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**Australian Government**

**National Health and  
Medical Research Council**



# Procedures and Requirements for Meeting the NHMRC Standards for Clinical Practice Guidelines

August 2022 version 1.2

## Electronic document

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ISBN Online: 1864964642

This document replaces *NHMRC standards and procedures for externally developed guidelines* (2007).

This document will apply to all externally developed clinical practice guidelines for which intention to seek NHMRC approval is registered on or after 31 August 2022.

## Preferred citation

National Health and Medical Research Council. *Procedures and requirements for meeting the NHMRC standards for clinical practice guidelines*. Melbourne: National Health and Medical Research Council; 2020.

## Revision history

The following table describes a summary of the changes made to this document since original publication.

Version	Date	Amendment notes
1	May 2011	First publication
1.1	January 2012	Minor formatting corrections
1.2	August 2022	Update

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NHMRC Reference code: CP133

# Table of contents

How to contact NHMRC	i
About NHMRC approval	ii
<b>1. Introduction</b>	<b>1</b>
Purpose	1
Scope	2
Before starting guideline development	2
<b>2. Procedures for seeking NHMRC approval</b>	<b>5</b>
Summary	5
Document preparation	7
Stage 1      Register intention to seek NHMRC approval	8
Stage 2      Develop guideline in accordance with NHMRC requirements	9
Stage 3      Release draft guideline for public consultation	10
Stage 4      Submit final draft guideline	11
Stage 5      Publish approved clinical practice guideline	13
<b>3. Requirements for meeting NHMRC standards</b>	<b>15</b>
Introduction	15
A. Governance and stakeholder involvement	15
B. Scope and purpose	16
C. Evidence review	17
D. Guideline recommendations	18
E. Guideline structure and style	20
F. Public consultation	21
G. Dissemination and implementation of guidelines	22
<b>Abbreviations and special terms used</b>	<b>23</b>
<b>References</b>	<b>26</b>
<b>List of tables and figures</b>	
Box 1.1      Summary of NHMRC standards for clinical practice guidelines	1
Box 1.2      Summary of what has changed	3
Table 2.1    Summary of procedures to seek NHMRC approval of clinical practice guidelines	5
Table 2.2    Summary of documents required for NHMRC approval of clinical practice guidelines	7

## How to contact NHMRC

Email: [clinicalguidelines@nhmrc.gov.au](mailto:clinicalguidelines@nhmrc.gov.au)

Telephone: 02 6217 9000

At any time please contact NHMRC to:

- provide updates on the timeline for development of a clinical practice guideline seeking NHMRC approval
- ask for more information, including dates of NHMRC Council meetings to facilitate timing of guideline submission for consideration for approval
- submit documents as required
- enquire about a guideline submission.

Proposed clinical practice guidelines should be listed on Guidelines in Development Register:

[Register a Guideline for NHMRC Approval](#)

## About NHMRC approval

NHMRC approval of a clinical practice guideline recommendations is generally valid for a maximum of five years, and applies only to the version of the recommendations that have been approved by NHMRC. Updates or changes to recommendations must be resubmitted for approval.

Approval of externally developed clinical practice guideline recommendations indicates that NHMRC considers them to be based on the systematic identification and synthesis of the best available scientific evidence for health professionals practising in Australia.

NHMRC will only approve guideline recommendations that meet all the mandatory requirements listed in [Part 3](#) of this document. Developers are encouraged to meet the desirable requirements to improve guideline quality and implementability.

Guideline recommendations approved by NHMRC are recognised in Australia and internationally as representing current medical knowledge and best practice in health care.

### More information

Resources for developers of clinical practice guidelines are available at [Guidelines for Guidelines](#).

# I. Introduction

The National Health and Medical Research Council (NHMRC) has a statutory responsibility to provide leadership in the development of high-quality clinical practice guidelines in Australia. Under Section 14A of the Commonwealth [National Health and Medical Research Council \(NHMRC\) Act 1992](#)<sup>1</sup>, NHMRC can also approve selected clinical practice guidelines developed by other organisations.

As part of this role, NHMRC sets standards in clinical practice guideline development (outlined in [Box 1.1](#)). Clinical practice guidelines should be based on the systematic identification and synthesis of the best available scientific evidence and make clear recommendations for health professionals practising in an Australian health care setting. The NHMRC requirements for developing clinical practice guidelines are designed to ensure that the standards are upheld.

The *Procedures and requirements for meeting the NHMRC standards for clinical practice guideline recommendations* replace those described in *NHMRC standards and procedures for externally developed guidelines* ((2007), and reflect the [NHMRC Standards for Guidelines](#) published in 2016. The procedures and requirements draw on Australian and international best practice and incorporate dimensions from internationally validated guideline appraisal instruments.<sup>2-4</sup>

This document applies to all new and revised clinical practice guideline recommendations seeking NHMRC approval from 31 August 2022. Key changes to the approval process are outlined in [Box 1.2](#).

## Box 1.1 Summary of NHMRC standards for clinical practice guidelines

To meet the NHMRC standards, clinical practice guidelines must:

1. be relevant and useful for decision making
2. be transparent
3. be overseen by a guideline development steering group
4. identify and manage conflicts of interest
5. be focused on health and related outcomes
6. be evidence informed
7. make actionable recommendations
8. be up to date
9. be accessible.

## Purpose

The purposes of this document are to:

- describe the [NHMRC standards](#) for clinical practice guidelines
- outline the procedures for NHMRC approval of clinical practice guideline recommendations developed by external organisations ([Part 2: Procedures](#))
- set out the requirements that must be met in the preparation of clinical practice guideline recommendations to ensure that the NHMRC standards are upheld ([Part 3: Requirements](#)).

## Scope

### Target users

This information is provided for developers of clinical practice guidelines who intend to seek NHMRC approval. Ideally, it should be read *before* beginning the process of developing a clinical practice guideline. This document may also be useful to funders of clinical practice guidelines who wish to be informed by the NHMRC standards.

NHMRC will consider for approval guidelines that have been produced under the auspices of expert organisations including medical colleges, peak bodies representing medical specialists, medical special interest associations, professional societies, public or private health organisations, non-government agencies and federal or state government agencies.

The NHMRC does not consider for approval clinical practice guideline recommendations:

- developed and issued by individuals who are not officially sponsored or supported by one of the above types of organisations
- developed, published or funded by industry groups (or organisations whose main source of funding is derived from industry groups) with a financial interest in the guideline clinical area.

### Types of guidelines to which this document applies

These procedures and requirements apply to clinical practice guideline recommendations developed for national use within Australia.

**Box 1.2 Summary of what has changed**

*Procedures and requirements for meeting the NHMRC standards for clinical practice guidelines* have been updated. Developers should note the following key differences from version 1.1:

- The NHMRC levels and grades of evidence have been rescinded and no longer apply to NHMRC approved or developed guidelines.
- NHMRC will only consider and approve guideline recommendations developed using the GRADE framework ([GRADE](#)).
- NHMRC approval applies to guideline recommendations. Following approval by NHMRC, guideline developers can make changes to parts of their guidelines that are not recommendations without having to seek NHMRC re-approval.
- Developers are no longer required to circulate the public consultation draft to the Therapeutic Goods Administration (TGA), Pharmaceutical Benefits Advisory Committee (PBAC) and Medical Services Advisory Committee (MSAC) as part of the public consultation process.
- Developers must nominate up to eight potential reviewers who are clinical experts in area/s covered by the guideline and are independent of the guideline development process. NHMRC will engage independent clinical expert reviewers as part of the approval process ([Part 2: Procedures, Stage 4](#)).
- Requirement A.4.1 has now been designated mandatory and renumbered [A8](#).

## Before starting guideline development

### Expertise and resources

Guideline development is a complex, lengthy and resource-intensive task. It is the responsibility of the guideline developer to ensure that the resources required (financial support, access to clinical and methodological expertise, and project management and administrative capacity) have been considered and secured prior to commencement.

During guideline development, NHMRC staff are available to provide developers with further information or clarification of the NHMRC standards. Developers are strongly advised to access methodological expertise, in addition to and separate from clinical or content expertise, to assist in the systematic identification, appraisal and interpretation of clinical evidence.

Developers are advised to carefully review relevant modules of NHMRC's [Guidelines for Guidelines](#) series before beginning work on their guidelines.



## Managing timelines

Indicative times taken for NHMRC to respond at each stage of the approval process are summarised in [Table 2.1 in Part 2](#). Developers are requested to make an accurate estimate of the guideline development timelines and key milestones (public consultation and submission of the final draft guideline for consideration for approval) at the beginning of the development process. It is the developer's responsibility to notify NHMRC if the timelines change during the development process. Delays may affect eligibility for consideration of the final draft guideline for approval ([Part 2: Procedures, Stage 2](#): Providing a timetable of key milestones).

## Version control

A clinical practice guideline seeking NHMRC approval should not be disseminated, prior to approval, other than for public consultation purposes. Drafts circulated for this purpose should be clearly marked as such.

For administrative purposes, the final draft guideline should be submitted electronically as a text document (e.g. Word document, rich text format document or PDF). Developers should be aware that amendments may be requested by NHMRC prior to approval.

## Guideline implementation

NHMRC recognises that implementation of guideline recommendations is critical for clinical practice improvement. It should be considered throughout the development of the guideline.

In practice, however, many developers of clinical practice guidelines do not have a role in implementation, or do not have access to funding to implement guideline recommendations. Often, the working group responsible for developing the guideline recommendations is not the same group responsible for implementation.

In recognition of this, a set of requirements are included in [Part 3: Requirements, G](#). It is a mandatory requirement that clinical practice guidelines seeking NHMRC approval must, as a minimum, contain a plan for dissemination of the guideline ([Part 3: Requirement G.1](#)) and should highlight key guideline recommendations that are most likely to lead to improvements in health outcomes for consideration in implementation ([Part 3: Requirement G.2](#)). It is a desirable requirement ([Part 3: Requirement G.3](#)) that, where possible, a plan for implementing the guideline is also provided.

NHMRC requires that a document with the dissemination and /or implementation plan along with the key recommendations for implementation is submitted as a separate document to the main body of the clinical practice guideline for consideration of approval at [Part 2: Procedures, Stage 4](#). NHMRC approval will cover the guideline recommendations, but not the specific activities or the identified key recommendations contained within the dissemination or implementation plan. It will be the guideline developer's responsibility to liaise with the relevant authorities to put these activities into action.

## 2. Procedures for seeking NHMRC approval

### Summary

The procedures are described as five stages in the following section. The responsibilities of the guideline developer and NHMRC at each stage are summarised in Table 2.1.

**TABLE 2.1. Summary of procedures to seek NHMRC approval of clinical practice guidelines**

STAGE	WHAT THE DEVELOPER MUST DO	WHAT NHMRC WILL DO
Stage 1. Register intention to seek NHMRC approval	<b>As soon as possible:</b>	
	Notify NHMRC of the intention to seek NHMRC approval. <a href="#">Register a Guideline for NHMRC Approval</a>	Formally advise developer, in writing, of NHMRC CEO's decision whether to consider the guideline for approval. Normally this takes 2–4 weeks from date of registration unless the CEO seeks advice from Council.
<b>MILESTONE: NHMRC AGREES TO CONSIDER GUIDELINE FOR APPROVAL</b>		
Stage 2. Develop guideline in accordance with NHMRC requirements	<b>As soon as possible:</b>	
	Submit timeline of key milestones. An accurate estimate of date for planned public consultation is required.	Acknowledge the proposed timeline in writing.
	<b>3–6 months before planned public consultation period:</b>	
	Submit progress report (including nominations of potential clinical expert reviewers). Address any issues identified by NHMRC within one month from receipt of response to progress report.	Inform developer in writing if any major issues or gaps in the development process are identified (4–8 weeks from receipt of progress report).
	<b>At any time:</b>	
	Notify NHMRC in writing if timelines change.	Advise developer of any updates as required.

STAGE	WHAT THE DEVELOPER MUST DO	WHAT NHMRC WILL DO
Stage 3. Release draft guideline for public consultation	<p>Confirm the start date of the public consultation period with NHMRC 2 weeks prior to the publication of the first notice of public consultation.</p> <p>Provide the draft guideline and details of public consultation, including dates, web links and submission requirements to NHMRC five days prior the start date of the public consultation period.</p> <p>Release draft guideline for public consultation in accordance with requirements (Refer to <a href="#">Part 3: Requirements, F</a>).</p> <p>Provide draft guideline to relevant stakeholders, including the Director- General, Chief Executive or Secretary of state, territory and Commonwealth departments of health (and other relevant government departments as appropriate to your guideline topic), key professional organisations (such as specialty colleges) and consumer organisations that will be involved in or affected by the implementation of guideline recommendations.</p> <p>Document and address all comments received during public consultation.</p> <p>Notify NHMRC of intended date for submission of final guideline draft for approval (at least 2 months prior to submission date).</p>	<p>Notify Council members of the public consultation period and how to access the draft.</p> <p>Request that Council members who wish to provide comments as individuals<sup>†</sup> do so directly to developer during the specified public consultation period.</p> <p>Encourage Council members to seek advice from their jurisdictions or other expert sources within their networks, as they see fit.</p>
Stage 4. Submit final draft guideline	<p>Submit final draft guideline to NHMRC for approval (at least 2 months prior to the Council meeting at which developer requests the final draft guideline to be considered).*</p> <p>Address any issues raised by reviewers as requested by NHMRC.</p> <p>Address any issues raised at or prior to Council meeting.</p>	<p>Arrange independent methodological and clinical expert review of final draft of guideline.</p> <p>Consider methodological and clinical expert reviewers' comments. Seek further information from developer in preparation of papers for Council consideration (if required).</p> <p>Inform developer in writing whether the guideline is approved by NHMRC (up to 4 weeks after Council meeting).</p>
<b>MILESTONE: NHMRC APPROVES GUIDELINES</b>		
Stage 5. Publish approved clinical practice guideline	<p>Publish and disseminate guideline within 16 weeks of date of NHMRC approval, in accordance with NHMRC publishing requirements.</p>	<p>Inform developer of the NHMRC publishing obligations and requirements.</p> <p>NHMRC will publish an approval announcement in the NHMRC Tracker<sup>6</sup>.</p>

\* Developers should approach NHMRC to request information on upcoming Council Meeting dates.

<sup>†</sup> Comments submitted at this Stage represent those of individual Council members and/or their jurisdictions, and not those of the NHMRC Council.

## Document preparation

It is the responsibility of the guideline developer to document all processes and to demonstrate how they meet the NHMRC mandatory requirements for approval. A list of documents required for submission to NHMRC is summarised in Table 2.2.

**TABLE 2.2. Summary of documents required for NHMRC approval of clinical practice guidelines**

DOCUMENT NAME	DESCRIPTION	SUBMISSION TIME
Progress report	Provides details of aspects of the guideline development process. The developer must submit a progress report to confirm the intention to seek NHMRC approval.	Approximately 6 months (and not later than 3 months) before the draft guideline is released for public consultation.  If the timeline is altered due to delays in guideline development, NHMRC may request further progress reports.
Draft guideline	Draft guideline with recommendations.	Public consultation draft and final draft versions required.
Summary of recommendations	A document separate from the main guideline document that lists the recommendations.	Submitted with final draft for approval.
Technical report	A record of the evidence review process (refer to <a href="#">Part 3: Requirements</a> for the information to be included).	Submitted with final draft for approval.  Should also be made available with public consultation draft.
Administrative report	Non-technical information relating to process of guideline development (refer to <a href="#">Part 3: Requirements</a> for the information to be included).	Submitted with final draft for approval.  May also be made available with public consultation draft.
Dissemination plan	A document separate from the main guideline document which contains, at a minimum, details of the dissemination plan for the guideline.  This document should also highlight key guideline recommendations that are most likely to lead to improvements in health outcomes, for consideration in implementation.	Submitted with final draft or approval.  Should also be made available with public consultation draft.
Public consultation submissions summary	Documents details of public consultation submissions and guideline developer responses (further information on public consultation is available at: <a href="#">Guidelines for Guidelines</a> ).	Submitted with final draft or approval.

For NHMRC administrative purposes, developers must submit documents electronically as a text document (e.g. DOC, PDF or rich text format). Once approved, developers may choose to publish their final guideline in print, electronic or interactive online formats. Special arrangements are in place for 'Living Guidelines' published on the [MAGICApp](#) platform. Please contact NHMRC if you intend to publish on this platform.

The information that is required to be included in the guideline (including appendices), the administrative report and the technical report is detailed in [Part 3: Requirements](#). All information in the technical and administrative reports must be readily accessible to the public when the guideline is published ([Part 3: Requirements E.11–E.12](#)).

## Stage I. Register intention to seek NHMRC approval

### Registration

Before proposing a new clinical practice guideline, it is the responsibility of guideline developers to undertake a formal needs analysis to inform the guideline scope. This should include an assessment of burden of disease and identification of the clinical problem (including variation in clinical practice) which supports a guideline of national significance.

All developers intending to seek NHMRC approval of clinical practice guidelines should register proposed guidelines with NHMRC before starting the development process ([Register a Guideline for NHMRC Approval](#)).

#### IMPORTANT

Early notification prior to commencement will enable NHMRC to process this request and notify developers in a timely manner. Developers should ensure that the timing of registration of a guideline seeking NHMRC approval will enable progress report submission timelines to be met.

### Initial assessment of eligibility for approval consideration

Following registration, NHMRC will assess the scope of the proposed clinical practice guideline to determine whether the registered guideline will be considered by NHMRC for approval.

The final decision on whether to agree to consider a guideline for approval is made by the NHMRC's CEO. The CEO may choose to seek further advice from NHMRC Council before making this decision. NHMRC will formally advise the developer, in writing, of the CEO's decision.

Only guidelines intended to apply nationally will be considered for approval. NHMRC will not consider for approval guidelines developed for a specific local context or health service.

If the CEO declines to consider a guideline for approval, a reason will be stated.

## Stage 2. Develop guideline in accordance with NHMRC requirements

### Provide a timetable of key milestones

When beginning the guideline development process, it is essential that the developer determines an accurate estimate of when the guideline will be released for public consultation, as well as an estimate of the final submission date.

At any time in the development process the developer must notify NHMRC if the dates of public consultation or final submission change, to allow the planned NHMRC-commissioned review process to be adjusted. At any time NHMRC may request more information from developer, if appropriate.

A realistic and accurate timeline is crucial, as it is a mandatory requirement ([Part 3: Requirement C4](#)) that the systematic review is current and includes evidence published within:

- 12 months of the date on which the draft guideline is released for public consultation
- 20 months of the date on which the final draft guideline is submitted to NHMRC for approval.

#### IMPORTANT

Estimates of timelines for public consultation and final submission must be as accurate as possible. Delays may affect eligibility for consideration of the final draft guideline for approval.

### Evidence review

Each guideline should be based on a systematic review and critical appraisal of the current scientific literature ([Part 3: Requirements, C](#)). Further guidance on evidence review, including the use of GRADE is available at [Guidelines for Guidelines](#).

### Progress report

To confirm the intention to seek NHMRC approval for a clinical practice guideline, the developer must submit the first progress report approximately 6 months (and not later than 3 months) before the draft guideline is released for public consultation.

NHMRC will inform the developer in writing if any major issues or gaps in the development process are identified within 4–8 weeks from receipt of the progress report.

If delays in guideline development occur that alter the timeframes for the public consultation and/or final submission dates, further progress reports may be requested by NHMRC.

At this time developers will also be requested to nominate potential clinical expert reviewers for the final assessment at [Part 2: Procedures, Stage 4](#). Guidance for developers on identifying appropriate potential clinical expert reviewers is available at [Guidelines for Guidelines](#).

## Other documents the developer must prepare during Stage 2

In addition to the draft guideline, the draft technical and administrative reports (see [Part 2: Document Preparation](#)) must be prepared during this stage.

The technical report must be submitted with final draft for approval. It should also be made available with public consultation draft.

The administrative report must also be submitted with final draft for approval. It may also be made available with the public consultation draft.

## Stage 3. Release draft guideline for public consultation

### Publishing a notice of public consultation

In accordance with [Section 14A of the NHMRC Act 1992 \(Cwlth\)](#)<sup>1</sup> and [NHMRC Regulation 2016 \(Cwlth\)](#)<sup>7</sup>, developers seeking NHMRC approval must publish a notice inviting public submissions on the draft guideline for a **minimum** period of 30 days ([Part 3: Requirement F.1](#)). In summary:

- The notice must contain a summary of the draft guidelines and state where copies of the draft guidelines could be obtained. Developers should ensure that this public consultation draft guideline is clearly marked to indicate its draft status.
- The notice must identify the last day the developer will accept submissions, which must be, **at a minimum**, 30 days after the notice is first published.

The developer may also undertake additional consultation at this time or at any time during guideline development.

Developers may wish to use additional methods to publicise their public consultation period (including media releases or public events).

If the public consultation draft refers to NHMRC approval, it must clearly indicate that the guideline has not yet been approved by NHMRC and that approval, if granted, would apply to the final draft that is yet to be submitted for consideration following any amendments made after public consultation. Before public consultation, developers should contact NHMRC for advice on the permitted wording of references to NHMRC and NHMRC approval.

### Notifying NHMRC of public consultation

Developers are requested to confirm the start date of the public consultation period with NHMRC 2 weeks prior to the publication of the first notice of public consultation.

Developers are requested to liaise with the NHMRC staff to ensure the draft guideline and details of public consultation, including dates, web links and submission requirements are provided to NHMRC five working days prior to the start date of the public consultation period.



When the draft clinical practice guideline is released for public consultation, NHMRC will notify Council members. Council members will be encouraged to consider the public consultation draft as individuals and/or seek expert advice from their jurisdictions or other expert sources within their networks, as they see fit. Comments and feedback from a Council member will be submitted the directly to the developer during the specified public consultation period.

## Advice from relevant authorities

The guideline developer is required to send a public consultation draft guideline to the Director- General, Chief Executive or Secretary of each state, territory and Commonwealth health department (and other relevant government department as appropriate to your guideline topic).

## Consulting with other stakeholders

The guideline developer is required to identify and consult with key professional organisations that will be involved in, or affected by, the implementation of the clinical recommendations of the guideline. This may include specialist colleges whose members are target users, or which will disseminate the guideline to members, and foundations whose interest area/s are covered by the guideline. Guidance for developers on consulting with stakeholders is available at [Guidelines for Guidelines](#).

The guideline developer is required to identify and consult with key consumer organisations that will be affected by the guideline recommendations.

## After public consultation

The developer must document all the submissions lodged in response to the public consultation notice and record them in a summary table that sets out each comment received and a justification as to why each comment resulted in an amendment of the guideline or not. Information on preparing a public consultation submissions summary is available at: [Guidelines for Guidelines](#).

Where advice has been specifically sought from relevant authorities and any other stakeholders, all responses (including nil response) should be documented and the resulting amendments or other actions clearly stated in the public consultation submissions summary table.

The public consultation submissions summary must be submitted to NHMRC with the final draft guideline at [Part 2: Procedures, Stage 4](#). The final draft submitted for approval should include all amendments and changes made as a result of the public consultation comments.



## Stage 4. Submit final draft guideline

Developers must notify NHMRC of the intended date for submission of the final draft guideline for approval at least 2 months prior to the intended submission date. Developers can request information from NHMRC on upcoming Council meeting dates.

Final draft guidelines should be submitted at least 2 months prior the Council meeting at which developers request the draft guideline to be considered.

For example, developers who wish their guideline to be considered at a Council meeting scheduled for 1 July must notify NHMRC on or earlier than 1 March of their intention to submit. Developers must also submit the final draft guideline no later than 1 May.

### Documents to be submitted at final draft stage

For administrative purposes, the final draft guideline should be submitted to NHMRC as text documents (e.g. a Word document, rich text format document or PDF). Developers may choose to publish their final guideline in print, electronic or interactive online formats.

Developers should be aware that amendments to the final draft guideline may be requested by NHMRC. Accordingly, the final draft guideline should be marked to indicate its draft status. Before being considered for approval by NHMRC, the final draft guideline should not be circulated, other than for purposes of review by the writing group or guideline committee.

The following documents must be submitted with the final draft guideline:

- the technical report (described in [Part 2: Procedures, Document Preparation](#))
- the administrative report (described in [Part 2: Procedures, Document Preparation](#))
- the public consultation submissions summary (described in [Part 2: Procedures, Stage 3](#))
- the dissemination plan (and implementation plan, if one has been developed) (described in [Part 2: Procedures, Document Preparation](#)).

### Guideline reviews prior to Council consideration for approval

NHMRC will commission independent methodological and clinical expert reviews of the final draft guideline.

#### Independent methodological review

The purpose of the independent methodological review is to assess the draft clinical practice guideline and related process documentation to determine whether the development process undertaken was appropriate to meet the NHMRC standards (i.e. NHMRC processes have been adhered to and NHMRC requirements have been met). Independent methodological reviewers will have expertise in evidence review methodology and guideline development. These reviewers will be commissioned by NHMRC after determining that they have no current or prior association with the guideline development process.

#### Independent clinical expert review

The purpose of the independent clinical expert review is to evaluate the appropriateness of the clinical recommendations, based on an overview of the body of evidence.

NHMRC will select clinical expert reviewers with:

- appropriate clinical content expertise
- no current or prior association with guideline development process
- no affiliations with the developer or funding bodies.

Clinical expert reviewers will be asked to consider whether:

- the appropriate evidence been identified and reviewed in line with the scope and clinical questions posed by this guideline
- the risks and potential harms of recommendations been fully considered in the context of clinical practice, including any medicolegal implications
- other relevant guidelines exist on the same topic (including Australian guidelines, international guidelines or other well-referenced guidance) and, if so, whether these are in conflict with recommendations made in the guideline. If such conflicts are identified, the clinical expert reviewers will consider whether the new guideline recommendations are justified by current evidence and their rationale is clearly explained.

To streamline the time taken for NHMRC to engage appropriate clinical expert reviewers, developers are requested to nominate up to eight potential clinical expert reviewers and provide a list of these with their progress report submitted at [Part 2: Procedures, Stage 2](#). Guidance for developers on identifying appropriate potential clinical expert reviewers is available at: [Guidelines for Guidelines](#).

## After review

NHMRC may request amendments, clarification or further documentation as a result of reviewer comments prior to consideration by Council. This may need to occur quickly to meet timelines for Council meetings, and will be negotiated with developers individually, where appropriate.

Council and CEO will consider the final draft guideline and associated documentation along with the independent clinical expert and methodological reviewers' reports. The Chair of the multidisciplinary group convened to develop the guideline may be invited to attend the Council session to address any outstanding issues raised.

NHMRC may request additional amendments to the guideline prior to approval.

NHMRC will formally notify the guideline developer of the CEO's decision in writing up to four weeks after the Council meeting. If recommendations approved, NHMRC approval will be valid for a maximum of five years unless otherwise stipulated. Approval may be for a shorter period in clinical areas in which new evidence is emerging rapidly.

## When NHMRC approval is declined

If a final draft guideline's recommendations are not approved, NHMRC will advise the developer 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 further consideration within 1 month of this notification.

# Stage 5. Publish approved clinical practice guideline

## Publishing obligations and requirements for NHMRC approved guidelines

After a clinical practice guideline is considered and its recommendations approved, NHMRC will inform the developer of publishing obligations. These include use of the mandatory NHMRC statement of approval and NHMRC logo. Guideline recommendations developed by external organisations and approved by NHMRC may not be represented as developed or published by NHMRC. For example, a developer organisation may not use the expression 'an NHMRC guideline' or 'NHMRC recommendations' when promoting NHMRC approved clinical practice guideline recommendations.

Developers should contact NHMRC to request further information on the publishing requirements following approval (including the use of the NHMRC logo and approval statement), and not proceed to publishing until this had been addressed.

The developer must publish the clinical practice guideline within 16 weeks of the date of approval stated in the official notification. Following publication, NHMRC will publish an approval announcement in NHMRC Tracker<sup>6</sup> subscription service and provide information on the NHMRC website for readers on how to obtain the guideline recommendations and associated documents.

The NHMRC will not assume any responsibility for the publication or dissemination of externally developed guideline recommendations beyond what is stipulated above.

## Companion publications

Developers may choose to develop companion documents, 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 target user groups prior to finalisation.<sup>9</sup>

NHMRC does not provide approval for companion documents. Developers should not display the NHMRC logo or approval statement on companion documents.

## Post-approval changes to guideline recommendations

Any changes made to the wording of NHMRC approved guideline recommendations may require re-approval by NHMRC. Please contact NHMRC at [clinicalguidelines@nhmrc.gov.au](mailto:clinicalguidelines@nhmrc.gov.au) before making any changes .

## 3. Requirements for meeting NHMRC standards

### Introduction

This section sets out all the requirements that a guideline developer must fulfil before a clinical practice guideline will be considered for NHMRC approval. Developers should familiarise themselves with all the requirements before beginning the guideline development process. The tables in this section indicate where each requirement must be documented as a minimum.

NHMRC will only approve guidelines that meet **all** of the conditions listed as “mandatory”. Developers are encouraged to meet the “desirable” requirements to improve guideline quality and implementability.

Links to NHMRC Guidelines for Guidelines modules are provided in the table where specific ‘how to’ guidance is available. Developers should ensure they are familiar with all modules before they begin work on their guideline.

### A. Governance and stakeholder involvement

REQUIREMENT	DOCUMENTED IN:
<b>Mandatory</b> The guideline/development process must meet <b>all</b> the following conditions:	
<b>A.1</b> The organisation/s responsible for developing and publishing the guideline is/are named.	Must be in Guideline but can also be in Administrative report
<b>A.2</b> Sources of funding for guideline development, publication and dissemination are stated. <a href="#">Guidelines for Guidelines   Transparency.</a>	Must be in Guideline but can also be in Administrative report
<b>A.3</b> A multidisciplinary group that includes end-users, relevant disciplines and clinical experts is convened to develop the purposes, scope and content of the guideline, and the process and criteria for selecting member are described. <a href="#">Guidelines for Guidelines   Guideline Development Group.</a>	Must be in Guideline but can also be in Administrative report
<b>A.4</b> Consumers participate in the guideline development, and the processes employed to recruit, involve and support consumer participants are described. <a href="#">Guidelines for Guidelines   Consumer Involvement</a>	Administrative report
<b>A.5</b> A complete list of all the people involved in the guideline development process is provided, including the following information for each person: name, profession or discipline, organisational affiliation and role in the guideline development process.	Must be in Guideline but can also be in Administrative report
<b>A.6</b> Potential competing interests are identified, managed and documented, and a competing interest declaration is completed by each member of the guideline development group. <a href="#">Guidelines for Guidelines   Identifying and Managing Conflicts of Interest</a>	Administrative report
<b>A.7</b> A list of organisations that will be approached to endorse the guideline is provided.	Must be in Guideline but can also be in Administrative report
<b>A.8</b> The guideline development process includes participation by representatives of Aboriginal and Torres Strait Islander peoples and culturally and linguistically diverse communities (as appropriate to the clinical need and context), and the processes employed to recruit, involve and support these participants are described. <a href="#">Guidelines for Guidelines   Engaging Aboriginal and Torres Strait Islander Peoples</a>	Administrative report
<b>Desirable</b> The guideline/development process should meet the following conditions, where applicable:	
<b>A.2.1</b> The amount and percentage of total funding received from each funding source is stated. <a href="#">Guidelines for Guidelines   Transparency.</a>	Administrative report

## B. Scope and purpose

REQUIREMENT	DOCUMENTED IN:
<b>Mandatory</b> The guideline/development process must meet <b>all</b> the following conditions:	
<b>B.1</b> The purpose of the guideline is stated, including the clinical questions (see <a href="#">Requirement C.1</a> ), issue or problems the guideline addresses. <a href="#">Guidelines for Guidelines   Scoping Guideline</a>	Must be in Guideline but can also be in Technical report
<b>B.2</b> The health care settings to which the recommendations apply is described, including the health system level (e.g. primary care, acute care) and clinical stage (e.g. whether the guideline covers prevention, screening, assessment, treatment, rehabilitation or monitoring).	Guideline
<b>B.3.</b> The intended end users of the guideline are clearly defined, and any relevant exceptions are identified. <a href="#">Guidelines for Guidelines   Engaging Stakeholders</a>	Guideline
<b>B.4</b> The population to which the guideline recommendations will apply is defined (e.g. children, adolescents, adults or older adults) and population subgroups for which specific information is required are identified and described. <a href="#">Guidelines for Guidelines   Equity</a>	Guideline
<b>B.5</b> Issues relevant to Aboriginal and Torres Strait Islander peoples (such as particular risks, treatment considerations or sociocultural considerations) are identified and described. <a href="#">Guidelines for Guidelines   Engaging Aboriginal and Torres Strait Islander Peoples</a>	Guideline
<b>Desirable</b> The guideline/development process should meet the following conditions, where applicable:	
<b>B.5.1</b> Issues relevant to special-needs groups such as culturally and linguistically diverse communities or groups with low socioeconomic status (e.g. particular risks, treatment considerations or sociocultural considerations) are identified and described. <a href="#">Guidelines for Guidelines   Equity</a>	Guideline

## C. Evidence review

REQUIREMENT	DOCUMENTED IN:
<b>Mandatory</b> The guideline/development process must meet <b>all</b> the following conditions:	
<b>C.1</b> Clinical questions addressed by the guideline are stated in a structured and consistent format to define the boundaries of the topic, i.e. by specifying the relevant population, intervention/s (e.g. treatment/s or diagnostic test/s), comparator/s and outcomes measured. <a href="#">Guidelines for Guidelines   Forming Questions</a>	Technical report Guideline
<b>C.2.</b> Systematic searches for evidence are undertaken and the search strategy is documented, including the search terms and databases searched.	Technical report
<b>C.3.</b> The population groups specified in the search strategy include Aboriginal and Torres Strait Islander peoples and any population subgroups that have been identified (see <a href="#">Requirement B.4 and B5</a> ).	Technical report
<b>C.4.</b> The publication period covered by the searches is stated, and the latest date is within 12 months of the first day of public consultation and within 20 months of submission of the final draft guideline to NHMRC for approval.	Technical report
<b>C.5.</b> The inclusion and exclusion criteria used to select studies for appraisal are described. <a href="#">Guidelines for Guidelines   Selecting Studies</a>	Technical report
<b>C.6.</b> For each clinical question, the developer has provided an evidence table, which summarises the systematic assessment and critical appraisal of all studies that meet the inclusion criteria (i.e. the body of evidence on which a recommendation will be based). Each evidence table should include information on study design, outcomes, level of evidence, the findings of meta-analysis (if performed) and other relevant information. <a href="#">Guidelines for Guidelines   Synthesising Evidence</a>	Technical report
<b>C.7</b> For each clinical question, the developer has provided an evidence statement form, which documents the synthesis and evaluation of the body of evidence to determine the grade of each recommendation, in accordance with NHMRC-approved method (GRADE®).	Technical report
<b>C.8</b> For each recommendation, the developer has provided an evidence summary, which briefly states the outcomes of each clinical studies on which the recommendation was based.	Guideline
<b>C.9</b> A recommended date for future update of the guideline is identified.	Guideline
<b>Desirable</b> The guideline/development process should meet the following conditions, where applicable:	
<b>C.3.1</b> The population groups specified in the search strategy include groups such as culturally and linguistically diverse communities or other groups for whom specific sociocultural factors (including ethnicity, gender, age, disability, socioeconomic status and location) in prevention or treatment outcomes should be considered.	Technical report
<b>C.3.2</b> Search strategies include search terms to identify evidence related to consumers' perceptions and experiences.	Technical report
<b>C.3.3</b> Dependent on the guideline scope, the search strategy is designed to identify evidence for all relevant alternatives for screening, prevention, diagnosis or treatment of the condition addressed by the guideline, including relevant complementary and alternative medicine approaches.	Technical report
<b>C.3.4</b> Search strategies include search terms to identify evidence related to cost effectiveness and resource implications of practice.	Technical report
<b>C.8.1</b> If gaps in the evidence are identified during the evidence review, these are described in the guideline and areas for further research are noted.	Guideline



## D. Guideline recommendations

REQUIREMENT	DOCUMENTED IN:
<b>Mandatory</b> The guideline/development process must meet <b>all</b> the following conditions:	
<b>D.1</b> The wording of recommendations is specific, unambiguous, clearly describes the action/s to be taken by users and matches the strength of the body of evidence. <sup>9</sup>	Guideline
<b>D.2</b> The wording of recommendations is written in plain English and is consistent throughout the guideline.	Guideline
<b>D.3</b> For each evidence-based recommendation, the supporting references are listed and the grade of recommendation is indicated in accordance with NHMRC-approved method (GRADE <sup>8</sup> ).	Guideline
<b>D.4</b> Recommendations formulated in the absence of quality evidence (where a systematic review of the evidence was conducted as part of the search strategy) are clearly labelled. The preferred term for this type of recommendation is a <u>consensus-based recommendation</u> .	Guideline
<b>D.5</b> Any further recommendations included in the guideline, where the subject matter is outside of the scope of search strategy, are clearly labelled as such. The preferred term for this type of recommendation is a <u>practice point</u> .	Guideline
<b>D.6</b> The method used to arrive at consensus-based recommendations or practice points ( <a href="#">Requirements D.4 and D.5</a> ) (e.g. voting or formal methods, such as Delphi) is documented.	Must be in Administrative report. Can also be in Guideline
<b>D.7</b> Areas of major debate about the evidence and the recommendations are identified and the various significant viewpoints are outlined in the guideline text (even if the guideline development working group members eventually reached a decision).	Guideline
<b>D.8</b> The strengths and limitations of the body of evidence reviewed are described in the guideline text and areas of uncertainty are acknowledged.	Guideline
<b>D.9</b> The guideline acknowledges current national guideline recommendations approved by NHMRC or endorsed by major authorities, and any deviations from these are explicitly noted in the guideline text and the rationale provided.	Guideline
<b>D.10</b> Where a guideline makes any recommendation/s specifying intervention/s that are not available or restricted in Australia <sup>v</sup> , the text clearly indicates this, and the developer has consulted the relevant authority/ies (see <a href="#">Requirement E.3</a> ).	Guideline
<b>D.11</b> Where evidence is identified showing that Aboriginal and Torres Strait Islander peoples or other population groups have specific prevention or treatment outcomes, this evidence is clearly identified and considered in the formulation of the recommendations.	Guideline
<b>D.12</b> The harms (risks or side effects) and benefits of each recommended intervention and its alternatives are described in the guideline text and the rationale for the recommendation is explained.	Guideline
<b>D.13</b> Any safety, legal or potential misuse issues related to the clinical recommendations are identified and described in the guideline text.	Guideline
<b>D.14</b> The potential impact of each recommendation on clinical practice or outcomes is described in the text.	Guideline

v. Such as the use of medicines that are not registered by the Therapeutic Goods Administration or outside registered indications, the use of medicines that are not listed for reimbursement by the Pharmaceutical Benefits Scheme, or services for which patients and practitioners are not reimbursed through the Medicare Benefits Schedule.

REQUIREMENT	DOCUMENTED IN:
<b>D.15</b> The guideline and recommendations have been assessed by at least 2 reviewers, independent of the guideline development process, using the <a href="#">AGREE II</a> instrument. <sup>3, 5</sup>	Administrative report
<b>Desirable</b> The guideline/development process should meet the following conditions, where applicable:	
<b>D.2.1</b> Recommendations are formulated using consistent grammar, syntax and wordings, so they can readily be adapted for electronic implementation strategies (e.g. electronic decision support systems and automatic data collection).	Guideline
<b>D.8.1</b> Recommendations that are likely to be affected by new evidence after the guideline has been approved (e.g. major clinical trials underway at the time of guideline publication) are identified and the implications for the guideline recommendations are explained in the guideline text.	Guideline
<b>D.9.1</b> Clinical recommendations that deviate from current practice are identified.	Guideline
<b>D.9.2</b> The resource implications and cost effectiveness of any recommended practice, compared with current or established practice, are explicitly stated in the guideline text.	Guideline
<b>D.11.1</b> Where evidence is identified showing that sociocultural factors (including ethnicity, gender, age, disability, socioeconomic status and location) affect treatment or prevention outcomes (see <a href="#">Requirement C.3.1</a> ), this evidence is clearly identified and considered in the formulation of the recommendations.	Guideline
<b>D.12.1</b> Absolute measures of both efficacy and harm are stated for each management option where evidence is available, e.g. expressed as number needed to treat (NNT), number needed to screen (NNS), or number needed to harm (NNH) as relevant to the recommendation.	Guideline
<b>D.13.1</b> Ethical issues are considered when formulating the recommendations and any such issues identified and described.	Guideline
<b>D.16</b> If evidence for complementary and alternative medicine options is identified, the risks and benefits of these are stated in the guideline text and appropriate recommendations included.	Guideline
<b>D.17</b> If there is a lack of rigorous evidence for a complementary and alternative medicine/therapy commonly used in practice, this is explicitly stated in the guideline text.	Guideline
<b>D.18</b> Recommendations that consider consumer self-management options are included, where relevant.	Guideline
<b>D.19</b> Recommendations emphasise consumer and carer involvement in treatment and care decisions, where relevant.	Guideline



## E. Guideline structure and style

REQUIREMENT	DOCUMENTED IN:
<b>Mandatory</b> The guideline/development process must meet all the following conditions:	
<b>E.1</b> The guideline includes a title page listing: <ul style="list-style-type: none"> <li>(i) the date of publication</li> <li>(ii) the authorship (organisation or individuals)</li> <li>(iii) the publisher</li> <li>(iv) copyright information including the copyright holder</li> <li>(v) address for requesting permission to reproduce material in the text</li> <li>(vi) the ISBN number<sup>i</sup></li> <li>(vii) a preferred citation for the guideline publication.</li> </ul>	Guideline
<b>E.2</b> The guideline is easy to navigate and includes a table of contents or index with hyperlinks or bookmarks to facilitate navigation.	Guideline
<b>E.3</b> The guideline includes a brief (e.g. 1-page) plain English summary.	Guideline
<b>E.4</b> The guideline includes an executive summary that lists all recommendations and their grade using NHMRC-approved method (GRADE <sup>8</sup> ). The summary of recommendations is available as a separate document, and the guideline text states where to obtain this document.	Guideline/ Summary of Recommendations
<b>E.5</b> A glossary of technical terms, acronyms and abbreviations is provided, and terms are used consistently throughout the guideline.	Guideline
<b>E.6</b> Where medicines are mentioned in the guideline, generic names are used and brand names are avoided.	Guideline
<b>E.7</b> The document design and layout enables recommendations to be identified easily within the text and is suitable for people with visual impairment.	Guideline
<b>E.8</b> References in the text are clearly identified and the citations clearly listed. For electronic references, the source location (e.g. website address) and date accessed is stated.	Guideline
<b>E.9</b> Chapter and heading levels are consistent, clearly distinguishable by the document design and layout, and assist with the navigation throughout each topic of the guideline.	Guideline
<b>E.10</b> The guideline information is sequenced in a logical manner which is applicable to the intended end user.	Guideline
<b>E.11</b> The technical report is either (i) included in the guideline document, or (ii) provided in a readily accessible location, such as a website, which is indicated in the guideline.	Guideline
<b>E.12</b> The administrative report is either (i) included in the guideline document, or (ii) provided in a readily accessible location, such as a website, which is indicated in the guideline.	Guideline

<sup>i</sup> International Standard Book Numbers (ISBN) are obtained from an ISBN Agency and can only be obtained when the final document is available. Details available from the National Library of Australia: <http://www.nla.gov.au/services/ISBN.html>

## F. Public consultation

REQUIREMENT	DOCUMENTED IN:
<b>Mandatory</b> The guideline/development process must meet <b>all</b> the following conditions:	
<b>F.1</b> The process for public consultation on the draft guideline complies with <a href="#">Section 14A of the NHMRC Act 1992 (Cwlth)</a> <sup>1</sup> and accompanying regulations <sup>7</sup> .	Administrative report
<b>F.2</b> Details of submissions received during public consultation and the response of the guideline development working group to the submissions (including whether, why and how the guideline was altered) are provided as a separate document to the NHMRC.	Public consultation submissions summary
<b>F.3</b> During the public consultation period, the developer has undertaken and documented consultation with: <ul style="list-style-type: none"> <li>the Director-General, Chief Executive or Secretary of each state, territory and Commonwealth health department</li> <li>other relevant government departments as appropriate to your guideline topic</li> <li>relevant authority/ies<sup>v</sup>, when a guideline makes any recommendation/s specifying interventions that are not available or restricted in Australia (see <a href="#">Requirement D.10</a>).</li> </ul> <a href="#">Guidelines for Guidelines   Public Consultation</a>	Administrative report, Public consultation submissions summary
<b>F.4</b> The developer has identified and consulted with key professional organisations (such as specialty colleges) and consumer organisations that will be involved in, or affected by, the implementation of the clinical recommendations of the guideline.	Administrative report, Public consultation submissions summary
<b>Desirable</b> The guideline/development process should meet the following conditions, where applicable:	
<b>F.2.1</b> A version of the public consultation submissions summary is publicly available, with submissions de-identified.	Administrative report

## G. Dissemination and implementation of guidelines

REQUIREMENT	DOCUMENTED IN:
<b>Mandatory</b> The guideline/development process must meet <b>all</b> the following conditions:	
<b>G.1</b> A plan for the dissemination of the guideline is submitted as a separate document from the clinical practice guideline. <a href="#">Guidelines for Guidelines   Dissemination and Communication</a>	Dissemination plan
<b>G.2</b> Key recommendations that are most likely to lead to improvements in health outcomes are highlighted for consideration in implementation. <a href="#">Guidelines for Guidelines   Implementation</a>	Dissemination plan
<b>Desirable</b> The guideline/development process should meet the following conditions, where applicable:	
<b>G.3</b> A practical implementation plan is provided as a separate document, based on considerations of the Australian health care context and identification of appropriate organisation/s where the key recommendations may be directed. <a href="#">Guidelines for Guidelines   Implementation</a>	Implementation plan (may be part of dissemination plan)
<b>G.4</b> Resources to support implementation of the guidelines are developed, such as summaries and other tools for different health care professionals, and the guideline indicates where these can be obtained.	Guideline
<b>G.5</b> Accompanying consumer information is provided.	Guideline
<b>G.6</b> Versions of the plain English summary and consumer information are available in different languages, if appropriate.	Guideline
<b>G.7</b> Suggestions for local adaptation and adoption of the guideline are provided.	Guideline
<b>G.8</b> Measures are developed for determining the extent to which key guideline recommendations are implemented.	Guideline
<b>G.9</b> An evaluation strategy is developed and described to assess the extent to which guideline recommendations are adopted into routine practice.	Guideline

# Abbreviations and special terms used

<b>Administrative report</b>	A report containing non-technical information about the guideline development process that must be made available to the public and NHMRC, but which is not required for inclusion in the guideline document. This report will include information such as a list of contributors, conflict of interest declaration and statement of funding (as detailed in <a href="#">Part 3: Requirements</a> ). The means by which this report can be accessed (electronic and/or in print) must be provided within the guideline.
<b>Body of evidence</b>	All studies identified for each clinical question by the systematic literature search which meet the specified inclusion criteria
<b>Clinical practice guideline/s</b>	Statements that include recommendations intended to optimise patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. <sup>9</sup>
<b>Clinical practice</b>	The performance of health professionals' within any health care settings.
<b>Consumers</b>	Members of the population using a specified health service or receiving a specified type of health care. Consumers can include patients and potential patients, carers and organisations representing consumers' interests. As a member of a committee, steering group or similar, consumer representatives voice the consumer perspective and takes part in the decision-making process on behalf of consumers
<b>Complementary medicine/s</b>	Complementary medicines (also known as 'traditional', 'integrative' or 'alternative' medicines) include vitamin, mineral, herbal, aromatherapy and homoeopathic products. Refer to Schedule 14 of the Commonwealth <i>Therapeutic Goods Regulations 1990</i> for a list of the type of substances or products covered by the term 'complementary'. Active complementary medicine substances are defined in Section 52F of the Commonwealth <i>Therapeutic Goods Act 1989</i> . Essentially, if the substance is a designated active ingredient that has an established identity and tradition of use, it is a complementary medicine substance.
<b>Companion document</b>	A secondary publication directly adapted or derived from a clinical practice guideline as guidance for a particular group (e.g. patients or a particular health professional discipline), such as a consumer version of a guideline, clinical practice algorithm or summary publication
<b>Consensus-based recommendations</b>	Recommendations formulated by the guideline development group, using a consensus-reaching process, in the absence of high-quality evidence (where a systematic review of the evidence was conducted as part of the guideline search strategy).
<b>Council</b>	The Council of the NHMRC, as established under Section 20 the Commonwealth <i>National Health and Medical Research Council Act 1992</i> . <sup>1</sup> The functions of the Council are to provide advice to the NHMRC Chief Executive Officer and perform other functions conferred on it.
<b>Desirable requirement</b>	Requirements which developers are encouraged to meet to improve guideline quality and implementability
<b>Evidence-based recommendation</b>	Recommendations formulated by the guideline development group based on high-quality evidence and graded according to an NHMRC-approved method (where a systematic review of the evidence was conducted as part of the guideline search strategy).

## Abbreviations

<b>Evidence summary</b>	A summary prepared for each clinical practice guideline recommendation, which briefly summarises the body of evidence on which the recommendation was based, including outcomes, level of evidence and reference citation of clinical studies.
<b>Evidence tables</b>	A table prepared for each clinical question addressed by a clinical practice guideline, which summarises the systematic assessment and critical appraisal of all studies that meet inclusion criteria (i.e. the body of evidence on which a recommendation will be based). Each evidence table should include information on study design, outcomes, level of evidence, the findings of meta-analysis (if performed) and other relevant information.
<b>Evidence statement form</b>	A form summarising the development group's synthesis of the body of evidence for each clinical question, taking into account factors relating to the evidence base, consistency, clinical impact, generalisability and applicability of the body of evidence, which is used to support the formulation and grading of recommendations.
<b>External guideline developer (Developer)</b>	An organisation, other than NHMRC, that is responsible for developing a clinical practice guideline (previously referred to as a third-party developer).
<b>Final draft guideline</b>	The draft clinical practice guideline that is submitted to NHMRC for consideration for approval after addressing issues raised at public consultation stage. Developers should be aware that amendments to the final draft guideline may be requested by NHMRC and thus it should be marked to indicate its draft status. A final draft guideline should not be circulated for clinical use prior to consideration by NHMRC for approval.
<b>Grade of recommendation</b>	A rating assigned to a clinical practice recommendation according to the strength of the evidence on which it is based. The NHMRC-preferred system for grading recommendations is GRADE <sup>8</sup> .
<b>GRADE</b>	The Grading of Recommendations Assessment, Development and Evaluation system, which is an international system for grading evidence when developing clinical practice guidelines.
<b>Guidelines for Guidelines</b>	Guidelines for Guidelines provides guideline developers with practical advice on how to meet the NHMRC standards. It covers every aspect of the planning, development, review, implementation and updating of guidelines.
<b>Health professionals</b>	Any health workers who provide health care and related medical services, including doctors, nurses, Aboriginal health workers and allied health professionals.
<b>Independent clinical expert review</b>	An NHMRC-commissioned evaluation of draft clinical practice guidelines by experts in the relevant clinical area/s, who were not involved in the guideline development process.
<b>Independent methodological review</b>	An NHMRC-commissioned evaluation of draft clinical practice guideline and related process documentation (including technical reports and administrative reports) by an expert in evidence review methodology and guideline development who was not involved in the guideline development process.
<b>Living guideline</b>	A rapidly updated guideline developed using techniques such as those described <a href="#">here</a> .
<b>Mandatory requirement</b>	Requirements that must be met to obtain NHMRC approval.

<b>NHMRC</b>	National Health and Medical Research Council.
<b>Practice points</b>	Points of guidance included in the guideline used to support evidence-based recommendations, where the subject matter is outside of the scope of search strategy, and which were formulated based on expert opinion using a consensus process.
<b>Procedures</b>	A set of tasks which must be carried out by developers seeking NHMRC approval of clinical practice guidelines
<b>Public consultation draft guideline</b>	The interim version of the draft clinical practice guideline that is released for public consultation. Developers should ensure that this public consultation draft guideline is clearly marked to indicate its draft status.
<b>Requirements</b>	The set of conditions necessary for meeting the NHMRC standards for clinical practice guidelines.
<b>Standards (NHMRC standards)</b>	The NHMRC standards for high quality clinical practice guidelines (i.e. that clinical practice guidelines are based on the systematic identification and synthesis of the best available scientific evidence for health professionals practising in an Australian health care setting). The standards are met by fulfilling all the mandatory requirements set out in this document
<b>Technical report</b>	A report containing information about the evidence review and recommendation formulation process used in the guideline development that must be made available to the public, but which is not required for inclusion in the main guideline document. This report will include information such as research questions, literature search strategies, evidence evaluation methodologies and evidence tables (as detailed in <a href="#">Part 3: Requirements</a> ). The means by which this report can be accessed (electronic and/or in print) must be provided within the guideline.
<b>User (end users)</b>	The specific group or range of health workers for whom the clinical practice guidelines are intended, to inform their work in a health setting.

# References

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9. Institute of Medicine (IOM). *Clinical Practice Guidelines We Can Trust*. Washington, DC: The National Academies Press; 2011.