Smoking cessation interventions and services

NICE National Institute for Health and Care Excellence

Consultation on draft guideline – deadline for comments 5pm on Wednesday 1 November 2017 email: SmokingCessationServices@nice.org.uk

	Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly. We would like to hear your views on the draft recommendations presented in the short version and any comments you may have on the evidence presented in the full version. We would also welcome views on the Equality Impact Assessment. We would like to hear your views on these questions: 1. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why. 2. Would implementation of any of the draft recommendations have significant cost implications? 3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.) See section 3.9 of Developing NICE guidance: how to get involved for suggestions of general points to think about when commenting.
Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank):	**Royal College of Nursing**

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Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	**None declared**
Name of commentator person completing form:	[**Wendy Preston (RCN Head of Nursing Practice), Helen Donovan (RCN Professional Lead for Public Health Nursing), RCN Member: Dr Maria Duaso (Lecturer, Adult Nursing)**]
Type	[office use only]

Comment number	**Document** (**full** version, **short** version or the **appendices**	**Page number** Or **'general'** for comments on the whole document	**Line number** Or **'general'** for comments on the whole document	**Comments** Insert each comment in a new row. Do not paste other tables into this table, because your comments could get lost – type directly into this table.
Example 1	Full	16	45	We are concerned that this recommendation may imply that ……..
Example 2	Full	16	45	Question 1: This recommendation will be a challenging change in practice because ……
Example 3	Full	16	45	Question 3: Our trust has had experience of implementing this approach and would be willing to submit its experiences to the NICE shared learning database. Contact…….
1	General	General	General	The Royal College of Nursing welcomes proposals to develop guidelines for smoking cessation interventions and services.

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				RCN staff and members who care for people with smoking related illness and respiratory issues and members who have specialist interest and knowledge of respiratory conditions and smoking related illness reviewed these draft guidelines on behalf of the RCN.
2	Full	General questions	General questions	NICE asked for views on the following general questions: 1. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why. 2. Would implementation of any of the draft recommendations have significant cost implications? 3. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.) See below for our answers: **1. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why.** **The recommendation which will have the biggest impact is 1.1.1 (page 4 line 2-3) *"ensure evidence-based stop smoking interventions and services are available for everyone who smokes".*** The NHS Five Year Forward View stated that *"The future health of millions of children, the sustainability of the NHS, and the economic prosperity of Britain all now depend on a radical upgrade in prevention and public health".* Given that smoking remains the leading cause of preventable premature death and is a relapsing condition killing about 80,000 people a year in England, access to smoking cessation treatment and interventions is an essential element in delivering such a radical upgrade. Smoking cessation treatment has significant potential to reduce NHS treatment costs and increase quality of life for patients. Evidence from Ottawa shows that specialist smoking cessation support compared to usual care in hospitals is highly effective and cost-effective: • 35% of the patients who participated in the Ottawa Model were smoke-free at 6-month follow up, compared to only 20% of the usual care participants. • Patients who received the Ottawa Model were 50% less likely to be re-admitted to the hospital for any cause, and 30% less likely to visit an emergency department in the 30 days following their initial hospitalization. • Smokers who received the Ottawa Model were 21% less likely to be re-hospitalized and 9% less likely to visit an emergency department, 2 years following their hospitalization. • Most importantly, the study showed a 40% reduction in 2-year mortality risk among patients who received the Ottawa Model.

				The Ottawa model uses the same overall combination of interventions (behavioural support from a trained advisor, and pharmacotherapy) as stop smoking services in the UK which have been shown to be effective. A randomised study carried out in a UK hospital similarly found improved outcomes through providing bedside support to smokers in hospital. Interventions doubled the uptake of support, and doubled quit rates, among general medical patients. Both these models involving bringing smoking cessation support to the hospital bedside as recommended in PH48. It is important to note that effective support for smokers must be across secondary, primary and community care. *Sources:* *Mullen KA, Coyle D, Manuel D, Nguyen HV, Pham B, Pipe AL, et al. Economic evaluation of a hospital-initiated intervention for smokers with chronic disease, in Ontario, Canada. Tob Control. 2015;24(5):489-96. Available from:* *Mullen KA, Manuel DG, Hawken SJ, Pipe AL, Coyle D, Hobler LA, et al. Effectiveness of a hospital-initiated smoking cessation programme: 2-year health and healthcare outcomes. Tob Control. 2016;0:1-7. Available from:* Murray, R.L., Leonardi-Bee, J., Marsh, J., Jayes, L., Li, J., Parrott, S., and Britton, J. *Systematic identification and treatment of smokers by hospital based cessation practitioners in a secondary care setting: cluster randomised controlled trial.* BMJ, 2013; **347**: f4004. Smoking is a leading cause of cancer, and the evidence is growing that smokers diagnosed with cancer live longer, and have better quality lives, if they quit. For example smokers diagnosed with lung cancer live on average just over a year if they keep smoking, however, they live more comfortably and for nearly two years, if they quit. *Source: NIHR. Cancer survivors who quit smoking sooner can live longer. 12 September 2017.* Advice to all smokers to quit and access to specialist stop smoking services have been core to all NICE guidance which includes reference to quitting smoking since PH1 was first published in 2006. However, there is growing evidence that access to treatment is on the decline and a postcode lottery is developing. • In response to public health funding cuts local authorities are cutting funding and decommissioning stop smoking services. *Sources: ASH. Burning Injustice All Party Parliamentary Group on Smoking and Health. January 2017.* *Buck D. Chickens coming home to roost: local government public health budgets for 2017/18. King's Fund. July 2017*

				• A growing number of CCGs are refusing to pay for GP prescriptions of stop smoking medications in contravention of DH guidance. *Source: ASH. Burning Injustice All Party Parliamentary Group on Smoking and Health. January 2017.* • The prevention CQUIN focuses on identifying and, where required, providing advice and providing access to specialist services for inpatients in community and mental health trusts (2017-19) and all acute trusts (2018-19). Currently hospitals across the UK are falling "woefully short" of implementing NICE guidelines on helping patients who smoke to quit so unless access to treatment in hospitals can be upgraded rapidly the success of the CQUIN depends on universal access to specialist stop smoking services in primary care. *Source: BTS. Smoking cessation policy and practice in NHS hospitals. British Thoracic Society, December 2016* • Since the transfer of public health budgets to local authorities in 2010 the number of prescriptions of stop smoking medications have fallen by 55% from a peak of 2.5 million in 2010/11 to under 1.2 million in 2015/16. Use of consumer e-cigarettes by smokers to quit does not fully account for this decline. *Source: Public Health Prescribing Cost. LGA Knowledge Hub.* • Only 24% of smokers with cancer are offered advice to quit by their GPs and only 13% are prescribed stop smoking treatment. The situation is not much better for smokers with coronary heart disease, only 48% are offered advice to quit by GPs and only 22% are prescribed stop smoking treatment. Inconsistency of care in this way is inappropriate; all smokers should receive the same level of support. *Source: NIHR. Cancer survivors who quit smoking sooner can live longer. 12 September 2017.* **The other recommendation with very significant potential impact is that on e-cigarettes (1.3.8-1.3.9 – page 8 lines 7-18)** If more smokers could be encouraged to switch to these devices and stop smoking, very significant gains could be made. In 2015 the Royal College of Physicians reviewed all the available evidence on these devices and stated: "Electronic cigarettes have the potential to make a major contribution towards preventing the premature death, disease and social inequalities in health that smoking currently causes in the UK" *Source: Promote e-cigarettes widely as a substitute for smoking says new RCP report. Royal College of Physicians* Research has also modelled the population impact in the future if more smokers switched, in the USA where e-cigarettes are available as in the UK. They estimated that: "compared with the Status Quo, replacement of cigarette by e-cigarette use over a 10-year period yields 6.6 million fewer premature deaths with 86.7 million fewer life years

				lost in the Optimistic Scenario. Under the Pessimistic Scenario, 1.6 million premature deaths are averted with 20.8 million fewer life years lost. The largest gains are among younger cohorts, with a 0.5 gain in average life expectancy projected for the age 15 years cohort in 2016." *Source: Levy, D, Borland, R, Lindblom, E et al (2017) Potential deaths averted in the USA by replacing cigarettes with e-cigarettes, Tobacco Control, doi: 10.1136/tobaccocontrol-2017-053759. [Epub ahead of print*] **2. Would implementation of any of the draft recommendations have significant cost implications?** Smoking cessation treatment is not just cost- effective but cost-saving. As NICE has itself estimated a £1 investment in smoking cessation leads to a return of (including NHS savings and value of health gains): £0.63 at 2 years, £1.46 at 5 years, £2.82 at 10 years, £9.35 lifetime. *Source: NICE, Tobacco Return on Investment Tool, October 2015* Hospital smoking cessation services are cost effective and the British Thoracic Society developed a Case for Change paper and return on investment tools: https://www.brit-thoracic.org.uk/standards-of-care/quality-improvement/smoking-cessation/ Smoking cessation services in the UK have been found to be highly cost-effective whether they are delivered in pharmacies, in primary care, one to one or in groups. *Sources: Bauld, L, Boyd, K, Briggs, A, Chesterman, J, Ferguson, J, Judge K and Hiscock, R. (2011) One year outcomes for smokers accessing group-based and pharmacy-led smoking treatment services: a cost-effectiveness study,* Nicotine and Tobacco Research*. 13(2):135-45. doi: 10.1093/ntr/ntq222* *Godfrey, C, Parrott, S, Coleman, T and Pound, E (2005) The cost-effectiveness of the English smoking treatment services: evidence from practice,* Addiction*, 100, 2, 70-83.* For the new recommendations around e-cigarettes - these are consumer products and therefore neither the NHS or local authorities would bear the cost. **3. What would help users overcome any challenges? (For example, existing practical resources or national**

				initiatives, or examples of good practice.) It is essential that the guidelines direct the reader to comprehensive guidance on commissioning of support for smokers to quit in all settings, including use of electronic cigarettes, provided by organisations such as Public Health England and the National Centre for Smoking Cessation and Training (NCSCT).
3	Full	1	4	This guideline replaces NICE's guidelines on brief advice and referral for smoking cessation (PH1) and smoking cessation services (PH10). We are concerned that the bullet point *"Health, social care and other frontline staff with links to stop smoking services"* does not make clear brief advice, we would recommend revising to read *"Health, social care and other frontline staff who engage with smokers"*
4	Full	4	1	The link from 'Making decisions using NICE guidelines' to GMC information about prescribing medicines off-label, General Medical Council's prescribing guidance: prescribing unlicensed medicines, is broken. It is also not clear from the guideline what opportunities might arise from this with respect to prescribing consumer e-cigarettes as an unlicensed medicine – it would be helpful if the guideline could spell this out? In secondary care, if a bedside service exists (as per PH48) then referral is fine. Otherwise, if the referral option means 'signposting' the smoker to a remote community-based service, at their initiative, the likelihood is that nothing will happen. It is therefore important that people are provided with advice, pharmacotherapy and a referral to services.
5	Full	4	4-7	We strongly support this section which spells out the need to *"ensure evidence-based stop smoking interventions and services are available for everyone who smokes."*
6	Full	4	8	**Section.1.1.2**.: This section needs to make aware that needs assessments may not include data from those who are most in need, for example groups with highest smoking prevalence such as Gypsy/Travellers communities, people with low literacy levels, people with a mental health illness.
7	Full	4	10	Specific groups should also include hospital inpatients and cross refer to PH48 guidance on smoking: acute, maternity and mental health services.
8	Full	4	10	This section should also specifically list people with a substance use disorder as rates of smoking in this already disadvantaged group are very high – perhaps the highest across all health conditions – therefore warrants singling out and separated from mental health, in particular as the two types of service (i.e. mental health and substance misuse) are commissioned and provided by very different organisations. Therefore it may not be sufficient to assume that people with a substance use disorder are accounted for under the mental health umbrella.
9	Full	5	1, 25	In line with PH26 this should include partners who smoke not just pregnant women. And in line 25 it should specify that all pregnant smokers and smokers being offered elective surgery should be referred to specialist stop smoking services. (see comment number 14)

				However, if only a referral is offered it is highly likely that nothing will happen as either the smoker will decline the offer or the service fails to find them. Smokers should be provided with advice and pharmacological support in addition to referral.
10	Full	5	3-20	We strongly support this section which sets targets and outlines how performance should be monitored. However, we are concerned that 10ppm is too high and does not reflect the best evidence on what we expect an ex-smoker's CO level to be and many services use a lower level than this. Smokers who have quit smoking typically achieve levels of zero to 1 ppm and the 10ppm threshold dates back to a study that is now more than 30 years old. A more recent paper suggests that 6.5ppm is the upper limit for a non-smoker. This is especially relevant when related to young people who in our members' experience can have readings as low as 4 and yet report being a smoker. Source: Deveci S et al. The measurement of exhaled carbon monoxide in healthy smokers and non-smokers. Respiratory Medicine. Volume 98, Issue 6, June 2004, Pages 551-556 It should also be noted that it is now standard practice in pregnancy to use 4ppm as the cut off and this is recommended by the Smoking in Pregnancy Challenge Group. Source: Bauld, L, Hackshaw,L, Ferguson, J et al (2012) *Implementation of routine biochemical validation and an 'opt out' referral pathway for smoking cessation in pregnancy*, Addiction, 107, S2, 53-60.
11	Full	6	10	**Section.1.2.4.** Patients unwilling to be referred to a local specialist stop smoking service should still be able to receive behavioural interventions if the healthcare professionals who see them have been trained according to the National Centre for Smoking Centre and Training (NCSCT)'s training standards and have the competency to do so.
12	Full	6	12-14	This could be made clearer for example to read: "*(the National Centre for Smoking Cessation and Training (NCSCT) programmes explains how)"*
14	Full	6	18	Given the impact smoking has on surgical outcomes both in terms of the success of operations and the average recovery time, quitting smoking in advance is a priority objective. Therefore opt out, not opt in, referral should be the standard and the words *"Offer to"* should be removed throughout the guidance. See ASH briefing: Smoking and surgery developed in partnership with the Royal College of Surgeons of Edinburgh, the Royal College of Anaesthetists and the Faculty of Public Health. It was endorsed by the Royal College of Surgeons, Royal College of Physicians and the Royal College of General Practitioners.
15	Full	6	22	*"Smoking cessation aids"* sounds like it means pharmacotherapy only – it would be better worded along the lines

				"Providing help to quit smoking"
16	Full	6	26	The term *"nicotine replacement products"* should be revised to read *"nicotine containing products"* on general sale, in line with the terminology used by the MHRA. The term "Nicotine replacement" is associated in practitioners' minds with licensed NRT or "Nicotine Replacement Therapy" i.e. a long established set of licensed medicines including patches, gum etc. which does not include consumer e-cigarettes.
17	Full	7	1	To be consistent this should include not just pharmacotherapy and behavioural options but also e-cigarettes.
18	Full	7 7	6 13	This says, *"which combination of pharmacotherapy is most effective"* without saying what this is, or where the information could be found as to what it is. The list in lines 13-25 gives all the options equal weight and does not make clear that some options are much more effective than others. For a review of the effectiveness of different options when used in practice in England see: Kotz, D, Brown, J, West, R (2013) 'Real world' effectiveness of smoking cessation treatments: a population study, Addiction, doi: 10.1111/add.12429 Additional information should be added on the relative effectiveness of different options. They should not be treated the same. As combination therapy is more effective this should come first in options i.e. offer combination or single therapy….
19	Full	8	6	As above, the heading *"Nicotine replacement products"* on general sale should be revised to read *"Nicotine containing products"* on general sale, in line with the terminology used by the MHRA. As set out above the term "Nicotine replacement" is associated in practitioners minds with licensed NRT or "Nicotine Replacement Therapy" ie a long established set of licensed medicines including patches, gum etc. which does not include consumer e-cigarettes. Using the term Nicotine Replacement Products to include e-cigarettes and NRT will be confusing and is not consistent with terminology used elsewhere.
20	Full	8	7	There should be two sub-headings first on *"Use of licensed NRT bought over the counter".* Under this should be the following paragraph: *"Smokers using licensed nicotine replacement therapy (NRT) products bought over the counter should be given brief advice to quit and encouraged to use NRT as recommended on the pack."* There should then be another sub-heading: *"Use of nicotine-containing e-cigarettes"*
21	Full	8	8	The final scope for the guideline states that the update will include *"Advice and referral options for people using consumer e-cigarettes (or similar consumer electronic nicotine delivery systems)."* The guidance as drafted does not meet the requirements set out in the scope as it is insufficiently detailed. It is essential that it does as ASH is regularly contacted by healthcare professionals wanting guidance on what to say to patients using e-cigarettes to help them quit.

				To meet the requirements of the scope we recommend adding at the end of line 8 before the full stop: *"(the NCSCT briefing on e-cigarettes includes recommendations on electronic cigarettes for stop smoking practitioners and services)"*
22	Full	8	9	As shown by research carried out jointly by Action on Smoking and Health (ASH) and UK Centre for Tobacco & Alcohol Studies (UKCTAS) with the NCSCT smokers often ask for advice about e-cigarettes from stop smoking practitioners. We therefore recommend that this statement should be amended to read 'For those using, or interested in using, a nicotine containing e-cigarette, explain that'. *Source: Hiscock, R., Bauld, L., Arnott, D., Dockrell, M., Ross, L., & McEwen, A. (2015). Views from the coalface: what do English Stop Smoking Service personnel think about e-cigarettes?. International journal of environmental research and public health, 12(12), 16157-16167.*
23	Full	8	13	The statement that *"some smokers have found them helpful to quit smoking cigarettes"* is accurate but very weak. The same is true for pharmacotherapy, such as NRT and varenicline but we don't, and shouldn't, qualify pharmacotherapy in that way. The guidance needs to acknowledge more positively that e-cigarettes are popular aids to quit smoking, (in fact they are the most popular aid, and have been for some time) and that when used in conjunction with other support, smokers using e-cigarettes have some of the highest success rates. Indeed a recent BMJ study estimated that, in England, e-cigarettes lead to 16,000 - 22,000 additional smokers quitting a year. *Source: Beard E, West R, Michie S, et al. 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. BMJ 2016;354:i4645.* The evidence is not just from the UK. The substantial increase in e-cigarette use among US adult smokers was associated with a statistically significant increase in the smoking cessation rate at the population level. *Source: Zhu et al. E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys. BMJ 2017;358:j3262* Given the above we recommend removal of the word "some"
24	Full	8	14-15	The statement that *"there is currently little evidence on the long-term benefits or harms of these products"* is confusing and potentially misleading. Indeed when these draft guidelines went out for consultation, it was misinterpreted by the media to suggest that NICE was cautioning smokers against using e-cigarettes. See Daily Mail:

				Smokers `should be told of little evidence on benefits or harms of e-cigarettes´. There has been considerable coverage in the UK press, particularly the tabloid press, on e-cigarette safety which reports research findings as suggesting there are serious risks from vaping. However, the most frequent source of such studies are animal and in-vitro studies with unclear relevance for human exposure, which typically do not compare the risks with smoking, and often use levels of exposure far above anything human vapers are exposed to. Research which reports the impact of e-cigarettes on users' health is what is most relevant and what needs to be taken into consideration. Such research has to date been reassuring. For example see the following studies: A study published in March 2017 compared exposure to nicotine, tobacco-related carcinogens, and toxins among smokers of combustible cigarettes only, former smokers with long-term e-cigarette use only, former smokers with long-term nicotine replacement therapy (NRT) use only, long-term dual users of both combustible cigarettes and e-cigarettes, and long-term users of both combustible cigarettes and NRT. Long-term, for the purpose of the study, was defined as more than or equal to six months. There were 181 participants in the study, with 36 to 37 members in each group. After confounders were controlled for no clear between-group differences in biomarkers of nicotine intake (salivary or urine) were found. The e-cigarette-only and NRT-only users had significantly lower metabolite levels of one of the most important groups of carcinogens in tobacco, Tobacco Specific Nitrosamines (TSNAs), and also of toxic volatile organic compounds (VOCs) than tobacco smokers or dual users (tobacco smokers also using e-cigarettes or NRT). The levels of exposure in dual users and those only smoking combustible cigarettes to these compounds were similar. The conclusions were that: "Former smokers with long-term e-cigarette–only or NRT-only use may obtain roughly similar levels of nicotine compared with smokers of combustible cigarettes only, but results varied. Long-term NRT-only and e-cigarette–only use, but not dual use of NRTs or e-cigarettes with combustible cigarettes, is associated with substantially reduced levels of measured carcinogens and toxins relative to smoking only combustible cigarettes." *Source: Shahab L. Goniewicz ML. Blount BC. Brown J. McNeill A. Alwis U. Feng J. Wang L. West R. Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users: A Cross-sectional Study. Annals of Internal Medicine. March 2017.* A study published in May 2017 randomised smokers to switch partially or completely to vaping or stop using nicotine products altogether. Acute changes in select physiological parameters associated with cardiovascular physiology (systolic and diastolic blood pressure (BP) and heart rate (HR)), pulmonary function (FVC, FEV1, and exhaled CO and NO) and adverse events were measured in 105 clinically confined subjects who were randomized into groups that either completely or partially switched from conventional cigarettes to e-cigarettes or completely discontinued using tobacco and nicotine products altogether. Use of the e-cigarettes for five days under the various study

				conditions did not lead to higher BP or HR values, negative respiratory health outcomes or serious adverse health events. Reductions in BP and HR vital signs were observed in most of the participants that either ceased tobacco and nicotine products use altogether or switched completely to using e-cigarettes. Pulmonary function tests showed small but non-statistically significant improvements in FVC and FEV1 measurements in most use groups. Statistically significant ($p < 0.05$) benefits associated with smoking reduction were also noted in exhaled CO and NO levels. All study products were well tolerated. To summarise the conclusions "The study findings suggest that there are potential cardiovascular and pulmonary function benefits when smokers switch to using e-cigarette products. This further reinforces the potential that e-cigarettes offer smokers seeking an alternative to conventional tobacco products." *Source: D'Ruiz C, O'Connell G, Graff D, Yan X. Measurement of cardiovascular and pulmonary function endpoints and other physiological effects following partial or complete substitution of cigarettes with electronic cigarettes in adult smokers. RegulToxicolPharmacol. 2017 May 3;87:36-53. doi: 10.1016/j.yrtph.2017.05.002. [Epub ahead of print]* A recent prospective 3.5-year observational study, currently in press, has investigated lung health outcomes in a small cohort of daily e-cigarette users who have never smoked and a matched group of never smokers. No significant changes could be detected in the e-cigarette users or between e-cigarette users and control subjects in any of the health outcomes investigated, including lung function amongst others. Moreover, no pathological findings could be identified on high-resolution computed tomography of the lungs and no respiratory symptoms were consistently reported in the E-Cigarette user group. *Source: Polosa R. Cibella F. Caponnetto P. Maglia M. Prosperini U. Russo C. Tashkin D (in press) Health impact of E-cigarettes: a prospective 3.5-year study of regular daily users who have never smoked. Under Review at Scientific Reports.* In the light of the evidence, it would be more helpful to redraft the recommendation more positively, and to include encouraging statement to switch completely rather than *"dual use"* along the lines: *"Explain that e-cigarette users will gain most health benefit by switching completely and not continuing to smoke."*
25	Full	9	3-6	There is no reference to best practice configuration of specialist stop smoking services. In particular there is sufficient evidence from a recent high quality meta-analysis of RCTs to conclude that stop smoking support when included as part of a lifestyle intervention is not an effective approach, and there should be a recommendation setting this out as follows: *"Stop smoking support should be provided as a stand alone service and not as part of a lifestyle intervention package as this has not been shown to be effective. (Lifestyle intervention packages can include measures to reduce alcohol*

				intake, increase physical activity and adopt a healthy diet.)" Meader N, King K, Wright MA, Graham HM, Petticrew M, Power C, White M, Sowden AJ. Multiple Risk Behavior Interventions: Meta-analyses of RCTs. American Journal of Preventive Medicine. Volume 53, Issue 1, July 2017, Pages e19-e30 ASH's 2016 survey of local authorities found that 1 in 5 services are now being commissioned as part of a lifestyle service. It is essential that the guidelines make clear that the evidence does not support such an approach as has also been highlighted in the Government's recent Tobacco Control Plan. Sources: ASH, Cutting Down: The reality of budget cuts to local tobacco control, November 2016 DH, Towards a Smokefree Future: Tobacco Control Plan for England. July 2017 Furthermore, there is no reference here to the use of consumer e-cigarettes and that smokers using e-cigarettes should be supported by services. The evidence from the service returns indicates that where services support the use of e-cigarettes the success rates in quitting are higher. Therefore line 3 should include, after the word "pharmacotherapy" the wording "or consumer e-cigarettes". Source: NHS Digital, Statistics on NHS Stop Smoking Services: England, April 2016 to March 2017, August 2017
26	Full	9	7	**Section.1.3.12**: Even if advised to do so by their healthcare professional, not all patients will self-refer, or attend a separate stop smoking service, especially those for whom accessing health services is already problematic. Therefore if someone has agreed to try to quit, the healthcare professional who is able to prescribe (i.e. GP, nurse prescriber etc.) can optimise the chances of the person quitting by prescribing Nicotine Replacement Therapies (NRT) where appropriate.
27	Full	9	8	There is no reference to GP referral to specialist services here. After preferences the wording *"and where appropriate refer to specialist stop smoking services."* Should be added.
28	Full	10-11	1 -5 10-28 1-22	This text should be updated to bring it in line with the recommendations on page 4 that smokers should be prioritised where they have *"health conditions made worse by smoking or who have a smoking-related illness*" rather than refer only to smokers with respiratory and CVD conditions.

				Section 1.6 and 1.7 on Women who are pregnant or planning a family, and NRT for mothers of infants and young children are shaded grey as not for updating. However, these sections are out of date and inconsistent with PH26. We would therefore, suggest that the wording is removed and refer those working with pregnant women, mothers and families to the recommendations set out in PH26. For example PH 26 recommends an opt-out not opt-in process and carbon dioxide (CO) monitoring which is best practice and has been shown to be effective (see NIHR evaluation of BabyClear programme which follows NICE guidance). Furthermore PH26 includes recommendations that "Partners and others in the household who smoke" should be encouraged and supported to quit smoking. This is in line with the scope and page 19 lines 1-3 of the draft guideline which both say, *"Recommendations in areas that are not being updated may be edited to ensure that they meet current editorial standards, and reflect the current policy and practice context."*
29	Full	12	1	This is an NCSCT standard and this should be mentioned i.e. *"the NCSCT Standard for training in smoking cessation treatments or its updates."*
30	Full	12	8	**Section.1.8.4:** This is a very important point, but requires liaison and consultation with the professional bodies responsible for setting the curriculum for healthcare professionals, and adequate resources should be given for this process.
31	Full	12	10	**Section.1.8.5**: In addition to individual staff training, a broad-based adoption of a smoke-free policy by the whole organisation is also required.
32	Full	13	18	The section on closed institutions should also recommend allowing access to nicotine containing e-cigarettes as an option for smokers unable or unwilling to quit, as is already the case in prisons and some other closed institutions. This is in line with the scope which says, "Recommendations in areas that are not being updated may be edited to ensure that they meet current editorial standards, and reflect the current policy and practice context." This would also bring these guidelines in line with guidance CQC is providing to inspectors on the issue and best practice policies such as those at South London and Maudsley NHS Trust. Sources: CQC, Brief Guide: Smoke free policies in mental health inpatient services, January 2017: SLAM, Smokefree Policy, February 2017
33	Full	13	25	The section on employers should include a recommendation to develop a policy on use of e-cigarettes using PHE

				framework advice for businesses and employers. This is in line with the scope and page 19 lines 1-3 of the draft guideline which both say, *"Recommendations in areas that are not being updated may be edited to ensure that they meet current editorial standards, and reflect the current policy and practice context."*
34	Full	13	26	**Section.1.11.1**: Consider workplace smokefree policy guidance on using e-cigarettes, which supports their use as a smoking cessation aid (i.e. does not only permit e-cigarette users to use the same space as smokers, thereby potentially undermining their quit attempts) and also recognises the relative harm towards others caused by e-cigarettes as opposed to tobacco cigarettes. See Public Health England (PHE) E-cigarettes guidance on this matter.
35	Full	14	26-28	Products can only make medicinal claims if they receive a marketing authorisation by the medicines regulator the MHRA, otherwise they have to meet the requirements set out in the Tobacco Products Directive (TPD) as transferred into UK law by the Tobacco and Related Products Regulations 2016. Therefore the words *"health use"* should be removed and replaced with *"medicinal use"* and the words *"but will not be granted a licence for medicinal use".* in line 27-28 should be removed as they are now redundant. The words *"will also be subject to regulation by the MHRA"* need to be updated to *"are subject to regulation by the MHRA"* as the Directive is now in force. In addition the words *"European Union Tobacco Products Directive"* should be replaced by the *"Tobacco and Related Products Regulations 2016"* as per page 8 line 12. NB NICE needs to be aware that Committee of Advertising Practice/Broadcast Committee of Advertising Practice (CAP/BCAP) are currently consulting on removing the prohibition in the advertising rules for health claims. The consultation closed on Monday 16th October but it is not clear when the decision will be made.
36	Full	15	12	In line with our previous comment 19, with respect to page 8 line 6, the heading *"Nicotine replacement products"* on general sale should be revised to read "Nicotine containing products" on general sale, in line with the terminology used by the MHRA. The term "Nicotine replacement" is associated in practitioners' minds with NRT or "Nicotine Replacement Therapy" i.e. a long established set of licensed medicines including patches, gum etc. which does not include consumer e-cigarettes.
37	Full	17	14-17	The information in the Context section needs updating. The most recent Statistics on smoking in England were published in June 2017.
38	Full	17	19-21	The most recent data on costs of smoking to society were published in the Tobacco Control Plan for England in July 2017, See page 8. Total cost is estimated to be in excess of £11 billion. This does not include social care costs which have been estimated to be £1.4 billion every year, up from £1.1 billion in 2014. This is made up of £760 million in costs borne by local authorities, with a further £630 million being spent by those who have to self-fund their care. See ASH report.
39	Full	17	22-26	The Statistics on NHS stop smoking services in England were most recently published for the period April 2016 to March 2017 and the guideline should be updated with the most recent data.

40	Full	17	26	In addition to a reduction in the number of people using the stop smoking services there has also been a significant decline in the number of prescriptions for pharmacotherapies see table 2.1 from Statistics on Smoking in England 2017. The number of prescriptions of stop smoking medications has fallen by over 50% between 2010/11 when it peaked and 2015/16. This information should be added after line 26.
41	Full	18	11-17	The section on commissioning should also include reference to the role of the Sustainability and Transformation Plans and any other relevant local strategies and plans as is the case on page 4 lines 4-7.
42	Full	18	13	The Overview section refers to Cochrane reviews but not to the importance of population level data on smoking behaviour and stop smoking services in the real world, and specifically in the UK context. This includes data from stop smoking service returns, peer-reviewed journal articles from the Smoking Toolkit Survey, as well as the ASH YouGov surveys which specifically provide useful data on attitudes and behaviour with respect to e-cigarettes. There should be reference to the importance of a wide variety of data not just Cochrane reviews which rely on RCTs.
43	Full	19-20	27-30 1-6	The section on economic modelling makes clear that smoking cessation treatment is highly effective and cost-effective, but does not put it in context with other treatments. This is crucial given the growing postcode lottery in smokers' access to smoking cessation treatment as set out in the APPG on Smoking and Health report Burning Injustice, Reducing tobacco-driven harm and inequality, Recommendations to the government, local authorities and the NHS published in January 2017 and the King's Fund analysis by David Buck Chickens coming home to roost: local government public health budgets for 2017/18 published in July 2017.
44	Full	20	9	Update to include latest data and full cost to society including social care costs not just NHS costs. See Tobacco Control Plan p.8 and ASH report on social care costs. These guidelines are for commissioners including local authorities which are not responsible for NHS spend but are responsible for social care costs and concerned about the wider societal impacts.
45	Full	24	9-10	Unless people are asked whether they smoke they cannot be given advice and referral. Yet there is good evidence that all too often people are not asked, and even when they are asked, are often not given advice and referral. Therefore this section should reinforce the need for people to be asked about their smoking behaviour.
46	Full	27	9-19	There is no mention here either of the evidence that NRT is not effective at helping smokers quit when bought over the counter but is when prescribed by a doctor, reinforcing the importance of the recommendations on prescribing and encouraging effective use of medication. *Source: Kotz D, Brown J, West R. 'Real-world' effectiveness of smoking cessation treatments: a population study. Addiction. 2014 Mar;109(3):491-9. doi: 10.1111/add.12429. Epub 2013 Dec 20.*
47	Full	28	7-9	We do not agree that *"There is limited evidence on the type and range of stop smoking services that should be available to tackle high rates of smoking and reduce health inequalities particularly on quit rates amongst those from disadvantaged groups."* and we recommend that this sentence be removed. This also relates to research

				recommendations, see below. There is evidence that the standard stop smoking services model is effective and provides appropriate support to tackle high rates of smoking and reduce health inequalities. Considerable public funds have been spent on studies in the UK, commissioned by the Department of Health, NIHR and the Chief Scientist's Office of the Scottish government that specifically aimed to provide this type of evidence. To ignore these studies or not mention them simply because they are not RCTs is to exclude a significant body of relevant evidence. Sources: *Hiscock R, Dobbie F and Bauld L (2015). Smoking Cessation and Socioeconomic Status: An Update of Existing Evidence from a National Evaluation of English Stop Smoking Services. Biomed Research International. http://www.hindawi.com/journals/bmri/aa/274056/ doi:10.1155/2015/274056.* *Hiscock, R, Murray, S, Brose, L.S, McEwan, A, Leonardi Bee, J, Dobbie, F and Bauld, L (2013) Behavioural therapy for smoking cessation: The effectiveness of different intervention types for disadvantaged and affluent smokers Addictive Behaviours 38(11): 2787–2796. doi: 10.1016/j.addbeh.2013.07.010* *Dobbie, F, Hiscock, R, Leonardi-Bee, Murray, S, Shahab, L, Aveyard, P, Coleman, T, McEwen, A, McRobbie, H, Purves, R and Bauld, L (2015) Evaluating Long-term Outcomes of NHS Stop Smoking Services (ELONS): a prospective cohort study. Health Technology Assessment. Vol 19 issue 95 November ISSN 1366-527,* *Bauld, L., Ferguson, J., McEwen, A., & Hiscock, R. (2012). Evaluation of a drop - in rolling - group model of support to stop smoking. Addiction, 107(9), 1687-1695.* *Also the following papers looks at costs specifically:* *Boyd, K. A., & Briggs, A. H. (2009). Cost-effectiveness of pharmacy and group behavioural support smoking cessation services in Glasgow. Addiction, 104(2), 317-325.* *Bauld, L, Boyd, K, Briggs, A, Chesterman, J, Ferguson, J, Judge K and Hiscock, R. (2011) One year outcomes for smokers accessing group-based and pharmacy-led smoking treatment services: a cost-effectiveness study,* Nicotine and Tobacco Research. *13(2):135-45. doi: 10.1093/ntr/ntq222*
48	Full	28	12-20	This is an important recommendation. It would be helpful to acknowledge that the evidence so far suggests e-cigarettes are a helpful aid to quitting (see references below).

				We recommend the addition of an opening sentence on line 13 to read, "The evidence so far suggests that consumer e-cigarettes are an effective aid to quitting smoking, but more research is needed in this rapidly evolving area." We would also suggest adding at the end of line 20 *'It is also important to investigate whether supporting the use of e-cigarettes in quit attempts through stop smoking services or by healthcare professionals can increase their effectiveness.'* There is some evidence from the stop smoking service returns that this is the case, but it needs to be properly researched. Two of the most commonly cited reasons in the annual ASH smokefree GB survey for electronic cigarette use are to quit smoking or prevent relapse. See ASH Factsheet Use of e-cigarettes (vapourisers) among adults in Great Britain. Population level evidence from the UK shows that e-cigarettes are now the most widely used quitting aid and that they are helping smokers to quit. Brown J, Beard E, Kotz D, Michie S, and West R. Real-world effectiveness of e-cigarettes when used to aid smoking cessation: A cross-sectional population study. *Addiction* 2014. 109: doi: 10.1111/add.12623. Beard E, West R, Michie S, and Brown J 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. BMJ 2016;354:i4645 And it is worth noting that the evidence is not just from the UK. A recent US study concludes that the substantial increase in e-cigarette use among US adult smokers was associated with a statistically significant increase in the smoking cessation rate at the population level. Zhu S-H, Zhuang Y-L, Wong S, Cummins SE, Tedeschi GJ. E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys. BMJ 2017;358:j3262
49	Full	28	4-11	Research Recommendation: "*What is the relative effectiveness and cost effectiveness of different types of service model to deliver stop smoking interventions and behavioural support?"* See our comments above on statements regarding the evidence on stop smoking services. If the above text is included as a research recommendation, the explanatory text below needs to be changed to make it clear that there ARE recent studies that already directly address this question, it is simply that NICE did not review them in their evidence reviews because they were not Randomised Controlled Trials. For example, NIHR commissioned a study costing in excess of £750,000 (the ELONS study) which was recently published in full in their journal Health

				Technology Assessment. This was conducted by researchers in the UK Centre for Tobacco and Alcohol Studies. The aim of the study was to explore the factors that determine longer term abstinence from smoking following intervention by Stop Smoking Services (SSS). The study objectives were to: 1) use routine data to examine the effectiveness of SSS by trusts and intervention type 2) explore the reach of services by identifying what proportion of the local population set a quit date with services using routine data 3) describe the factors that determine longer term abstinence from smoking or relapse to smoking amongst clients who set a quit date with services in a sample of trusts in England 4) examine the relationship between client characteristics (in particular socio-economic status, age, gender, disability and ethnicity), adherence to treatment, intervention type received, and longer term abstinence 5) create an evidence base to guide delivery of interventions by stop smoking services so that these interventions will have maximal effect on smoking cessation and population health Source: *Dobbie, F, Hiscock, R, Leonardi-Bee, Murray, S, Shahab, L, Aveyard, P, Coleman, T, McEwen, A, McRobbie, H, Purves, R and Bauld, L (2015) Evaluating Long-term Outcomes of NHS Stop Smoking Services (ELONS): a prospective cohort study. Health Technology Assessment. Vol 19 issue 95 November ISSN 1366-527,* Other publications from this study and indeed previous studies from UKCTAS which also sought to explore similar questions are referenced in our comment 39 above. If this research recommendation is to stay included, we are sure that NICE would agree that NIHR or other funders drawing on this to commission a study similar to ELONS study would not be a prudent use of public funds. An alternative, if the recommendation stays in, would be to modify the 'Why this is important' text that appears on line 6-11 on page 28. Suggestions for modifications: There is limited evidence *from randomised controlled trials* on the type and range of stop smoking services that should be available to tackle high rates of smoking and reduce health inequalities particularly on quit rates amongst those from disadvantaged groups. There is also little known from *randomised controlled trials* on the impact of the provider of the service and content of the package on effectiveness outcomes.

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				Of course the reason why there are no UK RCTS of stop smoking services, but instead a series of well-designed observational studies, is because these services already exist and are publicly funded. To randomise smokers to receive them or not receive them would be considered unethical given the volume of published evidence that already shows that they are effective. It would also be difficult to randomise smokers to different configurations of services (for example, pharmacy based one to one vs more intensive group support) because studies have already been published that compare different configurations of support within the services but without randomisation (i.e *Bauld, L, Boyd, K, Briggs, A, Chesterman, J, Ferguson, J, Judge K and Hiscock, R. (2011) One year outcomes for smokers accessing group-based and pharmacy-led smoking treatment services: a cost-effectiveness study,* Nicotine and Tobacco Research*. 13(2):135-45. doi: 10.1093/ntr/ntq222)* In our view this research recommendation needs to be modified, or at least with caveats to make clear that the gaps are in evidence from RCTs, not the evidence overall.
50	Full	30-40		We have made suggestions for substantive changes to the recommendations which apply to the recommendations as repeated here too.
51	Full	31	Table	**Changes in recommendation 4**. The sentence *"Nurses who are trained NHS stop smoking counsellors may 'refer' to themselves where appropriate"* has been removed without providing a justification. The new wording suggests that only brief intervention and pharmacotherapy can be provided outside specialist services. Patients who would like to quit but do not wish to be referred to smoking cessation specialist services should be able to receive behavioural therapies as well as pharmacological interventions if the healthcare professional has been trained according to the NCSCT's training standards and deems this appropriate.

Insert extra rows as needed

Smoking cessation interventions and services

NICE National Institute for Health and Care Excellence

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