primary and secondary care collaboration and require local and national action across England's health and care system. Delivery across both primary and secondary care could generate a sense of urgency and further enable proactive identification of smokers and allow support and pharmacotherapy to be offered to all, thereby increasing supported quit attempts. <ol style="list-style-type: none"> a. This could be reflected by developing a prescribing report that expands on the current innovation scorecard in 	<p>comprehensive opt-out secondary care smoking cessation program for in and out-patients see recommendation 1.14.</p> <p>This guideline aligns with your points regarding a focus on those at high risk of tobacco related harm including people with mental health issues using acute or secondary care services and those who are pregnant with a focus on identification, prevention, and support to quit and maintenance of non-tobacco behaviour. The committee outline the need for greater research regarding the support of people with a mental health condition to stop smoking and developed a research recommendation to investigate how those with a mental health condition can be effectively supported and the challenges and opportunities that may be presented. Recommendation 1.14 focuses on 'support to stop smoking in secondary care services' with recommendations focused on information on stopping smoking for those using these services. It specifies planning and working with planned or likely inpatients regarding their smoking on entry to secondary care settings via their personal plan. Recommendation 1.1.4 goes on to offer and, if the person agrees, arrange for them to</p>

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				<p>secondary care supporting the adoption and implementation of NICE TA123.</p> <p>b. National varenicline PGD commissioned to enable simpler access to effective pharmacotherapy (via services, pharmacies and/or GP practices)</p> <p>c. With strong collaboration in the new ICS structure, it would be possible to Make Every Contact Count (MECC). This could be a more system-based approach to the management and treatment of Smoking Cessation with further integration of services, pharmacy and/or GP practices or by expanding large scale Public Health programmes or immunisation programmes or</p>	<p>receive behavioural support to stop smoking either during their current outpatient visit or their inpatient stay. 1.14 also highlights that people who smoke who are receiving secondary care services in the community or at outpatient clinics should receive immediate support at outpatient site including weekly sessions for at least 4 weeks post smoking cessation and be referred if the person prefers.</p> <p>The guideline provides several recommendations focused on high-risk populations which includes those with mental health issues. Recommendation 1.11.8 highlights a focus on parents or carers of people using acute or mental health services. Recommendations 1.14.7-14 highlight the specific elements of behavioural support in acute and mental health services; Recommendation 1.14.15 -18 highlights pharmacotherapies in acute and mental health services and specific advice on what treatment, when and how as well as wider policy (indoor/outdoor smoking); Recommendation 1.14.19 provides advice regarding support for those with a severe mental health condition; Recommendations 1.14.20 - 22 outlines support for those who</p>

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				<p>the flu programme to include smoking cessation support</p> <p>2. Establish a comprehensive opt-out secondary care smoking cessation program for in and out-patients in each of the 132 Hospitals NHS Trust in England</p> <p>a. The delivery of a comprehensive secondary care Smoking Cessation (SC) programme, as exemplified by the CURE project in Manchester or the Ottawa Model for Smoking Cessation would help reduce smoking-related readmission rates, A&E attendance and mortality⁴ leading to system wide benefits and potential cost savings to the NHS</p> <p>3. Harness secondary care capabilities and expertise to accelerate improvement in key, at risk patient</p>	<p>have abstained whilst in acute or mental health services (treatments, medically licensed nicotine containing products); Recommendation 1.15.13 outlines harm-reduction self-help for high-risk individuals including those with mental health issues. Recommendation 1.22.4 highlights the prioritisation of high-risk groups for tobacco related harms including those with mental health conditions.</p> <p>The guideline makes several recommendations that seek to support the reduction in the prevalence of smoking in pregnancy. Recommendations 1.18 to 1.20 focus on identifying pregnant women who smoke and referring them for stop-smoking advice and following them up; on providing support for example through nicotine replacement therapy and other pharmacological support; incentives for pregnant women to stop smoking; enabling all pregnant women to access stop-smoking support; helping partners in the household of a pregnant women, who smoke to stop.</p>

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				<p>populations. Support focused action in key two patient populations, where there is significant unmet need.</p> <p>a. Addressing the burden of smoking and smoking-related disease in Mental Health inpatient Units. In the general population, smoking prevalence amongst people with mental health conditions is estimated to be around 33%⁵; however, this figure is significantly higher in secure mental health units, where an estimated 70% of inpatients smoke⁶. Given the challenges associated with this difficult-to-treat population and the need to engage healthcare professionals in new approaches, a bespoke smoking cessation strategy designed particularly for people with severe mental ill</p>	

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				<p>health (such as that deployed by the SCIMITAR pilot and SCIMITAR+ trial) may increase engagement with services and boost the chances of sustained quitting^{7,11}. In the SCIMITAR example from the north of England, quitting support was delivered by mental health nurses and consisted of both behavioural support and pharmacotherapy, resulting in greater engagement with stop smoking services and improved quit rates at 6 months compared to usual care.</p> <p>b. Support for the reduction in the prevalence of smoking in pregnancy from 10.7% to 6%⁸. The NHS Long Term Plan reiterates the NHS's commitment to a 50%</p>	

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				<p>reduction in stillbirth, maternal mortality, neonatal mortality and serious brain injury and a reduction in preterm birth rate, from 8% to 6%, by 2025⁹. There are many examples of healthcare organisations and maternity services offering stop smoking support in pregnancy, after birth and to partners/families of mums and mums-to-be with some achieving dramatic reductions in mortality. We are aware of local focus in this patient population including a Dorset Public Health Quality Improvement Pilot provides that smoking cessation support for family members looking to quit to improve the environment for smoking, pregnant women; this includes weekly contact, CO monitoring at every visit and accesses the</p>	

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				<p>very age group (20-45 year olds) who typically do not access healthcare/SC support. Since establishing a range of initiatives in the Dorset region to keep women and babies healthier, there has been almost a halving of smoking prevalence, from 13% to 7%¹⁰.</p> <ol style="list-style-type: none"> 1. PHE Strategy 2020-2025 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/831562/PHE_Strategy_2020-25.pdf 2. SmokingStatistics.pdf (ash.org.uk) 3. NHS 2021/22 priorities and operational planning guidance 4. CURE Programme https://thecureproject.co.uk/ <p>Wythenshawe hospital represents a typical Hospital Trust size and therefore results can be extrapolated across all Hospital Trusts. There will be variation depending on the size of</p>	

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				<p>individual Trusts and on the specific amount of staffing resource required</p> <p>5. McManus S, Meltzer H, Campion J (2010) Cigarette smoking and mental health in England http://www.natcen.ac.uk/media/660073/smoking_and_mental_health_-_final_report_revised%20and%20final.pdf</p> <p>6. Jochelson, K. & Majrowski, W. (2006) Clearing the Air: Debating Smoke-Free Policies in Psychiatric Units, London: King's Fund.</p> <p>7. Gilbody et al. Smoking cessation in severe mental illness: combined long-term quit rates from the UK SCIMITAR trials programme Br J Psych 2019; 1-3. doi:10.1192/bjp.2019.192</p> <p>8. Smokefree generation: tobacco control plan for England, updated 13 January 2020, 5 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/630217/Towards_a_Smoke_free_Generation_-</p>	

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				<p>_A_Tobacco_Control_Plan_for_England_2017-2022__2_.pdf</p> <p>9. Saving Babies' Lives Version Two saving-babies-lives-care-bundle-version-two-v5.pdf (england.nhs.uk)</p> <p>10. https://www.poole.nhs.uk/about-us/latest-news/2017-news-archive/national-recognition-maternity.aspx</p> <p>Gilbody et al (2019) Lancet Psych 6 (5): 379-390</p>	
Pfizer	Comments form	Q2	Q2	<p>Would implementation of any of the draft recommendations have significant cost implications?</p> <p>It is well recognised smoking has a cost to the economy and catastrophic impact on health:</p> <ul style="list-style-type: none"> In addition to the human cost, smoking costs the economy £14.7 billion per year, £2.5 billion of which falls to the NHS¹ The UK is a world leader in tobacco control, but smoking remains our biggest preventable killer. In England alone, 78,000 people a year - or 200 per day - die from smoking¹ 	<p>Thank you for your comment. The economic analyses undertaken to support the development of the guideline align with the information you have presented. It showed smoking cessation interventions are highly cost effective. Moreover, that the main driver of cost effectiveness is the effectiveness of the intervention - the results consistently indicated that the most effective intervention was the most cost-effective.</p>

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				<p>This can clearly be seen in the burden smoking-related morbidity has specifically for secondary care:</p> <ul style="list-style-type: none"> • Approximately 1.3m smokers are admitted to hospital in England each year², providing a clear opportunity to ensure every patient is supported and discharged with SC support; this key teachable moment enables trained healthcare professionals to engage smokers and encourage a quit attempt³ • 520,000 smoking related hospital admissions in people aged 35 and over in England in 2015/16⁴ • Potential savings from readmission attributable to smoking; based on the results achieved using the Ottawa Model in Canada, by supporting 13,500 smokers with pharmacotherapy and support, a trust over one year period could potentially save a total cost of £2,527,200* from reduced readmissions⁵ <p>Interventions can have dramatic effects and it is well recognised treating smoking can be highly cost effective</p>	

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				<ul style="list-style-type: none"> Stopping smoking completely is associated with a 43% decreased risk of hospitalisation for smokers with COPD⁶ NNTs for Smoking Cessation are low (Cochrane review demonstrated a range from 11 to 23 across all treatments)⁷ NICE estimates for every £1 invested, £2.37 is saved on treating smoking-related disease and lost productivity⁸ <p>To achieve the current interim smokefree target an additional 900,000 smokers must successfully quit by the end of 2022 (from 6.4m to 5.5m adult smokers)</p> <ul style="list-style-type: none"> By focusing on just one of the critical activities like scaling CURE nationally across England, this could deliver 741,000 extra 4-week quitters if similar support programmes were establish in each of the Hospital NHS Trusts across England⁹ <p>Smoking cessation programmes already exist in community settings but are variable in their involvement of pharmacy. Hospitals are adopting the Ottawa Model of Smoking Cessation (OMSC), which:¹⁰</p>	

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				<ul style="list-style-type: none"> • Will be adopted throughout England (NHS Long Term Plan, 2019) – led by the NHSE/I Prevention team • Is a 12-week programme • Requires follow-up smoking cessation treatment after discharge from hospital • Increased 1-year quit rates by 11% (Mullen, 2010) • Is expected to save the NHS £85m within 1 year (Royal College of Physicians, 2018) <p>We believe that the critical activities outlined would deliver significant savings to the NHS and clear system benefits helping towards achieving the 2030 smokefree target of 5% while reducing health inequalities and increasing supported quit attempts.</p> <ol style="list-style-type: none"> 1. Tobacco Commissioning Support: principle and indicators Tobacco commissioning support: principles and indicators - GOV.UK (www.gov.uk) 2. NHS digital https://digital.nhs.uk/data-and-information/publications/statistical/statistics-on-nhs-stop-smoking-services-in-england/april-2018-to-march-2019 accessed November 2019 3. McBride et al. Health Education Research, 2003 18, 156–170 	

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				<p>4. Public Health England Cost of smoking to the NHS in England https://www.gov.uk/government/publications/cost-of-smoking-to-the-nhs-in-england-2015/cost-of-smoking-to-the-nhs-in-england-2015</p> <p>5. Mullen et al Tobacco Control 2017;26:293-299</p> <p>6. Godtfredsen NS V Risk of Hospital admission for COPD following smoking cessation and reduction: Thorax 2002 57: 967-972</p> <p>7. Cahill K et al – Cochrane Database Syst rev 2016 Issue 5. Art. No.: CD006103</p> <p>8. Action on Smoking and Health. ASH: Facts at a glance: Tobacco Economics. ASH Daily News for 15 May 2019 - Action on Smoking and Health</p> <p>9. month quit rate outcomes at Wythenshawe hospital https://thecureproject.co.uk/outcomes</p> <p>10. PhIF: Smoking Cessation Transfer of Care September 2020</p> <p>*Calculations based on experience from the Ottawa model implemented in Canada. Due to differences in healthcare systems data cannot be directly extrapolated to the UK.</p>	
Pfizer	Comments form	Q4	Q4	The recommendations in this guideline were largely developed before the coronavirus pandemic. Please tell us if there are any	Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned.

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				<p>particular issues relating to COVID-19 that we should take into account when finalising the guideline for publication?</p> <p><i>“More progress is needed, and BTS is urging NHS leadership to use the current reconfiguration of healthcare prompted by COVID-19 pandemic to embed properly funded and organised smoking cessation in all its reformed services, making the best use of all the new digital solutions and innovations that resulted from dealing with the pandemic.”¹</i></p> <p>COVID has reminded us of the importance of health generally, and specifically respiratory health. We also recognise that the pandemic related backlog will be with us for some time, with the waiting list now at the highest level since comparable records began². When wards and beds are full, this puts intense pressure on the system, and many patients may be unable to get the critical care they need and can be very costly, making the commitment to prevent ill health even more important.</p> <p>COVID-19 related recommendations to enhance smoking cessation support and delivered system-wide benefits.</p>	<p>Several of the recommendations speak to and support the points you raise.</p> <p>In terms of proactive identification there are several recommendations that seek to proactively identify and offer support to specific groups of 'high-risk' smokers and smokers in general. This includes recommendations 1.11 and 1.18 which refers to pro-active identification. Recommendations 1.11.8 to 1.11.11 seek to identify smoking among carers, family and other household members; 1.11.9 adopts a proactive approach to identification and subsequent support and opt-in referral.</p> <p>In terms of MECC several of the recommendations align with the principles of MECC. Recommendation 1.11.1 considers MECC in the sense that it requests that “at every opportunity” people should be asked “if they smoke or have recently stopped” with 1.11.2 to 1.11.7 highlighting approaches to support, referral and recording and follow-up – a more specific reference to this is outlined in the rationale and impact section relating to recommendations 1.12.1 to 1.12.6 where the</p>

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				<ul style="list-style-type: none"> • Proactive identification and offer of support to all smokers <ul style="list-style-type: none"> ○ In preparation for the annual winter 'spike', this provides additional opportunities to identify smokers, gives extra support to reducing smoking-related hospital admissions, and offers more chances to provide pharmacotherapy and behavioural support to all. ICS enabled place-based collaboration can transform the way we provide smoking prevention support and ensure patients get the right service in the right place. ○ Make Every Contact Count (MECC) by expanding large scale Public Health programs immunisation programmes or the flu programme to include smoking cessation support • Embed new ways of working and delivery of care – address the inequalities highlighted by the pandemic 	<p>committee discussed the alignment with MECC principles.</p> <p>Capturing and embedding new ways of working and delivering care is captured in this guideline. Recommendations in 1.22 outline considerations for the commissioning and designing of services to make interventions accessible to those who smoke including recommendation 1.22.1 which refers to the use of Integrated Care Systems plans, health and wellbeing strategies to make outlined interventions accessible. It is beyond the remit of NICE guidance to specify sources of funding or how interventions are supported locally for example the use of COVID accelerator funds.</p> <p>Monitoring features as a part of several recommendations. Recommendation 1.23.1 outlines the need to work in partnership to monitor and evaluate smoking prevention training and intervention. Recommendation 1.16.7 and 1.16.24 refers to monitoring in terms of local smokeless tobacco cessation and 1.14.23 and 1.20.1 refer to the monitoring in terms of people's use of prescribed drugs affected by smoking or stopping smoking and</p>

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				<ul style="list-style-type: none"> ○ Supported by COVID accelerator funds, all ICS finalise commitments to tobacco dependence treatment services, improving patient outcomes by prioritising the expansion of smoking cessation services ○ Local commitment and national monitoring of the Tobacco Dependency ambitions with a standardised, evidence-based approach would deliver an increase in supported quit attempts and help towards reducing those health inequalities felt in many communities in England ○ Local-based joint working agrees to a use of robust tool for measuring and implementing NICE Technology Appraisal (TA123) across both primary and secondary care ○ National varenicline PGD commissioned to enable simpler access to effective pharmacotherapy (via 	<p>pregnant women who are receiving support to stop smoking respectively. Recommendation 1.22.22 to 26 focuses on monitoring stop-smoking services by commissioners and managers and refers to target setting for smoking cessation services</p> <p>Recommendation 1.12.1 outlines the use of varenicline for adults who smoke (but not pregnant or breastfeeding women in line with NICE technology appraisal 123) however the consideration of Patient Group Direction was beyond the remit of this guideline.</p> <p>The guideline makes recommendation specifically for several settings including secondary care. Recommendation 1.14 focuses on 'support to stop smoking in secondary care services' with recommendations focused on information on stopping smoking for those using these services. It specifies planning and working with planned or likely inpatients regarding their smoking on entry to secondary care settings via their personal plan. Recommendation 1.14 goes on to offer and, if the person agrees, arrange for them to receive behavioural support to stop smoking either during their current outpatient visit or</p>

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				<p>services, pharmacies and/or GP practices)</p> <ul style="list-style-type: none"> • Comprehensive secondary care opt-out smoking cessation service across all NHS England hospitals <ul style="list-style-type: none"> ○ Delivery of CURE style program could reduce readmission rate, A&E attendance, and mortality with careful local place-based joint working. This could free up capacity allowing systems to recover from pandemic backlog ○ Update discharge pathways to allow the inclusion of discharge with an entire course of pharmacotherapy, reducing additional touchpoints on the patient quit journey • Accelerate smoking services in crucial patient populations <ul style="list-style-type: none"> ○ Establishing bespoke smoking cessation strategies and agree to ICS delivering plans where there is a significant unmet 	<p>their inpatient stay. 1.14 also highlights that people who smoke who are receiving secondary care services in the community or at outpatient clinics should receive immediate support at outpatient site including weekly sessions for at least 4 weeks post smoking cessation and be referred if the person prefers.</p>

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				<p>need, maternity units or where smoking prevalence is significantly higher, like mental health</p> <p>CRUK projected that England would not achieve its ambition until 2037³ if current smoking prevalence trends continue. By implementing these four practical recommendations, ICSs could increase their number of supported quit attempts that deliver the change of pace required to realise the ambition to be smoke-free by 2030.</p> <ol style="list-style-type: none"> 1. NHS Hospitals showing very slow progress on helping people quit smoking, with staff lacking training and the tools to help patients who smoke - British Thoracic Society https://www.brit-thoracic.org.uk/about-us/pressmedia/2020/smoking-cessation-audit-2019-news-release/ 2. Longer waits, missing patients and catching up The Health Foundation Smoking Prevalence projections for England, Scotland, Wales and Northern Ireland based 	

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				on data to 2018/19 Cancer Research UK February 2020	
Pfizer	Guideline	023	020	<p>Rec 1.12.5 – In this section, it is recommended that smokers should be advised the options which are most likely to result in them successfully stopping smoking. These are varenicline, combination NRT and nicotine-containing e-cigarettes.</p> <p>The draft 2021 update to the recommendations is based upon data presented in Evidence Review K “Cessation and harm reduction treatments” and the associated appendices. We would highlight that, notwithstanding the NMA included in the Evidence Review, data which allow for comparative efficacy claims between e-cigarettes and varenicline or combination NRT are very limited and the limitations of the e-cigarette trials included in the Review (including variance in design, conduct, intervention, length and measured abstinence) impact upon the applicability of the findings of the NMA.</p> <p>This should preclude e-cigarettes from being presented as first-line options alongside established pharmacological interventions such as NRT, varenicline and bupropion, the</p>	<p>Thank you for your comment and for your assessment of the NMA that underpins these recommendations. All of the information you provide is already included in the write up of the NMA and has been discussed in depth by the committee, however most of the shortcomings you note are equally applicable to other nodes in the network. Inconsistency checking does not raise any concerns about the internal coherence of the NMA. The findings from the NMA are to be considered in conjunction with other evidence, particularly</p> <p>on e-cigarettes, presented in the reviews for this guideline update:</p> <ul style="list-style-type: none"> • Safety of e-cigarettes (other existing reviews on pharmacotherapies and NRT, and review on long-term health effects of e-cigarette question [Review M]) • Adverse events of e-cigarettes (adverse events of e-cigarettes as presented in this review) • Acceptability, and barriers and facilitators to use (review on barriers and facilitators to using e-cigarettes [Review L])

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				<p>first-line therapies recommended in NICE Guideline NG92.</p> <p>Main limitations identified in the NMA:</p> <p>1. Small number of e-cigarette studies compared to the number of studies for other smoking cessation treatments included in the NMA</p> <ul style="list-style-type: none"> • Although 9 studies were identified which reported on adverse events of e-cigarettes, only 4 of these met the NMA inclusion criteria (most notably, sufficiently long follow-up period) • Most of the included studies (all were parallel RCTs) had high risk of bias or some concern, based on the Cochrane risk of bias tool: Carpenter 2017 (high risk of bias), Cravo 2016 (high risk of bias), Holliday 2019 (high risk of bias), Lee 2018 (some concerns), Masiero 2018 (some concerns), Tseng 2016 (some concerns), Walker 2019 (low risk) – e-cigarettes+NRT patch <p>2. Subgroup analyses not available for e-cigarettes</p> <ul style="list-style-type: none"> • Studies containing mental health subgroup analyses were identified for 	<p>The limitations of the NMA and underpinning evidence (as you identify) were discussed by the committee within the context of their experience and expertise. They reached a consensus view, supported by the evidence, that the use of e-cigarettes would extend the range, and therefore the availability, of effective stop smoking interventions and was important for this reason</p>

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				<p>all smoking cessation treatments except for e-cigarettes and waitlist (participants waiting for treatment)</p> <p>3. Small number of studies and wide 95% confidence intervals in pairwise relative effectiveness comparisons</p> <ul style="list-style-type: none"> • 6 studies were identified with 3,835 participants in total. Only up to 3 studies could be combined in any single meta-analysis, due to different comparators or follow-up times, which is why the meta-analysis had wide confidence intervals, often including the line of no effect • Varenicline and NRT long/short acting treatments had narrow 95% CIs when compared with other cessation interventions (with an exception of comparisons with placebo, which typically contained fewer studies in the meta-analysis and wider CIs) – p. 116-123 • Forest plots of e-cigarettes in relative effectiveness comparison with most other interventions showed wide 95% CIs and a small number of studies included in the meta-analysis (Figures 18-19, p. 124): 	

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				<ul style="list-style-type: none"> ○ E-cigarette vs. placebo e-cigarette: 2 studies, risk ratio [95% CI]: 2.02 [0.97, 4.21] ○ E-cigarette vs. usual care: 2 studies, risk ratio [95% CI]: 4.92 [1.43, 16.91] ● Forest plots of e-cigarettes in pairwise adverse event comparisons with most other interventions also showed wide 95% CIs and a small number of included studies (p. 129-132): <ul style="list-style-type: none"> ○ E-cigarettes vs. no drug treatment, nausea: 2 studies, risk ratio [95% CI]: 2.95 [0.36, 24.19] ○ E-cigarettes vs. NRT, cardiovascular events: 2 studies, risk ratio [95% CI]: 2.86 [0.30-27.38] ○ E-cigarettes vs. NRT, death all causes: 2 studies, risk ratio [95% CI]: 1.60 [0.21, 12.25] <p>4. Only studies with short follow-up effectiveness data for e-cigarettes were included in NMA</p> <ul style="list-style-type: none"> ● There is not enough evidence to know whether there are long-term harms from e-cigarette use and that short- 	

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				<p>term outcomes are robust indicators of long-term outcomes, which were not available in the included e-cigarette studies</p> <ul style="list-style-type: none"> ○ A similar point was highlighted in 1.12.14 of NICE prevention guidance draft • Relative effectiveness data at 6-month follow-up (or longer) was available for all smoking cessation treatments except for e-cigarettes <p>5. Committee was not confident in the robustness of evidence on e-cigarettes included in NMA:</p> <ul style="list-style-type: none"> • Committee had low confidence the evidence from a small number of studies that showed that e-cigarettes did not cause any more adverse events than NRT or e-cigarettes without nicotine, because studies were usually designed to investigate effectiveness and not adverse events, meaning they may not have been large enough to show effect • There were only 2 studies about the long-term harms of using nicotine-containing e-cigarettes, and the committee suggested that this 	

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				<p>evidence was highly uncertain and not sufficient to confirm long-term effects of e-cigarettes</p> <p>6. Heterogeneity across e-cigarette studies included in NMA:</p> <ul style="list-style-type: none"> Although the committee decided that the identified studies should be included in the NMA, they acknowledged the variations in the studies: <i>'One study 16 (Lee 2018) investigated cessation in pre-operative patients who might have an increased motivation to quit compared with those in the other studies. Another study (Halpern 2018) took place in a workplace, and despite having the largest sample size, had very low uptake of any intervention, this may be due to the included participants not having actively chosen to take part in the study. Type of e-cigarette device used may also introduce heterogeneity: studies did not always clearly report e-cigarette generation, but the committee agreed that Bullen (2013) and Lee (2018) would have used first generation e-cigarettes and</i> 	

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				<p><i>that these may be less effective due to generally containing lower levels of nicotine and potentially providing a less satisfying experience (see review L: barriers and facilitators to using e-cigarettes).'</i></p> <p>Further, given the evidence that suggests significant proportions of e-cigarette users are also dual-users who continue to smoke^{1,2,3}, in order to reach the ambitious goals of a smoke-free nation by 2030⁴ we would advise that more emphasis be placed upon established interventions including behavioural therapy and licensed pharmacotherapies as well as a focus on full abstinence from smoking.</p> <ol style="list-style-type: none"> 1. Owusu et al (2019) Prev Med Rep 16: 101009 2. Piper (2020) Nicotine Tob Res 22 (5): 672-680 3. West R, Proudfoot H, Beard E, et al. Electronic Cigarettes in England - Latest Trends https://smokinginengland.info/graphs/e-cigarettes-latest-trends 4. Advancing our health: prevention in the 2020s https://www.gov.uk/government/consul 	

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				tations/advancing-our-health-prevention-in-the-2020s	
Pfizer	Guideline	024	009	Rec 1.12.7 – The wording concerning varenicline dosing in this section states “For varenicline agree a quit date set within the first 1 to 2 weeks of treatment...” and we would request that this be re-worded to align to the licensed indication: “ <i>The patient should set a date to stop smoking. Varenicline dosing should usually start at 1-2 weeks before this date</i> ”	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website. We have amended the recommendation to match the SPC
Pfizer	Guideline	026	007	<p>Rec 1.12.15 – The section on the use of nicotine-containing e-cigarettes includes a recommendation to discuss:</p> <ul style="list-style-type: none"> • how long the person intends to use nicotine-containing e-cigarettes for • using them for long enough to prevent a return to smoking, and • how to stop using them when they are ready to do so <p>However, it is unclear what advice should be offered to smokers to enable them to reduce their e-cigarette usage. Indeed, we would highlight the Hajek 2019 NEJM study¹, included in Evidence Review K, which indicates that, of those e-cigarette users who are still abstinent from smoking at 12 months 80% are still using e-cigarettes. Whilst this</p>	<p>Thank you for your comment. Recommendation 1.12.13 includes a link to some resources which includes advice on how to stop using nicotine containing e-cigarettes when the person is ready to do so.</p> <p>In this guideline, switching completely from smoking to any nicotine-containing product is considered to be stopping smoking rather than harm reduction. This is outlined in the glossary and hyperlinked in the guideline document</p>

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				<p>may be supportive of recommendations elsewhere indicating a need to consider risk of relapse it is also suggestive of smokers remaining nicotine-dependent long-term. Further, no pharmacotherapy is licensed for the cessation of e-cigarette use. We would request that all reference to utilising e-cigarettes to support a quit attempt is made in the context of the national policy of driving complete cessation.</p> <p>1. Hajek et al (2019) NEJM 380: 629-637</p>	
Pfizer	Guideline	028	004	<p>In the section on the provision of support in acute, maternity and mental health settings and elsewhere, patients are referred to smoking services and behavioural support based on their agreement to be involved. We would highlight the robust approaches laid out in the Ottawa Model for Smoking Cessation, which include the identification of all smokers at admission, the referral of all smokers on an opt-out basis to in-house smoking cessation services, the initiation of smoking cessation support before discharge and the referral to long-term support (potentially including discharge with a full course of pharmacotherapy)^{1,2}. Implementing similar opt-out programmes at trust-level nationally represents an opportunity to accurately audit</p>	<p>Thank you for your comment. The evidence on opt-out referral schemes was in scope for pregnant women only. The committee have made recommendations on opt out referral schemes for pregnant women (see Recommendations 1.18.2 and 1.18.3). Opt-out referral schemes were not within scope for other population groups. Please see the scope document on the NICE website.</p>

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				<p>smoking prevalence, address smoking-related re-admissions and maximise quit attempts during acute 'teachable moments'. For key, as risk populations such as mental health patients and pregnancy, please see response to Q1 above.</p> <ol style="list-style-type: none"> 1. Mullen et al Tobacco Control 2017;26:293-299 2. CURE Programme https://thecureproject.co.uk/ 	
Pfizer	Guideline	032	001	<p>There is potential for confusion in this section between the priority of initiating a quit attempt in all smokers who are admitted to secondary care services and maintaining smoke-free grounds when patients have opted out of a supported quit. We would request that the guidance is clarified to state that all support for temporary abstinence is only offered following an opt-out referral to in-house smoking cessation services, in line with the Ottawa Model for smoking cessation^{1,2} and that the implementation of an in-house smoking cessation service be recommended as a priority for all trusts. A reference to these services and a supported quit attempt should be included at the start of and in preference to any recommendation concerning support for temporary smoking cessation.</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.</p>

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				<ol style="list-style-type: none"> 1. Mullen et al Tobacco Control 2017;26:293-299 2. CURE Programme https://thecureproject.co.uk/ 	
Pfizer	Guideline	057	001	<p>Rec 1.22 – Pfizer would like it to be recognised over the past years, there has been a significant decline in observed support for smokers, including;</p> <ul style="list-style-type: none"> • A reduction in the number of smokers setting a quit date (all pharmacotherapies, from 816,000 (2011) to 222,000 (2019)¹ • A reduction in the number of successful smokers that quit (self-reported and carbon monoxide [CO] confirmed) from 289,000 (2011) to 70,000 (2019)¹ • A decline in smoking cessation prescription items from 2.56m (2011) to 740,000 (2018), according to NHS Stop Smoking Services data² • Although cigarette smoking prevalence has seen a steady decline in 2021 this has had a slightly increased in 2021³ <p>A key contributing factor to this has been the reduction in smoking cessation services across the UK.</p>	<p>Thank you. The change in services is discussed in the context section of the guideline.</p> <p>The current guideline includes recommendations for both primary and secondary care, but it is beyond the remit of this guideline to recommend tools for measuring the prescribing of varenicline.</p>

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				<p>To prevent disease and reduce the health impact and inequalities of smoking we believe any plan must critically include a focus in both primary and secondary care.</p> <p>The Innovation Scorecard in secondary care⁴ has implemented a robust tool for measuring, but we believe an updated estimate report for the prescribing of varenicline initiated in primary care should be developed, using an appropriate data set such as Defined Daily Doses or GP practice data for NHS England (total quantity prescribed). This would help support the adoption and implementation of the NICE Technology Appraisal (NICE TA123) and enable uptake of varenicline to previously observed levels⁴.</p> <ol style="list-style-type: none"> 1. Statistics on NHS Stop Smoking Services in England April 2019 to March 2020 – NHS Digital https://digital.nhs.uk/data-and-information 2. Statistics on NHS Stop Smoking Services – NHS Digital https://files.digital.nhs.uk/D9/5AACD3/smok-eng-2019-rep.pdf 3. Top Line Findings - Graphs - Smoking in England 	

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				4. NICE Technology Appraisals in the NHS in England (Innovation Scorecard) To December 2020 - NHS Digital	
Pfizer	Guideline	057	006	Rec 1.22.2 – It is unclear if this recommendation is intended as an aid for those who are already abstinent or as a step in the quit pathway for all smokers. We would request that this be amended to state that providers of stop-smoking support should offer all forms of pharmacotherapy.	Thank you. The recommendation specifies 'stop-smoking support' providers and so is for anyone who uses those services.
Pfizer	Guideline	059	001	<p>Stop Smoking Support in Secondary Care - as recognised in Rec 1.21.8, 1.21.9 & 1.21.10, there is a need for local stop-smoking pathways to be aligned between secondary and primary care to ensure continuity of care. In line with the Ottawa Model for smoking cessation and experience of implementing similar programmes in the UK^{1,2}, we would include the following actions for all secondary care trusts:</p> <ul style="list-style-type: none"> • Opt-out referral to in-house/secondary care stop smoking service • Proactive referral of all smokers to community or primary care services for ongoing support of quit attempt • Where this is not possible or is not a reliable course of referral, discharge 	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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				<p>from hospital with full course of pharmacotherapy</p> <p>Further to this, we believe this is a moment of extraordinary opportunity for the UK, with the establishment of designated Integrated Care Systems (ICS) across England. Led by the nominated Senior Responsible Officer (SRO), local place-based joint working could better deliver against the NHS Long Term Plan's objectives, prioritising leading causes of ill-health, and improve outcomes for patients.</p> <p>These developments could be particularly significant regarding the integration of services and pathways across primary and secondary care, and the setting of clear local priorities.</p> <ol style="list-style-type: none"> 1. Mullen et al Tobacco Control 2017;26:293-299 2. CURE Programme https://thecureproject.co.uk/ 	
Pfizer	Guideline	059	010	<p>Rec 1.22.14 – We would request that this recommendation be broadened to include reference to the availability of licensed pharmacotherapy in secondary care. Historically, access to all forms of pharmacotherapy has been highly variable geographically and has depended upon local</p>	<p>Thank you for your comment. Please see recommendation 1.22.13 which reflects your comment.</p>

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				<p>formulary decisions. We would request that it be clarified that all forms of prescription pharmacotherapy should also be included in secondary care formularies.</p> <p>Further information could be provided to support the development of trust Patient Group Directives, whereby access to smoking cessation pharmacotherapy is not limited to a prescribing decision from a specialist¹.</p> <p>1. British Thoracic Society Quality Improvement Tool – Smoking Cessation https://www.brit-thoracic.org.uk/media/70093/bts-qi-tool-smoking-cessation-v1.pdf</p>	
Pfizer	Guideline	063	027	<p>Section entitled “People working in closed institutions” – We would include an additional recommendation that staff should receive training on the benefits of smoking cessation on mental health, in order to dismiss common preconceptions that smoking helps patients ‘manage’ mental health conditions, improve mental health and morbidity outcomes for patients and address the health inequality experienced by those with Mental Health conditions¹. This represents an opportunity to address the 10-20 year disparity in life expectancy for mental health patients</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.</p>

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				<p>compared to the general population, a difference which is largely driven by the prevalence of smoking in these patients².</p> <ol style="list-style-type: none"> 1. South London & Maudsley Smoke Free Policy: https://maudsleylearning.com/wp-content/uploads/2020/04/Smoke-Free-Policy-v7-April-2020.pdf 2. Action on Smoking and Health Factsheet 12: https://ash.org.uk/wp-content/uploads/2019/08/ASH-Factsheet_Mental-Health_v3-2019-27-August-1.pdf 	
Pfizer	Guideline	090	007	<p>Given the limited evidence for health benefits of smoking reduction^{1,2}, we would advise that the importance of full cessation be given greater prominence in all sections where harm reduction strategies are discussed, with statements such as “The approaches for harm reduction in this guideline should not detract from providing the highly cost effective interventions to help people stop smoking altogether” or “Advise people that stopping smoking in one go is the best approach” (see 1.15.1) appearing at the start of each recommendation. Reaching the challenging NHS Long Term Plan target of making the nation smoke-free by 2030^{3,4} can only be</p>	<p>Thank you. Harm reduction is a small part of this guideline and is mentioned here as part of the context section.</p>

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				<p>achieved by maximising every opportunity for smokers to attain full cessation.</p> <ol style="list-style-type: none"> 1. Hackshaw et al BMJ 2018; 360: j5855 2. Chang et al Nicotine & Tobacco Research 2021 23,(4): 635–642 3. PHE strategy 2020-25 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/831562/PHE_Strategy_2020-25.pdf <p>NHS Long Term Plan https://www.longtermplan.nhs.uk/online-version/</p>	
PrescQIPP	Guideline	General	General	<p>Given the overall lack evidence on clinical and cost effectiveness and long term data on safety, we are concerned about the proposal to allow future prescribing of e-cigarettes if a licensed medicinal product becomes available particularly as these licensed products could have a higher nicotine content than currently specified and allowable under the UK Tobacco and Related Products Regulations 2016. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/962221/Vaping_in_England_evidence_update_February_2021.pdf and Licensing procedure for electronic cigarettes as medicines - GOV.UK (www.gov.uk). As with all</p>	<p>Thank you. The future medicinal licensing of e-cigarettes is for the MHRA and the decision about how these would need to be evaluated for that purpose would be theirs. If a manufacturer applied for a licence for a nicotine containing e-cigarette then the MHRA would need to authorise and license it as a medicine. As part of this process they would be assessed for clinical effectiveness and safety. Any products so licensed would fall under these recommendations.</p>

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				medicines and medical devices, these products would need to be assessed for clinical and cost effectiveness before they are commissioned and prescribing is permitted.	
PrescQIPP	Guideline	022	024	Clarity is needed on what is meant by 'Ensure the following are <i>accessible</i> to adults who smoke' with respect to unlicensed e-cigarettes.	Thank you for your comment. The committee was aware that local areas have very different commissioning arrangements for smoking cessation and agree that the most important thing was ensure that people had access to the range of interventions. The recommendation begins 'Ensure' and is therefore a strong recommendation.
PrescQIPP	Guideline	022	028	'Ensure medicinally licensed products are accessible'. Should an e-cigarette product be licensed in the future, its clinical and cost effectiveness would need to be evaluated before it was commissioned, and prescribing was permitted.	Thank you. Nicotine containing e-cigarettes that applied for a licence would be assessed for clinical effectiveness and safety by the MHRA as part of the licensing process. At that point, NICE would consider reassessing the cost-effectiveness of the product.
PrescQIPP	Guideline	023	005	The guideline suggests making e-cigarettes 'accessible' as a stopping smoking intervention. As there are currently no licensed e-cigarettes so they cannot be prescribed, does this mean making unlicensed e-cigarettes available free of charge from smoking cessation service as part of a quit attempt? If yes, how will this be funded?	Thank you for your comment. The committee was aware that local areas have very different commissioning arrangements for smoking cessation and agree that the most important thing was to ensure that people had access to the range of interventions.
PrescQIPP	Guideline	026	001	The guideline states that there is not enough evidence to know whether there are long-term harms from e-cigarette use. We are concerned	Thank you for your comment. The guideline does not advocate that e-cigarettes are prescribed. The committee has

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				<p>about the proposal to allow future prescribing of a medicinal product for which we have inadequate long term safety data, particularly as these licensed products could have a higher nicotine content than currently specified under the UK Tobacco and Related Products Regulations 2016. ; https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/962221/Vaping_in_England_evidence_update_February_2021.pdf and Licensing procedure for electronic cigarettes as medicines - GOV.UK (www.gov.uk).</p>	<p>recommended that nicotine containing e-cigarettes are one of a number of options to be made accessible to adults who smoke. As part of their discussions, they considered the potential long-term effects of using these products. The rationale and impact section relating to this recommendation outlines the issues the committee considered. These include the following: The extensive harms of smoking are well known, and the committee agreed it is unlikely that e-cigarettes could cause similar levels of harm There was a small amount of evidence about short-term adverse events of e-cigarettes that did not show that they caused any more adverse events than NRT, e-cigarettes without nicotine or no treatment. Experts from the MHRA described to the committee the monitoring process for both short- and long-term harms of using e-cigarettes, and that as of March 2020 no major concerns had been identified. The committee was not aware of any harms that had been identified since then. Monitoring is ongoing and the evidence may change in the future. The committee agreed that with the limited data on effects of longer-term use, people</p>

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					<p>should only use e-cigarettes for as long as they help prevent them going back to smoking</p> <p>E-cigarettes are relatively new devices, and it is important to understand whether they cause any health harms or benefits aside from their potential to reduce smoking-related harm (see research recommendation 1).</p> <p>If a nicotine containing e-cigarette were to become licensed, its effectiveness and safety would have been thoroughly assessed by the MHRA before the device became available.</p>
PrescQIPP	Guideline	032	009	<p>This section states: 'encourage the use of medicinally licensed nicotine-containing products to help them abstain and, if possible, prescribe them'.</p> <p>Should an e-cigarette product be licensed in the future, its clinical and cost effectiveness would need to be evaluated before it was commissioned and prescribing was permitted.</p>	<p>Thank you. The future medicinal licensing of nicotine containing e-cigarettes is a task for the MHRA.. If the MHRA were to authorise the use of e-cigarettes and license them as a medicine for stopping smoking they would be assessed for clinical effectiveness as part of that process. At that point NICE would consider whether to assess the cost-effectiveness.</p>
PrescQIPP	Guideline	036	015	<p>This section states: 'If possible, supply or prescribe medicinally licensed nicotine-containing products'.</p> <p>Should an e-cigarette product be licensed in the future, its clinical and cost effectiveness would need to be evaluated before it was commissioned and prescribing was permitted.</p>	<p>Thank you. The future medicinal licensing of nicotine containing e-cigarettes is a task for the MHRA.. If the MHRA were to authorise the use of e-cigarettes and license them as a medicine for stopping smoking they would be assessed for clinical effectiveness as part of that process. At that point NICE would</p>

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					consider whether to assess the cost-effectiveness.
Primary Care Respiratory Society	Guideline	General	General	A significant omission from the current document is a recommendation regarding the management of second hand smoke exposure in the home, specifically for children. There are several recommendations regarding smoking and young people with regard to retail shops, schools etc, but little about tackling the home influence. There is also a short paragraph about getting carers/parents on board with helping smoking cessation, but again no real mention of the influence of second hand smoking and how to deal with it especially in young people who may or may not be smoking already. The benefits to the wider family of quitting smoking is something that should form part of the dialogue around the benefits of quitting	Thank you for your comment. The management of second hand smoke exposure in the home is outside the scope of this guideline. Please see the scope document on the NICE website. The guideline does acknowledge the risk posed by second hand smoke with recommendations outlining the need to raise public awareness of the harm of second hand smoke in the context of using medicinally licensed nicotine-containing products (1.8.1); the provision of clear advice regarding the danger of second hand smoke for those using acute, maternity and mental health services (1.14.1) and during contact with partners, parents and other household members of people using acute, maternity and mental health services when identifying smoking (1.11.11); and in the context of the development of policy for smoke free grounds (1.21.2); and when training those who advise people how to stop smoking (1.23.4 and 1.23.11).
Primary Care Respiratory Society	Guideline	General	General	We would recommend providing guidance on how to support those attempting to stop e-cig use. While the document repeatedly says that	Thank you for your comment. Supporting people to stop e-cigarette use is outside the scope of this guideline which was focussed

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				HCPs should offer advice, what that advice should be is not defined	specifically on tobacco. Please see the scope document on the NICE website.
Primary Care Respiratory Society	Guideline	General	General	There is no acknowledgement of the potential value of long-term smoking cessation aid use (e-cigs or NRT) to prevent relapse to tobacco smoking	Thank you for your comment. Recommendation 1.17 (Adherence and relapse prevention) contains recommendations which suggest offering the opportunity for a further course of pharmacotherapy to prevent a relapse to smoking (1.17.2). However, the evidence regarding both the use of pharmacotherapy and/or NRT was mixed and whilst the committee acknowledged the importance of preventing relapse after a successful quit attempt, they were not confident that the evidence supported a recommendation regarding the use of NRT to help prevent relapse but have recommended the use of pharmacotherapy (recommendation 1.17.2). To this end a research recommendation (research recommendation: relapse prevention) has been developed to foster research into the effectiveness of nicotine replacement therapy or nicotine-containing e-cigarettes for preventing relapse after a successful quit attempt.
Primary Care	Guideline	General	General	Consider mentioning that ICS are less effective in people with respiratory conditions if they also smoke tobacco	Thank you for your comment. Inhaled corticosteroids (ICS) were outside the scope

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Respiratory Society					of this update. Please see the scope document on the NICE website.
Primary Care Respiratory Society	Guideline	General	General	A case study illustrating the value and use of integrated care systems for tobacco cessation service delivery would be valuable	Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned.
Primary Care Respiratory Society	Guideline	008	001	Rec 1.1.7 While we recognise that CYP are an important target for smoking prevention campaigns we would suggest acknowledging the need for prevention of uptake and reuptake as well as quitting in adults	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Primary Care Respiratory Society	Guideline	008	018	Rec 1.1.4. We would suggest that it be made clear that the messaging and language may need to be tailored so it is appropriate for different target groups	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Primary Care Respiratory Society	Guideline	008	025	Rec 1.1.5 We would suggest adding a comment to use the full range of media used by adults – both younger and older – as these may differ from CYP	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Primary Care Respiratory Society	Guideline	046	General	The recommendations for NRT use during pregnancy do not go far enough with recommending short and long-acting NRT for highly dependent smokers. This is especially crucial considering that during pregnancy nicotine can be metabolized up to 60% faster	Thank you. Recommendations about using short and long acting NRT are in section 1.12 of the guideline.
Primary Care	Guideline	061	016	Why has a 4-week cut-off been selected? Given the ongoing risk for relapse we would	Thank you for your comment. This comment relates to a greyed-out area of the guideline

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Respiratory Society				suggest ongoing monitoring for at least 6 months and preferably to at least 12 months	and is outside of the scope for this update. Please see the scope document on the NICE website.
Primary Care Respiratory Society	Guideline	069	015 - 016	The product section is missing lozenge and mouth spray options	Thank you for your comment. We have added mouth spray and lozenge to the definition.
Proprietary Association of Great Britain	Guideline	General	General	<p>PAGB welcomes many of the new inclusions and ambitions within this document. However, public health funding cuts have seen the overall budget for smoking cessation services reduced by 34% between 2013/14 and 2017/18.¹ We are supporting calls for an increase in funding for smoking cessation services, across the country.</p> <p>Without an increase in funding there will continue to be local variations in outcomes with over 100,000 smokers no longer having access to any local authority commissioned support to quit smoking across 3% of local authorities that have cut all provision.² Furthermore, without sufficient funding inequalities will continue. New statistics have shown that smoking is responsible for nearly twice as many cancer cases in lower income groups compared to higher income groups, and across England more than 27,000 cases</p>	Thank you for your comments. The resource impact of the recommendations has been considered but it is outside of NICE's remit to recommend increases in central Government, regional or local funding. The guidelines presented are based on the best available evidence of effectiveness and cost-effectiveness and provide guidance for those tasked to take action.

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				<p>of cancer a year are associated with poverty, or deprivation.³</p> <p>Smoking costs the economy more than £11bn each year: £2.5bn falling on the NHS, £5.3bn on employers, and £4.1bn on wider society.^{iv} Furthermore, evidence shows if current/ex-smokers had never smoked, the difference in the equivalent rates of economic activity would boost the UK economy by £19.1 billion a year or 1.9% of earnings.^v Smoking cessation is one of the most cost-effective interventions, with every £1 spent on smoking cessation estimated to save £10 on future healthcare costs and health gains.^v Smokers who successfully quit reduce their lifetime cost to the health and care system by almost 50%.^{vi}</p> <p>¹ PAGB, <i>Smoking Cessation Services in England: the widening divide between investment and ambition across England</i> (June 2019) available here: https://www.pagb.co.uk/content/uploads/2020/01/20190625-Smoking-cessation-spend-outcomes-v2-0.pdf</p> <p>ⁱⁱ Action of Smoking and Health, <i>Cuts to local funding for smokers requires national Government action</i>, (March 2019), available here: https://ash.org.uk/media-and-news/press-releases-media-and-news/cuts-to-</p>	

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				<p>local-funding-for-smokers-requires-national-government-action/</p> <p>ⁱⁱⁱ Cancer Research UK, <i>England: Smoking responsible for twice as many cancers in most deprived groups</i> (August 2021) available here: https://news.cancerresearchuk.org/2021/08/03/england-smoking-responsible-for-twice-as-many-cancers-in-most-deprived-groups/</p> <p>^{iv} Cancer Research UK, <i>The Economic Case for Local Investment in Smoking Cessation</i> (accessed May 2020) available here: https://www.cancerresearchuk.org/sites/default/files/economic_case_for_local_investment_in_smoking_cessation_printed_version.pdf</p> <p>^v International Longevity Centre, <i>Up in smoke, The impact of smoking on health and economic activity</i> (August 2021) available here: https://ilcuk.org.uk/wp-content/uploads/2021/07/Up-in-smoke-The-impact-of-smoking-on-health-and-economic-activity.pdf</p> <p>^{vi} NICE, <i>Funding public health protects our communities and children, saves lives... and can save money</i> (accessed May 2020) available here: https://www.nice.org.uk/media/default/About/what-we-do/NICE-advice/Local-government-briefings/Do-public-health-interventions-offer-value-for-money.pdf</p>	

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				vii Public Health England, <i>It's time for a truly smokefree NHS</i> (December 2016) available here: https://publichealthmatters.blog.gov.uk/2016/12/06/its-time-for-a-truly-tobacco-free-nhs/	
Proprietary Association of Great Britain	Guideline	General	General	The policy landscape surrounding smoking cessation is also currently in a state of flux. A new Tobacco Control Plan (TCP) is due to be published in 2021 and will support the Government's ambitions for a smoke-free nation by 2030. The TCP should be updated to set out a strategy for how the smokefree 2030 ambition will be met, taking into account the impact of the Government's COVID-19 response on access to smoking cessation support and the above-mentioned abolition of Public Health England. It is important that the guideline is updated in line with relevant outputs from the TCP.	Thank you for your comment and for the information provided. NICE will review the situation once the new Tobacco Control Plan is published and take appropriate action regarding the guideline and associated materials as required.
Proprietary Association of Great Britain	Guideline	General	General	We understand that quitting smoking is one of the most challenging behaviour changes a person can make. Once a smoker takes the first step of acknowledging the need to quit, smoking cessation services must ensure they have access to a broad range of evidence-based tools and services to help support them in achieving this goal.	Thank you for your comment.
Proprietary Association	Guideline	General	General	Pharmacists are well placed to support smoking cessation services specifically, as	Thank you for your comment. PHAC have considered the evidence of effectiveness,

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of Great Britain				well as supporting people who ask for VBA. Pharmacies are situated at the centre of communities and are easily accessible by the majority of the local population. There are over 11,000 community pharmacies in England and over 99% of people living in areas of the highest deprivation are within a 20-minute walk of a community pharmacy. However, the draft guideline has very little mention of the importance of unlocking the unique opportunities that community pharmacists have to use VBA to signpost and support people towards smoking cessation services and quitting aids, such as NRT.	barriers and facilitators, and cost-effectiveness as well as expert testimony and contributions from expert co-optees to the committee in the development of this guideline. The guideline on page 2 outlines 'who is it for?' and within this refers to health and social care professionals and people with a remit to improve the health and wellbeing of children and young people, which would include pharmacists. The guideline recommendations specify for example 'those working in public health' and 'retailers of medicinally licensed nicotine-containing products' (Recommendation 1.8); Recommendation 1.11 is aimed at 'health and social care professionals' which would include pharmacists. So whilst pharmacists may not be explicitly mentioned, they are implicit in the groups outlined for whom the guideline is aimed at.
Proprietary Association of Great Britain	Guideline	General	General	Pharmacists already have a role in supporting smoking cessation. However, to enable pharmacists take on a greater clinical role in line with their skills, and to support people and patients with their health and wellbeing, pharmacists should be able to populate patient medical records. Enabling pharmacists to write to patients' records would mean that advice and treatment given in other health settings	Thank you for your comments. Redefining the current clinical capabilities and role of community pharmacists is outside the scope of this guideline and outside the remit of NICE.

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				(including by GPs and in hospital) can take general health, underlying conditions and medicines use such as quitting aids into account, providing a consistent and comprehensive record of an individual's treatment.	
Proprietary Association of Great Britain	Guideline	003	N/A	<p>At the introduction of the guideline, the document notes that there are references to Public Health England (PHE). It recognises that from Autumn 2021 PHE will no longer exist in its current form, so the references will be updated when the new structures are in place.</p> <p>This is a useful update, however NICE may wish to consider a further review once the new health and care legislation is passed into law. The delivery and funding mechanisms for local services are in development as part of new Integrated Care Systems, and this could particularly impact the delivery of local smoking cessation services. As such, a further review will be needed to ensure the guideline is up to date and in line with the changing NHS landscape at local, regional and national level.</p> <p>Furthermore, the NHS Long Term Plan also brought with it the creation of Primary Care Networks (PCNs). PCNs are being tasked with</p>	<p>Thank you for your comment. NICE routinely checks that published guidelines are current, accurate and up to date via our surveillance function which explores if there is any new evidence to contradict, reinforce or clarify guideline recommendations. Surveillance also identifies new interventions that may need to be considered within a guideline and explores changes in context, such as those you have highlighted, that may mean modifications are needed, for example, changes in policy, infrastructure, legislation or costs. A proactive approach is taken that includes reacting to events at any time after guideline publication (for example, publication of a key study).</p>

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				a greater role in population health improvement, including through a new service specification for health inequalities. It will be important to ensure the guideline refers to this service specification once it is in place as embedding smoking cessation advice and support into this service specification and in wider community services will help to promote opportunistic very brief advice (VBA) and referrals to smoking cessation services at a population health level.	
Proprietary Association of Great Britain	Guideline	022	019 - 021	<p>Within a month of the COVID-19 pandemic lockdown, 96% of local authorities reported that smokers still had access to support from a trained advisor, and 88% reported that smokers could still access medications or e-cigarettes via the services available.vii Many local authorities continue to use remote and digital technologies to ensure continued access when face-to-face consultations are not appropriate.</p> <p>The only mention of digital services within the guideline is on page 22, and it references the reader to a separate guideline on behaviour change: digital and mobile health interventions.</p> <p>However, we would suggest that this guideline would benefit from the addition of key questions to support health professionals to</p>	<p>Thank you for your comment.</p> <p>NICE's guideline NG183 considered the evidence regarding smoking behaviour and has recommendations focused on the development, commissioning, consideration and use of digital and mobile health interventions and smoking. This evidence was not considered specifically in the context of this guideline (Tobacco: preventing uptake, promoting quitting, and treating dependence) and has been cross-referred to.</p> <p>The guideline document provides the evidence-based recommendations and the underpinning rationales and impact of these recommendations. The addition of any additional recommendation content for example 'key questions' as outlined without evidence being considered is outside NICE's</p>

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				<p>evaluate these new models of service delivery, so that any shortcomings can be addressed to enhance and maintain access to quitting support, including NRT and other licensed medications. This would ensure that positive lessons can be embedded for the long term. It is also vital that new digital services do not replace face-to-face services for those who need them, but a blend of both models can be adopted where proven effective. This will help to ensure that there is no detrimental impact on health inequalities or cuts to services targeted at hard-to-reach or vulnerable groups.</p> <p>^{viii} Action on Smoking and Health, <i>Stop smoking services open to smokers thanks to rapid response of local councils</i> (29 May 2020) available here: https://ash.org.uk/media-and-news/press-releases-media-and-news/stop-smoking-services-open-to-smokers-thanks-to-rapid-response-of-local-councils/</p>	<p>methods and process for guideline development.</p>
Proprietary Association of Great Britain	Guideline	026	010	<p>We recommend adding a line to this section that states – “including holding a discussion on additional methods of support pathways, such as licensed forms of NRT”. This would ensure that people being offered support to stop smoking are aware of the full range of options open to them.</p>	<p>The recommendation to which you refer (1.12.15) relates specifically to nicotine containing e-cigarettes. However as outlined in recommendation 1.12.1, nicotine containing e-cigarettes are one option among several that the committee has recommended are made accessible to adults who smoke, including medicinally licensed products such as NRT. Recommendation</p>

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					1.12.2 recommends people are told about the range of options and 1.12.3 recommends they are provided with behavioural support regardless of the option they choose. Recommendations 1.12.10 to 1.12.12. provide further details on the information and advice that should be provided to people who choose to use medicinally licensed products.
Proprietary Association of Great Britain	Guideline	050	011 - 014	<p>The guidelines states that health professionals should “Consider NRT at the earliest opportunity in pregnancy and continue to provide it after pregnancy if the woman needs it to prevent a relapse to smoking, including if the pregnancy does not continue (see BNF information on NRT). [2021]”</p> <p>The guideline should be updated to note to clearly reinforce “after pregnancy”.</p> <p>Increasing evidence has shown that a high proportion (47%-63%) of women who quit smoking during pregnancy relapse during the postpartum period.viii Therefore, the guideline should also include a recommendation for continued smoking cessation support to be discussed at the woman’s 6-week post-natal check with their GP.</p> <p>ix Harmer C, Memon A. Factors associated with smoking relapse in the postpartum period: an analysis of the child health surveillance</p>	Thank you. The recommendation specifies ‘after pregnancy’ as you suggest.

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				system data in Southeast England. Nicotine Tob Res. 2013 May;15(5):904-9. doi: 10.1093/ntr/nts221. Epub 2012 Oct 8. PMID: 23045522.	
Proprietary Association of Great Britain	Guideline	057	001 - 008	The update on commissioning and designing services states: “Ensure service specifications require providers of stop-smoking support to offer nicotine replacement therapy (NRT) for as long as needed to help prevent a relapse to smoking.” This is an important addition that will enable people to have access to NRT when they need it. However, we would suggest adding a line that states the need for “appropriately trained professionals have regular checks with the individual, so as to ensure they continue to be on the path towards smoking cessation”.	Thank you for your comment. Section 1.22 of the guidance focuses on the commissioning of services. Please see the recommendations in section 1.17 which consider relapse prevention and in particular recommendation 1.17.1 which covers the importance of discussing relapse prevention from an early stage and at every contact.
Proprietary Association of Great Britain	Guideline	057	022 - 023	There is only a brief reference in the guideline to the NICE guidance on lung cancer. The integration of smoking cessation into the lung health check programme is an important intervention to prevent smoking-related ill-health from escalating. Implementation should therefore be measured and evaluated to understand the impact and reach of the guideline, particularly in light of the COVID-19	Thank you for your comment. We only refer to other NICE guidance when a recommendation links to it.

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				pandemic response, which resulted in many of these services being temporarily halted.	
Public Health England – Breathe 2025	Guideline	General	General	<p>The guidelines, quite rightly, make a range of recommendations for research (see page 72-76). Yet there is only one acknowledgement of the need to take into account the outcomes of any such research, in section 1.9.2 bullet 2 which recommends “Use the best available evidence of effectiveness, such as Cochrane reviews”.</p> <p>To our knowledge some, if not all, of the research recommendations are already being taken forward. For example, NIHR has funded ‘Helping Pregnant Smokers Quit: A Multi-Centre RCT of Electronic Cigarette and Nicotine Patches’, although unfortunately the research may not be available before the guidelines are published so is unlikely to be able to be taken into account during the consultation. NIHR is also funding research on smoking cessation in underserved groups such as prisoners and the homeless.</p> <p>As the evidence continues to develop and evolve, it is important that in the overview section of the guidelines there is a generic recommendation that research outcomes are taken into account. We suggest something</p>	<p>Thank you for your comment. The research recommendations developed by PHAC seek to address the gaps in the evidence identified during the guideline development process with the hope of stimulating research in these areas for consideration when this guideline or aspects of this guideline are considered for update.</p> <p>NICE routinely checks that published guidelines are current, accurate and up to date via our surveillance function which explores if there is any new evidence to contradict, reinforce or clarify guideline recommendations. Surveillance also identifies new interventions that may need to be considered within a guideline and explores changes in context that may mean modifications are needed, for example, changes in policy, infrastructure, legislation or costs. A proactive approach is taken that includes reacting to events at any time after guideline publication (for example, publication of a key study).</p>

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				along the lines, "When developing and implementing policies to prevent uptake, promote quitting and treat dependence it is essential to use the best available evidence of effectiveness, such as Cochrane reviews".	
Public Health England – Breathe 2025	Guideline	General	General	<p>Financial incentives for quitting smoking are not highlighted as an effective intervention in the general population. They should be. There is high certainty evidence of their effectiveness in the general population of people who smoke (as well as in pregnancy, where they are currently highlighted).^{1 2}</p> <p>¹ Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 7. Art. No.: CD004307</p> <p>² Hartmann-Boyce J, Livingstone-Banks J, Ordóñez-Mena JM, Fanshawe TR, Lindson N, Freeman SC, Sutton AJ, Theodoulou A, Aveyard P. Behavioural interventions for smoking cessation: an overview and network meta-analysis. Cochrane Database of Systematic Reviews 2021, Issue 1. Art. No.: CD013229</p>	Thank you for your comment. Incentives were only considered in pregnant women. Incentives for other populations is outside the scope of this guideline. Please see the scope document on the NICE website.
Public Health England –	Guideline	046 - 047	General	3 and 4ppm CO levels are both used in this section (p46 line 15 says 4ppm and p47 line 9 says 3ppm). The Smoking in Pregnancy Challenge Group recommends that women	Thank you for your comment. The different carbon monoxide levels refer to different groups of pregnant women: smokers and non-smokers and to different actions. The

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Breathe 2025				<p>with a reading of 4ppm or above should be referred for smoking cessation support. Evidence suggests that 4ppm is the optimal cut-off for correctly identifying pregnant women who smoke and minimising the number of false positives.^{10 11}</p> <p>¹⁰ Bailey BA. Using expired air carbon monoxide to determine smoking status during pregnancy: preliminary identification of an appropriately sensitive and specific cut-point. Addictive behaviors. 2013 Oct 1;38(10):2547-50.</p> <p>¹¹ Bauld L, Hackshaw L, Ferguson J, Coleman T, Taylor G, Salway R. Implementation of routine biochemical validation and an 'opt out' referral pathway for smoking cessation in pregnancy. Addiction. 2012 Dec;107:53- 60.</p>	<p>reference to 4 ppm in recommendation 1.18.2 is in the context of the provision of an opt-out referral to receive stop-smoking support for pregnant women. The reference to 3 ppm in recommendation 1.18.4 refers to women who do not smoke and to provide help to identify the source of the carbon monoxide level of 3 ppm.</p>
Public Health England – Breathe 2025	Guideline	013	005 - 007	<p>1.6.4 – While it is important to avoid inadvertently making e-cigarettes desirable to young people, it is just as important to avoid inadvertently reinforcing misperceptions that e-cigarettes are as harmful as smoking. Findings from the annual Smokefree GB survey commissioned by ASH show that the perception among 11–18-year-olds that cigarettes and e-cigarettes are equally harmful has increased since 2013. In 2021, only 43.8% of 11–18-year-olds knew that e-cigarettes were less harmful than cigarettes.³ Similarly, among</p>	<p>Thank you for your comment. This is stated clearly elsewhere in the guideline and the committee were clear that they did not want to say anything that might promote the use of e-cigarettes in under 18s.</p>

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				<p>adults, around a third (32%) believed e-cigarettes were more or equally as harmful as cigarettes in 2021, compared to 42% who thought they were less harmful.⁴ This is relevant because adults will be responsible for giving children advice about e-cigarettes.</p> <p>An additional sentence should be added to recommendation 1.6.4 consistent with the wording on page 26 lines 1-4, that "However, it is also important to make clear that although there is not enough evidence to know whether there are long-term harms from e-cigarettes, they are likely to be substantially less harmful than smoking."</p> <p>³ ASH. Use of e-cigarettes among young people in Great Britain. 2021 ⁴ ASH. Use of e-cigarettes (vapes) among adults in Great Britain. 2021</p>	
Public Health England – Breathe 2025	Guideline	017	001 - 003	<p>We welcome the recommendation to involve community pharmacies in local campaigns and maintain links with other professional groups such as dentists, fire services and voluntary groups.</p> <p>We would like to see welfare and benefits officers/advisors included in this list because they have a unique opportunity to screen for smoking, provide very brief advice and signpost to smoking cessation services as part</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.</p>

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				of their interventions to help people manage their financial situation.	
Public Health England – Breathe 2025	Guideline	028	010 - 013	<p>1.14.1 – We would like to see this section include a bullet point to highlight the mental health benefits of quitting smoking. A recent Cochrane review found that smokers who stop have better mental health than those who continue to smoke and that the benefits to mental health were estimated to be equivalent to anti-depressants.⁵ Quitting can also help reduce the severity of psychotic symptoms and in some cases, contribute to reductions in prescribed medications and shorter hospital stays.⁶</p> <p>⁵ Taylor GM, Lindson N, Farley A, Leinberger-Jabari A, Sawyer K, te Water Naudé R, Theodoulou A, King N, Burke C, Aveyard P. Smoking cessation for improving mental health. Cochrane Database of Systematic Reviews. 2021(3).</p> <p>⁶ Taylor, D.M., Barnes, T.R.E., Young, A.H., (2021) The Maudsley Prescribing Guidelines in Psychiatry, 14th Edition, ISBN: 978-1-119-77223-1 July 2021 Wiley-Blackwell 976 Pages</p>	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Public Health England – Breathe 2025	Guideline	029	011	We are pleased to see the recommendation that every smoker will be offered behavioural support in acute, maternity and mental health care settings but we are disappointed that this offer is only recommended “if the person	Thank you for your comment. The evidence on opt-out referral schemes was in scope for pregnant women only. The committee has made recommendations on opt out referral schemes for pregnant women (see

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				<p>agrees". We recommend that behavioural support is provided on an opt-out basis – as described in the Ottawa Model and in the RCPs Hiding in Plain Sight.⁷ The Ottawa model is also recommended in the NHS Long Term Plan.⁸</p> <p>It is often the case that at the point of screening for smoking and provision of Very Brief Advice at admission, people coming into mental health care settings are usually distressed and unlikely to be able to weigh up this decision. We recommend a more proactive approach which ensures those that need specialist support have access to it using an opt-out approach.</p> <p>⁷ Royal College of Physicians. Hiding in plain sight: Treating tobacco dependency in the NHS. 2018</p> <p>⁸ NHS England. The NHS Long Term Plan: Smoking. January 2019</p>	<p>Recommendations 1.18.2 and 1.18.3). Opt-out referral schemes were not within scope for other population groups. Please see the scope document on the NICE website.</p>
Public Health England – Breathe 2025	Guideline	030	014	<p>We do not believe that the recommendation to provide support to smokers within 24 hours of admission goes far enough to ensure patients comfort or ease their distress. We would welcome a recommendation to provide support within 30 minutes of arrival to hospital. For example, SLAM NHS Foundation Trust provide 'Tea and NRT' to smokers on arrival to hospital</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.</p>

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				as an over the counter medication. This avoids the delays caused by getting a prescriber and is hugely beneficial since the half-life of nicotine is approximately 2 hours and longer delays will result in unnecessary discomfort.	
Public Health England – Breathe 2025	Guideline	032	004 - 009	<p>1.14.20 - We welcome the recommendation to tell smokers about the different types of medicinally licensed nicotine containing products, how to use them and if possible, prescribe them. However, we are disappointed that e-cigarettes are not also recommended as a vital intervention for smokers who are in a situation where they need to temporarily abstain. If this guideline only recommends the use of NRT to support tobacco abstinence, this represents an extremely challenging scenario for trusts that currently offer e-cigarettes to service users and risks further disadvantaging people with mental health ill health, who will be left behind. We would worry that failure to include e-cigarettes as a safe, valid and effective way to support temporary abstinence will enable some service providers to opt out of and we will find ourselves in a situation where the teachable moment to support stopping smoking and switching to an e-cigarette is lost.</p> <p>SLaM NHS Foundation Trust provide mental health care services from 4 large London</p>	<p>Thank you for your comment. The evidence on the use of nicotine containing e-cigarettes to support temporary abstinence was not reviewed as part of this guideline update and therefore recommendations have not been made in this area.</p> <p>Regarding differing needs between people admitted to acute hospital settings and to mental health settings, these recommendations are greyed out as they are outside the scope for this update. Please see the scope document on the NICE website.</p>

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				<p>based hospitals (50 wards). Typically, about half of the adult smokers admitted to hospital are current smokers, it is rare to find a smoker at the point of admission who decides to make a quit attempt. For the overwhelming majority (95%) their decision at the point of admission is to use whatever support is available to temporarily abstain. Currently, the preferred option to support temporary abstinence is an e-cigarette, because smokers feel that this more closely matches the experience of smoking compared with using NRT products. SLaM have used e-cigarettes in this way since 2012 and typically provide around 400 free e-cigarette starter packs each month. In about 30% of cases the smokers find that the provision of a free e-cigarette starter pack, given with the intention to support temporary abstinence on admission is so effective that they decide to continue using it and do not return to smoking.</p> <p>In 2019 ASH conducted a survey of mental health trusts which found that 42% of mental health trusts in England provide free e-cigarettes to adult smokers on admission to hospital to support temporary abstinence, and as such we believe there is ample evidence to support this consensus practice.⁹ More</p>	

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				generally in this section of the guidance, we think a distinction should be made between the needs of people admitted to an acute hospital setting and people admitted to a mental health setting. The unique needs of people in mental health crisis is completely different and deserves a more bespoke response. 9 ASH. Progress towards smokefree mental health services. Findings from a survey of mental health trusts in England. 2019	
Public Health England – Breathe 2025	Guideline	051	General	1.20.12 – We are concerned that this guideline doesn't link to any guidance or information to support the implementation of incentive schemes. This could include case studies of existing schemes, key competencies for staff or dedicated training. The Smoking in Pregnancy Challenge Group has produced a briefing to support the commissioning and delivery of incentive schemes. ¹⁶ The briefing summarises the evidence from previous incentive schemes, sets out lessons for practice and will be updated in line with emerging evidence. The guidance should link to the Challenge Group briefing to ensure that commissioners have access to practice-focused information to support the delivery of incentive schemes. We also recommend that the guidance should link to case studies and guidance from previous incentive schemes.	Thank you. The recommendations are based on the evidence of effectiveness, and the implementation of the recommendations is primarily a local commissioning decision.

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				16 Smoking in Pregnancy Challenge Group. Evidence into Practice: Supporting smokefree pregnancies through incentive schemesv. 2019	
Public Health England – Breathe 2025	Guideline	051	015 - 016	1.20.12 – bullet 3 – This sentence should use the word “incentive” instead of “reward”. Incentive payments are not rewards; they are incentives to change behaviour and the terminology used should reflect that. This is particularly important given the sensitivity in the media around the use of financial incentives in pregnancy.	Thank you for your comment. PHAC considered your comment and the wording has been amended to reflect your comment.
Public Health England – Breathe 2025	Guideline	051	015 - 016	1.20.12 – bullet 3 – The guideline should recommend that the offer of incentives be extended into the postnatal period for a minimum of 3 months to prevent women relapsing to smoking. Evidence suggests nearly half of women who quit smoking during pregnancy relapse within 1-year post-partum. ¹³ This harms the health of the mother and makes it more likely that children will be exposed to secondhand smoke in the home, leading to higher rates of sudden infant death (SIDS), lower respiratory tract infection, middle ear disease, asthma and many other diseases. ¹⁴ Consequently, supporting women and their partners to stay smokefree after their baby is born is key to helping them maintain a smokefree home and protecting them and their	Thank you. The committee considered this. Please see the committee discussion section of evidence review J which says that “The committee discussed the duration of incentive provision and agreed that this should occur at least until the end of pregnancy (including pregnancies that do not progress), however that it wasn’t clear whether provision would be beneficial in the post-partum period “

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				<p>children from harmful tobacco smoke. Evidence from a 2019 Cochrane review shows that providing incentives into the postnatal period is effective for supporting women to stay smokefree.¹⁵ Additionally, Greater Manchester Health and Social Care Partnership are currently awaiting publication of a RCT looking at the provision of incentives for 1-year post-partum.</p> <p>13 Jones, M., Lewis, S., Parrott, S., Wormall, S., & Coleman, T. Re-starting smoking in the postpartum period after receiving a smoking cessation intervention: A systematic review. <i>Addiction</i>, 2016, 111(6), 981–990</p> <p>14 Royal College of Physicians. <i>Passive smoking and children. A report by the Tobacco Advisory Group</i>. London: RCP, 2010</p> <p>15 Notley C, Gentry S, Livingstone-Banks J, Bauld L, Perera R, Hartmann-Boyce J. Incentives for smoking cessation (Review). <i>Cochrane Database of Systematic Reviews</i>. 2019. Issue 7. Art. No.: CD004307</p>	
Public Health England – Breathe 2025	Guideline	051	005	<p>Research is underway on the effectiveness of e-cigarettes as a quitting aid for pregnant smokers and the impact of their use on birth outcomes, but will not be published in time to be taken into account in this guidance. Despite the lack of evidence specific to pregnancy at the current time, advice on the</p>	<p>Thank you. The committee did not see any evidence on the effectiveness of nicotine containing e-cigarettes during pregnancy and therefore is unable to make a recommendation in this area</p>

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				<p>use of e-cigarettes in pregnancy should not be excluded from the guidance. E-cigarettes are already being used by some women as an aid to quit smoking during pregnancy, and midwifery and stop smoking practitioners are being asked for advice on their use. If they are unable to provide any advice, there is an increased risk that women may revert to smoking, which is a leading modifiable risk factor for many poor birth outcomes. That is why the Smoking in Pregnancy Challenge Group, an alliance of medical organisations such as the RCOG, RCM and RCGP, working together with charities such as the Lullaby Trust, Sands and Tommys, has produced peer reviewed resources for healthcare professionals and pregnant women on use of e-cigarettes.¹² These resources are widely used and are regularly updated in line with the evolving evidence base.</p> <p>Therefore, after the section on 'Nicotine replacement therapy and other pharmacological support' (pages 50 line 8 to 51 line 5) a section should be added headed 'Use of e-cigarettes in pregnancy'. This should state that "If a pregnant woman has chosen to use an e-cigarette to quit or to reduce the number of cigarettes that she smokes, she should not be discouraged from doing so, as</p>	

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				any risks to the fetus is likely to be extremely small compared to continued smoking". Then go on to say "It is important to give pregnant smokers clear, consistent and up-to-date information about nicotine containing e-cigarettes (for example see the Smoking in Pregnancy Challenge Group resources on e-cigarettes). See also the section in the guideline on advice on nicotine-containing e-cigarettes." 12 Smoking in Pregnancy Challenge Group. Webpage: Using e-cigarettes before, during and after pregnancy.	
Public Health England – Breathe 2025	Guideline	052	006	We are concerned that the guideline 'Enabling all pregnant women to access stop-smoking support' does not explicitly recommend that stop smoking materials and support be provided in languages other than English. Although the NICE guideline on patient experience in adult NHS services recommends that healthcare services are accessible for non-English speakers, given high rates of smoking among some migrant communities, the guideline should explicitly highlight the need to provide stop smoking materials and advice in a range of languages. Migration Observatory analysis of the Annual Population Survey 2019, shows that women	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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				born in new EU accession countries, including Poland, Romania and Lithuania, have much higher rates of smoking than those born in the UK (22% compared to 13%). ¹⁷ Among men, those who are foreign-born are more likely to smoke than UK-born men, and men born in new EU accession countries more than twice as likely to smoke as UK-born men (34% compared to 15%). To ensure that these communities are not underserved by stop smoking support, we believe that the list starting on page 52, line 11, should include a point saying "Ensure resources and advice for stopping smoking are available in a range of different languages, taking into account local demographics." ¹⁷ The Migration Observatory. The health of migrants in the UK. August 2020	
Public Health England – Breathe 2025	Guideline	059	010 - 011	Clarify statement "Include nicotine-containing products as options for sale in secondary settings (for example, in hospital shops.)" The guideline should specify whether this refers to NRT and/or e-cigarettes to avoid any confusion.	Thank you. Nicotine containing products is defined in the glossary section of the guideline. The definition of nicotine containing products has been amended to clarify that it includes nicotine containing e-cigarettes.
Public Health England – Breathe 2025	Guideline	062	General	1.23 – [PH5] Smoking: workplace interventions - Recommendation 4: 'Ensure smoking cessation support and treatment is delivered only by staff who have received training that complies with the 'Standard for training in	Thank you. Training is covered in recommendations 1.23.2 to 1.23.4. Additionally, 1.23.2 cross references to recommendations 1.13 which reference NCSC training.

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				<p>smoking cessation treatments' has been deleted. The reason given for deletion is that 'tailoring support and treatment is a general principle recommended in NICE's guideline on patient experience in adult NHS services.' We do not support this deletion.</p> <p>The National Training Standard was produced by the National Centre for Smoking Cessation and Training (NCSCT) on behalf of the Department of Health and includes all behaviour change techniques (BCTs) for which there is evidence of effectiveness. It does not prevent tailoring support and treatment as appropriate, therefore the rationale for deletion is not justified. Practitioners trained to deliver interventions according to the standard have been proven to be effective in adding significant value to quit attempts.¹⁸ Removal of the Training Standard is likely to lead to a return to the situation prior to the establishment of the NCSCT where people provided training based on opinion, rather than the evidence, for what effective training should contain. This recommendation should therefore be reinstated.</p> <p>Related to this point, the National Training Standard is mentioned in 1.12 (in a rather non-</p>	

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				<p>specific manner) and again under Quitlines (1.12.20). However, section 1.23, line 12-26, 'Those who advise people to stop smoking' fails to include any mention of the Standard. While the subtitle may suggest this section is specific to those who identify smokers and prompt quit attempts (i.e. deliver VBA), there is nothing further in this section on training for those who deliver ongoing stop smoking support (i.e. behavioural support), as has been the case in previous versions of the document. At minimum this should be included for stop smoking services. The wording found in the 2018 NG92 recommendation on this subject served this purpose. The key being 1) stop smoking support is provided by trained staff and 2) that training be consistent with the National Training Standard. Given the level of depth the document goes into for maternity care and closed institutions, there should be at least the equivalent depth provided for all settings (stop smoking services, maternity care, closed institutions, primary care) who are delivering stop smoking support. This should consist of the National Training Standard as default, plus additional training for those working with specific population such as mental health and pregnancy.</p>	

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				<p>Overall, there is little said in the new NICE guidance on stop smoking services and stop smoking support delivered in other settings compared to previous guidance documents. There is also a level of specificity in some sections that is not consistently applied in the document (e.g. lots of detail in maternity care section and smokeless tobacco and only a few bullets on other important areas of practice). This risks making the document less clear and less user friendly than previous NICE guidance.</p> <p>18 Brose L, West R, Michie S, McEwen A. Changes in success rates of smoking cessation treatment associated with take up of a national evidence-based training programme. Preventive Medicine 2014;69C:1-4</p>	
Public Health England – Breathe 2025	Guideline	075	007 - 013	<p>We suggest considering the addition of two further points regarding recommendations for further research into relapse prevention. Firstly, we see a clear need for more research on varenicline for relapse prevention, given the committee acknowledges its likelihood of increasing long-term abstinence and supporting Cochrane evidence.¹⁹ Secondly, we suggest it would be a good idea to recommend more trials looking at relapse prevention interventions delivered to people</p>	<p>Thank you. Research recommendations in NICE guidelines are specifically to address gaps in the research that the committee considered while making their recommendations. They do not address general gaps in the evidence.</p>

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				<p>who have been abstinent for 4+ weeks, as there is little evidence in this group. The committee's emphasis on the importance and paucity of this kind of longer-term evidence is reflected in evidence review N: "For this reason, the committee focussed on evidence where relapse was clearly additional to cessation and delivered at a later point (this included behavioural interventions for assisted abstainers [Figure 11, GRADE profile 5], and pharmacotherapy for assisted abstainers [Figure 13-16, GRADE profile 6]). There is a paucity of evidence on this type of longer term relapse prevention." (p.66 of evidence review N)</p> <p>19 Livingstone-Banks J, Norris E, Hartmann-Boyce J, West R, Jarvis M, Chubb E, Hajek P. Relapse prevention interventions for smoking cessation. Cochrane Database of Systematic Reviews 2019, Issue 10. Art. No.: CD003999</p>	
Public Health England – Breathe 2025	Guideline	078	027 - 029	<p>This states that nicotine e-cigarettes are of similar effectiveness to NRT. There is moderate certainty evidence that they are more effective than NRT (including in studies where participants are offered combined short and long-acting NRT) and this should be made clear.20</p>	<p>Thank you. The pairwise meta-analysis found a pooled risk ratio of 1.47 (1.25 – 1.72) for nicotine e-cigs vs single NRT for abstinence at 3 months. The network meta-analysis uses the effectiveness data and NMA models from Thomas' (2020) review as well as results of NICE-conducted rerun searches. This NMA (based on 192 studies) showed no significant</p>

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				20 Hartmann-Boyce J, McRobbie H, Butler AR, Lindson N, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Fanshawe TR, Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2021, Issue 4. Art. No.: CD010216	effect of e-cigarettes compared to NRT (RR of 1.23 [CrI: 0.73, 1.95]) or long + short NRT (RR: 0.84 [CrI 0.48, 1.40]). The discrepancy between pairwise and NMA effect estimates is likely to be due to the modifying effect of indirect treatment estimates within the network. Consistency checking did not identify any concerns with the model that was used for the NMA and the committee focussed their discussion on the results of this NMA.
Public Health England – Breathe 2025	Guideline	079	008 - 013	This section states the committee had low confidence in the finding of no difference in adverse events in people using nicotine e-cigarettes compared to NRT, e-cigarettes without nicotine, and no treatment, because the studies were powered to investigate effectiveness and not adverse events. Though this is an issue for serious adverse events, where events are rare, for non-serious adverse events, which this section appears to refer to at first glance, this is not an issue of underpowering because non-serious adverse events are more common than cessation (a study powered to detect a difference in cessation would also be powered to detect a difference in adverse events). If this section is on serious adverse events, it should be clarified that that is the case. If not, it should be	Thank you. Details of the adverse events reported are contained in evidence review K and are adverse events rather than serious adverse events. The rationale and impact section describes the committees consideration of the recommendations and their view is consistent with the findings in the systematic review you reference.

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				reworded. The latest Cochrane review has moderate certainty evidence of no difference in rates of adverse events (non-serious) between nicotine and non-nicotine e-cigarettes. ²¹ 21 Hartmann-Boyce J, McRobbie H, Butler AR, Lindson N, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Fanshawe TR, Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2021, Issue 4. Art. No.: CD010216	
Public Health Wales – All Wales Tobacco Control Leads group	Guideline	023	005	Help Me Quit services in Wales currently do not provide nor advocate e-cigarette use as a smoking cessation aid. This recommendations goes against the current position on e-cigarettes in Wales. If e-cigarettes are to be used in line with other NRT products where do people using these products stand when they are prohibited to be used such as workplaces, public indoor areas, school grounds, hospitals and playgrounds (in line with new smoking ban – health boards/councils around Wales class e-cigarettes the same as tobacco cigarettes). This will surely impact upon their quit attempt if they are prohibited to using them freely in comparison to other NRT products.	Thank you for your comment. E-cigarettes are one option recommended be accessible to adults amongst other options which include medicinally licensed products, behavioural support, and brief advice. Patient informed choices in decision making regarding their health is a key element within this guideline and within NICE's work more broadly. Recommendation 1.12.4 outlines that those providing stop-smoking support or advice should discuss with people which options to use to stop smoking considering preferences, health and social circumstances as well current medications, contraindications, potential adverse effects and previous experience of stop-smoking aids. NICE guidelines are written specifically for England,

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Public Health Wales – All Wales Tobacco Control Leads group	Guideline	023	026	The evidence outlines the effectiveness of an e-cigarette to help people to stop smoking but does not specify if they are offsetting cigarette smoking for e-cigarettes over the longer term. No mention of whether they were able to stop the using the e-cigarette or whether e-cigarette use continued?	Thank you for your comment. The committee were asked to look specifically at stopping tobacco use for this guideline. Use of e-cigarettes and stopping e-cigarettes is outside the scope of this guideline. Please see the scope document on the NICE website
Public Health Wales – All Wales Tobacco Control Leads group	Guideline	025	021 022 023	Do we have this information? This would require re-training for all Help me Quit advisors across Wales. There are currently no medically licensed e-cigarettes and therefore brand to brand would vary, as would liquid capsules so advising would be extremely difficult.	Thank you for your comment. The Public Health Advisory Committee (PHAC) agreed that based on the evidence considered that people who are interested in using e-cigarettes should be given up-to-date information on what is known about e-cigarettes to help them make an informed decision about whether to use them. Recommendation 1.12.13 hyperlinks to examples of where this information could be accessed (NCSCT e-cigarette guide and Public Health England's information on e-cigarettes and vaping). The NCSCT 'E-cigarettes: a guide for healthcare professionals' for example has sections within it about device technology, E-liquid, puffing technique and device types.
Public Health Wales – All	Guideline	026	007	This is a training gap	Thank you for your comment. Recommendation 1.12.13 links to some training resources and information which

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Wales Tobacco Control Leads group					should be helpful to professionals providing stop smoking support and advice.
Public Health Wales – All Wales Tobacco Control Leads group	Guideline	026	008	Does this not encourage prolonged use? NCSCT training advocates use for as long as they need or want to use them	Thank you for your comment. The first bullet point of recommendation 1.12.15 is intended to initiate the discussion. In the following bullet points the committee has recommended that e-cigarettes are used for long enough to prevent a return to smoking and that there is a discussion on how to stop using them when the person is ready to do so. The approach is therefore broadly consistent with the training to which you refer.
Public Health Wales – All Wales Tobacco Control Leads group	Guideline	026	009	Advice and guidance on their use and safety would need to be built into HMQ practice. Do we have this information?	Recommendation 1.12.13 outlines examples of where information can be accessed which includes an online training module and PHE resources
Public Health Wales – All Wales Tobacco	Guideline	026	017	Training and knowledge gap – is this information available? We would need a practice guide to support advisors. Would this not be dependent on what type of vape and e-liquid they were using?	Thank you for your comment. Recommendation 1.12.13 includes a link to some resources which discusses issues such as getting enough nicotine and the strength of the e-liquid.

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Control Leads group					
Public Health Wales – All Wales Tobacco Control Leads group	Guideline	031	021	What is the level of expertise required? How do we ensure we are delivering this recommendation appropriately?	Thank you for your comment. The level of expertise will be for local systems to agree. However, in the studies which underpin this recommendation, structured smoking cessation interventions were delivered by trained mental health smoking cessation practitioners. These were generally experienced mental health nurses who worked in conjunction with the participant and the participant's primary care physician or mental health specialist to provide an individually tailored smoking cessation service.
Public Health Wales – All Wales Tobacco Control Leads group	Guideline	031	022	Help Me Quit uses an evidence based abrupt cessation model. This may be more challenging for clients with complex mental health issues. What are the implications for training and delivery if the model is tailored to each client? It is important the approach taken is consistent.	Thank you for your comment. The committee has noted in the rationale and impact section that relates to this recommendation, that it is important that stop smoking support is available to everyone and that people with mental health conditions should not be treated differently in this. However, they also recognised that it is important to consider if additional support could be appropriate. For this reason recommendation 1.14.19 focuses on offering additional support to those who may need it.

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Public Health Wales – All Wales Tobacco Control Leads group	Guideline	044	018	Current practice allows another attempt to be made after 6 months with pharmacotherapy after a quit	Thank you. This is consistent with the recommendation.
Public Health Wales – All Wales Tobacco Control Leads group	Guideline	051	008	Who specifically should receive the vouchers (ie is there a target population within pregnant women as a whole?). Who will fund these vouchers? What's to stop pregnant women cheating the system to benefit from these vouchers?	Thank you. The recommendation specifies women who are pregnant should be recipients of the vouchers. Vouchers will be funded through local commissioning arrangements.
Public Health Wales – All Wales Tobacco Control Leads group	Guideline	057	006	As the services focus on abrupt cessation this would not necessarily lend itself to offering NRT for 'as long as needed'? This would also be an added financial pressure for local Health Boards	Thank you. The committee recommend that NRT is provided for as long as needed in all stop smoking support.
Quality Standards & Indicators Team	Guideline	General	General	QS82 GE report highlights preventing access to/supply of illicit tobacco as an area for quality improvement which was not addressed by guidance at the time. This resulted in placeholder statement 9 of that quality	Internal. Although the supply of illicit tobacco was within scope, no evidence was identified and

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				standard. This guideline would be an opportunity to address the lack of recommendations in this area. I note that this was part of reviewed evidence but has not resulted in recommendations being made.	therefore no new recommendations were made.
Quality Standards & Indicators Team	Guideline	046	012	Rec 1.18.2 – I am concerned that use of the term 'opt-out referral' does not match language in NICE guidance elsewhere, when 'offer referral' would be used. Use of 'opt-out referral' would likely impact QS22 Statement 5, Statement 9 and QS43 Statement 2. If we used this language in the statements they may not be widely understood. Rec 1.18.3 then uses the term 'refer' so this should also be consistent.	Thank you. The committee agreed it was important to specify that this referral was opt-out. The language is clear and agreed by NICE editorial colleagues.
Royal College of Nursing	Guideline	015	017	<i>Would implementation of any of the draft recommendations have significant cost implications?</i> Although employers do offer support, in reality this could have a major cost implication should staff wish to give up smoking. At the moment, smoking support groups and access to NRT are at alternative organisations, e.g. the non-statutory sector and universities. In terms of cost this would be an issue to source, however if agreed on a medical (GP) prescription then it may save costs, because if the devices were	Thank you for your comment. It was not clear if your comments on cost implications were general or focused on recommendation 1.8.3 (p.15, line 17).

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				posted they may be sold online to third parties/misused.	
Royal College of Nursing	Guideline	015 037	021 027	<p><i>What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)</i></p> <p>We think it is important to consider e-cigarettes in conjunction with NRT in this section. Although NRT is available in clinical practice (such as the community substance misuse setting) this is not always sought, although service users desire to stop smoking. We have found that service users are more keen to try e-cigarettes and we understand this should be promoted following recent recommendations.</p> <p>There is mention of: people from lesbian, gay, bisexual and transgender groups</p> <p>Please include intersex and queer (LGBTQI). It is vital to include high risk groups prone to BBVs including men who have sex with men (MSM).</p>	<p>Thank you for your comment. Thank you for raising your concern regarding intersex and queer groups. This has been discussed with the NICE editorial team and the Public Health Advisory Committee (PHAC) and has been amended to LGBT+ in line with NICE editorial style.</p> <p>Recommendation 1.8 has been carried forward and the evidence underpinning this recommendation has not been reviewed. Please see the scope document on the NICE website. For clarification recommendations 1.8 focus specifically on using medically licensed nicotine-containing products. At the time of consultation, no nicotine-containing e-cigarettes were licensed as a medicine for stopping smoking by the Medicines and Healthcare products Regulatory Agency (MHRA) but further down in this recommendation (p.16, line 6-7) recommendations on what advice to provide about nicotine-containing e-cigarettes are hyperlinked.</p> <p>For reference recommendation 1.12 (Stop-smoking interventions) highlight both NRT</p>

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				In addition, generally a lot of focus has been placed upon pregnant women and mental health services- understandably, this is what the statistics show us in terms of target groups. Please consider acknowledging child, adolescence, mental health services (CAMHS). Past experience indicates that this is a target area, particularly if you mention 12-year-old children, if smoking was eliminated at an early age their health would flourish.	professionals in primary care and community settings and health and social care professionals in all acute, maternity and mental health services (including both inpatient and community mental health services, health visitors and midwives) respectively which would not exclude addiction services or CAMHS.
Royal College of Nursing	Guideline	039	019 - 020	<p>Comments: Recent studies conducted in the UK suggests South-Asian communities living in the UK are consumers of smokeless tobacco products. This puts them at high risk for developing oral cancers. South-Asia has a diverse range of communities, and it makes it difficult to identify all the local names of smokeless tobacco products available in the UK, but this could impact a challenge in implementing the services to this community, if interventions need to be tailored to this group, we should be using local names when referring to these products.</p> <p>Suggestions: Suggest we should use the local names of the products which are given in the South-Asians languages such as Paan, Gutkha, Khaini or Mawa. Firstly, this could be</p>	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website. For clarity the glossary defines smokeless tobacco (which is hyperlinked in recommendation 1.16.1 at the start of this set of recommendations) and addresses the comment you raise.

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				done by understanding the smokeless tobacco product differences which are available in the UK through sellers. Secondly, collecting local product names data or surveys through primary care and later categorizing products for easy identification. Thus, using local names of smokeless tobacco products can strengthen behavioural changes of this group and improve the effectiveness of the interventions.	
Royal College of Nursing	Guideline	059	010 - 011	<p>Comments: This is a good move. Including nicotine-containing products for sale in the secondary care settings is welcoming, but the impact of this recommendation would be a challenge in hospital settings. It is unlikely patients or staff will consider this option mainly because hospitals allow patients and staffs to bring tobacco products inside the hospitals (Although they are locked for the risk of fire safety), Also, patients and staffs are allowed to go out to smoke as long as they are smoking outside the 'No smoking' zone of the hospital.</p> <p>Suggestions: Restrict tobacco products to be brought into the hospitals, Encourage the use of nicotine containing products available inside the hospital shops. This could make a good impact of the suggested recommendation.</p>	Thank you. Consideration of smokefree secondary services was outside of the scope for this update, however it is addressed in 1.22.10. Please see the scope document on the NICE website. In terms of your suggestion regarding restriction of tobacco products to be brought into hospitals, no evidence was identified in this area so the Public Health Advisory Committee (PHAC) could not make any recommendations.

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Royal College of Nursing	Guideline	062	022	<p>The recommendations in this guideline were largely developed before the coronavirus pandemic. Please tell us if there are any particular issues relating to COVID-19 that we should take into account when finalising the guideline for publication.</p> <p>Consider online training- all of the training offered to students in the university is online, occasionally f2f. It is important to ensure acknowledgement of social distancing, face masks and washing hands as a standard- commenting on the current legislative changes in the UK. If there are frequent changes in UK legislation as a result of the pandemic, perhaps e-cigarettes could be posted to GP surgeries and community centres for access?</p>	<p>Thank you for your comment. Pre-qualification training is out of scope for this guideline. Please see the scope document on the NICE website. . Training is covered in recommendations 1.23.2 to 1.23.4. Additionally, 1.23.2 cross references to recommendations 1.12 which reference NCSCT training.</p>
Royal College of Physicians	Guideline	016	019	NG 92 published in 2018 not 2008	Thank you for your comment. This has now been amended in line with your comment
Royal College of Physicians	Guideline	017	008	NG 92 published in 2018 not 2008	Thank you for your comment. This has now been amended in line with your comment
Royal College of Physicians	Guideline	025	005	<p>Section 1.12.14 Advice on nicotine containing e-cigarettes</p> <p>We welcome the recommendation to consider nicotine containing e-cigarettes in the treatment of tobacco addiction</p>	Thank you for your comment. The Public Health Advisory Committee (PHAC) have considered your comment and have outlined that the additional statement is not required as recommendation 1.12.1 already outlines that nicotine-containing e-cigarettes along

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				<p>We would strongly encourage a separate bullet point at the start of the section such as:</p> <p>‘E-cigarettes are an effective option/intervention to help people quit smoking’</p> <p>This bullet point explicitly states the effectiveness of nicotine containing e-cigarettes in helping people to quit smoking. An explicit statement is supported by evidence review K, (page 59) where e-cigarettes have an RR of 2.25 in quit success (and supported by the cost-effectiveness estimates in table 14 on page 66 of evidence review K).</p> <p>The need for an explicit statement on the effectiveness of e-cigarettes in helping people quit is required to help overcome incorrect biases/assumptions/data interpretation that may be held by the public/health care professionals/public health practitioners/healthcare organisations in this highly polarised subject area, which has the impact of smokers continuing to smoke tobacco cigarettes rather than quitting successfully using an e-cigarette. More smokers would successfully stop smoking if they switched completely to e-cigarettes, reassured that they</p>	<p>with other stop-smoking interventions should be accessible to adults who smoke. Recommendation 1.12.5 highlights that nicotine-containing e-cigarettes when combined with behavioural support are more likely to result in successfully stopping smoking, and recommendation 1.12.14 outlines that in advising people how to use nicotine-containing e-cigarettes that the use of e-cigarettes is likely to be substantially less harmful than smoking. On this basis PHAC have not amended the guideline.</p>

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				<p>are an effective means to quit, yet the use of e-cigarettes has largely plateaued.</p> <p>https://ash.org.uk/wp-content/uploads/2021/06/Use-of-e-cigarettes-vapes-among-adults-in-Great-Britain-2021.pdf</p> <p>https://smokinginengland.info/graphs/e-cigarettes-latest-trends</p> <p>Such a bullet point would help counterbalance the subsequent bullet points ie:</p> <ul style="list-style-type: none"> • e-cigarettes are not licensed medicines but are regulated by the Tobacco and Related Products Regulations 2016 • there is not enough evidence to know whether there are long-term harms from e-cigarette use 	
Royal College of Physicians	Guideline	026		<p>An Opt-out approach for stop smoking treatment should be explicitly stated as the standard approach in Primary Care settings and Secondary Care settings (page 27 sections 1.13 and 1.14), as stated for pregnancy section (page 46 rec 1.18.2). The opt-out approach without delaying referral to another service, can double quit attempts and quit success and makes treatment more</p>	<p>Thank you for your comment. This is outside of the scope for this update. Please see the scope document on the NICE website.</p>

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				<p>accessible for those patients who are ready to quit</p> <p>The Ottawa model has clearly demonstrated that an opt-out approach in these settings increases quit attempts and quit rates</p> <p>https://tobaccocontrol.bmj.com/content/26/3/293</p> <p>It could read:</p> <p>Provide an opt-out referral to receive stop-smoking support for all people attending Primary or Secondary care services who:</p> <ul style="list-style-type: none"> • Say they smoke or have stopped smoking in the past 2 weeks or • Have a carbon monoxide reading of 4 ppm or above or • Have previously been provided with an opt-out referral but have not yet engaged with stop-smoking support 	
Royal College of Physicians	Guideline	026	0022	NG 92 published in 2018 not 2008	Thank you for your comment. This has been amended.
Royal College of Physicians	Guideline	027	003	NG 92 published in 2018 not 2008	Thank you for your comment. This has been amended.

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Royal College of Physicians	Guideline	027	008	NG 92 published in 2018 not 2008	Thank you for your comment. This has been amended.
Royal College of Physicians of Edinburgh	Guideline	025	025	<p>1.12.14 The College has consistently urged a cautious approach to the use of e-cigarettes since their introduction to the market, in the light of an incomplete evidence base and the 'do no harm' principle.</p> <p>E-cigarettes may be useful for a minority of individual smokers as a route out of using combustible tobacco, however the wider public health picture needs to be considered if NICE is considering recommending their use. Access to e-cigarettes needs to be controlled carefully; they are not products for children or non-smokers. The recently published 2021 WHO global tobacco report urges that it should be anticipated that nicotine and tobacco products will evolve, and to plan for their regulation (1). There is still a lot we do not know about e-cigarettes and further research is required. E-cigarettes are not a single standardised product, and are not without significant potential harm (2).</p> <p>While a minority of individual smokers may find e-cigarettes to be a way of ceasing tobacco</p>	<p>Thank you for your comment.</p> <p>E-cigarettes are one option recommended be accessible to adults amongst other options which include medicinally licensed products, behavioural support, and brief advice. Patient informed choices in decision making regarding their health is a key element within this guideline and within NICE's work more broadly. Recommendation 1.12.4 outlines that those providing stop-smoking support or advice should discuss with people which options to use to stop smoking, considering preferences, health and social circumstances as well current medications, contraindications, potential adverse effects and previous experience of stop-smoking aids. NICE considers this will include discussions into the points you raise and recommendation 1.12.14 acknowledges the lack of evidence regarding long-term harms from e-cigarette use. PHAC have also developed seven research recommendations focused on e-cigarettes with the hope of stimulating further research in this area.</p>

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				<p>smoking, this needs to be weighed carefully against the whole population impacts including the prevalence of dual use/relapse and impacts on the next generation. If including this non-NHS prescription in cessation advice, we consider that NICE should also be clear that dual use provides no harm reduction, may potentially increase harm in the long term (3), and that support to quit e-cigarettes should be provided as part of NHS smoking cessation services (4).</p> <p>(1) WHO 2021 Global Tobacco report P.104 Tobacco control must anticipate nicotine and tobacco products will evolve rapidly and plan for their regulation</p> <p>(2) Ibid p2</p> <p>(3) <i>recommendation from WHO 2021 report ibid for support to quit ENDS; also a learning outcome of work in prisons when e-cigs were supplied and where prisoners who quit tobacco then wanted support to quit e-cigs.</i></p> <p>(4) WHO report: Therefore, the country's national tobacco cessation services should consider providing support for ENDS users to quit</p>	

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Royal College of Physicians of Edinburgh	Guideline	053	019 (ongoing approach throughout policy section)	<p>1.21 The College represents over 13,000 Fellows and Members in over 90 countries, covering 54 medical specialties and interests. Many of the College's Fellows and Members are based in low and middle-income countries (LMIC), which are struggling with the combustible epidemic, and lack resources and expertise to take on a new, additional epidemic. The College is concerned that a perceived 'endorsement' of e-cigarettes by NICE could be widely quoted –including out of context- and therefore negatively affect public health in LMIC. It is also concerned that using the term 'e-cigarettes' may be widely perceived to cover a range of products with very different impacts and profiles, also being promoted by commercial interests as recreational goods.</p> <p>The College urges the precautionary principle - in that the studies on e-cigarettes are in the early days (indeed, researchers are still finding out new harms of smoking tobacco 60 years after it was first noted) even in high-income countries. The health profile of using tobacco and exposure to asbestos both took decades to become clear. There are virtually no data on the effects of e-cigarettes in low and middle-income countries, regarding harm, economic</p>	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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				<p>impact, gateway drug, effect of use as quitting aide, ingredients, additives, the effects of second-hand vape, re-normalisation of smoking, the effect of vaping on COVID, etc. We do not yet know the long-term effects of e-cigarettes on health and this must be recognised in NICE guidelines and recommendations.</p> <p>There is great concern in low and middle-income countries that although the vaping/tobacco companies state the purpose is to help smokers quit, where the industry is allowed to advertise and promote, it is clearly aimed towards young people as an exciting and fun new way of smoking. The College supports the WHO position on e-cigarettes, which states "Evidence reveals that these products are harmful to health and are not safe. However, it is too early to provide a clear answer on the long-term impact of using them or being exposed to them"(1). Even in the UK which currently regulates e-cigarettes in line with European legislation, the Scottish Government identified domestic e-cigarette advertising as an under-regulated feature and passed legislation in 2016 to address this (1b).</p>	

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				<p>The WHO has stated its concern “that children who use these products are up to three times more likely to use tobacco products in the future. The Organization recommends governments to implement regulations to stop non-smokers from starting to use them, to prevent renormalization of smoking in the community, and to protect future generations” (2).</p> <p>Currently, 32 countries have banned the sale of electronic nicotine delivery systems (ENDS). A further 79 have adopted at least one partial measure to prohibit the use of these products in public places, prohibit their advertising, promotion and sponsorship or require the display of health warnings on packaging (2). This is a very different approach from the one taken in the UK and it is approach that the College now urges NICE to consider, in line with the WHO Global Tobacco report – (27 July 21) subtitled: addressing new and emerging products. In this report, the WHO restates the importance of tackling the global tobacco epidemic, and is also clear in recommending that new and emerging products should be included in and regulated along with tobacco products under the WHO</p>	

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				<p>Framework Convention on Tobacco Control (FCTC)/MPOWER framework.</p> <p>The College would like to highlight three examples of restrictions on e-cigarettes in Brazil, India and Thailand as illustrations of actions that could be taken in the UK to enhance harm reduction from e-cigarettes, and as a caution that statements by NICE may be co-opted for commercial lobbying purposes against health measures elsewhere:</p> <p>In Brazil, the sale of e-cigarettes is allowed, but only under license from the national Health Surveillance Agency as smoking cessation devices. Even if licensed, these products are subject to age restrictions, a ban on vaping in enclosed spaces, and an advertising ban (3).</p> <p>A Lancet article in August 2020, reviewing action taken in India stated that “In the interest of public health, electronic cigarettes (e-cigarettes) were banned in September, 2019, by the Indian Government. Indeed, concerns around the use of e-cigarettes have been mounting worldwide.</p> <p>Beyond the issue of nicotine addiction, the ingredients used in flavouring agents and</p>	

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				<p>additive agents, like propylene glycol and vegetable glycerin, can also be harmful for health. When heated, these additive agents can produce various compounds, including formaldehyde and acetaldehyde, which are carcinogenic to humans.</p> <p>Disposal of waste from e-cigarettes and the manufacture of e-cigarettes could also pose potential environmental hazards. Notably, increased e-cigarettes use among adolescents has been a particular concern, and severe lung disease has been associated with the use of e-cigarettes in the USA (4).</p> <p>In Thailand, e-cigarettes have been banned since 2014 due to “health reasons and that it was originally suggested because electronic cigarettes were luring young people into smoking” (5).</p> <p>The proportion of people using tobacco has declined in most countries, but population growth means the total number of people smoking has remained stubbornly high. Currently, of the estimated 1 billion smokers globally, around 80% live in low- and middle-income countries (LMICs). Tobacco is responsible for the death of 8 million people a</p>	

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				<p>year, including 1 million from second-hand smoke (2).</p> <p>While e-cigarettes should be regulated to maximise protection of public health, tobacco control must remain focused on reducing tobacco use globally (2). It is however clear that tobacco companies deploy novel products within public health interference strategies (2b) and there are indications that these products are viewed by tobacco companies as additional rather than replacement products.</p> <p>The College recommends that unless and until an e-cigarette product is available as an NHS prescription option, NICE should exercise greater caution with regards to framing these products in terms of cessation, and should consider the whole population and longer term health impacts. It should recognise that the term 'e-cigarettes' covers a multitude of devices and liquids with unknown profiles and impacts, and also that the statements of health agencies have been co-opted to promote commercial interests in the UK and internationally. At a minimum, NICE should state that if any of the Guidelines support, endorse or promote E-cigarettes that these Guidelines do not apply to LMIC.</p>	

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				<p>(1) https://www.who.int/news-room/q-a-detail/tobacco-e-cigarettes</p> <p>(1b) Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 (legislation.gov.uk)</p> <p>(2) https://www.who.int/news/item/27-07-2021-who-reports-progress-in-the-fight-against-tobacco-epidemic</p> <p>(2b) “novel and emerging nicotine and tobacco products...are creating another layer of interference by the tobacco industry and related industries, which is still reported by Parties as the most serious barrier to progress in implementing the WHO FCTC”.</p> <p>World Health Organization, The Convention Secretariat calls Parties to remain vigilant towards novel and emerging nicotine and tobacco products, 13 September 2019</p> <p>(3) https://www.smokefreeworld.org/health-science-technology/health-science-technology-agenda/data-analytics/global-state-of-smoking-landscape/state-smoking-brazil/</p>	

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				<p>(4) https://www.thelancet.com/journals/lanpub/article/PIIS2468-2667(20)30063-3/fulltext / DOI: https://doi.org/10.1016/S2468-2667(20)30063-3</p> <p>(5) http://thaiembassy.se/en/ban-on-electronic-cigarettes-in-thailand/</p>	
Sheffield Health and Social Care NHS Foundation Trust	General			<p>We welcome the opportunity to respond to this consultation. The bringing together of all NICE previous guidelines on tobacco into one place is really helpful.</p> <p>Since the publication of NICE PH 48 <i>Smoking: acute, maternity and mental health services</i> we, along with other mental health trusts, have built up considerable experience and learning in relation to reducing harm from tobacco in the populations we serve. We have a greater understanding of the factors involved in promoting the culture change necessary to enable a reduction in harm from tobacco, and the complexities inherent in smoke free implementation within mental health settings.</p> <p>NICE PH48 has been a vital instrument for change. This new guideline will form the bedrock for the work that still needs to be undertaken locally and nationally to address</p>	<p>Thank you for your comment. Regarding differing needs between people admitted to acute hospital settings and to mental health settings, these recommendations are greyed out as they are outside the scope for this update. Please see the scope document on the NICE website. We will, however, pass these references on to our surveillance colleagues for future review.</p>

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				<p>the disproportionate burden and adverse health effects smoking has on people with mental health conditions and ensure that people with severe mental illness are not left further behind as smoking prevalence reduces in the population as whole. As such, we are concerned that the recommendations do not sufficiently reflect the differences between secondary care acute and mental health settings. At present the recommendations often consider the needs of people admitted to an acute hospital and people admitted to a mental health setting as one population, requiring the same approach. We would urge that, where necessary, that the guideline is amended, to ensure that specific needs of people admitted to secondary care mental health settings are addressed.</p> <p>Accounts of some of our Trust experiences are referenced below:</p> <ul style="list-style-type: none"> • Ratschen E, Stewart P, Horspool M, Leahy M Smokefree acute adult mental health inpatient wards: the service user experience. <i>BJPsych bulletin</i> April 2018 • <i>Smoke-free implementation in the Sheffield NHS trust - Case study - GOV.UK</i> in: Public Health England 	

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				Guidance: <i>Health matters: reducing health inequalities in mental illness.</i> www.gov.uk , December 2018.	
Sheffield Health and Social Care NHS Foundation Trust	Guideline	013	001 - 004	We welcome the recommendation to discourage children, young people and adults who do not smoke from experimenting with or regularly using e-cigarettes, and to talk about e-cigarette separately from tobacco products.	Thank you.
Sheffield Health and Social Care NHS Foundation Trust	Guideline	023	005	We welcome the inclusion of nicotine containing e-cigarettes as a stop smoking intervention	Thank you.
Sheffield Health and Social Care NHS Foundation Trust	Guideline	025 026	019 - 028 001 - 006	We welcome recommendations and clarity on the advice to give regarding the use of nicotine-containing e-cigarettes.	Thank you.
Sheffield Health and Social Care NHS Foundation Trust	Guideline	026	011 - 014	We welcome the guidance to health professionals and e-cigarette users to use the MHRA Yellow Card scheme regarding both side effects and safety. As e-cigarettes are 'categorised as appliances rather than medicines' [pg. 99 – line 16 Tobacco: evidence review for treatment for smoking cessation and harm reduction, June 2021) we seek	Thank you for your comment. This is however not within NICE's remit. The recommendation on reporting side-effects includes a link to the MHRA yellow card scheme webpage. This webpage includes a section for reporting side-effects or safety concerns with e-cigarettes.

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				clarification as to whether e-cigarette will be added to the Yellow Card scheme for reporting 'Medical Device Adverse Incidents'.	
Sheffield Health and Social Care NHS Foundation Trust	Guideline	028	010 - 014	<p>We fully agree with the recommendation to provide information on the short- and long-term health benefits of stopping smoking at any time and we agree with the example given which highlights the importance of stopping before surgery. We would also like to see an additional example included, highlighting the mental health benefits of quitting.</p> <p><u>Reference:</u> Taylor G, McNeill A, Girling A et al/ Change in mental health after smoking cessation; systematic review and meta-analysis. BMJ 2014;348:g1151 doi: 10.1136/bmj.g1151</p>	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Sheffield Health and Social Care NHS Foundation Trust	Guideline	029	019 - 021	<p>We welcome the recommendation that every smoker will be offered behavioural support in acute, maternity and mental health care settings. In mental health we would wish to see this offered on an 'opt out' rather than 'opt-in' method.</p> <p>The <i>NHS Long Term Plan</i> states that the NHS will support "people in contact with NHS services to quit based on a proven model implemented in Canada and Manchester". Both of these proven models use an opt-out basis for referrals to an in-house tobacco</p>	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. In addition, opt out referral schemes were not within scope for population groups other than for pregnant women. Please see the scope document on the NICE website.

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				dependence treatment team. Patient choice remains unaffected and freedom to choose whether to engage in behavioural support or treatment remains. An opt-out basis to referrals to a specialist, in-house tobacco treatment team is also an essential part of the clinical pathway with the QUIT programme, which is being implemented in all Trusts within the South Yorkshire and Bassetlaw Integrated Care System. The role out of this programme in mental health services is also contributing to early implementer evaluation by NHS England to inform its response to the NHS Long Term Plan	
Sheffield Health and Social Care NHS Foundation Trust	Guideline	030	012 014 - 015	Recommendation: for people who are admitted to secondary care... provide immediate support if necessary, otherwise within 24 hours of admission. This recommendation requires clarification with respect to mental health settings. Immediate support to treat tobacco dependency is, by definition, necessary for people admitted to an inpatient setting who have to abstain from smoking, in order to prevent avoidable nicotine withdrawal and agitation. We would welcome recommendation to provide within 30 minutes of arrival into hospital.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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Sheffield Health and Social Care NHS Foundation Trust	Guideline	032	001 - 021	<p>Recommendations for supporting people who have to stop smoking temporarily – to use acute and mental health services</p> <p>We are concerned that the recommendations do not sufficiently reflect the differences between secondary care acute and mental health settings, and that they do not adequately address the needs of people admitted to a mental health inpatient unit (obliged to temporarily abstain from smoking in line with Trust smoke free policies). Specifically, we are concerned that the recommendations imply e-cigarettes are not part of the tobacco dependency treatment package available to support patients admitted to a smoke free inpatient mental health unit.</p> <p>We are disappointed in the lack of public health evidence to date on whether e-cigarettes are effective and cost effective for smoking harm reduction (<i>Tobacco: evidence reviews for treatments for smoking cessation and harm reduction</i>, pg. 86, line 10) and note the importance placed by the committee on using expert testimony where there is a lack of evidence.</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. In addition, the use of nicotine containing e-cigarettes for temporary abstinence was not included within the scope of the update. Please see the scope document on the NICE website.</p>

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				<p>The use and provision of e-cigarettes to support patients during a smoke free stay has become an important component of our tobacco dependence treatment offer; an ASH survey of mental trusts indicated that 42% of UK trusts responding provide free e-cigarettes to adults smoking on admission to hospital (<i>ASH, Progress towards smoke free mental health services.</i>, 2019). People with severe mental illness tend to smoke more cigarettes and are more heavily addicted than smokers overall. Whilst nicotine replacement therapy has vital role to play, in our experience, service users often prefer e-cigarettes to manage nicotine withdrawal.</p> <p>As noted by the guideline committee, whilst 'smoking rates have substantially decreased in the general population, for those with mental health conditions rates have remained stagnant, indicating an increasing health inequality which needs addressing' (<i>Tobacco: evidence reviews for treatments for smoking cessation and harm reduction</i>, pg. 90, lines 9 – 12). We also note the expert evidence provided by Martin Jarvis, with respect to the great potential value of e-cigarettes in addressing social inequalities in health attributable to cigarette smoking (<i>NICE</i></p>	

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				<p><i>Guideline: tobacco Evidence review K for cessation and harm reduction treatments (Appendices).</i> In this context, we are really concerned about the lack of a recommendation for the use of nicotine-containing e-cigarettes to support temporary abstinence. Our view is that this lack of a recommendation will further disadvantage people with mental ill health - through restricting informed choice, and the opportunity for people with severe mental illness who smoke to switch to a less harmful alternative to tobacco, with the potential for specialist advisors and the care team to build on this experience to promote smoking cessation.</p> <p>We note the content of the investigative film 'Vaping Demystified' to support informed decision making about using vaping products (yorkshirecancerresearch.org.uk). We also note research by Caponnetto et al study (2021) showing that adults who smoke and were not motivated to quit, when provided a new generation e-cigarette with a high nicotine content, demonstrated substantially decreased cigarette consumption without causing significant side effects.</p> <p><u>Reference:</u> Caponnetto P, DiPiazza J, Kim J et al. A Single-Arm, Open-Label, Pilot, and</p>	

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				<p>Feasibility Study of a High Nicotine Strength E-Cigarette Intervention for Smoking Cessation or Reduction for People With Schizophrenia Spectrum Disorders Who Smoke Cigarettes, <i>Nicotine & Tobacco Research</i>, Volume 23, Issue 7, July 2021, Pages 1113–1122, https://doi.org/10.1093/ntr/ntab005</p> <p>A situation in which nicotine-containing e-cigarettes are not part of the potential support offer to people who have to stop smoking temporarily, would represent an extremely challenging scenario with respect to ensuring the provision of smoke free environments within secondary care mental health settings, deprive patients of the maximum opportunities of using an inpatient smoke free stay as a springboard to stop smoking altogether, and set the clock further back.</p>	
Sheffield Health and Social Care NHS Foundation Trust	Guideline	034	015 - 016	<p>Recommendation: for staff in secondary care and closed institutions who do not want, or are not ready, to stop smoking in one go We welcome the recommendation advising staff to use medicinally licensed nicotine-containing products to help them not to smoke immediately before and during working hours. With respect to mental health settings, we would like to see a recommendation to support staff to use e-cigarettes, within locally agreed</p>	<p>Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. In addition, the use of nicotine containing e-cigarettes for temporary abstinence was not included within the scope of the update. Please see the scope document on the NICE website.</p>

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				parameters. We have many staff who have switched from tobacco to an e-cigarette and have used this as a gateway to stopping smoking completely.	
Sheffield Health and Social Care NHS Foundation Trust	Guideline	053	025	<p>Recommendations on Policy: ban staff from supervising or helping people to take smoking breaks. We welcome the continued inclusion of this recommendation in the guidance.</p> <p>We wish to point out that there is currently a lack clarity around what constitutes 'helping' people to take smoking breaks. We currently have no guidance for providers or staff with respect to storage and access to tobacco and related paraphernalia during admission. This is highly problematic.</p> <p>For mental health settings we would like to see the inclusion of further guidance, specifically to state that: Smoking breaks do not fall within the provision of Section 17 of the Mental Health Act, which allows detained patients to be granted leave of absence from the hospital in which they are detained</p>	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
Sheffield Health and Social Care NHS	Guideline	059	010 - 011	Recommendation: smoking support in secondary care to 'Include nicotine-containing products as option for sale in secondary care settings (for example, in hospital shops': Whilst	Thank you for your comment. This is a matter for local commissioning arrangements

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Foundation Trust				the recommendation to include nicotine containing products, such as e-cigarettes, as options for sale in secondary care settings is important and welcome, it will not aid access to nicotine containing products within our Trust. In common with many mental health trusts, our inpatient units are dispersed over a number of sites; only the one site located within an acute trust has access to a hospital shop. Asking wards to commence selling nicotine containing products is not feasible. Using vending machines severely limits choice of nicotine containing products, and is accompanied by many logistical and practical challenges, including ensuring machines are sited away from visitors under 18. If this recommendation is the only recommendation within the guideline to support patients admitted to an inpatient mental health unit to access e-cigarettes this disadvantages people admitted with a mental health problem compared with people admitted to large acute hospitals and raises equal opportunity issues.	
Sheffield Health and Social Care NHS Foundation Trust	Guideline	063 067	027 – 029 023 - 026	Terms used in the guideline: Closed Institutions - and related recommendation We believe that the current definition of this term is too narrow. The definition currently reads: ' <i>Secure environments where people are detained and where smoking is not permitted,</i>	Thank you for your comment. The definition has been updated.

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				<p><i>such as secure mental health units, immigration removal centres and custodial sites.'</i></p> <p>Within mental health, reference to secure units is usually taken to apply to forensic units. From a patient perspective being cared for within a smoke free environment, when detained under a section of the Mental Health Act within an acute admission ward or psychiatric intensive care unit, may be experienced as akin to being within a 'closed institution' – with respect to access to smoking. With this in mind, from a staff training point of view, the recommendations on training and stopping smoking (pg 63, line 28-29; pg 64. Line 1-15) apply equally to staff providing care to a proportion of people admitted to secondary mental health care services, as they do to those providing care within a closed institution.</p>	
Sheffield Health and Social Care NHS Foundation Trust	Guideline	073 075	005 - 008 010 - 013	<p>We welcome the following broad research recommendations:</p> <p><i>Recommendation 4: how can people with mental health conditions be supported effectively to stop smoking (individual and system level)?</i></p> <p><i>Recommendation 12: how can people who have recently stopped or temporary abstained from smoking in a smoke-free inpatient or</i></p>	Thank you. Research recommendations in NICE guidelines are specifically to address gaps in the research that the committee considered while making their recommendations. They do not address general gaps in the evidence.

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				<p><i>treatment environment be best supported after discharge to prevent relapse or to stop permanently</i></p> <p>Given the complexities surrounding smoke-free implementation within mental health settings, the continued high prevalence of smoking in people with severe mental illness, and the danger that people with severe mental illness are left even further behind, we would like to see the following focused research conducted within secondary care mental health inpatient (non-forensic) settings:</p> <ul style="list-style-type: none"> a. What is the best way (system and individual level) of supporting people who smoke to achieve temporary abstinence during an inpatient admission to an acute, psychiatric intensive care, or rehabilitation (i.e., non-forensic) mental health setting? Including <ul style="list-style-type: none"> o what is the best way to deliver this support in a way that is experienced by patients as a health care intervention, and maximises the likelihood that a smoke free stay acts as a 	

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				<p>springboard to engaging in relapse prevention support post-discharge?</p> <ul style="list-style-type: none"> ○ how best can reducing harm from tobacco interventions be fully integrated into care delivery, as an intrinsic component of a purposeful therapeutic admission and recovery focused care? <p>b. What is the impact of NHS mental health providers storing or not storing patient's tobacco paraphernalia during admission on: patient engagement with harm reduction and smoking cessation; smoke-free policy implementation; patient and staff wellbeing, smoking-related incidents</p> <p>c. What is the impact of offering regular carbon monoxide monitoring to patients who have to stop smoking temporarily as part of admission to a smoke free mental health unit, as a biofeedback and motivational aid to support reduction in harm from</p>	

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				<p>tobacco and promotion of smoking cessation.</p> <p>A further research recommendation:</p> <p>What is the impact (system and individual level) of a national, regional or local mass-media campaign to inform the general population at that all NHS buildings and grounds are smoke free (acute and mental health), and the expectations of patients and visitors accompanying this?</p>	
South London & Maudsley NHS Foundation Trust	General comment	General	General	<p>We welcome the opportunity to comment. We are pleased to see all the guidance on smoking prevention, harm reduction, treatment coming together in one place. We would like to see services for people with Learning Disability, those using prison healthcare services, homeless services and those using Substance Misuse services addressed in this update too. We are concerned that the failure to include reference to these service providers allows the potential for leaving those service users behind.</p>	<p>Thank you for your comment. Throughout the guideline recommendations are made for health and social care professionals which would include the services you describe. The recommendations in section 1.21 include those for closed institutions which are defined in the 'terms used' section of the guideline as including custodial sites.</p>
South London & Maudsley NHS	Recommendation	007	003 - 006	<p>These recommendations aim to prevent children, young people and young adults from taking up smoking. They cover anti-smoking mass-media and digital campaigns, measures to prevent tobacco being sold to and bought</p>	<p>Thank you for your comment. As outlined in the scope document on the NICE website, there were specific recommendations that were identified for review and update and others were carried forwards into the new</p>

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Foundation Trust				<p>for children and young people, and prevention interventions in educational settings. However, since most children and young people are influenced by their parents and/or carers we believe it is a missed opportunity not to make recommendations to address smoking in the home where children and young people grow up. The evidence confirms that children and young people are three times more likely to smoke if they grow up in a home where others smoke.</p> <p>A recommendation to address this issue could be to</p> <ul style="list-style-type: none"> (a) screen all parents/carers of young people who receive health and social care and (b) provide them with Very Brief Advice and signposting to local stop smoking services. <p>Another recommendation could be to ensure that all children, young people and young adults who grow up in residential care settings are cared for in a smoke free setting.</p>	<p>guideline. Smoke free homes were not identified for update. However there are recommendations that have been carried forward that acknowledge the risk posed by second hand smoke and which relate to your suggestions. For example please see recommendations outlining the need to raise public awareness of the harm of second hand smoke in the context of using medicinally licensed nicotine-containing products (1.8.1); the provision of clear advice regarding the danger of second hand smoke for those using acute, maternity and mental health services (1.14.1) and during contact with partners, parents and other household members of people using acute, maternity and mental health services when identifying smoking (1.11.9, 111.10 and 1.11.11); and when training those who advise people how to stop smoking (1.23.4 and 1.23.11).</p>
South London & Maudsley NHS Foundation Trust	Guideline	013	001 - 004	<p>We strongly support the recommendation to discourage children, young people and young adults who do not smoke from experimenting with or regularly using e-cigarettes and welcome the recommendation to talk about e-cigarettes separately from tobacco products.</p>	<p>Thank you for your comment.</p>

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South London & Maudsley NHS Foundation Trust	Guideline	015	007 - 008	<i>Explain that medicinally licensed nicotine containing products could be used as a partial or complete substitute for tobacco, either temporarily or in the long term.</i> More clarity is needed around the definition of 'long-term' – this is especially important for people with long-standing mental health, substance misuse and learning disability where prescribers place restrictions on access to treatments that would undoubtedly prevent relapse for those who have cut down or quit smoking.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
South London & Maudsley NHS Foundation Trust	Guideline	015	015 - 016	<i>Nicotine levels in medicinally licensed nicotine-containing products are much lower than in tobacco, and the way these products deliver nicotine makes them less addictive than smoking,</i> however it also means these products provide less relief for withdrawal symptoms compared with smoking tobacco, therefore combined medicinally licensed nicotine-containing products are required for moderately to heavily dependent smokers, especially in the early stages of treatment.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
South London & Maudsley NHS Foundation Trust	Guideline	017	001 - 003	We welcome the recommendation to involve community pharmacies in local campaigns and maintain links with other professional groups such as dentists, fire services and voluntary groups.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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				We would like to see welfare and benefits officers/advisors included in this list because they have a unique opportunity to screen for smoking, provide very brief advice and signpost to smoking cessation services as part of their interventions to help people manage their financial situation.	
South London & Maudsley NHS Foundation Trust	Guideline	022	028	Medicinally licensed products to help adults stop smoking include as we would expect Bupropion, varenicline and Nicotine Replacement Therapy (NRT) products. However, given that Bupropion and Varenicline are currently not available for use in England we think it's very disappointing there is no recommendation to use Cytisine – this stop smoking medication has been widely used in Eastern Europe for more than four decades and as an over the counter medication in Canada since 2018, its cost and clinically effective. It's an opportune time to include it as an option especially given the limited options.	Thank you for your comment. The Public Health Advisory Committee (PHAC) discussed the current supply chain issues but concluded that this does not materially change the recommendations within the guideline. Cytisine is not currently licensed for use in the UK and as such is outside the scope of this guideline. Any therapy not licensed in the UK is outlined as an exclusion criterion in the research protocol for evidence review K thus any study pertaining to Cytisine would have been excluded.
South London & Maudsley NHS Foundation Trust	Guideline	023	026	We welcome the inclusion of nicotine containing e-cigarettes as a stop smoking intervention. Can we check if the https://bnf.nice.org.uk/treatment-summary/smoking-cessation.html will be updated in line with this new recommendation? Currently it states that e-cigarettes cannot be	Thank you for your comment. . The BNF have their own processes for updating but take account of NICE guidance when they do this. It is not recommended within the guideline that smoking cessation services supply e-cigarettes.

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				supplied by smoking cessation services. This creates a problem for us if the most popular and the most effective way of stopping smoking is not accessible to the most vulnerable people in our community. If we follow this instruction the only people who can use an e-cigarette are those who can afford the start-up and on-going costs – and sadly these are prohibitive for many smokers in disadvantaged communities.	
South London & Maudsley NHS Foundation Trust	Recommendation	024	008	For patients who have chosen to use varenicline whilst admitted to a smoke free hospital / service we advocate NRT is prescribed for the first 1-2 weeks of treatment, together with varenicline as recommended by the Helping Smokers Quit London Clinical Senate (2016).	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
South London & Maudsley NHS Foundation Trust	Guideline	025		We welcome the emphasis on ensuring people know how to achieve a high enough dose of NRT – we suggest that in hospital /care settings people are supported to 'self-medicate' / 'self-manage' their medicinally licensed nicotine-containing products because this will reduce the barriers to access and it will enable smokers who are cutting down and quitting to use their products as required without having to approach a nurse to get access to these products from a locked cupboard in a locked room. It will also ensure	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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				smokers who have short periods of leave from hospital can maintain and build on their smoke-free progress.	
South London & Maudsley NHS Foundation Trust	Guideline	026	005 - 006	We agree that any smoking is harmful, and people using e-cigarettes should be advised to stop smoking tobacco completely but we think it's also important to recognise that not everyone is ready to stop smoking tobacco when they start using an e-cigarette and as such people who are in the process of switching should be encouraged and supported to use e-cigarettes to achieve tobacco harm reduction too.	Thank you for your comment. No evidence was identified relating to nicotine containing e-cigarettes and harm reduction. The guideline does however recognise that some people may not be ready or who are not able to 'stop in one go' and there are recommendations to address this in section 1.15 of the guideline.
South London & Maudsley NHS Foundation Trust	Guideline	026	011 - 014	We welcome the guidance to health professionals and vapers to use the MHRA Yellow Card scheme to report side effects and safety concerns. Since e-cigarettes are categorised as an appliance [pg 90 – line 16 evidence review) we seek clarification as to whether e-cigarettes will be added to the Yellow Card scheme for reporting 'Medical Device Adverse Incidents'.	Thank you for your comment, however this is beyond NICE's remit. The recommendation on reporting side-effects includes a link to the MHRA yellow card scheme webpage. This webpage includes a section for reporting side-effects or safety concerns with e-cigarettes.
South London & Maudsley NHS Foundation Trust	Guideline	026	015 - 017	We are pleased to see the emphasis placed on the importance of getting enough nicotine when using an e-cigarette to overcome withdrawal symptoms. We would like to see some reassurance provided here for vapers / prescribers to support the use of nicotine	Thank you for your comment. Recommendation 1.12 and the related rationale and impact section, outlines the stop smoking interventions that the committee recommended should be accessible to adults who smoke. Recommendation 1.12.5 focuses on advising

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				containing e-cigarettes together with other licensed stop smoking medications if indicated.	people which options are more likely to result in a successful stop smoking attempt when used in combination with behavioural therapy. Nicotine containing e-cigarettes are included in this list, but the committee did not recommend combining nicotine containing e-cigarettes with other options in this recommendation.
South London & Maudsley NHS Foundation Trust	Guideline	028	010 - 013	We fully agree with the recommendation to provide information on the short- and long-term health benefits of stopping smoking at any time and we agree with the example given which highlights the importance of stopping before surgery however we would also like to see an example to highlight the mental health benefits of quitting such as; Quitting smoking can improve mood and reduce anxiety. It can also help reduce the severity of psychotic symptoms and in some cases, contribute to reductions in prescribed medications and shorter hospital stays.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
South London & Maudsley NHS Foundation Trust	Guideline	029	011	We are pleased to see the recommendation that every smoker will be offered behavioural support in acute, maternity and mental health care settings but we are disappointed that this offer is only recommended "if the person agrees". Our preference is to provide opt-out access to behavioural support – as described in the Ottawa Model and in the RCP Hiding in	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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				Plain Sight Report. The Ottawa model is also recommended in the NHS Long Term Plan. In our experience, it is often the case that at the point of screening for smoking and provision of Very Brief Advice at admission, people coming into mental health care settings are usually distressed and unlikely to be able to weigh up this decision. We favour a more proactive approach which ensures those that need specialist support have access to it using an opt-out approach.	
South London & Maudsley NHS Foundation Trust	Guideline	030	014	We do not believe that the recommendation to provide support to smokers within 24 hours of admission goes far enough to ensure patients comfort or ease their distress. We would welcome a recommendation to provide support within 30 minutes of arrival to hospital. In our experience offering 'Tea and NRT' to smokers on arrival to hospital as an over the counter medication, without the delays caused by getting a prescriber is hugely beneficial since the half-life of nicotine is approximately 2 hours and longer delays will result in unnecessary discomfort.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
South London & Maudsley NHS	Guideline	030	018	It's great to see the recommendation to offer weekly behavioural support sessions, for at least 4 weeks after discharge – we have been doing this for the last 18 months and find it's an excellent way to prevent relapse. However,	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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Foundation Trust				practically we cannot offer this support as a face-to-face intervention as you have recommended because we do not have the premises to do so and moreover we have found our patients level of engagement in telephone support was greater (because they did not have the added expense and risks associated with travelling). We welcome the recommendation to provide this post-discharge support via telephone, social media platform accessible to the patient.	
South London & Maudsley NHS Foundation Trust	Guideline	030	026	Again for out-patients we suggest the provision of weekly behavioural support sessions, for at least 4 weeks after the date the patient stopped smoking should include the option of telephone/social media platform rather than as you suggest in only a face to face setting.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
South London & Maudsley NHS Foundation Trust	Guideline	031	021 022	We welcome the recommendation to provide stop smoking support in mental health services, and for people with a severe mental health conditions who may need additional support to stop smoking to be offered delivery by a specialist adviser with mental health expertise, with support tailored in duration and intensity to the person's needs.	Thank you for your comment.
South London & Maudsley NHS	Guideline	032	004 - 009	Recommendations for supporting people who have not decided to stop smoking but who need to temporarily abstain whilst in a smoke free care setting.	Thank you for your comment. The use of nicotine containing e-cigarettes to support temporary abstinence was outside of the

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Foundation Trust				<p>We welcome the recommendation to tell smokers about the different types of medicinally licensed nicotine containing products, how to use them and if possible, prescribe them. However, we are disappointed that e-cigarettes are not also recommended as a vital intervention for smokers who are in a situation where they need to temporarily abstain. If this guideline only recommends the use of NRT to support tobacco abstinence, this represents an extremely challenging scenario for us and risks further disadvantaging people with mental health ill health, who will be left behind. We would worry that failure to include e-cigarettes as a safe, valid and effective way to support temporary abstinence will enable some service providers to opt out of and we will find ourselves in a situation where the teachable moment to support stopping smoking and switching to an e-cigarette is lost. We provide mental health care services from 4 large London based hospitals (50 wards). Typically, about half of the adult smokers admitted to hospital are current smokers, it is rare to find a smoker at the point of admission who decides to make a quit attempt. For the overwhelming majority (95%) their decision at the point of admission is to use whatever</p>	<p>scope of this update. Please see the scope document on the NICE website. Regarding differing needs between people admitted to acute hospital settings and to mental health settings, these recommendations are greyed out as they are outside the scope for this update. Please see the scope document on the NICE website.</p>

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				<p>support is available to temporarily abstain. Currently, the preferred option to support temporary abstinence is an e-cigarette, because smokers tell us this more closely matches the experience of smoking compared with using NRT products. We have used e-cigarettes in this way since 2012, typically we now provide around 400 free e-cigarette starter packs each month. In about 30% of cases the smokers find that the provision of a free e-cigarette starter pack, given with the intention to support temporary abstinence on admission is so effective that they decide to continue using it and do not return to smoking.</p> <p>We note solid evidence from a recent ASH survey which confirms that 42% of mental health trusts in UK provide free e-cigarettes to adult smokers on admission to hospital to support temporary abstinence, and as such we believe there is ample evidence to support this consensus practice.</p> <p>More generally in this section of the guidance, we think a distinction should be made between the needs of people admitted to an acute hospital setting and people admitted to a mental health setting. The unique needs of people in mental health crisis is completely</p>	

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				different and deserves a more bespoke response.	
South London & Maudsley NHS Foundation Trust	Guideline	033	008 - 010	We think it's great to recommend prescribers inform smokers that it might be possible to reduce the dose of some prescribed drugs when they stop smoking, however we think this recommendation can go a little further by stipulating that the information about the interaction between smoking and some prescribed medications is provided in advance of any prescription choices being made, so that the patient can make an informed decision about which treatment option to select and how to best support its effectiveness.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
South London & Maudsley NHS Foundation Trust	Guideline	034	015 - 016	We agree that staff in secondary care and closed institutions who do not want, or are not ready, to stop smoking in one go should be given advice to use medicinally licensed nicotine-containing products to help them not to smoke immediately before and during working hours. However, we would also like to see this recommendation go further to recommend that staff in these situations are supported to use e-cigarettes. In our experience, where staff have successfully stopped smoking by switching to use an e-cigarette this has proved instrumental as they act as a positive role model for patients and	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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				can provide an additional layer of support and reassurance.	
South London & Maudsley NHS Foundation Trust	Guideline	051	008	We welcome the recommendation to refer pregnant smokers to a scheme which offers voucher incentives	Thank you for your comment.
South London & Maudsley NHS Foundation Trust	Guideline	053	025	It is extremely helpful to see the recommendation to ban staff from supervising or helping people to take smoking breaks, however we would like to see this go a little further to specifically state that staff must not help smokers by providing storage facilities for smoking materials (tobacco, cigarettes, cigars, matches and lighters).	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
South London & Maudsley NHS Foundation Trust	Guideline	054	029 - 030	We think the recommendations for communicating the smoke free policy are old school (pamphlets, posters and signage) in addition to this we would like to highlight the importance of using digital platforms (websites, Facebook, twitter, and electronic personal health care records).	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
South London & Maudsley NHS Foundation Trust	Guideline	057	002 - 005	In regard to commissioning and designing services we agree to recommend use of integrated care systems plans, health and wellbeing strategies, and other relevant local plans to make a range of interventions in the section on stop-smoking interventions	Thank you for your comment. All the of the recommendations in the guideline apply to those aged 12 or over unless otherwise specified.

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				available but we believe this must not be limited to adult smokers – 80% of adult smokers start to smoke before the age of 20, and a significant proportion start before the age of 14, if we only focus on adults we will never get ahead of the curve and will fail in our duty and responsibility to prevent ill health and premature mortality.	
South London & Maudsley NHS Foundation Trust	Guideline	059	010 - 011	Whilst we welcome the recommendation to include nicotine-containing products as options for sale in secondary care settings such as hospital shops, this is not feasible in our hospital settings where only one of the four hospitals has a shop and this has limited opening hours. We know this is an unrealistic expectation for most mental health care settings. We also think it's unreasonable to expect ward staff to be responsible for selling such items, managing stock levels and finances. We also do not support the provision of vending machines for nicotine containing products, as these require careful management and would have to be in an environment where people under age 18 could access.	Thank you for your comment. This is a matter for local commissioning arrangements. The committee considered that secondary care settings should have effective nicotine containing products on sale where possible.
South London & Maudsley NHS	Guideline	061	001	We are pleased to see the recommendation that there is no suggestion that treatment should stop at 4 weeks, but welcome a tailored approach to meet individual needs – this fits	Thank you for your comment.

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Foundation Trust				well with the needs of people with severe mental ill health, autism and learning disability.	
South London & Maudsley NHS Foundation Trust	General Comment	073	001	<p>Other Recommendations for research</p> <ol style="list-style-type: none"> 1) What impact does screening for smoking status and provision of Very Brief Advice to the parents and carers of children and young people receiving care have on the uptake of smoking? 2) What impact does the screening for smoking status and provision of Very Brief Advice and signposting to local stop smoking services by welfare and benefits officers have on engagement with smoking cessation support? 3) What impact does the screening for smoking status and provision of Very Brief Advice and signposting to local stop smoking services by fire safety advisors have on engagement with smoking cessation support 4) How can the plain packaging messages be adapted to impact on uptake and continued smoking by people with mental health and learning disability? 5) What is the impact of ensuring smoking cessation interventions are provided free of charge for ex-smokers 	Thank you. Research recommendations in NICE guidelines are specifically to address gaps in the research that the committee considered while making their recommendations. They do not address general gaps in the evidence.

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				<p>who need long-term support to prevent relapse?</p> <p>6) What is the impact of providing free smoking cessation support (with no restrictions on access) in prison health care settings?</p> <p>7) What is the impact of a mass media campaign to ensure the general population are aware that all NHS services are completely smoke free in buildings and on the grounds?</p> <p>8) What is the impact of making smoking cessation training a mandatory part of all health care professionals undergraduate training?</p> <p>9) How can health gains achieved during a smoke-free admission to hospital be maintained and built upon following discharge?</p> <p>10) Are NHS service providers expected to store smoking materials (tobacco, cigarettes, matches and lighters) for patients and if they are how does this impact on recovery, clinical outcomes and wellbeing of patients and staff?</p> <p>11) What role do health visitors have in supporting smoke free homes for newborn babies and young children?</p>	

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				<p>12) What adaptations need to be made to ensure the Maudsley Guidelines for smoking Cessation Support are effective for people with severe and enduring mental health problems and for people with learning disability?</p> <p>13) Evaluate the impact of using digital scanners (rather than expensive ad hoc sniffer dog searches) to identify, manage and deter smokers from burning tobacco in health care settings?</p> <p>14) Investigate the impact of including messages about the increased risk for smokers to get flu, and pneumonia and to experience more severe complications of COVID-19, together with signposting to local smoking cessation support as part of the consent process for flu, pneumonia and COVID-19 vaccination programmes?</p> <p>15) Can personalised carbon monoxide monitors enhance engagement and success with smoking cessation treatment programmes especially in young people, those with Autism/ Learning Disability, those with mental health problems?</p>	

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South West Yorkshire Partnership NHS Foundation Trust	Guideline	General	General	No central service to provide materials in alternative formats such as braille, large prints audio and video. Is this something NICE can provide?	Thank you for your comment. It is beyond the remit of NICE to provide materials recommended within the guidelines in alternative formats. The guideline does refer to addressing of people whose first language is not English and those with a range of communication needs. If your comment is about accessibility of the NICE guideline and related NICE materials more details regarding this can be found on the NICE website.
South West Yorkshire Partnership NHS Foundation Trust	Guideline	General	General	No central service to provide materials in alternative formats such as braille, large prints audio and video. Is this something NICE can provide?	Thank you for your comment. It is beyond the remit of NICE to provide materials recommended within the guidelines in alternative formats. If your comment is about accessibility of the NICE guideline and related NICE materials more details regarding this can be found on the NICE website.
South West Yorkshire Partnership NHS Foundation Trust	Guideline	General	General	We feel behavioural support should be emphasised more throughout the guidelines and not just in 1 section.	Thank you for your comment. PHAC considered the evidence, expert testimony and contributions of committee co-optees in the development of the guideline and behavioural support is referenced throughout the recommendations. Behavioural support is recommended as part of recommendation 1.12 as an intervention and in terms of training to facilitate its implementation. Behavioural support is referenced in

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					<p>recommendation 1.14 in terms of raising awareness of the support available and referral to support in acute, maternity and mental health services, and advice to those trained in the delivery of behavioural support with and without other intervention. Behavioural support is referred to in recommendation 1.15 to support harm reduction. Behavioural support is referred to in recommendation 1.20 as something to consider alongside other treatments. Behavioural support is outlined in recommendation 1.22, recommending that secondary care service specifications and service-level agreements require staff to be trained to refer and potentially provide behavioural advice. Recommendation 1.23 highlights that frontline secondary care staff should be trained to refer people to behavioural support.</p>
South West Yorkshire Partnership NHS Foundation Trust	Guideline	General	General	No mention in the guideline around cannabis and other products smoked.	Thank you for your comment. Cannabis is outside the scope of this guideline.
South West Yorkshire Partnership	Guideline	General	General	In regard to smokeless tobacco there is no mention of hookah pipes or other types of products.	Thank you for your comment. Smoking refers to the use of all burned tobacco products which includes shisha/hookah. Smokeless

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NHS Foundation Trust					tobacco is defined in the 'Terms used in this guideline'.
South West Yorkshire Partnership NHS Foundation Trust	Guideline	031	021	We feel the word 'expertise' is exaggerating the expectations of the advisor. We suggest the word be changed to knowledge or training.	Thank you for your comment. The committee discussed this but were content with the existing wording.
South West Yorkshire Partnership NHS Foundation Trust	Guideline	035	010	Clarity on the 1st bullet point is this 1 or multiple products. An expected time frame would be useful.	Thank you for your comment. The recommendation states 'one or more products'. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
South West Yorkshire Partnership NHS Foundation Trust	Guideline	045	014	What is the expectation of the offer? Who offers and who provides?	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.
South West Yorkshire Partnership NHS Foundation Trust	Guideline	045	019 and 020	Can it be clarified how long do we have contact for and how frequently?	Thank you. The intent of this recommendation is not to specify how frequently or how long contact should last, but to recommend that the approach taken is reviewed at each contact.
University College	Evidence review K	General	General	As a group of clinicians, public health specialists, academics, and researchers we	Thank you for your comment . Cytisine is not currently licensed for use in the UK and as

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London Tobacco and Alcohol Research Group				<p>were recently asked by WHO to make a statement in support of the tobacco cessation medications varenicline and bupropion to be added to the WHO Model List of Essential Medicines (WHO EML) and also argued for cytisine to be added. Dr Natalie Walker led the statement, and I co-authored, and reproduce our case here with permission. I believe it should also be considered for review and inclusion by NICE.</p> <p>Varenicline belongs to a class of pharmacotherapies called nicotinic acetylcholine receptors (nAChRs) partial agonists, which combat nicotine addiction by reducing nicotine withdrawal symptoms and cravings through activation of dopaminergic pathways in the brain.¹ Varenicline also competitively inhibits nicotine from binding to nAChRs, thus reducing the reward obtained from tobacco consumption.¹ A Cochrane systematic review of nAChRs partial agonists for smoking cessation found varenicline to be the most effective single-form pharmacotherapy for smoking cessation.²</p> <p>We believe that if varenicline is added to the WHO EML, then cytisine should also be added. Like varenicline, cytisine is structurally</p>	<p>such is outside the scope of this guideline. Any therapy not licensed in the UK is outlined as an exclusion criterion in the research protocol for evidence review K thus any study pertaining to Cytisine would have been excluded.</p>

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				<p>similar to nicotine and acts as a partial agonist at nAChRs,³ although the medications have different half-lives (cytisine: 4.8 hours⁴ ; varenicline: 17 hours¹), and dosing regimens. Cytisine is a plant-derived alkaloid found in the Golden Rain (Laburnum anagyroides) and other members of the Fabaceae family.³</p> <p>Cytisine is one of the oldest smoking cessation medications, being available since the 1960s in Eastern and Central Europe. An extensive summary of the evidence base for cytisine as a smoking cessation medication can be found in the review by Tutka et al (2019), which includes a summary of research currently underway. ³</p> <p>Cytisine appears to be an ideal smoking cessation treatment when assessed using the APEASE criteria proposed by Michie et al (2014) as part of their framework for identifying suitable behaviour change interventions.⁵ Specifically, cytisine is effective, cost-effective, safe, affordable, practicable, acceptable, and equitable.</p> <ul style="list-style-type: none"> • Efficacy/Effectiveness: A recent systematic review found cytisine to be superior to placebo (abstinence at longest follow-up: Relative Risk 	

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				<p>= 1.74, 95% Confidence Intervals [CI] 1.38 - 2.19) based on data from eight trials (N=4,216).³ A pragmatic non-inferiority trial also found 25 days of cytisine to be superior to combination Nicotine Replacement therapy (NRT: Patch plus gum or lozenges for eight weeks) at supporting smoking abstinence (self-reported continuous abstinence [CA] at one month: 40% vs 31% respectively, Risk Difference [RD]= 9.3, 95% CI 4.2 - 14.5, N=1,310).⁶ This finding is supported by a cross-sectional study from a nationally representative household survey of 1403 adults in Russia, suggesting that, after adjusting for age and gender, cytisine was more effective than NRT for 90-day abstinence (adjusted Odds Ratio=2.91, 95% CI=1.28 - 6.59, p=0.011) among those who tried to quit smoking in the past year.⁷ A pragmatic non-inferiority trial found 12 weeks of cytisine to be at least as effective as varenicline (12 weeks) at supporting smoking abstinence (verified CA at six months: 12.1% vs 7.9% respectively, RD=4.3, 95% CI -0.22 - 8.79, N=679) in indigenous New Zealand Māori or extended family of Māori.⁸ As yet unpublished post-hoc Bayesian analysis of this trial indicates cytisine may be superior to varenicline. A clinical trial (N=2388) of cytisine has also been undertaken</p>	

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				<p>in two low-income 2 countries (Bangladesh and Pakistan) in tuberculosis patients who smoked, 9 and a cytisine versus nortriptyline for smoking cessation trial is currently underway in Thailand (a middle-income country). These trials are important given approximately 80% of all tobacco users are in low- and middle-income (LMIC) countries.</p> <ul style="list-style-type: none"> • Cost-effective: Research has shown cytisine to have the lowest cost per quality-adjusted-life-year of all tobacco cessation medications,¹⁰ and modelling suggests cytisine may be more cost-effective than varenicline.¹¹⁻¹² • Safe: Like nicotine (and many other medications), cytisine is toxic in animals and people when ingested in large amounts. However, when used at its current therapeutic dose (1.5–9 mg per day for 25 days) cytisine appears to be well tolerated, with few adverse events compared to a placebo (pooled RR=1.09, 95% CI 0.94-1.26),³ NRT (incidence rate ratio [IRR]: 1.67, 95% CI 1.38-2.01, p <0.001)⁶ or varenicline (IRR=0.56, 95% CI 0.49- 0.65, p<0.001).⁸ Adverse reactions to cytisine 	

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				<p>are generally non-serious and self-limiting, and are predominantly related to nausea, vomiting and sleep disturbance. Importantly, nausea occurs less frequently in people taking cytisine than in people taking varenicline,⁸ likely due to cytisine's lower potency at 5-HT₃ receptors.¹³ Cytisine is also well tolerated in Tuberculosis patients who smoke and want to quit.⁹ Observed adverse reactions are like those reported in a periodic safety update report provided to European authorities (based on more than seven million exposed persons).³</p> <ul style="list-style-type: none"> • Affordable: The cost of smoking cessation interventions is important to both tobacco users and healthcare funders. Yet, even in wealthy countries, current forms of cessation treatment are often considered unaffordable. A major advantage of cytisine (for governments/healthcare providers and individuals) over other pharmacological cessation products on the market is its current low cost^{3, 14} 	

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				<p>and affordability (based on the WHO criteria).¹⁵ For example, in Poland cytisine is 1.5% of the average monthly salary, compared to NRT (17.7% - 24.6% of the average monthly salary), varenicline (24.8% of the average monthly salary) or bupropion (27.3% of the average monthly salary).³ Varenicline is now off-patent in many countries and thus the presence of an in-class competitor in the market will likely exert a downward pressure on the price of both cytisine and varenicline once cytisine become more widely marketed. In many LMIC countries, the high cost of widely available NRT results in less-than-optimal dosing even in the instances it is used. A low cost cytisine treatment could also potentially also exert a downward pressure on the price of NRT products. It will be important that strategies are put in place to stop anti-competitive practices that block price competition for varenicline and cytisine, and to identify strategies to ensure a</p>	

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				<p>transparent and sustainable drug supply chain, particularly for LMIC countries.</p> <ul style="list-style-type: none"> • Practicable: Cytisine has been approved for use on prescription and/or over-the-counter (OTC) in 18 European Union (EU) countries (as an OTC product in Bulgaria, Czech Republic, Latvia, Lithuania and Poland), eight non-EU countries (Azerbaijan, Armenia, Ukraine, Belarus, Georgia, Moldova, Russia and Serbia), and five Central Asian countries (Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan and Uzbekistan), 3 although not all of these countries have cytisine available for people wanting to quit smoking. More recently cytisine has been approved in Canada as an OTC natural health product for smoking cessation. <p>3 Note that of the two nAChRs partial agonists available, only cytisine is available in the OTC category, helping to ensure greater access for people wanting to quit. Cytisine has a long history of use, there is a large safety database with few adverse events reported,</p>	

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				<p>3 and compliance with the current treatment regimen (1.5mg 25-day titration schedule) if not optimal, is acceptable when used in a community-based setting.^{6, 8} A doseranging study has just been published showing efficacy and tolerability of a higher dosage and simplified dosing schedule, which is now being explored in a phase 3 trial.¹⁶</p> <ul style="list-style-type: none"> • Acceptable: The public health impact of a tobacco cessation product not only depends on its efficacy and effectiveness, but also on its acceptability and reach in the population. Cytisine's 'natural' product status (i.e., it is sourced from plants grown in plantations, not synthesized in a laboratory, like varenicline) could increase its acceptability and use among indigenous people, tobacco users in countries where the use of herbal medicines is widespread (e.g., China, India), and in those who do not want to use NRT, varenicline or anti-depressants to help them quit tobacco use. 	

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				<p>For example, qualitative research suggests cytisine (in its currently marketed form) would be appealing to indigenous New Zealand Māori and people from the Pacific islands if it were promoted in a culturally appropriate manner.17-18</p> <ul style="list-style-type: none"> • Equitable: If cytisine was available at relatively low cost, given its appeal and wide margin of safety, cessation outcomes for tobacco users who live in countries where cytisine is licensed are likely to be equitable. However, despite calls for cytisine to be licensed worldwide9, 14, 19-20 it is relatively unknown outside Central/Eastern Europe (although some manufacturers of cytisine are working to license their product in other countries, including the USA). <p>We support the addition of varenicline and bupropion to the WHO EML, but we also strongly recommend that cytisine should be added and available OTC to offer choice. If varenicline and</p>	

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				<p>bupropion are not added to the WHO EML, cytisine certainly should be. Quitting tobacco is difficult and people who are tobacco dependent benefit from a choice to assist their quit attempts. The addition of cytisine alongside bupropion and varenicline will improve access to tobacco cessation medications, particularly for tobacco users in low- and middle-income countries (where people are motivated to quit smoking but have no/limited access to cessation medications), and potentially also for indigenous people; and will support 1.3 billion people around the world to quit tobacco use.</p> <p>References 1. Coe JW, Brooks PR, Vetelino MG, Wirtz MC, Arnold EP, Huang J, et al. Varenicline: an alpha4beta2 nicotinic receptor partial agonist for smoking cessation. J Med Chem 2005; 48(10): 3474-7. 2. Cahill K, Lindson-Hawley N, Thomas K, Fanshawe T, Lancaster T. Nicotine receptor partial agonists for smoking cessation. Cochrane Database of Systematic Reviews 2016:10.1002/14651858.CD006103.pub7. 3. Tutka P, Vinnikov D, Courtney RJ, Benowitz</p>	

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				<p>NL. Cytisine for nicotine addiction treatment: a review of pharmacology, therapeutics and an update of clinical trial evidence for smoking cessation. <i>Addiction</i> 2019; 114: 1951-1969 4. Jeong S-H, Newcombe D, Sheridan J, Tingle M. Pharmacokinetics of cytisine, an $\alpha 4\beta 2$ nicotinic receptor partial agonist, in healthy smokers following a single dose. <i>Drug Test Anal</i> 2014; first published online: 17 Sept 2014; doi: 10.1002/dta.1707. 5. Michie S, Atkins L, West R. <i>The Behaviour Change Wheel: a guide to designing interventions</i>. Great Britain: Silverback Publishing; 2014. 6. Walker N, Howe C, Glover M, McRobbie H, Barnes J, Nosa V, Parag V, Bassett B, Bullen C. Randomized comparison of cytisine versus nicotine for smoking cessation. <i>New Engl J Med</i> 2014; 371(25): 2353-62 7. Castaldelli-Maia JM, Martins SS, Walker N. The effectiveness of cytisine versus nicotine replacement treatment for smoking cessation in the Russian Federation. <i>Int J Drug Policy</i>. 2018; 58: 121-125. 8. Walker N, Smith B, Barnes J, Verbiest M, Parag V, Pokhrel S, Wharakura M-K, Lees T, Cubillos Gutierrez H, Jones B, Bullen C. Cytisine versus varenicline for smoking cessation in New Zealand indigenous Māori: A randomized controlled trial. <i>Addiction</i>. 2021; March:</p>	

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				<p>https://doi.org/10.1111/add.15489 9. Dogar O, Keding A, Gabe R, et al. Cytisine for smoking cessation in patients with tuberculosis: a multicentre, randomised, double-blind, placebo-controlled phase 3 trial. <i>Lancet Global Health</i> 2020; 8 (11): E1408-E1417. 10. Stapleton J. The case for licensing cytisine now for smoking cessation is overwhelming [letter]. <i>BMJ</i> 2013; 347: f5736. 11. Leaviss J, Sullivan W, Ren S, Everson-Hock E, Stevenson M, Stevens J, et al. What is the clinical effectiveness and cost-effectiveness of cytisine compared with varenicline for smoking cessation? A systematic review and economic evaluation. <i>Health Tech Assess</i> 2014; 18(33): 1- 119. 12. Anraad C, Cheung K, Hiligsmann M, Coyle K, Coyle D, Owen L, et al. Assessment of costeffective changes to the current and potential provision of smoking cessation services: An analysis based on the EQUIPTMOD. <i>Addiction</i> 2018; Feb 11. doi: 0.1111/add.14093.</p> <p>13. Lummis SCR, Price KL, Clarke A. Cytisine's lower potency at 5-HT3 receptors may explain its lower incidence of nausea and vomiting than varenicline. Society for Research into Nicotine and Tobacco (SRNT)-Europe 20th Annual Conference [virtual meeting] 17-19th September 2020. 14. Prochaska J, Das</p>	

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				<p>S, Benowitz N. Cytisine, the world's oldest smoking cessation aid. <i>BMJ</i> 2013; 347: f5198</p> <p>15. West R, Raw M, McNeill A, Stead L, Aveyard P, Britton J, Stapleton J, McRobbie H, Pokhrel S, Lester-George A, Borland R. Healthcare interventions to promote and assist tobacco cessation: a review of efficacy, effectiveness and affordability for use in national guideline development. <i>Addiction</i> 2015; 110(9): 1388–1403. 16. Nides M, Rigotti NA, Benowitz N, et al. A Multicenter, Double-blind, Randomized, Placebocontrolled Phase 2b Trial of Cytisinicline in Adult Smokers (The ORCA-1 Trial), <i>Nic Tob Res</i>, 2021; ntab073, https://doi.org/10.1093/ntr/ntab073 17. Thompson-Evans T, Glover M, Walker N. Cytisine's potential to be used as a traditional healing method to help indigenous people stop smoking: A qualitative study with Māori. <i>Nicotine Tob Res</i> 2011; 13(5): 353-360. 18. Nosa V, Leau K, Walker N. Cytisine as an alternative smoking cessation product for Pacific smokers in New Zealand. <i>Pacific Health Dialog</i> 2018; 21 (2): 89-95 19. Aveyard P, West R. Cytisine and the failure to market and regulate for human health. <i>Thorax</i> 2013; 68(11): 989. 20. Rigotti N. Cytisine - a tobacco treatment hiding in plain sight [editorial]. <i>New Engl J Med</i>. 2014; 371: 2429-2430.</p>	

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Yorkshire Cancer Research	Evidence review K	092	019 - 023	<p>Given the results of the cost effectiveness analysis in Table 14, we do not believe that the committee has given sufficient justification as to why a combination of e-cigarettes and NRT L/S are not included in Guideline Rec 1.12.5. Stop smoking service data between April 2019 and March 2020 from NHS Digital shows that the highest quit rates (74%) were seen when the quit attempt involved people using a licensed medicine and an e-cigarette one after another.²⁷ We are concerned that by not including this combination in the Guideline that people who smoke may find it difficult to access the most effective combination of cessation aids.</p> <p>²⁷ Public Health England (2016). Use of e-cigarettes in public places and workplaces: Advice to inform evidence-based policy making. Available from: https://www.gov.uk/government/publications/use-of-e-cigarettes-in-public-places-and-workplaces [Last accessed June 2020].</p>	<p>Thank you for your comment. The Public Health Advisory Committee (PHAC) considered evidence of effectiveness, cost-effectiveness, barriers and facilitators as well as expert testimony in their deliberations when developing NICE guidelines. The rationale and impact section of the guideline document outlines PHAC's thinking underpinning recommendation 1.12.5. It states that PHAC decided not to recommend some combinations of interventions even though they were as effective as individual options based on their experience, and concerns over adherence rates, the difficulty of obtaining prescriptions for multiple interventions at once and a lack of information on contraindications that made these combinations less feasible than other options.</p> <p>The PHAC agreed that people providing stop smoking support should offer behavioural support alongside any nicotine containing products the person is using, irrespective of whether they are providing the product to give people a better chance of stopping smoking. They also agreed that offering behavioural support to people using nicotine-containing e-cigarettes would increase their chances of stopping smoking.</p>

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Yorkshire Cancer Research	Evidence review K	096	033 - 041	<p>1) The title of this paragraph 'Implications of recommending e-cigarettes' and the discussion within this paragraph, implies that the committee recommend that e-cigarettes containing nicotine be made available in secondary care settings. However, there is ambiguity in the wording, since e-cigarettes containing nicotine are not explicitly mentioned, in favour of the term 'nicotine containing products'. This ambiguity is also seen in Rec 1.22.14 (pg 59, line 10) and on pg 88, line 24 of the Guideline. Making it explicit that e-cigarettes containing nicotine should be offered as part of a stop smoking service in secondary care presents an important opportunity to support smokers in these settings with the most popular and one of the most effective quitting aids and is a policy recommendation we would welcome and support.</p> <p>In addition, we suggest that the example of e-cigarettes containing nicotine being sold in hospital shops be expanded to include the suggestion that e-cigarettes containing nicotine could also be provided free of charge to smokers at the same location via a voucher funded by local commissioners/stop smoking</p>	<p>Thank you for your comment. The glossary defines 'nicotine-containing products'. The definition has been amended to make clear it includes nicotine containing e-cigarettes. Recommendation 1.11.4 outlines the offer of advice on using nicotine-containing products on general sale with reference to nicotine-replacement therapy and nicotine-containing e-cigarettes. Recommendation 1.12.1 outlines that nicotine-containing e-cigarettes should be accessible to adults who smoke and recommendation 1.12.5 highlights that nicotine containing e-cigarettes are more likely to result in successful quit attempts when combined with behavioural support. Recommendation 1.12.13 to 1.12.17 outline the advice that should be provided by people providing stop-smoking advice support or advice regarding nicotine-containing e-cigarettes. Based on the evidence and testimony considered by PHAC they did not make a recommendation regarding the free of charge provision of nicotine-containing e-cigarettes to smokers via vouchers or otherwise.</p>

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				<p>services. This would ensure that smokers experiencing higher levels of deprivation, who are more likely to be admitted into secondary care for longer periods²⁸ and who may find the cost of these products prohibitive, are offered the best chance of quitting successfully, for good. This is particularly important in reducing health inequalities.</p> <p>²⁸ Luben, R., Hayat, S., Khawaja, A. <i>et al.</i>, (2019). Residential area deprivation and risk of subsequent hospital admission in a British population: the EPIC-Norfolk cohort. <i>BMJ Open</i>, 9, e031251. doi: 10.1136/bmjopen-2019-031251</p>	
Yorkshire Cancer Research	Evidence review K	099	032	<p>(Related to rec 1.12.1 in draft guideline) We are concerned that relying on local decision making for how the accessibility of e-cigarettes is defined will result in a 'post code lottery' of service provision that will widen health inequalities. There is growing evidence that e-cigarettes have the potential to reduce health inequalities by effectively supporting smokers in lower socioeconomic groups and those with mental health conditions to quit. However, the cost of buying these products in vape shops can be prohibitive. This advice also contradicts that of Public Health England in their 2021 Vaping in England evidence review which states that '<i>Local authorities should continue to</i></p>	<p>Thank you for your comment. The reviews in this guideline did not look at evidence about the most effective ways of making nicotine-containing e-cigarettes accessible for cessation. The committee agreed that decisions about how to make e-cigarettes accessible should be made at a local level dependent on how stop smoking services and other relevant settings are set up and link together. To facilitate this the guideline makes recommendations on commissioning and designing services (1.22) outlining that integrated care systems plans, health and wellbeing strategies, and other relevant local strategies and plans make a range of</p>

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				<i>fund and provide stop smoking services and all stop smoking services should have a consistent approach to using vaping products.'</i> ^{ix}	interventions (including nicotine-containing e-cigarettes) accessible to adults who smoke. This is consistent with advice from PHE.
Yorkshire Cancer Research	Guideline	General	General	We suggest that the term 'e-cigarette(s)' is replaced with 'vaping product(s)'. E-cigarette is a term that was commonly used when the first devices became available. These devices resembled tobacco cigarettes, but there has since been a rapid evolution of the technology and products. The shape of the products now varies enormously. Furthermore, the word 'cigarette' is associated with harm, whereas the evidence is clear that e-cigarettes are far less harmful than tobacco cigarettes. Because of these two points, we believe that the term e-cigarette is no longer appropriate or accurate. We are also concerned that the continued use of this terminology exacerbates the misconceptions that e-cigarettes are equally or more harmful than tobacco cigarettes, still incorrectly perceived by 32% of the adult population. ⁴ Since 2020, Public Health England have used the term vaping products in their annual Vaping in England evidence updates and we believe it is important that NICE leads by example in the use of its terminology. ²³ For the purpose of this	Thank you for your comment. The term e-cigarettes was decided on during the scoping phase of this guideline. The committee considered your comments and have not changed the term 'e-cigarettes' to 'vaping products'. The glossary defines e-cigarettes and outlines that they are also called electronic cigarettes or vaping devices. The glossary definition is hyperlinked throughout the guideline document and PHAC considered this to be sufficient.

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				document, we use the term 'e-cigarette' as per NICE's nomenclature. ²³ Public Health England (2021). Vaping in England: an evidence update including vaping for smoking cessation, February 2021. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/962221/Vaping_in_England_evidence_update_February_2021.pdf [Last accessed February 2021].	
Yorkshire Cancer Research	Guideline	053 - 055		Rec 1.21 – we are concerned that the smokefree policy section has not been updated in line with the inclusion of e-cigarettes in Rec.1.12.1 and 1.12.5. Vaping is not covered by UK smokefree laws, which prohibit smoking in enclosed public places and workplaces and is left to organisations to decide their policy on an individual basis. We believe that without guidance, in line with the recommendations proposed by Public Health England, ²⁷ smokefree policies will continue to be prohibitive to those engaging in a quit attempt using e-cigarettes and may result in smoking relapse. ²⁷ Public Health England (2016). Use of e-cigarettes in public places and workplaces: Advice to inform evidence-based policy making. Available from:.	Thank you for your comment. This comment relates to a greyed-out area of the guideline and is outside of the scope for this update. Please see the scope document on the NICE website.

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				https://www.gov.uk/government/publications/use-of-e-cigarettes-in-public-places-and-workplaces [Last accessed June 2020].	
Yorkshire Cancer Research	Guideline	022	024	Rec 1.12.1. - We welcome the inclusion of e-cigarettes within the Guideline as a recommended stop smoking aid. This inclusion provides an important opportunity to effectively support the 7 million smokers in England to quit for good. We are, however, concerned that the term 'accessible' will not go far enough to enact service delivery change and would therefore recommend the term 'offered'.	Thank you for your comment. The committee was aware that local areas have very different commissioning arrangements for smoking cessation and agree that the most important thing was ensure that people had access to the range of interventions. The recommendation begins 'Ensure' and is therefore a strong recommendation.
Yorkshire Cancer Research	Guideline	026	003 - 004	Rec. 1.12.14 - We would recommend that this line also acknowledges the substantial reduction in the risk of vapour to bystanders in comparison to smoking. This has been identified by Public Health England's 2018 Evidence review of e-cigarettes and heated tobacco products ²⁵ and more recently the 2020 Committee on Toxicity of Chemicals in Food, Consumer Products, and the Environment report. ²⁶ We recommend that line 3-4 is changed to 'use of vaping products are likely to be substantially less harmful than smoking for those who smoke and the people around them'. ²⁵ Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (2020). Statement on the	Thank you for your comment. The outcomes for the evidence review did not include effects on bystanders. As the evidence has not been reviewed, the committee are unable to make recommendations in this area.

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				<p>potential toxicological risks from electronic nicotine (and non-nicotine) delivery systems (E(N)NDS – e-cigarettes). Available from: https://cot.food.gov.uk/sites/default/files/2020-09/COT%20E%28N%29NDS%20statement%202020-04.pdf [Last accessed September 2020].</p> <p>26 NHS Digital (2020) Statistics on NHS Stop Smoking Services in England April 2019 to March 2020. Available from: https://digital.nhs.uk/data-and-information/publications/statistical/statistics-on-nhs-stop-smoking-services-in-england/april-2018-to-march-2019 [Last accessed November 2020].</p>	
Yorkshire Cancer Research	Guideline	031	017 019 - 023	<p>Rec 1.14.19 – We are concerned that the link to recommendation 1.12.1 on line 17 is not specific/clear enough a recommendation for the provision of e-cigarettes as a stop smoking aid in mental health settings. We believe that a clear recommendation regarding their offer is required in recommendation 1.14.19 to avoid contradicting the NHS Long Term Plan's recommendation in this area (pg 31, para 2.11) 8.</p> <p>8 NHS England. The NHS Long Term Plan: Smoking. January 2019</p>	<p>Thank you. We have added a cross reference to the section on stop smoking recommendations directly underneath 1.14.19</p>

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Yorkshire Cancer Research	Guideline	059	010	Rec 1.22.14 – In line with our suggestions made in Comment 27, we recommend that the line 'Include nicotine containing products as options for sale in secondary care settings (for example in hospital shops)' be changed to 'Include nicotine-containing products, including e-cigarettes, as options for sale and offered free of charge, funded by local commissioners or stop smoking services via a voucher, in secondary care settings (for example in hospital shops)' to prevent ambiguity and be in keeping with the recommendations made in evidence review K, pg 96, line 40-41.	Thank you. Nicotine containing products is defined in the glossary section of the guideline. The definition of nicotine containing products has been amended to clarify that it includes nicotine containing e-cigarettes.
Yorkshire Cancer Research	Guideline	088	024	We recommend that this line be changed to 'The committee agreed that nicotine containing products, including e-cigarettes, should be available in secondary care settings...' to align with what is written in evidence review K, pg. 96 lines 40-41 and prevent any ambiguity.	Thank you. Nicotine containing products is defined in the 'terms used in this guideline' section. The definition of nicotine containing products has been amended to clarify that it includes nicotine containing e-cigarettes.
Yorkshire Cancer Research	Guideline	088	024	Rec 1.21 – In line with the recommendations made in Comments 27-29, the smokefree policy recommendations (Rec 1.21) must be updated to ensure that vaping is identified as a separate activity to smoking and not prohibited in smokefree policies, including those in secondary care settings.	Thank you. The recommendations in 1.21 are a greyed-out area of the guideline and outside of the scope for this update. Please see the scope document on the NICE website.

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