



Procedures and requirements for meeting the 2011 NHMRC standard for clinical practice guidelines

SUMMARY FOR DEVELOPERS

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This document is a summary of the *Procedures and requirements for meeting the 2011 NHMRC standard for clinical practice guidelines*.

This document will apply to all externally developed clinical practice guidelines for which intention to seek NHMRC approval is registered on or after 1 January 2011.

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Procedures and requirements for meeting the 2011 NHMRC standard for clinical practice guidelines

SUMMARY FOR DEVELOPERS

This guide summarises the key aspects of the new standard for approval of clinical practice guidelines by the National Health and Medical Research Council (NHMRC). It should be read in conjunction with the *Procedures and requirements for meeting the 2011 NHMRC standard for clinical practice guidelines*. Available at: <http://www.nhmrc.gov.au/guidelines/developers.htm>. The 2011 NHMRC standard will apply to all clinical practice guidelines for which intention to seek NHMRC approval is registered on or after 1 January 2011.

About NHMRC approval

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 Act \(NHMRC\) Act 1992*](#)¹ 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](#)). 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 rigorous, to ensure that this standard is upheld.

Approval of an externally developed clinical practice guideline indicates that NHMRC considers that the guideline meets the NHMRC standard for clinical practice guidelines. Guidelines with NHMRC approval are recognised in Australia and internationally as representing current medical knowledge and best practice in health care.

NHMRC approval of a clinical practice guideline is generally valid for a maximum of five years, and applies only to the version of the guideline that was approved by NHMRC. Subsequent versions must be resubmitted for approval.

Purpose and intended users

The standards and procedures set out in the *Procedures and requirements for meeting the 2011 NHMRC standard for clinical practice guidelines* replace those described in *NHMRC standards and procedures for externally developed guidelines (2007)*. Changes to the NHMRC standard are summarised in [Box 2](#). An overview of the approval process is provided in [Table 1](#). A list of the documents required for NHMRC approval is provided in [Table 2](#).

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.

BOX 1. Summary of NHMRC standard for clinical practice guidelines

To meet the NHMRC standard, clinical practice guidelines must:

- provide guidance on a clearly defined clinical problem based on an identified need
- be developed by a multidisciplinary group that includes relevant experts, end users and consumers affected by the clinical practice guideline.
- include a transparent process for declaration and management of potential conflicts of interest by each member of the guideline development group
- be based on the systematic identification and synthesis of the best available scientific evidence
- make clear and actionable recommendations in plain English for health professionals practising in an Australian health care setting
- be easy to navigate for end-users
- undergo a process of public consultation and independent external clinical expert review
- incorporate a plan for dissemination including issues for consideration in implementation.

BOX 2. Summary of what has changed

Procedures and requirements for meeting the 2011 NHMRC standard for clinical practice guidelines (2011) replaces *NHMRC standards and procedures for externally developed guidelines (2007)*. Developers should note the following key differences:

- All clinical practice guidelines seeking NHMRC approval must now register on the Guidelines in Development Register (www.clinicalguidelines.gov.au/in-development) at the beginning of the process (Part 2: Procedures, Stage 1). Early notification prior to commencement will enable NHMRC to process this request and notify developers in a timely manner. Developers should ensure that timing of registration will enable them to submit progress reports at required intervals.
- All clinical practice guidelines approved by NHMRC must now include a brief (1-page) plain English summary (Part 3: Requirements, E.3).
- Developers are now required to circulate the public consultation draft to relevant government agencies, including the Therapeutic Goods Administration (TGA), Pharmaceutical Benefits Advisory Committee (PBAC) and Medical Services Advisory Committee (MSAC), and to the Director-General, Chief Executive or Secretary of each Australian health department (state, territory and Commonwealth) as part of the public consultation process.
- Developers are now required to identify and consult 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.
- Developers are now required to engage at least 2 reviewers, who must be independent of the guideline development process, to assess the guideline using the AGREE II instrument²⁻³ prior to submission of the final draft guideline to NHMRC for approval. This enables the assessment of guidelines against internationally accepted appraisal instruments (Part 3: Requirements, D.15).
- Developers will be asked to nominate up to 6 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).
- As part of the public consultation process, NHMRC will notify NHMRC Council Members that the public consultation draft is available for their comment as individuals or on behalf of their jurisdictions (Part 2: Procedures, Stage 2).
- The NHMRC Guidelines Assessment Register (GAR) program has ceased. Guideline developers are now responsible for accessing methodological expertise (Part 1: Introduction, Expertise and resources).

TABLE 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	As soon as possible:	
	<p>Notify NHMRC of the intention to seek NHMRC approval via the Guidelines in Development Register.</p> <p>NB. Developers should ensure that the timing of registration of their guideline will enable them to submit progress report/s at the required intervals (see Stage 2).</p>	<p>Formally advise developer, in writing, of the 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.</p> <p>Notify AHMAC if NHMRC agrees to consider guideline</p>
MILESTONE: NHMRC AGREES TO CONSIDER GUIDELINE FOR APPROVAL		
Stage 2. Develop guideline in accordance with NHMRC requirements	As soon as possible:	
	Submit timeline of key milestones. An accurate estimate of date for planned public consultation is required.	Acknowledge the proposed timeline in writing.
	3–6 months before planned public consultation period:	
	<p>Submit progress report (including nominations of potential clinical expert reviewers).</p> <p>Address any issues identified by NHMRC within one month from receipt of response to progress report.</p>	Inform developer in writing if any major issues or gaps in the development process are identified (4–8 weeks from receipt of progress report).
	At any time:	
	Notify NHMRC in writing if timelines change.	Advise developer of any updates as required.
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 to the start date of the public consultation period.</p> <p>Release draft guideline for public consultation in accordance with requirements (Refer to Part 3: F. Public consultation).</p> <p>Provide draft guideline to relevant stakeholders, including TGA, PBAC and MSAC, the Director-General, Chief Executive or Secretary of state, territory and Commonwealth departments of health, and 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† 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	WHAT THE DEVELOPER MUST DO	WHAT NHMRC WILL DO
Stage 4. Submit final draft guideline	<p>Submit final draft guideline to NHMRC for approval (at least two 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>
MILESTONE: NHMRC APPROVES GUIDELINE		
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>Once published, assess guideline for inclusion on Clinical Practice Guidelines Portal[§] and announce in NHMRC publications (NHMRC Tracker[†] and NICS Update[§]).</p>

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

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

§ All clinical practice guidelines produced in Australia are assessed prior to inclusion on the NHMRC Clinical Practice Guidelines Portal (www.clinicalguidelines.gov.au/about.php).

TABLE 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 (progress report template available at http://www.nhmrc.gov.au/guidelines/developers.htm).	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 content intended for use in clinical setting.	Public consultation draft and final draft versions required.
Technical report	A record of the evidence review process (refer to Part 3: Requirements 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 Part 3: Requirements for the information to be included).	Submitted with final draft for approval. May also be made available with public consultation draft.

DOCUMENT NAME	DESCRIPTION	SUBMISSION TIME
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: http://www.nhmrc.gov.au/guidelines/developers.htm).	Submitted with final draft or approval.

Abbreviations

AHMAC: Australian Health Ministers Advisory Council

CEO: NHMRC Chief Executive Officer

Council: Council of the NHMRC

MSAC: Medical Services Advisory Committee

PBAC: Pharmaceutical Benefits Advisory Committee

TGA: Therapeutic Goods Administration

Contact details for these agencies are available from NHMRC:
clinicalguidelines@nhmrc.gov.au or 03 8866 0400

References

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4. NHMRC Tracker. Available from: <http://www.nhmrc.gov.au/media/tracker/tracker10/index.htm>.
5. NICS Update. National Health and Medical Research Council; Available from: http://www.nhmrc.gov.au/nics/news_events/newsletter/index.htm.