Appendix I: Review protocol templates

General notes:

- Templates are given below for 4 types of review questions (intervention, diagnostic, prognostic and qualitative). The fields and text of these templates can be modified to suit the question being undertaken, but approximately the same level of detail should be included for all types of review questions.
- For any guidelines or guideline updates that have separate methods documents, any information in the methods document should not be repeated in the protocol document; instead add a link to the methods document from the relevant sections of the protocol.

Intervention review protocol

Field	Content	Developer comments (delete before publication) [Ensure this column does not include any information that is needed to fully describe the evidence review – such information should be moved to the section that will not be deleted]	QA comments (delete before publication) [Ensure this column does not include any information that is needed to fully describe the evidence review – such information should be moved to the section that will not be deleted]
Review question	[State the question(s) to be addressed by the evidence review, clearly and precisely.]		
Type of review question	Intervention		
Objective	[What is the objective of the evidence review? Is any rationale/detail of what is known necessary?]		
Condition or domain being studied	[Give a short description of the disease, condition or healthcare domain being studied, for example, type 2 diabetes, physical activity in children.]		
Population	Inclusion: [Give summary criteria for the participants or populations being studied by the evidence review. For example, children and/or adults, line of treatment, previous treatment, severity of condition. The preferred format includes details of both inclusion and exclusion criteria.] Exclusion: [Give summary criteria for the participants or populations being studied by the evidence review. For example, children and/or adults, line of treatment, previous treatment, severity of condition. If there are no exclusion criteria, this should be clearly stated.]		

	[Should also include any defined rules for deciding on inclusion – for example, if a large proportion of the population in the study matches the population of interest, but not 100%.]		
Interventions	[Give full and clear descriptions or definitions of the nature of the interventions to be reviewed. This is particularly important for evidence reviews of complex interventions (interventions involving the interaction of several elements). If appropriate, an operational definition describing the content and delivery of the intervention should be given. If any off-label or unlicensed medicines are included as interventions, these should be labelled as such.]		
Comparators	[Give details of the alternatives against which the main subject/topic of the review will be compared. Control or comparison interventions should be described in as much detail as the intervention being reviewed. If the comparator is 'treatment as usual' or 'standard care', this should be described, with attention being paid to whether it is 'standard care' at the time that an eligible study was done, or at the time the evidence review is being done. If any off-label or unlicensed medicines are included as comparators, these should be labelled as such.]		
Types of study to be included	[Insert the list of study types that will be included in this evidence review (see appendix H of the manual for potentially relevant study designs for intervention questions). If some study types will only be included for a subset of the question or if a lack of evidence is identified for the preferred types, this should also be stated.] [Explain whether and how systematic reviews will be used in the evidence review – 3 possible		

	examples are given below (delete those that are not relevant).] Only primary studies will be included in this evidence review. Systematic reviews will not be searched for or included. Systematic reviews of relevant primary study designs will be searched for and used as a source of primary studies in this evidence review, but the systematic reviews will not be included as studies in the evidence review, and no data extraction of those systematic reviews will be undertaken. Systematic reviews of relevant primary study designs will be searched for and may be included as part of this evidence review if sufficiently high quality and applicable, with data extracted for both systematic reviews and primary studies.		
Other exclusion criteria	[Add details of any other exclusion criteria, with justification. Examples might include the location/settings of the studies, minimum sample size requirements, language of publication, or publication status.] [For reviews where meta-analysis is not expected to be undertaken, any minimum sample size requirements should be guided by the expected sample size needed for a study to be plausibly able to generate meaningful results. For reviews where meta-analysis is expected to be undertaken, sample size limits should not normally be applied as the power of an individual study is less relevant, and therefore a clear justification needs to be given for applying minimum sample size requirements in these cases.]		

Context	[This section should include any relevant background to the review question, such as changes to the question from the scope or previous versions of the guidance, together with a justification for those changes, such as information from the surveillance report, scoping process or committee discussion of the protocol (if the question is unchanged, this should also be stated). Also include details of any previous or in development NICE guidelines that will be updated by this question. This section does not need to be very detailed and does not need to provide substantial scientific context to the evidence review – it is usually only to capture the context of other NICE guidance and changes to the review question wording.]		
Outcomes	[Give the pre-specified outcomes of the evidence review, including details of how the outcome is defined and measured, and when these measurements are made, if these are part of the review inclusion criteria. Core outcome sets should be used if suitable based on quality and validity; one source is the COMET database. Splitting outcomes into critical and important is not mandatory in Centre for Guideline protocols, but if this distinction is made it should be reported here. Also give details of any minimally important differences that will be used to interpret the evidence, together with justifications for those choices.] [If any of the above information has not been determined at the time the protocol document is completed, for example, an outcome has been chosen but a list of questionnaires measuring that outcome has not been defined, then these		

	subsequent decisions should be clearly described in the evidence review document.] [Most reviews will have between 5 and 9 outcomes, and a clear justification should be given if the number is outside this range.] [For reviews including antimicrobials as interventions, include antimicrobial resistance as an outcome. For antibiotic sparing interventions, include antibiotic usage as an outcome.]		
Searches	[Give details of the sources to be searched, search dates (from and to), and any restrictions (for example, language or publication period). Sources include (but are not limited to) bibliographic databases, reference lists of eligible studies and review articles, key journals, trials registers, conference proceedings, Internet resources and contact with experts and manufacturers.] The following databases will be searched: [Amend if required] • Cochrane Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic Reviews (CDSR) • Embase • MEDLINE • [Add in additional sources] Searches will be restricted by: • [Date limitations] • [English language] • [Human studies]		

	• [Country limits] • [Any other filters] Other searches: • [Reference searching] • [Citation searching] • [Inclusion lists of systematic reviews] • [Websites] • [Grey literature] • MHRA and NHSE&I for safety of pharmacological interventions] • [UKHSA/PHE for antimicrobial interventions] [Modify text if required] The searches will be re-run 6 weeks before final submission of the evidence review document and further studies retrieved for inclusion. [Delete if not relevant] The full search strategies for all databases will be published in the final evidence review document.		
Data extraction (selection and coding)	[Modify text if required] All references identified by the searches and from other sources will be uploaded into EPPI reviewer and de-duplicated. 10% of the abstracts will be reviewed by 2 reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer. [If priority screening is being used add this text and give details of the stopping rules that will be used – information is available in the manual on the detail to give here] This evidence review will use		

	the priority screening functionality within the EPPI-reviewer software. [If the RCT classifier in EPPI-reviewer is being used, add this text] This evidence review will make use of the RCT classifier within the EPPI-reviewer software The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above. A standardised form will be used to extract data from studies (see the section on summarising evidence in the chapter of the manual on reviewing research evidence). Study investigators may be contacted for further information or missing data where time and resources allow.		
Risk of bias (quality) assessment	[Delete anything below not relevant to this review, and modify the text if required] Risk of bias for different study types will be assessed using the following checklists, as recommended in the manual: • Systematic reviews: ROBIS • Randomised controlled trials: Cochrane RoB tool (2.0) – the versions for cluster randomised and crossover trials will also be used if these study types are identified • Non-randomised controlled trials: Cochrane ROBINS-I • Cohort studies: Cochrane ROBINS-I • Case control studies: CASP case control checklist • Controlled before-and-after studies: EPOC RoB tool for before-and-after studies		

	• Interrupted time series: EPOC RoB tool for interrupted time series studies		
Strategy for data synthesis	[Describe below the approach that will be taken for data synthesis, this should include, where appropriate: • the approach to meta-analysis • if continuous data is being analysed the approach to the same outcome being reported on different numerical scales • the approach for dichotomous data • the approach to heterogeneity • the approach to sensitivity analysis, for example, for high risk of bias • the approach to NMA • the approach to GRADE • the approach to publication bias] [If the guideline/guideline update has a separate methods document, only issues specific to this question and not covered by the methods document need be included here.]		
Analysis of sub-groups	[Give details of any plans for the separate presentation, exploration or analysis of different types of participants (for example, by age, disease status, ethnicity, socioeconomic status, presence or absence of co-morbidities); different types of intervention (for example, drug dose, presence or absence of particular components of an intervention); different settings (for example, country, acute or primary care sector, person delivering the intervention, professional or family care); or different types of study (for example, randomised or non-randomised, or different types		

	of non-randomised study). Should also give information about how these subgroups will be used, including whether they will always be reported or only in the presence of heterogeneity, and whether the different subgroupings will be considered separately or jointly.]		
Health inequalities	[Give details of any health inequalities identified that are relevant to this review question. This will include issues identified in the EIA, but only issues of specific relevance to this question need be mentioned here. For most review questions no specific evidence is likely to be available on health inequalities. In such circumstances the following text is sufficient.] No specific items have been included in this review protocol to identify evidence related to health inequalities. The guideline committee will consider health inequalities when interpreting the evidence and making recommendations. [However, if any elements of the protocol have been designed to address health inequalities, they should be stated here. Possible examples of this may include: • Subgroups that have been included, if there is reason to believe such subgroups will be reported in studies and have different outcomes. • Outcomes that have been included as they may be correlated to or explain inequalities (for example, including adherence as an outcome if this is a possible mechanism by which health inequalities are generated/ exacerbated).		

	• Including a wider range of study types if there are reasons to believe some groups are systematically excluded from a particular study design.]		
Contact information	[Guideline email]@nice.org.uk [Developer to check with guideline coordinator for email address]		
Protocol amendments	[If any changes are made to the protocol and agreed after it is signed-off but before the evidence review is completed, these should be explained here. If post-hoc changes to the evidence review are made these should be reported as protocol deviations in the evidence review document, rather than by changing the protocol document]		

Diagnostic review protocol

Field	Content	Developer comments (delete before publication)	QA comments (delete before publication)
Review question	[State the question(s) to be addressed by the review, clearly and precisely.]		
Type of review question	Diagnostic		
Objective	[What is the objective of the evidence review? Is any rationale/detail of what is known necessary?]		
Condition or domain being studied	[Give a short description of the disease, condition or healthcare domain being studied, for example, type 2 diabetes. This description should clearly describe the target condition that the tests are attempting to diagnose, and where in the diagnostic pathway these tests may be used (for example triage or confirmation)]		
Population	Inclusion: [Give summary criteria for the participants or populations being studied by the review. For example, children and/or adults, line of treatment, previous treatment, severity of condition. The preferred format includes details of both inclusion and exclusion criteria.] Exclusion: [Give summary criteria for the participants or populations not being studied by the review. For example, children and or adults, line of treatment, previous treatment, severity of condition. If there are no exclusion criteria, this should be clearly stated.] [Should also include any defined rules for deciding on inclusion – for example, if a large proportion of the population in the study matches the population of interest, but not 100%.]		

Index tests	[Give full and clear descriptions or definitions of the nature of the tests to be reviewed. If appropriate, an operational definition describing the content and delivery of the tests should be given, as well as any pre-defined index test thresholds that will be prioritised. This section should be clear on whether what is being evaluated is individual tests or a multivariable prediction model and, if multiple individual tests are listed, whether you are interested in the accuracy of individual tests, test strategies combing multiple tests, or both.]		
Reference standards	[Give details of the reference standard(s) which the index test(s) in the evidence review will be assessed against. The preferred format includes details of both inclusion and exclusion criteria. Reference standard(s) should be described in as much detail as the tests being reviewed. If there are concerns about the accuracy of the reference standard that may impact the interpretation of the evidence review, this should be stated here.]		
Types of study to be included	The following study types will be included in the evidence review: • Cross-sectional studies • Cohort studies • Case control studies [Delete any from the above list not relevant to this evidence review. If any additional study designs are added, the reasoning for this should be explained (see appendix H of the manual for other potentially relevant study designs). If some study types will only be included if a lack of evidence is		

	identified for the preferred types, this should also be stated.] [Explain whether and how systematic reviews will be used in the evidence review – 3 possible examples are given below (delete those that are not relevant).] Only primary studies will be included in this evidence review. Systematic reviews will not be searched for or included. Systematic reviews of relevant primary study designs will be searched for and used as a source of primary studies in this evidence review, but the systematic reviews will not be included as studies in the evidence review, and no data extraction of those systematic reviews will be undertaken. Systematic reviews of relevant primary study designs will be searched for and may be included as part of this evidence review if sufficiently high quality and applicable, with data extracted for both systematic reviews and primary studies.		
Other exclusion criteria	[Add details of any other exclusion criteria, with justification. Examples might include the location/settings of the studies, minimum sample size requirements, language of publication, or publication status.] [For reviews where meta-analysis is not expected to be undertaken, any minimum sample size requirements should be guided by the expected sample size needed for a study to be plausibly able to generate meaningful results. For evidence reviews where meta-analysis is expected to be undertaken, sample size limits should not normally be applied as the power of an individual study is		

	less relevant, and therefore a clear justification needs to be given for applying minimum sample size requirements in these cases.]		
Context	[This section should include any relevant background to the review question, such as changes to the question from the scope or previous versions of the guidance, together with a justification for those changes, such as information from the surveillance report, scoping process or committee discussion of the protocol (if the question is unchanged, this should also be stated). Also include details of any previous or in development NICE guidelines that will be updated by this review question. This section does not need to be very detailed and does not need to provide substantial scientific context to the evidence review – it is usually only to capture the context of other NICE guidance and changes to the question wording.]		
Outcome measures	[Give the pre-specified outcomes of the evidence review, including details of how the outcome is defined and measured, when these measurements are made and follow-up, if these are relevant and part of the review inclusion criteria. Splitting outcomes into critical and important is not mandatory in Centre for Guideline protocols, but if this distinction is made it should be reported here. Also give details of any minimal important differences that will be used to interpret the evidence.]		
Searches	[Give details of the sources to be searched, search dates (from and to), and any restrictions (for example, language or publication period). The full		

	search strategy is not required, but may be supplied as a link or attachment. Sources include (but are not limited to) bibliographic databases, reference lists of eligible studies and review articles, key journals, trials registers, conference proceedings, Internet resources and contact with experts and manufacturers.] The following databases will be searched: [Amend if required] • Cochrane Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic Reviews (CDSR) • Embase • MEDLINE • [Add in additional sources] Searches will be restricted by: • [Date limitations] • [English language] • [Human studies] • [Country limits] • [Any other filters] Other searches: • [Reference searching] • [Citation searching] • [Inclusion lists of systematic reviews] • [Websites] • [Grey literature]		

	[Modify text if required] The searches will be re-run 6 weeks before final submission of the evidence review document and further studies retrieved for inclusion. [Delete if not relevant] The full search strategies for all databases will be published in the final review.		
Data extraction (selection and coding)	[Modify text if required] All references identified by the searches and from other sources will be uploaded into EPPI reviewer and de-duplicated. 10% of the abstracts will be reviewed by 2 reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer. [If priority screening is being used add this text, and give details of the stopping rules that will be used – information is available in the manual on the detail to give here] This review will make use of the priority screening functionality within the EPPI-reviewer software. The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above. A standardised form will be used to extract data from studies (see the section on summarising evidence in the chapter of the manual on reviewing research evidence). Study investigators may be contacted for further information or missing data where time and resources allow.		
Risk of bias (quality) assessment	[Delete anything below not relevant to this review, and modify the text if required]		

	Risk of bias for different study types will be assessed using the following checklists, as recommended in the manual: • Systematic reviews: ROBIS • Diagnostic test accuracy studies: QUADAS-2 • Prediction model studies: PROBAST		
Strategy for data synthesis	[Describe below the approach that will be taken for data synthesis, this should include, where appropriate: • the approach to meta-analysis • the approach to heterogeneity • the approach to sensitivity analysis, for example, for high risk of bias studies • the approach to GRADE • the approach to publication bias] [If the guideline/guideline update has a separate methods document, only issues specific to this question and not covered by the methods document need be included here.]		
Analysis of sub-groups	[Give details of any plans for the separate presentation, exploration or analysis of different types of participants (for example, by age, disease status, ethnicity, socioeconomic status, presence or absence of co-morbidities); different types of test or references standard; different settings (for example, country, acute or primary care sector, person conducting the test); or different types of study. Should also give information about how these subgroups will be used, including whether they will always be reported or only in the presence of heterogeneity, and whether the		

	different subgroupings will be considered separately or jointly.]		
Contact information	[Guideline email]@nice.org.uk [Developer to check with guideline coordinator for email address]		
Health inequalities	[Give details of any health inequalities identified that are relevant to this review question. This will include issues identified in the EIA, but only issues of specific relevance to this question need be mentioned here. For most review questions no specific evidence is likely to be available on health inequalities. In such circumstances the following text is sufficient.] No specific items have been included in this review protocol to identify evidence related to health inequalities. The guideline committee will consider health inequalities when interpreting the evidence and making recommendations. [However, if any elements of the protocol have been designed to address health inequalities, they should be stated here. Possible examples of this may include: • Subgroups that have been included, if there is reason to believe such subgroups will be reported in studies and have different outcomes. • Including a wider range of study types if there are reasons to believe some groups are systematically excluded from a particular study design.]		
Protocol amendments	[If any changes are made to the protocol and agreed after it is signed-off but before the evidence review is completed, these should be		

	explained here. If post-hoc changes to the evidence review are made these should be reported as protocol deviations in the evidence review document, rather than by changing the protocol document]		

Prognostic review protocol

Field	Content	Developer comments (delete before publication)	QA comments (delete before publication)
Review question	[State the question(s) to be addressed by the evidence review, clearly and precisely.]		
Type of review question	Prognostic		
Objective	[What is the objective of the evidence review? Is any rationale/detail of what is known necessary?]		
Condition or domain being studied	[Give a short description of the disease, condition or healthcare domain being studied, for example, type 2 diabetes. This description should clearly describe the target condition that the factors/covariates/tests are attempting to identify, and where in the pathway the tests may be used.]		
Population	Inclusion: [Give summary criteria for the participants or populations being studied by the evidence review. For example, children and/or adults, line of treatment, previous treatment, severity of condition. The preferred format includes details of both inclusion and exclusion criteria.] Exclusion: [Give summary criteria for the participants or populations not being studied by the evidence review. For example, children and/or adults, line of treatment, previous treatment, severity of condition. If there are no exclusion criteria, this should be clearly stated.] [Should also include any defined rules for deciding on inclusion – for example, if a large proportion of the population in the study matches the population of interest, but not 100%.]		

Predictive factors	[Give full and clear descriptions or definitions of the predictive factors to be reviewed. This section should be clear on whether what is being evaluated is individual factors or a multivariable prediction model and, if multiple individual factors are listed, whether you are interested in the factors individually, in combination, or both.]		
Confounding factors	[If there are any confounding factors that will cause you to exclude studies or downgrade the quality of the evidence if they are not adjusted for in the studies, these should be listed here. Confounding factors should be described in as much detail as the predictive factors being reviewed. If there are no such confounding factors, the text below can be used.] All studies of relevant predictive factors will be included, regardless of whether they adjust for confounding factors, and which factors they adjust for.		
Types of study to be included	The following study types will be included in the review: • Cohort studies • Case control studies [Delete any from the above list not relevant to this review. If any additional study designs are added, the reasoning for this should be explained (see appendix H of the manual for other potentially relevant study designs). If some study types will only be included if a lack of evidence is identified for the preferred types, this should also be stated.] [Explain whether and how systematic reviews will be used in the evidence review – 3 possible		

	examples are given below (delete those that are not relevant).] Only primary studies will be included in this evidence review. Systematic reviews will not be searched for or included. Systematic reviews of relevant primary study designs will be searched for and used as a source of primary studies in this evidence review, but the systematic reviews will not be included as studies in the evidence review, and no data extraction of those systematic reviews will be undertaken. Systematic reviews of relevant primary study designs will be searched for and may be included as part of this evidence review if sufficiently high quality and applicable, with data extracted for both systematic reviews and primary studies.		
Other exclusion criteria	[Add details of any other exclusion criteria, with justification. Examples might include the location/settings of the studies, minimum sample size requirements, language of publication, or publication status.] [For reviews where meta-analysis is not expected to be undertaken, any minimum sample size requirements should be guided by the expected sample size needed for a study to be plausibly able to generate meaningful results. For evidence reviews where meta-analysis is expected to be undertaken, sample size limits should not normally be applied as the power of an individual study is less relevant, and therefore a clear justification needs to be given for applying minimum sample size requirements in these cases.]		

Context	[This section should include any relevant background to the review question, such as changes to the question from the scope or previous versions of the guidance, together with a justification for those changes, such as information from the surveillance report, scoping process or committee discussion of the protocol (if the question is unchanged, this should also be stated). Also include details of any previous or in development NICE guidelines that will be updated by this question. This section does not need to be very detailed and does not need to provide substantial scientific context to the evidence review – it is usually only to capture the context of other NICE guidance and changes to the question wording.]		
Outcomes	[Give the pre-specified outcomes of the evidence review, including details of how the outcome is defined and measured, when these measurements are made and follow-up, if these are part of the review inclusion criteria. Splitting outcomes into critical and important is not mandatory in Centre for Guidelines protocols, but if this distinction is made it should be reported here.]		
Measures	[Give details of the statistical measures that will be used to assess the outcomes (for example, prognostic test accuracy measures such as sensitivity/specificity, model fit statistics, discrimination and calibration statistics for prediction models, or adjusted odds ratios or hazard ratios). Also give details of any minimal important differences that will be used to interpret the evidence.]		

Searches	[Give details of the sources to be searched, search dates (from and to), and any restrictions (for example, language or publication period). The full search strategy is not required, but may be supplied as a link or attachment. Sources include (but are not limited to) bibliographic databases, reference lists of eligible studies and review articles, key journals, trials registers, conference proceedings, Internet resources and contact with experts and manufacturers.] The following databases will be searched: [Amend if required] • Cochrane Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic Reviews (CDSR) • Embase • MEDLINE • [Add in additional sources] Searches will be restricted by: • [Date limitations] • [English language] • [Human studies] • [Country limits] • [Any other filters] Other searches: • [Reference searching] • [Citation searching] • [Inclusion lists of systematic reviews]		

	• [Websites] • [Grey literature] [Modify text if required] The searches will be re-run 6 weeks before final submission of the evidence review document and further studies retrieved for inclusion. [Delete if not relevant] The full search strategies for all databases will be published in the final evidence review document.		
Data extraction (selection and coding)	[Modify text if required] All references identified by the searches and from other sources will be uploaded into EPPI reviewer and de-duplicated. 10% of the abstracts will be reviewed by 2 reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer. [If priority screening is being used add this text, and give details of the stopping rules that will be used – information is available in the manual on the detail to give here] This evidence review will make use of the priority screening functionality within the EPPI-reviewer software. The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above. A standardised form will be used to extract data from studies (see the section on summarising evidence in the chapter of the manual on reviewing research evidence). Study investigators may be contacted for further information or missing data where time and resources allow.		
Risk of bias (quality) assessment	[Delete anything below not relevant to this review, and modify the text if required]		

	Risk of bias for different study types will be assessed using the following checklists, as recommended in Developing NICE guidelines: the manual: • Systematic reviews: ROBIS • Prognostic factor studies (without a multivariable prediction model) QUIPS • Prediction model studies: PROBAST		
Strategy for data synthesis	[Describe below the approach that will be taken for data synthesis, this should include, where appropriate: • the approach to meta-analysis • the approach to heterogeneity • the approach to sensitivity analysis, for example, for high risk of bias studies • the approach to GRADE • the approach to publication bias] [If the guideline/guideline update has a separate methods document, only issues specific to this question and not covered by the methods document need be included here.]		
Analysis of sub-groups	[Give details of any plans for the separate presentation, exploration or analysis of different types of participants (for example, by age, disease status, ethnicity, socioeconomic status, presence or absence or co-morbidities); different types of test or reference standard; different settings (for example, country, acute or primary care sector, professional or family care); or different types of study. Should also give information about how these subgroups will be used, including whether they will always be reported or only in the		

	presence of heterogeneity, and whether the different subgroupings will be considered separately or jointly.]		
Contact information	[Guideline email]@nice.org.uk [Developer to check with guideline coordinator for email address]		
Health inequalities	[Give details of any health inequalities identified that are relevant to this review question. This will include issues identified in the EIA, but only issues of specific relevance to this question need be mentioned here. For most review questions no specific evidence is likely to be available on health inequalities. In such circumstances the following text is sufficient.] No specific items have been included in this review protocol to identify evidence related to health inequalities. The guideline committee will consider health inequalities when interpreting the evidence and making recommendations. [However, if any elements of the protocol have been designed to address health inequalities, they should be stated here. Possible examples of this may include: • Subgroups that have been included, if there is reason to believe such subgroups will be reported in studies and have different outcomes. • Factors that have been included as they may be correlated to or explain inequalities (for example, including adherence as a prognostic factor if this is a possible mechanism by which health inequalities are generated/exacerbated).		

	• Including a wider range of study types if there are reasons to believe some groups are systematically excluded from a particular study design.]		
Protocol amendments	[If any changes are made to the protocol and agreed after it is signed-off but before the evidence review is completed, these should be explained here. If post-hoc changes to the evidence review are made these should be reported as protocol deviations in the evidence review document, rather than by changing the protocol document]		

Qualitative review protocol

Field	Content	Developer comments (delete before publication)	QA comments (delete before publication)
Review question	[State the question(s) to be addressed by the review, clearly and precisely.]		
Type of review question	Qualitative		
Objective	[What is the objective of the evidence review? Is any rationale/detail of what is known necessary?]		
Condition or domain being studied	[Give a short description of the disease, condition or healthcare domain being studied, for example, type 2 diabetes, physical activity in children.]		
Population	Inclusion: [Give summary criteria for the participants or populations being studied by the evidence review. For example, children and or adults, line of treatment, previous treatment, severity of condition. The preferred format includes details of both inclusion and exclusion criteria.] Exclusion: [Give summary criteria for the participants or populations not being studied by the review. For example, children and or adults, line of treatment, previous treatment, severity of condition. If there are no exclusion criteria, this should be clearly stated.]		
Phenomena of interest	[Give a description of the types of information the evidence review is targeted to identify, and the key domains within which themes are likely to be structured.]		
Types of study to be included	[Modify the list below if required – only interviews and focus groups are likely to be included in most NICE qualitative reviews.]		

	Studies using the following methods for data collection will be included in the review: • Interviews • Focus groups • [Other methods - for example, observation, open ended survey questions] [Explain whether and how published qualitative evidence syntheses will be used in the review – 3 possible examples are given below (delete those that are not relevant).] Only primary studies will be included in this evidence review. Qualitative evidence syntheses will not be searched for or included. Qualitative evidence syntheses of relevant primary study designs will be searched for and used as a source of primary studies in this evidence review, but the qualitative evidence syntheses will not be included as studies in the evidence review, and no data extraction of those syntheses will be undertaken. Qualitative evidence syntheses of relevant primary study designs will be searched for and may be included as part of this evidence review if sufficiently high quality and applicable, with data extracted for both qualitative evidence syntheses and primary studies.		
Other exclusion criteria	[Add details of any other inclusion/exclusion criteria, with justification. Examples might include the location/settings of the studies, language of publication, or publication status.]		

Context	[This section should include any relevant background to the review question, such as changes to the question from the scope or previous versions of the guidance, together with a justification for those changes, such as information from the surveillance report, scoping process or committee discussion of the protocol (if the question is unchanged, this should also be stated). Also include details of any previous or in development NICE guidelines that will be updated by this review question. This section does not need to be very detailed and does not need to provide substantial scientific context to the evidence review – it is usually only to capture the context of other NICE guidance and changes to the question wording.]		
Searches	[Give details of the sources to be searched, search dates (from and to), and any restrictions (for example, language or publication period). The full search strategy is not required, but may be supplied as a link or attachment. Sources include (but are not limited to) bibliographic databases, reference lists of eligible studies and review articles, key journals, trials registers, conference proceedings, Internet resources and contact with experts and manufacturers.] The following databases will be searched: [Amend if required] • Cochrane Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic Reviews (CDSR)		

	• Embase • MEDLINE • CINAHL • PsycInfo • [Add in additional sources] Searches will be restricted by: • [Date limitations] • [English language] • [Human studies] • [Country limits] • [Any other filters] Other searches: • [Reference searching] • [Citation searching] • [Inclusion lists of systematic reviews] • [Websites] • [Grey literature] [Modify text if required] The searches will be re-run 6 weeks before final submission of the evidence review document and further studies retrieved for inclusion. [Delete if not relevant] The full search strategies for all databases will be published in the final review.		
Data extraction (selection and coding)	[Modify text if required] All references identified by the searches and from other sources will be uploaded into EPPI reviewer and de-duplicated. 10% of the abstracts will be reviewed by 2 reviewers, with any disagreements		

	resolved by discussion or, if necessary, a third independent reviewer. [If priority screening is being used add this text, and give details of the stopping rules that will be used – information is available in the manual on the detail to give here] This review will make use of the priority screening functionality within the EPPI-reviewer software. The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above. A standardised form will be used to extract data from studies (see the section on summarising evidence in the chapter of the manual on reviewing research evidence). Study investigators may be contacted for further information where time and resources allow.		
Risk of bias (quality) assessment	[Delete anything below not relevant to this review, and modify the text if required] Risk of bias for different study types will be assessed using the following checklists, as recommended in Developing NICE guidelines: the manual: • Qualitative evidence syntheses: SBU checklist • Primary qualitative studies: CASP qualitative checklist		
Strategy for data synthesis	[Describe the approach that will be taken for data synthesis and the use of CERQual.] [If the guideline/guideline update has a separate methods document, only issues specific to this question and not covered by the methods document need be included here.]		

	[If this evidence review will be used as part of a mixed-methods synthesis, give details here of how the linking of the quantitative and qualitative data will be undertaken.]		
Analysis of sub-groups	[Give details of any plans for the separate presentation, exploration or analysis of different types of participants (for example, by age, disease status, ethnicity, socioeconomic status, presence or absence or co-morbidities); different settings (for example, country, acute or primary care sector, professional or family care).]		
Contact information	[Guideline email]@nice.org.uk [Developer to check with guideline coordinator for email address]		
Health inequalities	[Give details of any health inequalities identified that are relevant to this review question. This will include issues identified in the EIA, but only issues of specific relevance to this question need be mentioned here. For most review questions no specific evidence is likely to be available on health inequalities. In such circumstances the following text is sufficient.] No specific items have been included in this review protocol to identify evidence related to health inequalities. The guideline committee will consider health inequalities when interpreting the evidence and making recommendations. [However, if any elements of the protocol have been designed to address health inequalities, they should be stated here. Possible examples of this may include: • Subgroups that have been included, if there is reason to believe such subgroups		

	will be reported in studies and have different outcomes. • Phenomena of interest that have been included as they may be correlated to or explain inequalities (for example, including adherence if this is a possible mechanism by which health inequalities are generated/ exacerbated). • Including a wider range of study types if there are reasons to believe some groups are systematically excluded from a particular study design.]		
Protocol amendments	[If any changes are made to the protocol and agreed after it is signed-off but before the evidence review is completed, these should be explained here. If post-hoc changes to the evidence review are made these should be reported as protocol deviations in the evidence review document, rather than by changing the protocol document. This section need not contain information on standard decisions made when undertaking qualitative syntheses (for example, refining coding frameworks based on the themes identified) but only substantive changes to the nature of the evidence review (for example, a change in the population of interest.]		

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