



Australian Government
National Health and
Medical Research Council

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WORKING TO BUILD A HEALTHY AUSTRALIA
www.nhmrc.gov.au

NHMRC procedures for third party development of clinical practice guidelines

Draft for consultation
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To be read in conjunction with
NHMRC requirements for approval of evidence based clinical practice guidelines

About this document

This document is for guideline developers who are interested in seeking NHMRC approval of their guidelines. It provides information about the process to follow when submitting guidelines to the NHMRC for consideration and should be read in conjunction with *NHMRC requirements for approval of evidence based clinical practice guidelines*.

This is version 1.1 of the *NHMRC procedures for third party development of clinical practice guidelines*, created XX of XX 2009. When submitting your guideline for NHMRC approval, please include a sentence stating the version of this document used.

DRAFT

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1. Introduction

The National Health and Medical Research Council (NHMRC) encourages the development of evidence-based guidelines by expert bodies, and approves guidelines developed by third-parties that meet NHMRC process and methodological requirements.

5 NHMRC will consider guidelines for approval that have been produced under the auspices of medical specialty associations, relevant professional societies, public or private health organisations, non-government agencies or government agencies at the federal or state level for national use within Australia. NHMRC does not approve guidelines developed and issued by an individual not officially sponsored or supported by one of the above types of
10 organisations.

NHMRC gives priority to guidelines that focus on topics that fall within national health priority areas or NHMRC strategic priorities.

The series of NHMRC publications on the development, implementation and evaluation of clinical practice guidelines are being reviewed. As part of this process, mandatory and
15 desirable requirements for gaining NHMRC approval have been developed (*NHMRC requirements for approval of evidence based clinical practice guidelines*). These requirements and other accompanying documents to support guideline development can be found at: [www.nhmrc.gov.au/\[page to be developed\]](http://www.nhmrc.gov.au/[page to be developed])

The aim of this paper is to inform organisations of the processes that need to be followed for
20 submission of clinical guidelines to the NHMRC for approval and should be used in conjunction with the *NHMRC requirements for approval of evidence based clinical practice guidelines* and accompanying documents. These approval processes apply to new, adapted or updated guidelines.

25 **Summary of key steps**

- Notify NHMRC of your intention to seek approval by submitting to the Guideline in Development Register before starting the guideline process. Registering your intent to seek approval does not mean that the NHMRC will agree to approve your guideline.¹
- Update any changes to the original timelines in the Register by notifying NHMRC at: clinicalguidelines@nhmrc.gov.au.
- Six months prior to the intended public consultation submission date, you should confirm your intention to seek NHMRC approval and specify the month you intend to send the guideline for public consultation. Complete a *first process report* (a suggested framework for this report is provided at Appendix 1) at this stage detailing
35 how you have met or intend to meet the NHMRC mandatory requirements.

¹ Developing a clinical practice guideline is complex and development can take a significant amount of time. It is the responsibility of guideline developers to ensure they have sufficient and appropriate resources to develop evidence based guidelines to the defined NHMRC standards. Sometimes during the development process the scope and timelines for the guideline may change. For these reasons NHMRC will only confirm that it will consider guidelines for approval prior to the proposed consultation phase.

- Within 3 months of submitting the first process report you will be notified of whether the NHMRC will consider the guideline for approval.²
- Where the NHMRC has indicated that the guideline will be considered for approval, a consultation draft should be provided to NHMRC at the beginning of the public consultation phase. Council members will be invited to provide you with initial feedback during the public consultation process.
- The guideline must be released for public consultation (see section 3).
- Provide NHMRC with a copy of the final proposed guideline and a *final process report* (a suggested framework for this report is provided at Appendix 2) which includes details of how the submissions made as part of the consultation process have been addressed.
- Once approved, negotiate with the NHMRC over the incorporation of the NHMRC logo and necessary text in the document. Publishing is the responsibility of the developer.
- The same approval process is required when future reviews of the guidelines are considered. NHMRC approval of guidelines is valid for a maximum of five years (unless otherwise stipulated) and applies only to the original developed guideline. Subsequent changes require resubmission for approval.

² The decision to consider a guideline for approval by the NHMRC is based in the first instance on the process being undertaken, not the content of the guideline.

2. Process for submitting guidelines for NHMRC approval

The key steps in seeking NHMRC approval of guidelines developed by third parties are outlined in Figure 1. The timeframes provided for this process are best indications and may not apply in all circumstances.

5

Prior to starting the guideline development process

Organisations or individuals intending to submit guidelines to the NHMRC for approval should register their intentions on the NHMRC Guidelines in Development Register (www.clinicalguidelines.gov.au).

- 10 The Guidelines in Development Register has been developed to provide a central point of reference for planned and in development Australian clinical practice guidelines, and to reduce duplication and foster greater collaboration between guideline developers.

The following information must be provided to NHMRC (clinicalguidelines@nhmrc.gov.au) for inclusion on the Guidelines in Development Register:

- 15
- Title/Working title
 - Topics covered
 - Scope
 - Organisation responsible for producing the guideline
 - Contact person
- 20
- Collaborating organisations
 - Important dates: estimated commencement and completion dates
 - Development status: consultation start/end dates
 - Funding details

- 25 The NHMRC will confirm receipt of the submission prior to uploading onto the register. If you require further information clinicalguidelines@nhmrc.gov.au is the first point of contact.

During the guideline development process

- 30 Guidelines should be developed to meet the requirements outlined in *NHMRC requirements for approval of evidence-based clinical practice guidelines*. It is the responsibility of the guideline development group to document carefully and demonstrate how they met the NHMRC mandatory requirements for approval.

- 35 You should contact NHMRC (clinicalguidelines@nhmrc.gov.au) six months before the intended public consultation submission date to confirm your intention to seek approval and to clarify the month you intend sending the guideline for public consultation. You should notify any variation in timelines and specifically of any changes to the planned timing of public consultation to: clinicalguidelines@nhmrc.gov.au. At this time you should also submit a *first process report* (a suggested framework for this report is provided at Appendix 1) detailing how you have met or intend to meet the NHMRC mandatory requirements outlined in *NHMRC requirements for approval of evidence-based clinical practice guidelines*.

Within 3 months of submitting the first process report, you will receive notification from the NHMRC of whether the guideline will be considered for approval by the NHMRC. The decision will be based on the information provided in the process report.

Completion of guideline

- 5 The NHMRC requires that both draft guidelines and proposed final guidelines are submitted in electronic format. This is to allow for all amendments that may need to be incorporated before publication.

The guideline development group is responsible for conducting the public consultation process (see section 3). At the beginning of the public consultation phase a copy of the draft
10 guideline, including evidence tables and dissemination plan, should be submitted in electronically to: clinicalguidelines@nhmrc.gov.au.

The guideline developer should notify the NHMRC (clinicalguidelines@nhmrc.gov.au) two months before they intend to submit the final guideline for approval. This allows the NHMRC enough time to arrange the independent peer review (see Section 4).

- 15 The final proposed guideline should be submitted in electronic format via email (clinicalguidelines@nhmrc.gov.au) with a completed *final process report* (a suggested framework for this report is provided at Appendix 2) which includes information about search strategies, methodology, and details of how the document was developed. A list of submissions received and the response of the guideline development committee to each
20 submission should also be included.

When you submit your guideline for approval the NHMRC will seek independent peer review and provide comments within 8 weeks of receiving the final draft guideline. You will be given an opportunity to comment on the independent peer review report and revise the draft document, if appropriate, prior to it being submitted for consideration of approval by the
25 NHMRC Council. If necessary, the NHMRC may seek further clarification from you.

Once the NHMRC is satisfied that the document meets NHMRC requirements it will refer the guideline, with its recommendation, to Council for consideration. Based on advice from Council, the CEO will make the final decision as to whether the guideline is approved or not within a month.

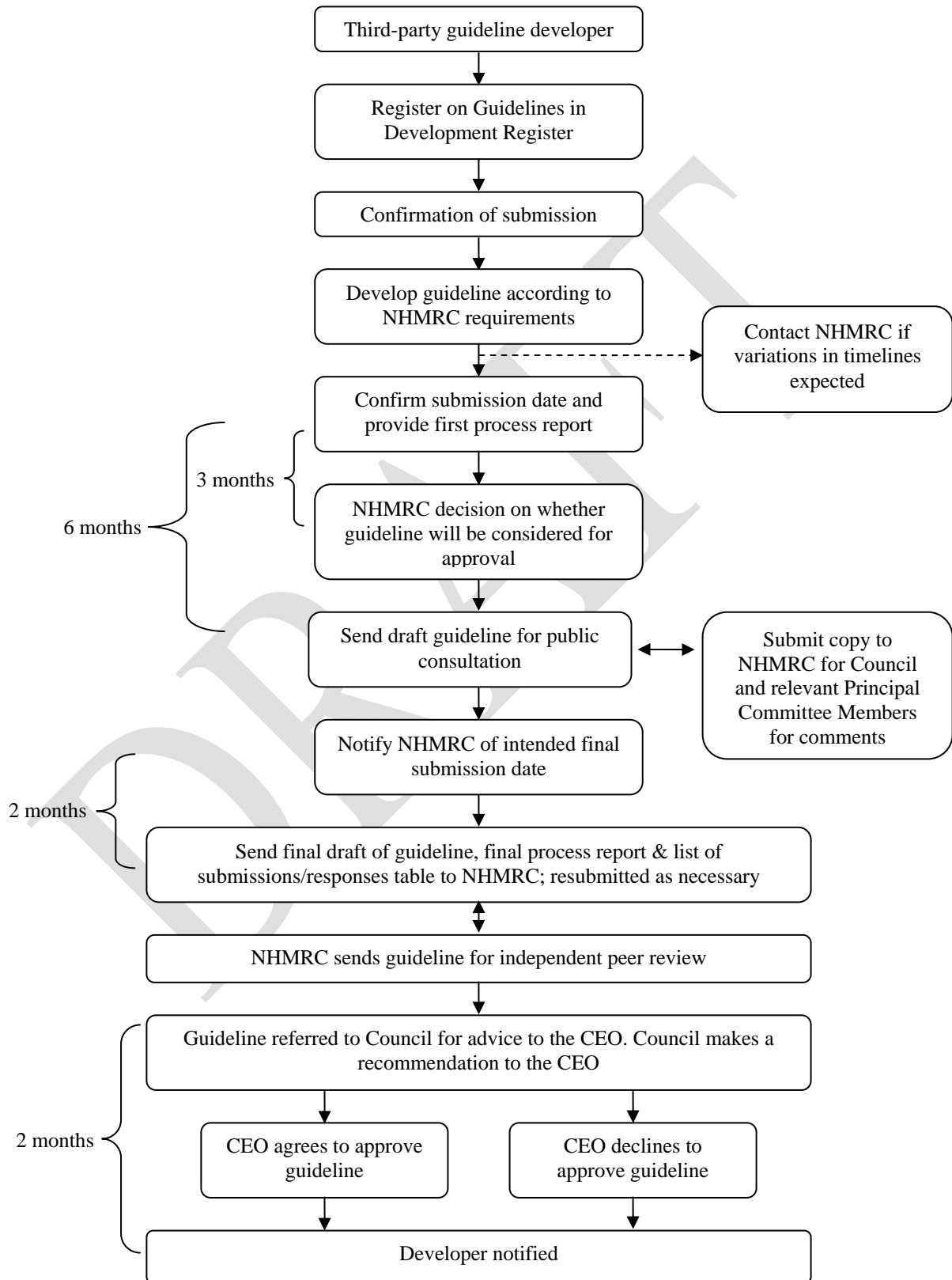
- 30 The NHMRC's decision about approval of the guidelines will be notified in writing to you. If the decision is not to give approval, you will be advised of the reasons for the decision. Any further matters arising, including matters relating to the reasons for refusal may be addressed to the CEO of the NHMRC for the further consideration within one month of this notification.

- 35 If granted, NHMRC approval will be valid for a maximum of five years unless otherwise stipulated. You should note that, in the case of a fast moving area, approval may be for a shorter period of time. You will be expected to acknowledge the period of approval prominently in the guideline and, if you continue to distribute or publish the guideline beyond the period of NHMRC approval you will be expected to remove reference to NHMRC
40 approval when the period expires.

Figure 1: Key steps in seeking NHMRC approval of guidelines developed by third parties

The timeframes provided for this process are best indications and may not apply in all circumstances.

5



3. Public consultation requirements

The *National Health and Medical Research Council Act 1992* (the Act) gives authority to the CEO of the NHMRC to approve guidelines prepared by another person or body outside the NHMRC.

5 Sub-section 14A(2) of the Act provides that:

“The Council may only advise the CEO to approve the guidelines if the Council is satisfied that the person or body, before submitting the guidelines to the CEO for his or her approval:

- 10 (a) prepared a draft of the guidelines that the person or body proposed to submit to the CEO; and
- (b) published a notice, in a manner and form acceptable to the Council:
 - i) containing a summary of the draft guidelines; and
 - ii) stating where copies of the draft guidelines could be obtained; and
 - iii) inviting persons or bodies to make submissions relating to the draft in accordance with the procedures, and within the period, specified in the notice; and
- 15 (c) had regard to any submissions received pursuant to the invitation referred to in subparagraph (b)(iii).”

The legislative requirements set out in section 14A of the Act must be met in full. The notice referred to in paragraph 14A(2)(b) of the Act should follow the format set out in Figure 2 and should be published in at least one major national daily newspaper and on the developer’s organisation website and in any other way which the guideline developer considers appropriate.

A period of at least 30 days should be allowed from the date on which the last notice appears for submissions to be lodged. A summary table of the submissions received, together with the justification as to why each submission comment was or was not included in the document, must be provided to the NHMRC at the time of lodging the final draft. The NHMRC may request copies of any of the submissions received.

Consultation of the kind described above represents the minimum level of consultation that must be carried out in order to satisfy the NHMRC that the requirements of section 14A of the Act have been met. Additional consultation with interested parties may be undertaken during the development of the guidelines.

Figure 2: Suggested format for public consultation notices

<p>NAME/LOGO OF DEVELOPER(S) DRAFT GUIDELINES ON (SUBJECT MATTER)</p> <p>Proposed for submission to the NHMRC for approval under section 14A of the <i>National Health and Medical Research Council Act 1992</i>.</p> <p>The (name of developer) has prepared draft guidelines on (subject matter).</p> <p>You are invited to make a submission to (name of developer) on the draft guidelines.</p> <p>How to make a submission You may make a submission in writing or on audio tape. Please send it to: (address of developer – postal, fax and email).</p> <p>Please include your name and an address or telephone number at which you can be contacted.</p> <p>Closing date Your submission must be received at the above address by (date).</p> <p>Further information A copy of the draft guidelines can be obtained from (address – may be a website address).</p>
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4. Independent peer review of guidelines

5 The purpose of the independent peer review is to ensure that the NHMRC's processes have been adhered to, relevant literature considered and that the guideline is appropriate and realistic for Australian circumstances. The review will consider methodological and clinical aspects and may also include consideration of layout, reliability and relevance to intended audiences.

5. Publication on the NHMRC website and use of the NHMRC logo

10 Guidelines developed by third parties that have been approved by the NHMRC must, when published, carry the NHMRC logo in addition to the logo of the developer on the front cover. The date of the CEO's approval must be clearly stated on the title page and may be included in any foreword or introduction. The full list of requirements for publishing is available from your nominated NHMRC Project Officer.

15 Guidelines developed by third parties approved by the NHMRC will be listed as such on the NHMRC website, with instructions on how copies may be obtained from the developer. The NHMRC will not assume any responsibility for the publication or dissemination of externally developed guidelines. The electronic version of the document will be available on the NHMRC guideline portal or on the developer's website with a link from the NHMRC
20 website.

6. Approval of companion documents

25 Developers may decide to develop companion documents, which are based on the evidence found in the guideline document, for consumers and health care professionals such as general practitioners and nurses. It is recommended that the intended audience of the companion documents should be involved in its development and that the draft documents be focus-tested with appropriate groups prior to finalisation.

30 If you wish the companion documents to display the NHMRC logo, you must seek agreement from the NHMRC within six months of the primary document being approved by the NHMRC.

It is not a requirement for developers to display the NHMRC logo on companion documents.

Appendix 1



FIRST PROCESS REPORT

Background

5 Guideline developers seeking NHMRC approval of their clinical practice guideline are required to submit a First Process Report to NHMRC at clinicalguidelines@nhmrc.gov.au, six months prior to their intended public consultation submission date.

10 The purpose of the First Process Report is to detail how guideline developers have met or intend to meet the mandatory components of *NHMRC Requirements for Approval of Evidence-based Clinical Practice Guidelines*. The current document has been developed as a suggested framework for the First Process Report. As a guide, the First Process report, should not exceed 10 pages.

15 Within three months of submitting your First Process Report to NHMRC you will be advised if NHMRC will consider the guideline for approval. The decision to consider a guideline for approval by the NHMRC is based in the first instance on the process being undertaken, not the content of the guideline.

Please note: a Final Process Report (details at Appendix 2) is required with submission of your final guideline (following public consultation) to NHMRC for approval.

For further information please refer to the documents:

20 *NHMRC Procedures for Third Party Development of Clinical Practice Guidelines*
NHMRC Requirements for Approval of Evidence-based Clinical Practice Guidelines
or contact NHMRC:

by email: clinicalguidelines@nhmrc.gov.au or telephone: 03 8866 0400

Information for inclusion in the First Process Report

1. Guideline details

- 5 – Indicate the proposed guideline title, edition and details of prior editions (if applicable).
- Identify the intended date of the public consultation for the guideline.

2. Governance and stakeholder involvement

- 10 – Identify the agency or agencies responsible for development and publication of the guideline, and the source of all funding for the guideline development and its publication. Where more than one agency is involved in the development of the guidelines, please nominate the lead agency and list the associated agencies and their expected involvement.
- Explain how editorial independence will be maintained.
- 15 – List the members of the multidisciplinary group by discipline and affiliation and how this group was convened. Please note any other people involved in the development of the guideline by discipline and affiliation and what contribution was, or is to be made.
- Describe the mechanisms which have been employed to engage consumer participation. Consumers are defined as the target population identified in the guideline.
- 20 – Describe what processes have been instigated to identify and manage real or potential competing interests of the guideline development committee.

25 3. Endorsements

- List the organisations that you have sought, or will seek, to endorse the guideline.

4. Scope and purpose of the guideline

- Define the scope of the guideline.
- 30 *(The scope may include: the target population group(s) (including age) to whom the guideline recommendations will apply; the clinical setting/s to which the guideline will apply; whether the guideline will cover prevention, screening/assessment, treatment, rehabilitation and/or monitoring).*
- Explain the purpose of the guideline and the rationale for development.
- 35 *(What are the underlying questions/issues/problems motivating the development of the guideline?)*
- Specify the intended target audience of people who should use or not use the guideline.
- Describe any issues of special importance for Aboriginal and Torres Strait Islanders.

5. Evidence review

- Describe the process used to develop the clinical questions to be answered by the guideline.
- 5 - Describe the search strategy, including search terms used and the databases that were searched.
- Indicate the date/s the evidence review was undertaken, and name those undertaking the evidence review.
- Describe the inclusion and exclusion criteria used to select studies for appraisal.
- 10 - Provide the results of the search.
- Describe the data extraction process including tools used to critically appraise the selected studies.
- Note the location of evidence review if not in guideline.

15 6. Guideline content and development of recommendations

- Explain the methods that will be used to reach consensus.
(Such as the Delphi methodology)
- Explain the method that will be used to synthesise the evidence tables into recommendations.

20

7. Consultation

- Describe the proposed public consultation process.

8. Ancillary documents

- 25 - List the proposed tools and resources that will be developed to accompany the guideline.
(Such as patient brochures, clinical summaries, costing templates, flow charts).

- 30 **9. Note the proposed review date and the planned strategy for updating the final guideline or a proposed expiry date.**

Appendix 2



FINAL PROCESS REPORT

Background

5 Guideline developers seeking NHMRC approval of their clinical practice guideline are required to submit a Final Process Report when submitting their final guideline to NHMRC at clinicalguidelines@nhmrc.gov.au.

10 The purpose of the Final Process Report is to detail how guideline developers have met or intend to meet the mandatory components of *NHMRC Requirements for Approval of Evidence-based Clinical Practice Guidelines*. Please note that where the First Process Report may have included intended action, this Final Process Report should include completed items.

15 The current document has been developed as a suggested framework for the Final Process Report. As a guide, the Final Process report, should not exceed 10 pages.

For further information please refer to the documents:

NHMRC Procedures for Third Party Development of Clinical Practice Guidelines

NHMRC Requirements for Approval of Evidence-based Clinical Practice Guidelines

20 or contact NHMRC:

by email: clinicalguidelines@nhmrc.gov.au or telephone: 03 8866 0400

Information for inclusion in the Final Process Report

1. Guideline details

- Indicate the guideline title and edition.
- 5 - Identify the intended date of the public consultation for the guideline.

2. Governance and stakeholder involvement

- Identify the agency or agencies responsible for development and publication of the guideline, and the source of all funding for the guideline development and its publication. Where more than one agency is involved in the development of the guidelines, please nominate the lead agency and list the associated agencies and their expected involvement.
- 10 - Explain how editorial independence was maintained.
- List the members of the multidisciplinary group by discipline and affiliation and how this group was convened. Please note any other people involved in the development of the guideline by discipline and affiliation and what contribution was made.
- 15 - Describe the mechanisms which were employed to engage consumer participation. Consumers are defined as the target population identified in the guideline.
- Describe what processes were instigated to identify and manage real or potential competing interests of the guideline development committee.
- 20

3. Endorsements

- List the organisations that you have sought to endorse the guideline.

4. Scope and purpose of the guideline

- Define the scope of the guideline.
(The scope may include: the target population group(s) (including age) to whom the guideline recommendations will apply; the clinical setting/s to which the guideline will apply; whether the guideline will cover prevention, screening/assessment, treatment, rehabilitation and/or monitoring).
- 30 - Explain the purpose of the guideline and the rationale for development.
(What were the underlying questions/issues/problems motivating the development of the guideline?)
- Specify the intended target audience of people who should use or not use the guideline.
- 35 - Describe any issues of special importance for Aboriginal and Torres Strait Islanders.

5. Evidence review

- Describe the process used to develop the clinical questions to be answered by the guideline.
- 40

- Describe the search strategy, including search terms used and the databases that were searched.
- Indicate the date/s the evidence review was undertaken, and name those undertaking the evidence review.
- 5 - Describe the inclusion and exclusion criteria used to select studies for appraisal.
- Provide the results of the search.
- Describe the data extraction process including tools used to critically appraise the selected studies.
- Note the location of evidence review if not in guideline.

10

6. Guideline content and development of recommendations

- Explain the methods that were used to reach consensus.
(Such as the Delphi methodology)
- Explain the method that was used to synthesise the evidence tables into recommendations.

15

7. Consultation

- Describe the public consultation process.

20

8. Implementation and ancillary documents

- Provide an overview of the implementation plan including dissemination and evaluation.
- List the proposed tools and resources that will be developed to accompany the guideline.

25

(Such as patient brochures, clinical summaries, costing templates, flow charts).

9. Expiry date

- Identify a proposed date for guideline review and the strategy for updating the guideline, or a proposed expiry date.

30