

## Smoking cessation interventions and services

### Appendix B: Review protocol

*NICE guideline NG92*

*Appendices*

*March 2018*

**November 2021:** NICE guideline NG92 (March 2018) has been updated and replaced by NG209. The recommendations labelled [2018] or [2018, amended 2021] in the updated guideline were based on these evidence reviews.

See [www.nice.org.uk/guidance/NG209](http://www.nice.org.uk/guidance/NG209) for all the current recommendations and evidence reviews.

*FINAL*

*These evidence reviews were developed by  
Public Health Internal Guideline Development  
team*

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The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The recommendations in this guideline are not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

Local commissioners and/or providers have a responsibility to enable the guideline to be applied when individual health professionals and their patients or service users wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with compliance with those duties.

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# Approach and protocol for evidence review

## Smoking cessation interventions and services

### Document history

Stage	Date completed
Review team – draft	3 February 2016
Review team – finalised for QAM	9 February 2016
Quality assurance – approval	Date to be added
Review team – revision	26 May 2016 (ongoing)
QA Centre – sign off date	Protocol 15 February 2016
Review team revisions	To stepped approach – searching conducted across Review Questions, citation searching on included reviews prioritised
Revised following discussions at Technical Team Meeting 14/06/2016	To reflect the published scope and the Review of Cochrane Reviews (R0), i.e. varenicline, harm reduction

### Guideline reference

Guideline webpage	<a href="https://www.nice.org.uk/guidance/indevelopment/gid-phg94/">https://www.nice.org.uk/guidance/indevelopment/gid-phg94/</a>
Scope (draft)	<a href="https://www.nice.org.uk/guidance/GID-PHG94/documents/draft-scope">https://www.nice.org.uk/guidance/GID-PHG94/documents/draft-scope</a>
Committee	PHAC F

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## Introduction

This guideline will be a partial update of NICE guidelines on brief advice and referral for smoking cessation (PH1) and smoking cessation services (PH10), based on the review decisions for [PH1](#) and [PH10](#), stakeholder comments on the draft scope and engagement with Public Health England.

Particular consideration has been given to the inclusion of licensed therapeutically indicated or consumer (also known as regulated) e-cigarettes<sup>1</sup> in the guideline. The remit of this guideline is smoking cessation. This is not an update of the Tobacco harm reduction guideline (PH45).

The guideline will consider:

- **Brief advice**, very brief advice
- **Behavioural support**
- **Pharmacotherapies** (nicotine replacement therapy, including licensed e-cigarettes and bupropion)
- Variations in the effectiveness and cost effectiveness of the above by person delivering the intervention, setting and media used (namely, **digital media**)
- **Consumer e-cigarettes** (advice and referral)

The evidence reviews will take an innovative approach in order to make best use of available resources and deliver evidence review for a broad scope.

The evidence identification will use an iterative approach, developed over a series of discrete steps that take into consideration evidence identified in progressive stages (see stepped approach to evidence identification page 5). For some review questions, not all steps will be used as evidence is judged to be sufficient for the committee to make a new or updated recommendation (or agree that a recommendation is unchanged).

This approach is in line with [Developing NICE guidelines: the manual](#) which states, '*A flexible approach will allow evidence to be identified both systematically and in the most efficient manner*'.

The systematic review methods will also use expertise from PHAC, invited experts, stakeholders, which will include a call for evidence. Methods

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<sup>1</sup>Licensed, **therapeutically indicated e-cigarettes**—are, granted a marketing authorisation from MHRA (or EMEA) which indicates (in [section 4.1](#) of the summary of product characteristics) that the technology is for smoking cessation or harm reduction or **Consumer e-cigarettes** —are, regulated by the MHRA as [consumer](#) e-cigarettes, with no therapeutic indication and vaporising liquid with nicotine no more than 20 mg/ml

Collaboration with the [Cochrane Tobacco Addiction Group](#) on relevant evidence resources has also been established.

In addition to be above, the guideline development team will conduct systematic reviews of bibliographic databases on smoking cessation supported by other NICE guideline development methods such as focused use of call for evidence and expert testimony.

## **Review questions**

To identify the evidence to meet the requirements of the final scope published on the NICE website, the topic areas and principle review questions (RQ) are defined as follows:

### **Brief and very brief advice**

**RQ1** Is brief advice from a community, health or social care professional effective and cost effective?

**RQ2** Is very brief advice from a community, health or social care professional effective and cost effective?

### **Behavioural support**

**RQ3** Is behavioural support (delivered to a person or a group) effective and cost effective?

Review questions 1, 2 and 3 will also consider, within the evidence identified, the following supplemental review questions:

- RQ1S, RQ2S, RQ3S Do effectiveness and cost effectiveness vary according to the person delivering it and the way it is delivered (including media, for example print based media or digital media used or setting)?

### **Pharmacotherapy**

**RQ4** Is nicotine replacement therapy (established therapies, for example patch, gum or spray or newer, licensed e-cigarettes) or bupropion, on their own or combined with behavioural support, effective and cost-effective?

RQ4 will also consider within the evidence identified:

- RQ4S1 Do effectiveness and cost effectiveness vary when over the counter NRT is used (on its own or combined with behavioural support)?

- RQ4S2 (explored in analysis) Do effectiveness and cost effectiveness vary by NRT preparation used alone or in combination with other NRT or bupropion (on their own or combined with behavioural support)?

### ***Role of digital media***

**Review Question 5** Is digital media in smoking cessation interventions effective as an adjunct to very brief or brief advice, behavioural support, or pharmacotherapy?

### ***Options for consumer e-cigarettes***

**Review Question 6** What advice and referral options are appropriate for people using consumer e-cigarettes?

Review Question 6, about consumer e-cigarettes will draw on findings of components of RQ1/2/3S/R4. It may be particularly suited to being informed by a focused call for evidence.

## **Stepped approach to evidence identification**

The approach proposed includes the use of all elements of a comprehensive search strategy, but structures the approach as a set of ‘steps’ which inform decisions as to whether subsequent elements of the searching (and reviewing) are necessary to meet the needs of the committee considering update or development of recommendations.

A detailed search strategy is provided in the [appendix](#).

***Table 1 - Stepped search strategy***

<b>Step 1</b>	<b>Search CDSR<sup>2</sup></b> to identify Cochrane Systematic Reviews
<b>Step 2</b>	<b>Identifying primary studies</b> to supplement the Cochrane Reviews with more up to date information
<b>Step 3</b>	Identifying evidence from <b>grey literature</b> applicable to the UK
<b>Step 4</b>	<b>Named interventions</b> search for specific programmes, initiatives or services identified from sifting the results from steps 1-3.

<sup>2</sup> Cochrane Database of Systematic Reviews

<b>Step 5</b>	Additional searches to identify <b>cost effectiveness and economics</b> literature
<b>Pause</b>	Gap analysis to prioritise next searching activity. The next steps could include some or all of the following:
<b>Step 6</b>	Review of reviews to capture <b>non-Cochrane systematic reviews</b> and meta-analyses which address the gaps identified in the evidence
<b>Step 7</b>	Reference harvesting to <b>extract the primary studies</b> from the reviews and meta-analyses identified in steps 1 and 6
<b>Step 8</b>	Named <b>author</b> searches
<b>Step 9</b>	Gap search for <b>named populations or settings</b>
<b>Step 10</b>	Gap search for <b>aspects of care or delivery</b>

Consideration will be given to the need and value of conducting steps in **grey** fill.

The guideline development team will work closely with the [Cochrane Tobacco Addiction Group](#) (Cochrane TAG) to add value to the evidence reviews. This has included TAG offering access to review update schedules, intelligence on the likelihood that conclusions of reviews currently being updated, access to prepublication reports, expert networks and access to TAG database of trials (useful for steps 2, 4 and 5). The TAG will remain independent of NICE.

## Evidence selection methods

Methods for evidence review and reporting will conform to The Manual and use experience from preceding PHSC internal guidelines development-led guidelines.

A set of review question and method specification is provided below. The review of reviews (R0) will aim to provide a brief summary of the key characteristics of the Cochrane systematic reviews. The features of the specification will be broadly similar for reviews 1-3. Review 4 (consumer e-cigarettes) will focus on more descriptive evidence. Review 5 (digital media)

will draw on the findings of reviews 1-4, with supplementary inputs from a call for evidence.

The full search strategy is provided in the appendix. This has been peer quality assured by guidance information services (GIS) and reviewed and supported by the associate director – surveillance and methods.

### ***Analytical approach and presentation***

EPPI-reviewer 4 will be used for review management and meta-analysis.

Presentation of evidence tables, quality assessment and reporting will be in line with The Manual ([appendix H](#)). Evidence statements will be developed in line with The Manual.

Review of stop smoking service providers' and users' experience for people using consumer cigarettes (review question 6) will be presented in a short report format (similar to the TB 'information, education or other support used in practice' review for [NG33](#)) with descriptive 'summary' statements. Digital media in use in the interventions identified in reviews 1-4 will be described in short report format.

A number of elements within the protocols are common across review questions 1-3 namely:

- types of study to be included/excluded;
- participants/population,
- methods for selecting evidence (data screening);
- data extraction and quality assessment;
- strategy for data synthesis;
- analysis of subgroups
- any other information or criteria for inclusion or exclusion.

To reduce repetition these details have been given only in reference to question 1, for other questions please cross refer to question 1.

## **Review question 0: Review of reviews**

The review will consider systematic reviews of comparative studies.

<b>Review 0</b>	Review of reviews	
<b>Component</b>	<b>Description</b>	<b>Additional comments</b>
Review question		
Context and objective	A review of Cochrane systematic reviews will be undertaken to identify existing reviews that address or partially address the scope and review questions. If directly relevant published review-level evidence is identified, this could be used as a suitable basis for PHAC decisions about whether existing recommendations are either supported or require updating.	
Searches	The identification of evidence for this review will conform to the methods set out in chapter 5 of the Developing NICE Guidelines Manual. Cochrane Database of Systematic Reviews (CDSR) will be searched systematically to identify relevant quantitative and cost effectiveness evidence using a combination of subject headings and free-text terms to describe cigarettes, smoking, tobacco and nicotine (see appendix for details). No date or other limits will be applied to the search. The database search will be supplemented by browsing the publication lists for relevant Cochrane Groups (Airways, Consumers & Communications, Effective Practice & Organisation of Care, Lung Cancer, Oral Health, Public Health and Tobacco Addiction) on the Wiley website.	
Types of study to be included /excluded	Systematic reviews of comparative studies (Randomised or non-randomised controlled trials; before and after studies)	

Population	<p>All adults and young people aged 12 or over who smoke tobacco</p> <p>Exclusions: pregnant women</p>	
Intervention	<ul style="list-style-type: none"> <li>• Brief advice</li> <li>• Very brief advice</li> <li>• Behavioural support</li> <li>• Pharmacotherapies (nicotine replacement therapy, including licensed e-cigarettes and bupropion)</li> <li>• Digital media (used as part of any of the above interventions)</li> </ul> <p><b>Exclusions:</b></p> <ul style="list-style-type: none"> <li>• Varenicline</li> <li>• Telephone quitlines*</li> <li>• Mass media campaigns</li> <li>• Workplace interventions</li> <li>• Exercise interventions</li> <li>• Acupuncture, auricular therapy, hypnotherapy or physiotherapy for smoking cessation</li> <li>• Education and training</li> <li>• Strategies, policies and plans</li> </ul>	<p>*Telephone quitlines will be excluded if part of a national service. If the intervention includes quitlines as part of local service, the study will be included.</p>
Comparator	<ul style="list-style-type: none"> <li>• No intervention</li> <li>• Usual care</li> <li>• Period after, compared with before, intervention</li> <li>• Any of the above included interventions compared with each other</li> </ul>	

<p>Outcomes</p>	<ol style="list-style-type: none"> <li>1. Quitting: <ul style="list-style-type: none"> <li>• Number of people who smoke who quit smoking (this may be self-reported and/or biochemically validated) considered: <ul style="list-style-type: none"> <li>○ short term (up to 4 week) abstinence rates</li> <li>○ medium term (up to 3 months and 6 month) abstinence rates</li> <li>○ long term (1 year or longer) abstinence rates</li> </ul> </li> <li>• Number of people setting a quit date</li> <li>• Duration of quit attempt after intervention is delivered</li> <li>• Relapse rates</li> </ul> </li>   <li>2. Amount of tobacco people smoke (in context of smoking cessation not harm reduction)</li>   <li>3. Behavioural outcomes (for example, positive changes in knowledge about, and attitudes to, smoking)</li>   <li>4. Contact with and uptake of stop smoking services</li>   <li>5. Mortality and morbidity</li>   <li>6. Quality of life</li>   <li>7. Economic outcomes, such as: <ul style="list-style-type: none"> <li>• costs, savings and resource use</li> <li>• incremental costs, or incremental outcome/effects (QALYs) and ICERs)</li> </ul> </li>   <li>8. User experience or preferences (reported with the identified studies)</li> </ol>	
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<p>Selecting evidence (screening)</p>	<p>All references from the database searches will be screened on title and abstract against the criteria set out in the protocol. A random sample of 10% of titles and abstracts will be screened by two reviewers independently, with differences resolved by discussion. Full-text screening will be carried out by two reviewers independently on 100% of papers. Any differences will be resolved by discussion.</p>	
<p>Data extraction and quality assessment</p>	<p>Each included study will be data extracted by 1 reviewer and the data extraction sheet will be confirmed by a second reviewer. Any differences will be resolved by discussion or recourse to a third reviewer.</p> <p>Data will be presented using 'evidence profiles'. This is similar to evidence tables but with only key characteristics of the review, statements summarising each review's findings and potential relevance to updating recommendations. Quality assessment will be conducted using the AMSTAR quality appraisal checklist.</p>	
<p>Strategy for data synthesis</p>	<p>Data will be grouped and synthesised into concise evidence statements in line with <a href="#">Developing NICE guidelines: the manual</a>.</p>	

Analysis of subgroups or subsets	Not applicable.	
Any other information or criteria for inclusion or exclusion	<p>Settings – participants solely recruited from or interventions solely delivered in:</p> <ul style="list-style-type: none"> <li>• Workplaces, residential and custodial settings</li> <li>• Maternity services in primary care</li> <li>• Acute, secondary and mental health services including maternity care.</li> <li>• Educational institution</li> </ul> <p>Interventions – focusing on:</p> <ul style="list-style-type: none"> <li>• Smoking of non-tobacco products</li> <li>• Non-smoking use of tobacco</li> <li>• Population level approaches</li> </ul>	

***Review question 1 and 2: brief and very brief advice***

<b>RQ1 and RQ2</b>	Brief advice	
<b>Component</b>	<b>Description</b>	<b>Additional comments</b>
Review questions	<p><b>RQ1</b> Is brief advice from a community, health or social care professional effective and cost effective?</p> <p><b>RQ2</b> Is very brief advice from a community, health or social care professional effective and cost effective?</p>	2 review questions covered in review 1.
Context and objectives	To determine the effectiveness and cost effectiveness of:	

RQ1 and RQ2	Brief advice	
Component	Description	Additional comments
	<p><b>Brief advice</b> for smoking cessation or harm reduction from a community, health or social care professional</p> <p><b>very brief advice</b> for on smoking cessation or harm reduction from a community, health or social care professional</p> <p>To determine how effectiveness and cost effectiveness varies according to the person delivering it and the way it is delivered (including media used or setting).</p>	
Searches	<p>The identification of evidence for this review will conform to the methods set out in chapter 5 of the Developing NICE Guidelines Manual.</p> <p>Sources to be searched: the stepped approach will be used, following steps 1-5. It will begin with the CDSR and then seek up to date evidence from primary studies using a range of databases (see <a href="#">appendix</a>).</p> <p>Supplementary search techniques include: web searching for grey literature, checking reference lists of relevant systematic reviews, checking reference lists of all included studies to identify further relevant primary research and searching citations of included studies using Web of Science. These are outlined in steps 1-5 (see <a href="#">appendix</a> for detail).</p> <p>Limits: Filters, where available, will be used to limit to English language and exclude studies on animals, editorials, news items, letters and conference abstracts.</p> <p>Date ranges will adapt according to the step considered. Step 2 will search from an agreed margin from publication of most recent primary study included in the included reviews (or review search dates).</p> <p>UK relevant, international (OECD) evidence considered.</p>	<p>The focus of the reviews that informed recs in PH1 and PH10 will be taken into consideration in setting limits of searching by region. (A significant portion of the evidence included for PH1 and PH10 was UK-based, but other regions were also included.)</p>
Types of study to be included/ excluded	<p>Comparative studies:</p> <ul style="list-style-type: none"> <li>• Systematic reviews* of comparative studies (also as a source of primary studies)</li> <li>• Randomised or non-randomised controlled trials</li> <li>• Cohort studies</li> </ul>	<p>If a large number of papers are included at full text stage consideration will also be given to limiting any step 2, 3, 4 searches to higher</p>

RQ1 and RQ2	Brief advice	
Component	Description	Additional comments
	<ul style="list-style-type: none"> <li>• Before and after studies</li> </ul> <p>Studies will be included if they either contain a comparison group receiving different interventions (randomised, cluster randomised or quasi controlled trials) or present outcome data for both before and after an intervention (before and after studies, interrupted time series or cohort studies).</p> <p>Exclusions: See 'exclusion criteria'</p>	quality study designs.
Participants/ population	<p>All adults and young people aged 12 or over who smoke tobacco</p> <p>Particular interest in groups who have high rates of smoking or smoke more cigarettes</p> <p>Exclusions: See 'exclusion criteria'</p>	In the event of more evidence being identified that is feasible to consider in the time available, priority will be given to considering evidence on groups at greatest risk, as identified in the equity impact assessment and PHAC expertise.
Interventions	<p>Brief interventions involve opportunistic advice, discussion, negotiation or encouragement. They are commonly used in many areas of health promotion and are delivered by a range of primary and community care professionals.*</p> <p><b>Brief advice</b> interventions typically take <b>5-10 minutes</b> and include 1 or more of the following:</p> <ul style="list-style-type: none"> <li>• simple opportunistic advice to stop</li> <li>• an assessment of the person's commitment to quit</li> <li>• an offer of pharmacotherapy and/or behavioural support</li> <li>• provision of self-help material and referral to more intensive support such as Stop smoking services.</li> </ul> <p><b>Very brief advice:</b> simple opportunistic advice to stop smoking given as the opportunity arises, typically in less than <b>30 seconds</b>.</p> <p>Exclusions: See 'exclusion criteria'</p>	<p>*This may include non-healthcare professionals and/or practitioners working outside the health sector who have a remit for smoking cessation (for example, 'health trainers' working in local authority or other community settings).</p> <p>Studies comparing very brief advice with brief advice will be included.</p>

RQ1 and RQ2	Brief advice	
Component	Description	Additional comments
Comparator(s)/ control	Comparators that will be considered are: <ul style="list-style-type: none"> <li>• No intervention</li> <li>• Usual care</li> <li>• Period after, compared with before, intervention</li> <li>• Behavioural support interventions</li> <li>• Pharmacotherapy interventions</li> </ul>	
Outcomes	<ol style="list-style-type: none"> <li>1. Quitting:               <ul style="list-style-type: none"> <li>• Number of people who smoke who quit smoking (this may be self-reported and/or biochemically validated) considered:                   <ul style="list-style-type: none"> <li>○ short term (up to 4 week) abstinence rates</li> <li>○ medium term (up to 3 months and 6 month) abstinence rates</li> <li>○ long term (1 year or longer) abstinence rates</li> </ul> </li> <li>• Number of people setting a quit date</li> <li>• Duration of quit attempt after intervention is delivered</li> <li>• Relapse rates</li> </ul> </li> <li>2. Amount of tobacco people smoke</li> <li>3. Behavioural outcomes (for example, positive changes in knowledge about, and attitudes to, smoking)</li> <li>4. Contact with and uptake of stop smoking services</li> <li>5. Mortality and morbidity</li> <li>6. Quality of life</li> <li>7. Economic outcomes, such as:               <ul style="list-style-type: none"> <li>• costs, savings and resource use</li> <li>• incremental costs, or incremental outcome/effects (QALYs) and ICERs)</li> </ul> </li> <li>8. User experience or preferences (reported with the identified studies)</li> </ol>	<p>The primary outcomes reflect the stated aims of the scope (and clinical importance and key benefits to people who smoke).</p> <p>The secondary outcomes reflect the broader outcomes that may be reported.</p> <p>PHAC will be asked to comment on importance and priority of outcomes.</p> <p><i>Outcomes listed not exhaustive.</i></p> <p><i>Information to inform subgroup analysis will also be collected see below.</i></p>
Selecting evidence (screening)	<ol style="list-style-type: none"> <li>1. Title abstract screening</li> </ol> <p>All references from the database searches will be downloaded, de-duplicated and screened on title and abstract against the criteria above.</p> <p>Where no abstract is available and the title or</p>	

RQ1 and RQ2	Brief advice	
Component	Description	Additional comments
	<p>keywords indicate the study might be relevant a web search will be used to locate one; if none is found, references will be screened on title alone.</p> <p>A randomly selected initial sample of 10% of records will be screened by 2 reviewers independently. The rate of agreement for this sample will be recorded, and if it is over 90% then remaining references will screened by one reviewer only. Disagreement will be resolved through discussion.</p> <p>The option of selecting records for discussion will be included in the selection guide for reviewers. Discussion will be used to refine evidence selection.</p> <p>Where abstracts meet the inclusion criteria, or if it is unclear from the study abstract whether it does, the full text will be retrieved.</p> <p>2. Full text screening</p> <p>Full-text screening of papers will be carried out by 2 reviewers independently on a 10% sample and any differences resolved by discussion. The rate of agreement for this sample will be recorded, and if it is over 90% then remaining references will screened by one reviewer only. Disagreement will be resolved through discussion.</p> <p>The option of selecting records for discussion will be included in the selection guide for reviewers. Discussion will be used to refine evidence selection.</p> <p>Primary reason for exclusion will be recorded.</p> <p>Inter-rater agreement on inclusions will be recorded.</p> <p>3. Exclusions</p> <p>As noted in review question 0.</p> <p>Outcome – exclusions are unlikely on this basis alone.</p> <p>If a study does not report any comparative outcomes, attempts will be made obtain further information by searching on that record (part of the stepped approach) or to contact the researchers for further information (if resource allows). If not comparative data are obtained,</p>	

RQ1 and RQ2	Brief advice	
Component	Description	Additional comments
	<p>the record will be excluded and the reason noted.</p> <p>Full text records excluded for this review topic, but relevant to another reviewquestion will be noted.</p>	
Data extraction and quality assessment	<p>Data extraction of included studies will be conducted using approaches described in <a href="#">Developing NICE guidelines: the manual</a>. Each included study will be data extracted by 1 reviewer and the data extraction sheet will be confirmed by a second reviewer. Any differences in will be resolved by discussion or recourse to a third reviewer.</p> <p>Quality assessment for all included studies will be conducted using the tools in <a href="#">Developing NICE guidelines: the manual</a>. For economic evaluations, the economic evaluation checklist in Appendix H of <a href="#">Developing NICE guidelines: the manual</a> will be used to assess study quality. Each included study will be quality assessed by 1 reviewer and checked by another. Any differences in quality grading will be resolved by discussion or recourse to a third reviewer.</p> <p>Other quality appraisal tools will be considered, namely, Cochrane Risk of Bias (RoB) (included in appendix H).</p> <p>Each study will be rated (++, + or -) to denote its quality.</p>	
Strategy for data synthesis	<p>Data will be grouped and synthesised into concise evidence statements in line with <a href="#">Developing NICE guidelines: the manual</a>. See below for potential <i>a priori</i> groupings.</p> <p>If sufficiently homogeneous and high-quality data are located, meta-analysis will be conducted.</p> <p>All outcomes of direct relevance to the scope, including any adverse outcomes or unintended consequences, will be reported.</p>	
Analysis of subgroups or subsets	<p>Appropriate groupings for data synthesis may be based on the following:</p> <ul style="list-style-type: none"> <li>• Components of the intervention</li> <li>• Setting <ul style="list-style-type: none"> <li>○ Country, community, social care or healthcare setting</li> </ul> </li> </ul>	

RQ1 and RQ2	Brief advice	
Component	Description	Additional comments
	<ul style="list-style-type: none"> <li>• Population <ul style="list-style-type: none"> <li>○ Subgroup analyses may be undertaken to explore variations in the effectiveness and cost-effectiveness of brief advice and very brief advice among certain populations. Particular consideration will be given to any variations by age, gender, race, geographical location and socioeconomic status.</li> </ul> </li> <li>• Cessation attempt history, level of dependence</li> <li>• Intervention <ul style="list-style-type: none"> <li>○ Grouping according characteristics of the person delivering the intervention and media used will be considered</li> <li>○ Frequency of intervention</li> </ul> </li> <li>• Concomitant interventions and cessation aids used as part of quit attempt</li> </ul> <p>Further groupings will be considered once included studies have been identified. Any <i>post hoc</i> or explorative subgroup analysis will be labelled as such and reasons for the proposed grouping given.</p>	
Any other information or criteria for inclusion or exclusion	<p>Exclusions</p> <ul style="list-style-type: none"> <li>• Not English language</li> <li>• Research conducted in region outside those specified in the inclusion criteria: <ul style="list-style-type: none"> <li>○ Non OECD</li> <li>○ For some review questions, non EU or non UK</li> </ul> </li> <li>• Dissertations and theses</li> <li>• Opinion pieces (such as letters, editorials, commentaries)</li> <li>• Conference abstracts*</li> <li>• Poster presentations</li> <li>• Publications after the searching has concluded</li> </ul> <p><i>To be developed through each review step</i></p>	*Conference abstracts will be filtered out of search results for steps 2, 3 and 4. This will not be screened for inclusion as part of the main reviewing effort, but may be considered as a source of evidence to address gaps (such as in steps 5-10 of the staged approach).
Strategy to manage large number of full text	If a large number of papers are included at full text stage, advice will be sought from topic experts as to priority areas (settings,	

<b>RQ1 and RQ2</b>	<b>Brief advice</b>	
<b>Component</b>	<b>Description</b>	<b>Additional comments</b>
	<p>populations, interventions) for review.</p> <p>The focus of the reviews that informed recommendations in PH1 and PH10 will be taken into consideration in setting limits of searching by region. (A significant portion of the evidence included for PH1 and PH10 was UK-based, but other regions were also included.)</p> <p>If large numbers of papers are identified and included at full text, the following may be implemented:</p> <p>Consideration of any date limitations are informed by review search dates and experts if appropriate.</p> <p>Prioritising evidence review for:</p> <ul style="list-style-type: none"> <li>• Priorities for recommendation development</li> <li>• Areas of greatest uncertainty</li> <li>• Newer evidence</li> <li>• UK based studies</li> <li>• Studies with lower risk of bias</li> <li>• Groups at greatest risk</li> </ul>	

### **Review question 3: behavioural support**

<b>Review question 3</b>	Behavioural support	
<b>Component</b>	<b>Description</b>	<b>Additional comments</b>
Review question	<b>RQ3</b> Is behavioural support (delivered to a person or a group) effective and cost effective?	
Context and objectives	To determine the effectiveness and cost effectiveness of:  <b>behavioural support</b> delivered to a person or a group as part of a smoking cessation attempt  To determine how effectiveness and cost effectiveness varies according to the person delivering it and the way it is delivered (including media used or setting).	
Methods - summary	As review question 1	
Searches	As review question 1	The focus of the reviews that informed recommendations in PH1 and PH10 will be taken into consideration.
Types of study to be included/ excluded	As review question 1	
Participants/ population	As review question 1	
Interventions	Individual behavioural counselling  Individual behavioural counselling, , involves scheduled face-to-face meetings between someone who smokes and a counsellor trained in smoking cessation. Typically, it involves weekly sessions over a period of at least 4 weeks after the quit date and is normally combined with pharmacotherapy.  Group behaviour therapy  Group behaviour therapy programmes, involves scheduled meetings where people who smoke receive information, advice and encouragement and some form of behavioural intervention (for example, cognitive behavioural therapy). This therapy is offered weekly for at least the first 4 weeks of a quit attempt (that is, for 4 weeks following the quit date). It is normally combined	Based on description in PH10.  Studies comparing individual behavioural counselling with group behaviour therapy will be included

<b>Review question 3</b>	Behavioural support	
<b>Component</b>	<b>Description</b>	<b>Additional comments</b>
	with pharmacotherapy.	
Comparator(s)/ control	As review question 1	
Outcomes	As review question 1	
Selecting evidence (screening)	As review question 1	
Data extraction and quality assessment	As review question 1	
Strategy for data synthesis	As review question 1	
Analysis of subgroups or subsets	As review question 1	
Any other information or criteria for inclusion or exclusion	As review question 1 <i>To be developed through each review step</i>	

## Review question 4: pharmacotherapies

Review question 4	Pharmacotherapies	
Component	Description	Additional comments
Review question	<p><b>RQ4</b> Is nicotine replacement therapy (established therapies, for example patch, gum or spray or newer, licensed e-cigarettes) or bupropion, on their own or combined with behavioural support, effective and cost-effective?</p>	
Context and objectives	<p>To determine the effectiveness and cost effectiveness of:</p> <ul style="list-style-type: none"> <li>• Nicotine replacement therapy <ul style="list-style-type: none"> <li>○ established therapies, for example patch, gum or spray</li> <li>○ licensed e-cigarettes</li> </ul> </li> <li>• Bupropion</li> </ul> <p>Each pharmacotherapy used on its own or combined with behavioural support.</p> <p>To determine how effectiveness and cost effectiveness varies :</p> <ul style="list-style-type: none"> <li>• according to the person delivering it and the way it is delivered (including media used or setting).</li> <li>• when over the counter NRT is used (on its own or combined with behavioural support).</li> <li>• when NRT preparation used alone or in combination with other NRT or bupropion</li> </ul> <p>This could lead to development of updated recommendations on the effective use of NRT technologies, including therapeutically indicated e-cigarettes, bupropion and the role of behaviour support. The recommendation for varenicline will remain as per <a href="#">TA123</a> and will be referred to in the updated guideline in a similar format to the reference currently in PH10.</p>	Evidence on varenicline will be excluded from the review.
Method - summary	Broadly as for review question 2 (evidence identification and selection will include international [OECD] evidence)	The supplementary objectives (above) will be explored in the analysis of identified

<b>Review question 4</b>	Pharmacotherapies	
<b>Component</b>	<b>Description</b>	<b>Additional comments</b>
		evidence.
Searches	As review question 1 International (OECD) evidence considered.	The focus of the reviews that informed recs in PH1 and PH10 will be taken into consideration.
Types of study to be included/ excluded	As review question 1	
Participants/ population	As review question 1	
Interventions	Nicotine replacement therapy (NRT) or bupropion offered as an aid to help people to quit smoking or reduce the amount they smoke. These may be offered <ul style="list-style-type: none"> <li>• with or without behavioural support.</li> <li>• as combinations of pharmacotherapies</li> </ul> NRT may be accessed through healthcare services or 'over the counter' without accessing advice or support. For detail see 'Context and objectives' and 'Analysis of subgroups or subsets'	The applicability of evidence to UK practice will be carefully considered with PHAC.
Comparator(s)/ control	question <ul style="list-style-type: none"> <li>• No treatment</li> <li>• Usual care</li> <li>• Other nicotine replacement therapies or bupropion</li> <li>• Behavioural support;</li> </ul>	Usual care will involve advice, encouragement and support or referral to a smoking cessation service. It will also include account of a person's intention and motivation to quit and treatment concordance.
Outcomes	As review question 1	
Selecting evidence (screening)	As review question 1	
Data extraction and quality assessment	As review question 1	

<b>Review question 4</b>	Pharmacotherapies	
<b>Component</b>	<b>Description</b>	<b>Additional comments</b>
Strategy for data synthesis	As review question 1 Careful consideration will be given to the value for updating guideline recommendations and data availability to explore comparisons through stepwise indirect treatment comparison or network meta-analysis approaches.	If an ITC or NMA approach was to be implemented, it is proposed that evidence contributing to pairwise comparisons or a network would compare 2 or more of the comparators considered in the scope. Studies with only 1 in scope comparator would not be included.
Analysis of subgroups or subsets	As review question 1 The combinations of concomitant therapy and route of access to NRT (see 'context and objectives') will be explored in subgroup analysis. Comparisons will be made where evidence allows.	
Any other information or criteria for inclusion or exclusion	As review question 1 <i>To be developed through each review step</i>	

### ***Review question 5: options for consumer e-cigarettes***

<b>Review question 5</b>	Consumer e-cigarettes	
<b>Component</b>	<b>Description</b>	<b>Additional comments</b>
Review question	<b>RQ6</b> What advice and referral options are appropriate for people using consumer e-cigarettes for smoking cessation?	
Context and objectives	To determine: advice and referral options for people using consumer e-cigarettes for smoking cessation Including: Current practice in community, health or social care in England - focusing on Stop smoking	*To inform preference based recommendations, that may be introduced in the timescale of this guideline Stop Smoking

<b>Review question 5</b>	Consumer e-cigarettes	
<b>Component</b>	<b>Description</b>	<b>Additional comments</b>
	<p>services</p> <p>Regulatory, professional practice guidance or standards</p> <p>Service provider and user experience (perceptions and preferences)*</p> <p>The aim of this review is to help the committee develop recommendations on evidence-based support and advice for services to consider the place of consumer e-cigarettes for smoking cessation in client interactions.</p> <p>The scope question does not specify that committee should develop recommendations for the effective use of consumer e-cigarettes for smoking cessation as part of stop smoking services.</p>	<p>Services (SSS) are a relevant (and rich) setting to explore advice and referral options.</p>
Method - summary	<p>Distinct from other reviews as descriptive in nature.</p> <p>UK-based evidence relevant to current and emerging practice.</p> <p>This review will use steps 8-10, call for evidence and expertise.</p>	<p>The supplementary objectives (above) will be explored in the analysis of identified evidence.</p> <p>Regional focus for all reviews - for discussion.</p>
Searches	<p>Relevant databases and websites will be searched systematically to identify relevant quantitative and cost effectiveness evidence using a combination of terms for smoking cessation AND e-cigarettes. The searches will not distinguish between categories of e-cigarette.</p> <p>In addition relevant websites will be 'hand searched' for reports and service evaluations (see <a href="#">step 3</a> – grey literature search).</p> <p>Sources to be searched: the stepped approach will be used, following steps 3 and 8-10. It will begin with the grey literature and then seek up to date evidence from primary studies using a range of databases (see <a href="#">appendix</a>).</p>	<p>Principally, steps 3 and 8-10 will be used for this review.</p> <p>Focus on UK context.</p>
Types of study to be included/ excluded	<p>Descriptive report or summary of service providing smoking cessation</p> <p>The characteristics of the e-cigarettes considered in the evidence identified will be described in the review reports and, where</p>	

<b>Review question 5</b>	Consumer e-cigarettes	
<b>Component</b>	<b>Description</b>	<b>Additional comments</b>
	possible, comparability with the 2 categories of e-cigarette presented.	
Participants/ population	As review question 1	
Interventions	SC support (advice, behavioural support or pharmacotherapies) offered in community, social care or healthcare settings	
Comparator(s)/ control	(Past experience)	
Outcomes	<p>Descriptive, content such as:</p> <p>Issues for services and SC providers</p> <ul style="list-style-type: none"> <li>• volumes</li> <li>• practice/regulatory issues with e-cigarettes</li> </ul> <p>Service provider experience</p> <ul style="list-style-type: none"> <li>• perceptions of effectiveness, adverse effects, safety; opportunities and challenges for practice and place of e-cigarettes in SC pathway</li> <li>• experience</li> <li>• preferences</li> </ul> <p>Service user experience</p> <ul style="list-style-type: none"> <li>• perceptions of effectiveness, adverse effects, safety</li> <li>• intentions towards e-cigarettes, SC and SSS</li> <li>• experience</li> <li>• preferences</li> </ul> <p>Category of e-cigarette in use (post TPD2 implementation in May 2016)</p> <p>Role in smoking cessation pathways</p>	Effectiveness will be broad including outcomes for review 1 (where reported) and more subjective assessments.
Selecting evidence (screening)	As review question 1	
Data extraction and quality assessment	<p>Practice descriptions will be abstracted into standard data collection forms. These may include:</p> <ul style="list-style-type: none"> <li>• description of service setting – size, volumes of SC offered, demographic of service area, staff involved</li> </ul>	<p>PHAC will be asked for its view on applicability to UK practice.</p> <p>If large numbers of reports are identified,</p>

<b>Review question 5</b>	Consumer e-cigarettes	
<b>Component</b>	<b>Description</b>	<b>Additional comments</b>
	<ul style="list-style-type: none"> <li>• date service assessed and report produced</li> <li>• outcomes detailed above</li> </ul> <p>An assessment of applicability to current UK practice proposed by the review team.</p>	<p>the following may be implemented.</p> <p>Prioritising evidence review for:</p> <ul style="list-style-type: none"> <li>• Priorities for recommendation development</li> <li>• Areas of greatest uncertainty</li> <li>• Newer evidence</li> <li>• Reports on larger services</li> <li>• Studies with lower risk of bias</li> <li>• Groups at greatest risk.</li> </ul>
Strategy for data synthesis	Practice descriptions and service and user experience will be collated, themes identified and short summary statements developed.	
Analysis of subgroups or subsets	<p>Variations by characteristics of service will be explored (as evidence allows). This characteristics could include:</p> <ul style="list-style-type: none"> <li>• Setting – SSS, primary care, community or geography</li> <li>• Size</li> <li>• Client and community make-up (such as services offering SC for people from manual occupational, BME, LGBT or other groups)</li> </ul>	
Any other information or criteria for inclusion or exclusion		An approach that considers 'evidence saturation' will be applied. Selecting representative case study services will also be considered.

## **Review question 6: role of digital media**

<b>Review question 6</b>	Digital media	
<b>Component</b>	<b>Description</b>	<b>Additional comments</b>
Review question	5 Is digital media effective as an adjunct to very brief or brief advice, behavioural support, or pharmacotherapy?	
Context and objectives	To determine the effectiveness and cost effectiveness of: digital media in smoking cessation interventions (identified in the reviews)  To determine: digital media in use in smoking cessation interventions (identified) and in use in UK practice.	Note the objective of this review question is limited to exploring effectiveness, cost-effectiveness within the evidence identified on smoking cessation interventions.
Method - summary	Effectiveness, cost effectiveness and descriptive evidence to be considered.  The review will use evidence included in reviews 1-4; a call for evidence on the 'role' of digital media in smoking cessation interventions and services and expertise.	Elements of this review will; draw on the other reviews, but will be reported separately.  It will include a descriptive element 'cataloguing' digital media used in the evidence base and in UK practice.  Added value of descriptive components - for discussion.
Searches	As review question 1  Evidence included in reviews 1-4 will be reviewed  A call for evidence will be issued on the 'role' of digital media in smoking cessation interventions and services.	Greater range of interventions may be identified in the call for evidence. Review team will carefully consider if effectiveness evidence should be considered.
Types of study to be included/ excluded	As reviewquestion1	
Participants/ population	As review question 1	

<b>Review question 6</b>	<b>Digital media</b>	
<b>Component</b>	<b>Description</b>	<b>Additional comments</b>
Interventions	As review question 1 – with digital media	
Comparator(s)/ control	As review question 1 – with or without digital media	
Outcomes	As review question 1 – where comparisons with and without media use  Descriptive <ul style="list-style-type: none"> <li>• Named media</li> <li>• Category of digital media used</li> <li>• Role in smoking cessation (offered optionally, in addition or sole method, stage used, delivery)</li> </ul>	
Selecting evidence (screening)	As review question 1 – review of included studies for effectiveness evidence and descriptive information	
Data extraction and quality assessment	As review question 1 – for effectiveness evidence For descriptive information – abstracted into standard data collection forms.  Source of descriptive information will be presented and assessment of applicability to current UK practice proposed by the review team.	PHAC will be asked for its view on applicability to UK practice.
Strategy for data synthesis	As review question 1 – for effectiveness evidence As review question 4 – for descriptive information	
Analysis of subgroups or subsets	As review question 1 – for effectiveness evidence Subgroups by category of digital media used (as evidence allows)	
Any other information or criteria for inclusion or exclusion		Elements of this review will draw on the other reviews, but will be reported separately.

## Appendix

### *Variations to protocol*

Date	Description, rationale	Action
20160216	Changes post sign off – typographical; to expand review 1 to international (in line with PH1 and PH10)	International range indicated in table 1 and review question 1 table.
20160226	Description of approach to prioritising studies included in Cochrane reviews for step 2 added. Prioritisation necessary to limit volume of citations returned.	Criteria for not prioritising studies for citation searching added to evidence selection table in Appendix (step 2, RHS column)

Description – could include ‘importance’, urgency and rationale; Action - such as revision to protocol text, implementation in evidence review process

### ***Evidence identification (search strategy) protocol***

As of 24 August 2016	Details	Additional comments
Searches	<p><b>Search overview</b></p> <p>The searching will take an iterative approach and it will be developed in several stages, taking into account the evidence that has already been retrieved.</p> <p>The steps outlined below will be followed for the initial phases of searching. Steps 1-5 will be undertaken and then there will be a pause in the searching process as the literature retrieved up to that point is assessed. Steps 6-10 will then be undertaken if the reviewers decide that the quantity or quality of the evidence already gathered is not sufficient to answer all of the review questions.</p> <p>Steps 1-5 will include general searches for smoking cessation. Steps 6-10 are more likely to focus on the individual questions listed in section x above. All search results will be downloaded into a single file, covering all questions in section 1.5 of the final scope. The results will be handled in EndNote initially and then be transferred to a review</p>	<p>A search approach based on the classic model of information retrieval would not be suitable to answer these questions, given the time and resources available.</p> <p>The search strategies developed for the original NICE guidance were re-run (and amended as appropriate) as part of developing the draft scope. These searches retrieved around 22500 results from the Medline database.</p> <p>The total search results are normally estimated as two to three times higher than the Medline yield. This suggests that implementing a database-driven protocol would have retrieved approximately 45000-67500 results.</p> <p>The iterative approach aims to provide a better balance between precision and sensitivity. This is in accordance with the NICE guidelines development <a href="#">manual</a>, section 5.1, which states that the purpose of searching is “to identify the best available evidence to address a particular question without</p>

	<p>management system (anticipated to be EPPI-reviewer) for reviewing.</p> <p>This protocol may be amended as each step is undertaken, for example if more results are returned than can be processed in the time available. Additional steps may be added if appropriate. Any revisions will be agreed by the review team before being implemented. The revisions will be highlighted in an amended version of this protocol and a rationale explaining the decision will be provided.</p> <p>Full details of the activities associated with each step in the search are set out below. In summary, the steps to be undertaken are:</p> <ul style="list-style-type: none"> <li>• <b>Step 1</b> Identifying Cochrane Reviews</li> <li>• <b>Step 2</b> Identifying primary studies to supplement the Cochrane Reviews with more up to date information</li> <li>• <b>Step 3</b> Identifying evidence from grey literature applicable to the UK</li> <li>• <b>Step 4</b> Named interventions search for specific programmes, initiatives or services identified from sifting the results from steps 1-3.</li> <li>• <b>Step 5</b> Additional searches to identify cost effectiveness and economics literature</li> </ul>	<p>producing an unmanageable volume of results”. The stepped approach enables a continuous review of how best to find the evidence that is required.</p>
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	<p><i>Pause in searching to conduct gap analysis. A decision will be taken on the number, order and priority of the next searching activities. The next steps could include some or all of the following:</i></p> <ul style="list-style-type: none"> <li>• <b>Step 6</b> Review of reviews to capture non-Cochrane systematic reviews and meta-analyses which address the gaps identified in the evidence</li> <li>• <b>Step 7</b> Reference harvesting to extract the primary studies from the reviews and meta-analyses identified in steps 1 and 6</li> <li>• <b>Step 8</b> Named author searches</li> <li>• <b>Step 9</b> Gap search for named populations or settings</li> <li>• <b>Step 10</b> Gap search for aspects of care</li> </ul>	
	<p><b>Step 1</b> Identifying relevant <b>Cochrane Reviews</b> using the following methods:</p> <ul style="list-style-type: none"> <li>• Search the Cochrane Database of Systematic Reviews (CDSR) via the <a href="#">Wiley interface</a>.</li> <li>• Browse the lists of reviews published on the <a href="#">Cochrane Library website</a> by the following</li> </ul>	<p>The search strategy for CDSR will be broad and aim to capture all Cochrane Reviews on smoking, tobacco, cigarettes and nicotine. This step is crucial to the later stages of the search and so it is important to be comprehensive.</p> <p>The search strategies in the later steps will not use the CDSR strategy as they will need to be more</p>

	<p>Cochrane Review Groups:</p> <ul style="list-style-type: none"> <li>○ Airways</li> <li>○ Consumers and Communication</li> <li>○ Effective Practice and Organisation of Care</li> <li>○ Lung Cancer</li> <li>○ Oral Health</li> <li>○ Public Health</li> <li>○ Tobacco Addiction</li> </ul> <p>No date limits will be applied to the Cochrane Reviews search results. The protocols for unpublished Cochrane Reviews will be included in the search results. Withdrawn or superseded Cochrane Reviews will not be added to the search results when manually browsing the website.</p> <p>Cochrane Reviews will only be included in the search results when manually browsing the website if they refer to smoking, tobacco, cigarettes or nicotine in the title or abstract or more than once in the full text.</p> <p>The Cochrane Review Group Trials Search Coordinators will be contacted if further information is required.</p>	<p>focussed and include terms for cessation activities. The names of any pharmaceutical products required in the search strategies will be derived from the latest version of the British National Formulary (BNF) as far as possible.</p>
	<p><b>Step 2</b></p>	<p>This stage is necessary to ensure the most recent</p>

	<p>Identifying <b>primary studies to supplement the Cochrane Reviews</b> with more up to date information.</p> <ul style="list-style-type: none"> <li>• Primary and secondary studies will be extracted from the following sources if they are journal articles relevant to the review questions and prioritised by the reviewers for this stage: <ul style="list-style-type: none"> <li>○ The surveillance reports and Evidence Updates to NICE Guidance PH1 and PH10</li> <li>○ Responses to the draft scope consultation.</li> </ul> </li> <li>• Forwards citation searching will be conducted using the following sources: <ul style="list-style-type: none"> <li>○ The Cochrane Reviews identified as relevant to the review questions in Step 1 (using all previous versions of the review and not just the current version).</li> <li>○ The included papers cited in the current version of the Cochrane Reviews if they are journal articles relevant to the review questions and prioritised by the reviewers for this stage</li> <li>○ NICE Guidance PH1 and PH10</li> </ul> </li> </ul>	<p>literature is captured given that:</p> <ul style="list-style-type: none"> <li>• Some time may have passed since the Cochrane Review was published</li> <li>• There is a time lag between the publication of a primary study and its inclusion in a Cochrane Review.</li> </ul> <p>The purpose of this stage is to find new evidence that has not been incorporated into the Cochrane Reviews. This stage is not aiming to provide comprehensive coverage of the evidence.</p> <p>Citation searching is used because this builds up a cluster of papers from those that are already known to be relevant. It is important to use several sources for the citation searching to avoid biasing the subsequent results in favour of one particular review.</p> <p>Doing citation searching on the included papers from one review might return papers that have already been cited in a different Cochrane Review. These will not be reviewed as part of step 2 (if that Cochrane Review has been selected in step 1) as they will form part of step 7 (see below).</p> <p>Any studies cited in the surveillance reports that are published in the format of grey literature (rather than a journal article) will be recorded in the step 3</p>
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	<ul style="list-style-type: none"> <li>○ The included papers (those contributing to the evidence statements) in NICE Guidance PH1 and PH10 if they are journal articles relevant to the review questions and prioritised by the reviewers for this process</li> <li>○ The papers from the surveillance reports and scope consultation response extracted above if they are journal articles relevant to the review questions and prioritised by the reviewers for this process.</li> </ul> <p>Only papers published in 2006-Current and in the English language will be included in the search results. Primary studies will not be included in the search results if they have already been cited in one of the Cochrane Reviews identified as relevant in step 1.</p> <p>The forwards citation searching will be conducted with <a href="#">Web of Science</a>. Only those references which NICE can access through its WOS subscription will be added to the search results.</p>	<p>results.</p> <p>Included papers for citation searching are prioritised according to:</p> <ul style="list-style-type: none"> <li>• Relevance to smoking cessation</li> <li>• Relevance to scope questions (studies focusing on groups, settings or interventions out of scope - not prioritised)</li> <li>• Relevance to 'general' population (studies from reviews focusing on groups with health conditions not prioritised)</li> </ul>
	<p><b>Step 3</b></p> <p>Identifying evidence from <b>grey literature</b> applicable to the UK on:</p> <ol style="list-style-type: none"> <li>1. questions in section 1.5 of the final scope if the project team decides that this type of</li> </ol>	

	<p>evidence would be useful for that particular question.</p> <p>2. named interventions</p> <p>using the following methods:</p> <ul style="list-style-type: none"><li>• Call for evidence</li><li>• Contact with experts on the NICE PHAC</li><li>• Search the following databases for their grey literature content:<ul style="list-style-type: none"><li>○ Health Management Information Consortium (HMIC) via Ovid</li><li>○ Social Policy and Practice (SPP) via Ovid</li></ul></li><li>• Search the following online resources for their grey literature content:<ul style="list-style-type: none"><li>○ <a href="#">NICE Evidence Search</a></li><li>○ <a href="#">OpenGrey</a></li><li>○ <a href="#">Social Care Online</a></li><li>○ <a href="#">Turning Research Into Practice</a> (TRIP)</li></ul></li><li>• A targeted <a href="#">Google.co.uk</a> search using the site: command and focusing on results from NHS and .gov.uk sites. It may also be necessary to restrict the search results to particular file types, such as PDF or Word formats. A series of focussed searches will be preferred to using one broad search strategy. The first 100 (or 10 pages) or</li></ul>	
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results will be sifted on screen for each of the search strategies.

- Browse the websites of relevant UK organisations including:
  - [Action on Smoking and Health \(ASH\)](#)
  - [Fresh North East](#)
  - [Local Government Association](#)
  - [National Audit Office](#)
  - [National Centre for Smoking Cessation and Training](#)
  - [NHS England](#)
  - [Public Health Agency for Northern Ireland](#)
  - [Public Health England](#)
  - [Public Health Wales](#)
  - [Royal College of Physicians](#)
  - [Royal College of Psychiatrists](#)
  - [Smokefree NHS](#)
  - [Scottish Government](#)
  - [Scottish Public Health Network](#)
  - [Scottish Public Health Observatory](#)
  - [Smokefree South West](#)
  - [Smoking Toolkit Study](#)
  - [Treat Tobacco](#)

- [Tobacco Free Futures](#)
- [UK Centre for Tobacco and Alcohol Studies](#)
- [University of Bath Tobacco Control Research Group](#)
- [University of Stirling Centre for Tobacco Control Research](#)
- [Welsh Assembly Government](#)

The following non-UK websites will be browsed if further evidence applicable to the UK is required:

- [Center for Disease Control and Prevention smoking and tobacco use](#)
- [European Commission tobacco policy](#)
- [World Health Organization tobacco policy](#)

Only papers published in 2006-Current referring to a programme or service based in the UK and published in the English language will be included in the search results.

The results obtained from websites will initially be sifted on screen. The results will be added to a Microsoft Word file by the searcher and passed to the review team if they refer to smoking cessation

	<p>and are relevant to one of the review questions. An initial sifting decision will be made using the title and abstract of the item in Word. Any items selected for inclusion at this stage will then be added to Endnote. The final flowchart in the report showing how the literature was handled will only include the number of items added to Endnote.</p>	
	<p><b>Step 4</b>  <b>Named interventions</b> search for specific programmes, initiatives or services identified from sifting the results from steps 1-3, using the following sources:</p> <ul style="list-style-type: none"> <li>• Applied Social Science Index and Abstracts (ASSIA) via ProQuest</li> <li>• Cochrane Central Register of Controlled Trials (CENTRAL) via Wiley</li> <li>• Embase via Ovid</li> <li>• Medline via Ovid</li> <li>• Medline-in-Process via Ovid</li> </ul> <p>Only papers published in 2006-Current referring to a programme or service based in the UK and published in the English language will be included in the search results.</p>	<p>The reviewers will identify a list of specific named interventions of interest during the previous steps. Focussed searches using these names will be run in several databases to identify additional journal articles discussing them.</p> <p>Any services with names that are too general for a search (e.g. “Stop Smoking”) will be excluded from this stage, where the searcher and the reviewers are in agreement.</p>
	<p><b>Step 5</b></p>	

	<p>Additional searches to identify <b>cost effectiveness and economics literature</b> using the following sources:</p> <ul style="list-style-type: none"> <li>• Benefit-Costs Results via <a href="#">Washington State Institute for Public Policy</a></li> <li>• Health Technology Assessment database via Wiley</li> <li>• EconLit via Ovid</li> <li>• EconPapers via <a href="#">RePEc</a></li> <li>• Medline and Medline-in-Process via Ovid using an appropriate search filter</li> <li>• NHS Economics Evaluation Database (NHS EED) via Wiley - note this has not been updated since March 2015, but may identify relevant evidence added up to this date.</li> </ul> <p>Only papers published in 2006-Current referring to a programme or service based in the UK and published in the English language will be included in the search results.</p>	
<p><i>Following Step 5 there will be a pause in the searching to conduct a gap analysis on the evidence already retrieved. A decision will then be taken on the number, order and priority of the next searching activities. The next steps could include some or all of the actions described in Steps 6-10 below. The decision on which steps to follow will be recorded in an amendment to this protocol.</i></p>		
	<p><b>Step 6</b></p>	<p>Following step 5, the retrieved evidence will be</p>

	<p>Review of reviews to capture <b>non-Cochrane systematic reviews and meta-analysis</b> which address the gaps identified in the evidence, using the following sources:</p> <ul style="list-style-type: none"> <li>• Campbell Collaboration library via the <a href="#">website</a></li> <li>• Database of Abstracts of Reviews of Effectiveness (DARE) via Wiley - note this has not been updated since March 2015</li> <li>• Database of Promoting Health Effectiveness Reviews (DoPHER) via <a href="#">EPPI Centre</a></li> <li>• <a href="#">Embase via Ovid [PL 22Aug16]</a></li> <li>• HealthEvidence.org via the <a href="#">website</a></li> <li>• Medline and Medline-in-Process via Ovid using an appropriate search filter</li> <li>• NIHR projects via the <a href="#">website</a> - all published systematic review questions and public health research programme topics will be browsed</li> <li>• Prospective Register of Systematic Reviews (PROSPERO) via <a href="#">CRD website</a></li> </ul> <p>Completed reviews and protocols published in 2006-Current in the English language will be included in the search results.</p>	<p>mapped against the review questions and any gaps identified. The following steps will be undertaken in a focussed way to fill those gaps and to prioritise the areas where evidence is lacking.</p> <p>Steps 6-10 may be undertaken in a different order to that stated here according to the search methods most likely to be appropriate for the gaps that have been identified.</p>
	<p><b>Step 7</b> Reference harvesting to <b>extract the primary</b></p>	<p>No attempt will be made to cross check the WOS results against the full bibliographies of the reviews</p>

	<p><b>studies from reviews and meta analyses</b> identified in earlier steps.</p> <p>The included papers will be extracted from:</p> <ul style="list-style-type: none"> <li>• Cochrane Reviews identified in step 1</li> <li>• Other reviews identified in step 6</li> </ul> <p>The references will be harvested using <a href="#">Web of Science</a>. Only those references which NICE can access automatically through its WOS subscription will be added to the search results.</p> <p>Only papers published in 2006-Current and published in English will be included in the search results.</p>	<p>to verify whether all of the references have been harvested.</p>
	<p><b>Step 8</b></p> <p>Named <b>author</b> searches.</p> <p>Additional searches will be undertaken for papers published by the key experts identified in the previous steps. Particular attention will be paid to identifying the most up to date research and will include articles currently in-press.</p> <p>The following sources are likely to be useful:</p> <ul style="list-style-type: none"> <li>• Browsing sources associated with the author e.g. university websites and institutional repositories</li> <li>• Medline and Medline-in-Process via Ovid</li> </ul>	

	<ul style="list-style-type: none"> <li>• <a href="#">PubMed</a></li> <li>• <a href="#">Web of Science</a></li> </ul> <p>The list of authors will be agreed with the reviewers and PHAC.</p> <p>Only papers published in 2006-Current and in English will be included in the search results.</p>	
	<p><b>Step 9</b></p> <p>Gap search for <b>named populations or settings</b>. Highly-focussed database searches will be undertaken for any population groups or settings named in the scope if the reviewers identify a gap during the previous steps.</p> <p>The list of databases will be tailored appropriately to the actual groups and settings requiring evidence but it is likely to include:</p> <ul style="list-style-type: none"> <li>• ASSIA via ProQuest</li> <li>• CENTRAL via Wiley</li> <li>• Embase via Ovid</li> <li>• Medline via Ovid</li> <li>• Medline-in-Process via Ovid</li> <li>• PsycINFO via Ovid</li> <li>• Trials Register of Promoting Health Interventions (TRoPHI) via <a href="#">EPPI Centre</a></li> </ul>	<p>The search strategy at this stage is likely to be highly focussed and appropriate techniques will be used to make it as precise as possible.</p> <p>The principal strategy will be developed in Medline and then adapted appropriately to the other sources, taking into consideration their size, search functionality and subject coverage.</p>

	<p>Only papers published in 2006-Current and in English will be included in the search results.</p> <p>Database functionality will be used to exclude comments, letters, news, animal studies and duplicates where possible.</p>	
	<p><b>Step 10</b></p> <p>Gap search for aspects of care.</p> <p>The list of databases will be tailored appropriately according to the evidence required but it is likely to include:</p> <ul style="list-style-type: none"> <li>• ASSIA via ProQuest</li> <li>• CENTRAL via Wiley</li> <li>• Embase via Ovid</li> <li>• Medline via Ovid</li> <li>• Medline-in-Process via Ovid</li> <li>• PsycINFO via Ovid</li> <li>• Trials Register of Promoting Health Interventions (TRoPHI) via <a href="#">EPPI Centre</a></li> </ul> <p>Only papers published in 2006-Current and in English will be included in the search results.</p> <p>Database functionality will be used to exclude comments, letters, news, animal studies and duplicates where possible.</p>	<p>The search strategy at this stage is likely to be broad but not comprehensive.</p> <p>The principal strategy will be developed in Medline and then adapted appropriately to the other sources, taking into consideration their size, search functionality and subject coverage.</p> <p>The strategies in the other databases may not be as comprehensive as those in Medline as the incremental yields from these databases are likely to be lower.</p> <p>The strategies will be limited appropriately if certain types of evidence are prioritised such as UK evidence or certain study designs.</p>

	Conference papers and dissertations will be downloaded in separate files to the principal results, where database functionality allows, enabling the reviewers to handle them separately if appropriate.	
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### ***Search strategy – syntax***

Strategy for Step 1 in the Cochrane Database of Systematic Reviews

To be run in Wiley Cochrane Library platform.

- #1 [mh "tobacco use"]
- #2 [mh "tobacco products"]
- #3 [mh "tobacco smoke pollution"]
- #4 [mh tobacco]
- #5 [mh "tobacco use disorder"]
- #6 [mh "tobacco use cessation"]
- #7 [mh smoking]
- #8 [mh "smoking cessation"]
- #9 [mh nicotine]
- #10 (smok\* or antismok\* or anti smok\* or anti-smok\* or tobacco\* or nicotin\* or cigar\* or cigs or ecig\* or e-cig\*):ti,ab
- #11 (bidi or bidis or kretek or hand roll\* or handroll\*):ti,ab
- #12 (bupropion\* or zyban\* or varenicline\* or champix\* or nicorette\* or niquitin\* or nicotinell\* or nicassist\*):ti,ab
- #13 {or #1-#12}
- #14 {or #1-#12} Publication Year from 2006 to 2015

**Table - Stepped search strategy by questions**

	<b>Description</b>	RQ1 & 2 brief advice	RQ3 behavioural support	R4 pharmacotherapies	RQ4 consumer e-cigarettes	RQ5 role of digital media
<b>Step 1</b>	<b>Search CDSR<sup>3</sup></b> to identify Cochrane Systematic Reviews	■	■	■		Within R1-3
<b>Step 2</b>	<b>Identifying primary studies</b> to supplement the Cochrane Reviews with more up to date information	■	■	■		Within R1-3
<b>Step 3</b>	Identifying evidence from <b>grey literature</b> applicable to the UK	■	□	■	■	(□)
<b>Step 4</b>	<b>Named interventions</b> search for specific, technologies, programmes, initiatives or services identified from sifting the results from steps 1-3	■	■	■	■	(□)
<b>Step 5</b>	Additional searches to identify <b>cost effectiveness and economics</b> literature	■	■	■		■ Focused on SC

<sup>3</sup> Cochrane Database of Systematic Reviews

	Description	RQ1 & 2 brief advice	RQ3 behavioural support	R4 pharmacotherapies	RQ4 consumer e-cigarettes	RQ5 role of digital media
<b><u>Pause</u></b>	Gap analysis to prioritise next searching activity. The next steps could include some or all of the following:					
<b>Step 6</b>	Review of reviews to capture <b>non-Cochrane systematic reviews</b> and meta-analyses which address the gaps identified in the evidence					
<b>Step 7</b>	Reference harvesting to <b>extract the primary studies</b> from the reviews and meta-analyses identified in steps 1 and 6					□ Gaps likely
<b>Step 8</b>	Named <b>author</b> searches				□	
<b>Step 9</b>	Gap search for <b>named populations or settings</b>				■	
<b>Step 10</b>	Gap search for <b>aspects of care or delivery</b>				■	