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Procedures and Requirements for Meeting NHMRC Standards for Clinical Practice Guidelines

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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 *National Health and Medical Research Council Act 1992*, NHMRC may approve guidelines developed by other organisations.

As part of this role, NHMRC published the 2011 *Procedures and Requirements for Meeting NHMRC Standards for Clinical Practice Guidelines* (Procedures and Requirements) outlining what guideline developers need to do to receive NHMRC approval of their guideline. In 2016 NHMRC issued *The 2016 NHMRC Standards for Guidelines* (NHMRC Standards) to help ensure guidelines developed in Australia are of high-quality, developed in a transparent way and make clear recommendations.

The NHMRC Guidelines for Guidelines handbook, provides practical advice to guideline developers on how to develop high quality guidelines that meet NHMRC Standards. There are also other resources available to support high quality guideline development that NHMRC recommends using.[a] The Procedures and Requirements draw on Australian and international best practice in evidence review and guideline development and incorporate dimensions from internationally validated guideline appraisal instruments.

The purpose of the Procedures and Requirements is to:

- outline the procedures for NHMRC approval of clinical practice guidelines
- set out the requirements that must be met in the preparation of clinical practice guidelines to ensure that the NHMRC Standards are met.

[a] Resources:

- World Health Organization. (2014). WHO handbook for guideline development, 2nd ed. World Health Organization. https://iris.who.int/handle/10665/145714
- The Living Guidelines Handbook: Guidance for the production and publication of living clinical practice guidelines [Internet]. 1.0. Australian Living Evidence Consortium; 2022. Available from: https://livingevidence.org.au/
- Cochrane Training. GRADE approach: JCE series. Cochrane. https://training.cochrane.org/online-learning/cochrane-methodology/grade-approach/jce-series
- Institute of Medicine (IOM). Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press; 2011

What is the NHMRC guideline approval program?

About the program

Under the *National Health and Medical Research Council Act 1992*, NHMRC has a legislative responsibility to raise the standard of individual and public health and foster the development of consistent health standards in Australia. As one way to meet this obligation, NHMRC may approve guidelines developed by other organisations that meet NHMRC Standards. These are known as **NHMRC approved guidelines**.

A guideline must follow the NHMRC Procedures and Requirements laid out in this document to meet the NHMRC Standards and receive NHMRC approval of the guideline.

What does NHMRC approval mean?

NHMRC approval of a guideline indicates to its users that NHMRC is satisfied that the guideline has been developed to a high-quality standard, is based on the best available evidence, and that the recommendations can be trusted to guide practice.

Throughout this document NHMRC uses the terms **guidelines** and **recommendations**. These terms differentiate the recommendations found within the guidelines and the guideline's supporting text. Although NHMRC will consider the guideline and recommendations in totality, it is recommendations that ultimately receive NHMRC approval.

Benefits for guideline developers

When you register your proposed guideline for NHMRC approval, NHMRC will offer you guidance to assist you in developing a guideline that is of high-quality and meets national standards.

The guidance NHMRC provides is free of charge and the approval process is not intended to create an additional logistical burden beyond what is normally required to develop a high-quality guideline.

Following the NHMRC guidance for meeting the NHMRC Standards for Guidelines demonstrates your commitment to a rigorous guideline development process to users and funders of your guideline.

Why does NHMRC approve guidelines?

NHMRC's mission statement is *'Building a healthy Australia'*. To deliver on this mission NHMRC develops and approves clinical practice guidelines that have the potential to improve health outcomes for all Australians.

NHMRC supports guideline developers to produce recommendations that are evidence-based and free from industry influence so that Australians have access to trustworthy health advice.

Registering your proposed guideline

You must register your proposed guideline with the NHMRC before starting the guideline development process for NHMRC to consider it for approval. NHMRC will not consider guidelines that are already in development.

What types of guidelines does NHMRC consider for approval?

NHMRC will only consider for approval guidelines that are of national significance and which address an Australian health priority. The guidelines must be developed by a recognised health organisation or special interest group for use in Australia.

NHMRC considers guidelines that use varying methods of development so long as the core methods will be developed to NHMRC Standards. This includes, for example, consideration of traditional guidelines, living guidelines and guidelines that have been adapted or adopted. For more information on the difference between living and traditional guidelines you can refer to the Living Guidelines Handbook.

Guidelines must be developed for use throughout Australia. NHMRC will not consider guidelines that are developed for use only in a specific state or territory, or a local health service.

NHMRC will not consider guidelines that are funded by industry, or by organisations or individuals that may receive financial benefit from the guidelines.

Preparing for registration

Before registering your proposed guideline with NHMRC, please contact the NHMRC guidelines team at clinicalguidelines@nhmrc.gov.au to arrange a time to discuss your guideline, the approval process and your potential eligibility.

When you register your proposed guideline, you will be required to submit a comprehensive needs analysis to demonstrate that the guideline is of national significance and fits the description of guidelines considered by NHMRC for approval.

The needs analysis should include an assessment of burden of disease and identification of the clinical problems (including known variations in clinical practice). Appendix A outlines what you must include in a needs analysis.[1]

You must provide references to support your needs analysis. You may also wish to include supporting data from the Australian Institute of Health and Welfare, the Australian Atlas of Healthcare Variation or the Australian Bureau of Statistics.

NHMRC expectations

NHMRC expects that guideline developers will publish high-quality guidelines which can improve health outcomes for Australians. To support guideline developers, NHMRC has published Guidelines for Guidelines modules that provide practical advice on how to meet NHMRC Standards. The modules cover aspects of planning, development, review, implementation and updating of guidelines. NHMRC strongly recommends that you carefully review these modules before commencing guideline development.

It is important to confirm that you have access to the necessary resources and skills to develop your guideline before you register it with NHMRC for approval. You will need to have sufficient

funding and access to clinical, methodological, administrative and project management expertise to develop a guideline that meets NHMRC standards.

NHMRC expects that guideline developers will notify NHMRC of their intention to seek NHMRC approval before you start developing your guideline, and to keep NHMRC informed of progress throughout the process.

NHMRC's role

NHMRC supports guideline developers with the NHMRC guideline approval process, with staff available to provide further clarification of the NHMRC Procedures and Requirements for meeting the Standards for Guidelines.

NHMRC does not provide methodological support or assist in the development activities of guidelines that are registered in the approval program.

Procedures for NHMRC approval

This section describes the procedures for NHMRC approval of guideline recommendations developed by other organisations (termed 'third party guidelines').

The procedures consist of 6 stages, starting from when you register your guideline (stage 1), then develop it (stage 2), conduct public consultation (stage 3), submit it to NHMRC for approval (stage 4), publish it (stage 5), and finally disseminate the recommendations (stage 6). This section outlines the responsibilities of guideline developers and NHMRC throughout these 6 stages.

Stage 1 – Register your proposed guideline

What you need to do

You must register your proposed guideline using this Clinical Guidelines Registration Form.

At registration, you will be asked to provide several key details including a formal needs analysis with supporting references (see Appendix A for further details), identification of the guideline's target audience, the clinical settings it covers, as well as information about the guideline's funding source.

Additionally, you will need to identify any risks that could affect the guideline's development.

What NHMRC will do

After you register your proposed guideline, NHMRC will assess the information you provided and determine whether the guideline will be considered for approval.

The final decision on whether to consider a guideline for approval is made by the NHMRC's Chief Executive Officer (CEO). The CEO may choose to seek further advice from NHMRC Council before making this decision.

NHMRC will formally advise you of the CEO's decision within 4 weeks of registration.

If the CEO agrees to consider your guideline for approval, NHMRC will organise a meeting with you to go through the next steps in the approval process.

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

Stage 2 – Develop your guideline

2.1 Provide a timetable of key milestones

What you need to do

Before you start the guideline development process, you will need to provide an estimated timeline for the key milestones, including forming the guideline development group, completing systematic reviews of evidence, proposed public consultation dates, and submitting the final draft for NHMRC approval. It is important to let NHMRC know if and when any changes occur to the timelines you have provided.

2.2 Complete a progress report

What you need to do

You will need to submit a progress report 6 months before the draft guideline is released for public consultation. This provides NHMRC with details of all aspects of the guideline development process.

NHMRC will confirm when a progress report is needed based on the type of guideline. For example, for living guidelines, the 6 months' timeframe may vary depending on the frequency of updates.

As part of the approval process, NHMRC will commission independent clinical expert (peer) review/s on the guideline's public consultation draft (at stage 3). At the time you submit your progress report you will be asked to nominate potential independent expert reviewers for NHMRC to contact.

Guidance on identifying appropriate potential independent expert reviewers is available at Guidelines for Guidelines – Independent Review.

What NHMRC will do

NHMRC will review the progress report and let you know if any major issues or gaps are identified within 4 weeks of receipt.

You will be asked to address any issues or gaps within 4 weeks from receipt of the NHMRC response.

NHMRC will contact potential independent experts for expert review.

2.3 Prepare the administrative and technical reports

You must submit a draft copy of the technical and administrative reports with the final draft of the guideline for NHMRC approval. Appendix B outlines a proposed table of contents for each report.

The technical report should include information about the evidence review and recommendation formulation process, covering research questions, literature search strategies, evidence evaluation methods, and evidence tables.

The administrative report typically contains non-technical information about the guideline development process. It must cover details about governance, the selection process to recruit committee members, conflict of interest declarations and processes and a plan for dissemination of the guideline.

Please note that the information requested in the administrative report can be published within the guideline or the technical report so long as it is accessible and includes all the information outlined in Appendix B – Proposed Structure of the Administrative Report.

Stage 3 – Public Consultation

Public consultation gives the community the opportunity to comment on advice and guideline recommendations that may affect them.

3.1 Notify NHMRC of public consultation

What you need to do

You must inform NHMRC of the public consultation dates at least 2 weeks before the start date of the public consultation.

You must provide NHMRC with the draft guideline, administrative and technical reports at least one week before the start date of the public consultation.

You will also be required to consult with relevant state, territory and Commonwealth government departments at this stage in the guideline development process.

If you are seeking re-approval of updates to NHMRC-approved recommendations, contact the NHMRC at clinicalguidelines@nhmrc.gov.au.

3.2 Publish a notice of public consultation

What you need to do

NHMRC requires you to publish a notice inviting public submissions on the draft guideline before the start date of the public consultation.

This notice must specify the last day you will accept submissions for consideration prior to submitting the guideline for NHMRC approval, which must be at least 30 days after the notice is first published. The notice must contain a summary of the draft guideline and state where copies of the draft guideline, administrative and technical reports can be obtained.

You must ensure that the public consultation draft guideline is clearly marked to indicate its draft status.

You are strongly encouraged to decide on a public consultation timeframe that accommodates the needs of your stakeholders. This may include choosing a timeframe beyond the minimum NHMRC requirement of 30 days.

You may wish to publicise your public consultation using social media, media releases or public events to ensure wide engagement with the public.

Guidance for developers on promoting public consultation is available at: Guidelines for Guidelines – Public Consultation.

What NHMRC will do

NHMRC will help you promote your public consultation by publishing a notification of public consultation in NHMRC's fortnightly *Tracker* newsletter and promoting the consultation through its networks.

3.3 NHMRC to commission independent reviews

NHMRC commissions an independent methodological review and an independent clinical expert (peer) review which is undertaken on the draft public consultation version of the guideline.

Independent methodological review

Independent methodological reviewers have expertise in evidence review and guideline development methodology. The purpose of the independent methodological review is to assess

whether NHMRC processes have been adhered to and whether the NHMRC requirements have been met when developing the guideline seeking NHMRC approval.

Independent expert review

NHMRC will seek reviews from the experts you have nominated and from additional experts with no current or prior association with the guideline development process or funding bodies. The purpose of the independent expert review is to evaluate the appropriateness of the clinical recommendations, based on an overview of the body of evidence.

NHMRC will provide you de-identified feedback from the reviews and may request clarifications, amendments, or additional documentation. This information will be shared with NHMRC Council when they meet to consider the guideline.

NHMRC may elect not to commission these reviews in certain circumstances (for example updates to guidelines where the methods have largely stayed the same or the scope hasn't changed). NHMRC will advise you if these circumstances apply to your guideline.

3.4 Respond to submissions

As a requirement of the NHMRC Act you must give regard to any submission that you receive in response to the public consultation notice. This includes providing all members of the guideline development group with copies of all submissions to read and carefully consider whether amendments are required in response to each submission.

You must document all the submissions you receive in a public consultation submissions summary. The summary must set out each submission received and a justification as to why it resulted in an amendment of the guideline or not. The resulting amendments or other actions must be clearly stated in the public consultation submissions summary, including rebuttals and nil responses.

The public consultation submissions summary must be submitted to NHMRC with the final draft guideline at Stage 4.

Information on preparing a public consultation submissions summary, including an example of a public consultation summary table is available at: Guidelines for Guidelines – Public Consultation.

Stage 4 – Submit your guideline for NHMRC approval

What you need to do

At least 8 weeks before the planned submission date, you must confirm with NHMRC your intention to submit the guideline to ensure that it is scheduled on the next NHMRC Council agenda. You can request information from NHMRC on the schedule of Council meetings which are typically held three times a year, in March, July and November.

The planned submission date to NHMRC must be at least 8 weeks prior to the NHMRC Council meeting at which you request the draft guideline be considered.

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

The following documents/information must be submitted together with the draft guideline:

- the technical report

- the administrative report*
- the public consultation submissions summary
- a summary of responses to the NHMRC-commissioned independent reviews.

If you are publishing your guideline and its associated documents electronically or in an interactive online format, you must submit them to NHMRC as text documents (for example, as a PDF).

The draft guideline should be marked to indicate its draft status and any recommendations should be marked as draft pending NHMRC approval.

***Please note that the information requested in the administrative report can be published within the guideline or the technical report so long as it is accessible and includes all the information outlined in Appendix B – Proposed Structure of the Administrative Report.**

What NHMRC will do

NHMRC Council and CEO will consider the draft guideline after it has been through public consultation at an NHMRC Council session.

You may be asked to nominate a representative from the guideline development group to attend the Council session to answer any questions that Council members may have.

After considering the draft guideline, NHMRC Council will make one of three recommendations to the CEO, either to approve the guideline recommendations, to approve the guideline recommendations with amendments, or not to approve the guideline recommendations.

NHMRC will formally notify you of the CEO's final decision in writing up to 4 weeks after the Council meeting. NHMRC may request that you make amendments to the draft guideline recommendations after consideration by Council and before NHMRC approval is granted.

Once NHMRC approval is granted it will be valid for a maximum period of five years, unless otherwise stipulated. Approval may be for a shorter period in clinical areas where the evidence base is rapidly evolving.

If draft guideline recommendations are not approved, NHMRC will notify you of the reasons for the decision.

Any further matters arising, including matters relating to the reasons for refusal may be addressed to the NHMRC's CEO for further consideration within 4 weeks of the notification.

Changing the guideline after approval

NHMRC makes a distinction between guideline recommendations and the supporting text of the guideline.

A change to the wording of a guideline recommendation after it has been approved by NHMRC will require re-approval by NHMRC. In most cases a change to recommendation wording will also require further public consultation.

The supporting text of the guideline (that is, everything that is not a recommendation) can be amended by the developer at any time, without reference to NHMRC and with appropriate version control to indicate what has changed to the users of your guideline.

Stage 5 – Publish your guideline

What you need to do

You must publish the guideline within 16 weeks of the date of approval stated in the NHMRC official notification. The guideline must be made freely available, and no charge may be levied or paywall imposed.

You must contact NHMRC to request further information on the publishing requirements before you publish your NHMRC approved guideline.

The final technical and administrative reports/information must be made accessible to the public and their location must be described or hyperlinked in the published guideline.

What NHMRC will do

NHMRC will inform you of the publishing obligations. These include instructions on the use of the mandatory NHMRC statement of approval and the NHMRC logo.

Following publication, NHMRC will publish an approval announcement in NHMRC's *Tracker* newsletter and provide information on the NHMRC website for readers on how to obtain the guideline recommendations and associated documents.

Stage 6 – Disseminate your guideline

It is a mandatory requirement that guidelines submitted for NHMRC approval must, as a minimum, contain a plan for dissemination of the guideline.

What you need to do

You are expected to undertake the tasks you outlined in the guideline's dissemination plan. This may require you to liaise early during the development phase with consumer and health professional organisations to inform your dissemination strategies.

You are encouraged to develop companion documents, based on the evidence found in the guideline document, for consumers and health professionals. These may include a consumer version of the guideline, clinical practice algorithm or factsheets.

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

Requirements for meeting NHMRC Standards

This section lists the requirements that a guideline must meet to receive NHMRC approval.

The requirements are designed to ensure that the NHMRC Standards for Guidelines are met by guideline developers.

NHMRC will only approve guidelines that meet **all** the requirements listed in sections A to G below as mandatory. In addition, you are strongly encouraged to meet the desirable requirements listed in A to G to further improve the quality of your guideline.

Desirable requirements are beneficial but not mandatory due to practical considerations, such as different resource constraints for guideline developers.

Practical advice on how to meet each requirement is available via the provided links to the relevant Guidelines for Guidelines modules.

Under each mandatory requirement there is an italicised explanation that clarifies why it is necessary.

A. Establishing your guideline development group and advisory panels

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
A.1	Establish a multidisciplinary guideline development group, including clinical experts, consumer representatives, and intended users, to develop the guideline's goals, scope, and content. *The composition of a guideline development group will influence the recommendations it makes.*	List all individuals involved in the guideline's development process, including their names, professions, organisational affiliations, and roles in the Administrative Report. Also, describe the selection process used to recruit the multidisciplinary group.	Guidelines for Guidelines | Guideline Development Group

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
A.2	Identify, manage, and document any existing or potential conflicts of interest for all individuals involved in the development of the guideline. *A trustworthy guideline should contain recommendations that are as free of bias as possible.*	Document the identified conflict of interests and any measures taken to manage them. Disclosed interests must be managed in accordance the *Privacy Act 1988*.	Guidelines for Guidelines | Identifying and Managing Conflicts of Interest
A.3	Recruit and support representatives from Aboriginal and Torres Strait Islander people in the guideline development group, based on clinical need and context. *Engaging with Aboriginal and Torres Strait Islander communities improves the cultural sensitivity and relevance of guidelines.*	Describe the recruitment and support processes in the Administrative Report and provide a rationale if representation is absent.	Guidelines for Guidelines | Engaging Aboriginal and Torres Strait Islander Peoples
A.4	Recruit and support representatives from communities needing cultural or language considerations in the guideline development group, based on clinical need and context. *Engaging with people who need cultural or language considerations improves the cultural sensitivity and relevance of guidelines.*	Describe the recruitment and support processes in the Administrative Report and provide a rationale if representation is absent.	

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
A.5	Ensure diverse and inclusive gender representation in the guideline development group. Women must hold at least 40% of positions unless a justification is provided for a different composition based on the gender distribution of experts in the field and those likely to be impacted by the guideline.[2] *Balanced gender representation ensures that the guideline addresses diverse needs and perspectives, resulting in more equitable recommendations.*[3]	Report gender composition of the group developing the guideline.	
A.6	Ensure the views and needs of people living in rural and remote communities impacted by the recommendations are represented. *A geographically representative development group ensures that the unique health challenges and needs of rural and remote areas are accurately addressed.*	List all representatives of rural and remote communities on the guideline development group.	
A.7	Recruit and support at least 2 consumers (who might be patients, carers or advocates from patient organisations) in the guideline development group. *Guidelines can only meet the needs of the population if they are developed with meaningful and authentic engagement with consumers.*	List all consumers including their names, consumer roles and organisational affiliation. Describe the recruitment and support process.	Guidelines for Guidelines | Consumer Involvement

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
A.8	Where multiple panels contribute to different aspects of the guideline (e.g., consumer panels or medical specialty panels), describe how the perspectives from these panels are integrated into the guideline development group.	Report the structure of the advisory panels providing input into the development of the guideline and describe the approval and sign-off processes of recommendations.	

	Desirable requirements What you should do to meet the Standards, where possible	What information you should make available	How to do it
A.9	Recruit into the development group a member with methodological expertise.	List the names of all members with methodological expertise involved in the guideline development process and describe their selection process.	Guidelines for Guidelines | Guideline Development Group
A.10	Recruit into the development group a member with experience in guideline implementation.	List the names of all members with guideline implementation experience involved in the development process and describe their selection process.	Guidelines for Guidelines | Guideline Development Group

B. Scoping your guideline

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
B.1	Define the purpose of the guideline and the issues and problems it aims to address. *A clearly defined purpose provides direction and focus for the guideline development process.*	A clearly defined purpose and issues the guideline aims to address must be made available in the guideline.	Guidelines for Guidelines | Scoping Guideline
B.2	Describe the healthcare setting to which the recommendations apply, including the health system level (e.g. primary care, acute care, community care) and clinical stage (e.g. whether the guideline covers prevention, screening, assessment, treatment, rehabilitation or monitoring). *A clear description of the guideline's healthcare setting guides health professionals on how to apply the recommendations.*	The healthcare setting is described in the guideline.	Guidelines for Guidelines | Scoping Guideline
B.3	Define the intended users of the guideline and identify any relevant exceptions. *Defining the intended users helps ensure that the guideline is developed to meet the specific needs and contexts of those users.*	The intended users are defined in the guideline.	Guidelines for Guidelines | Scoping Guideline

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
B.4	Define the population to which the recommendations will apply (e.g. older adults with dementia, all adults diagnosed with inflammatory arthritis). *Defining the target groups helps healthcare providers understand who the recommendations are intended for.*	The groups to which the recommendations will apply and subgroups for which specific information is required are defined in the guideline.	Guidelines for Guidelines | Equity
B.5	Identify issues relevant to Aboriginal and Torres Strait Islander people, such as particular risks and prevention and treatment considerations. *Identifying issues relevant to Aboriginal and Torres Strait Islander people ensures that guidelines are tailored to improve health outcomes for all Australians.*	Describe the identified issues in the guideline.	Guidelines for Guidelines | Engaging Aboriginal and Torres Strait Islander Peoples Guidelines for Guidelines | Equity
B.6	Identify issues relevant to sex and gender differences in prevention, diagnosis or treatment (such as delayed diagnosis, overprescribing and different responses to treatment). *Identifying sex and gender issues ensures that guidelines are equitable and effective for all genders leading to improved health outcomes.*[3]	Describe any identified issues in the guideline.	

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
B.7	Identify issues relevant to any population groups needing special consideration in prevention, diagnosis or treatment, based on clinical need and context. *Identifying issues relevant to population groups needing special cultural or social considerations ensures that guidelines are inclusive and tailored to meet the diverse needs of all individuals.*	Describe any identified issues in the guideline.	Guidelines for Guidelines | Equity
B.8	Consult with key professional and consumer organisations involved in or affected by the guideline to inform its scope. *Early input from stakeholders will make sure that your guideline is relevant and focused on the health topics of importance.*	The consultation process and its outcomes.	Guidelines for Guidelines | Scoping Guideline

C. Undertaking evidence review

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
C.1	Define the clinical questions in a consistent format specifying the relevant population, intervention or exposure, comparators and prioritised outcomes of interest (PI/ECO) or equivalent.[4] *Clear clinical questions provide a robust framework for what information needs to be gathered and assessed.*	Document the clinical questions in the guideline in a structured and consistent format.	Guidelines for Guidelines | Forming Questions
C.2	Establish a search protocol that defines the eligibility criteria for considering studies for appraisal and the methods that will be used to identify and appraise the studies. *Establishing clear criteria a priori ensures that all studies are evaluated based on the same standards.*	Document the inclusion and exclusion criteria used to select studies.	

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
C.3	Undertake a systematic search for evidence and document the search strategies including: • search terms used • dates the searches were run • databases searched • publication period covered by the searches • any filters and limits used • the number of studies identified. *Recommendations made in guidelines should be informed by well-conducted systematic reviews.*	Document the search strategies in the Technical Report.	Guidelines for Guidelines | Identifying the evidence
C.4	Ensure the population terms in the search strategies will retrieve research involving or relevant to Aboriginal and Torres Strait Islander people. *Ensuring that the search strategies are culturally sensitive informs recommendations that consider the health needs of Aboriginal and Torres Strait Islander people.*	Describe any identified issues in the guideline or note that no issues were identified.	Guidelines for Guidelines | Engaging Aboriginal and Torres Strait Islander Peoples Guidelines for Guidelines | Equity

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
C.5	Ensure the population terms in the search strategies will retrieve research involving or relevant to any population groups needing special consideration in prevention, diagnosis or treatment, based on clinical need and context. *All people should have a fair opportunity to attain their full health potential, and no one should be disadvantaged in achieving this potential if it can be avoided.*	Describe any identified issues in the guideline or note that no issues were identified.	Guidelines for Guidelines | Equity
C.6	Identify issues related to consumers' perceptions and experiences. *Identifying evidence on consumer perceptions and experiences ensures the guideline reflects practical relevance to consumers.*	List the identified issues and the mechanisms by which they were identified (e.g. expert opinion, stakeholder advice or evidence search) in the Technical Report.	Guidelines for Guidelines | Identifying the evidence
C.7	Specify the publication period covered by the searches (or those of the source systematic reviews). Ensure the latest date is within 12 months of the first day of public consultation and within 20 months of submitting the final draft guideline to NHMRC for approval. *A recent search date ensures that the guidelines are based on the most current evidence available.*	Document the publication dates covered by the searches in the Technical Report.	

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
C.8	Present the evidence identification and study selection process using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram. *Thorough documentation of the search process demonstrates transparency and reproducibility.*	Provide a PRISMA flow diagram in the Technical Report.	Guidelines for Guidelines | Identifying the evidence
C.9	Present details on the characteristics and methodology of each included study, including study design, population, interventions, comparisons, outcomes, and any other relevant factors in a table. *A 'Characteristics of Included Studies' table provides a clear and structured summary of study details, facilitating comparison and synthesis of evidence.*	Summarise the extracted information in a 'Characteristics of Included Studies' table in the Technical Report. This table should include columns for study design, participants, interventions/exposure, comparisons, outcomes, risk of bias and key findings.	Guidelines for Guidelines | Selecting Studies and Data Extraction
C.10	Assess the risk of bias in the included primary studies using a validated tool. *The findings of a systematic review depend strongly on the validity of its included studies.*	Describe the findings of the risk of bias assessment including the tool used and rationale for the judgments made in the Technical Report.	Guidelines for Guidelines | Assessing Risk of Bias

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
C.11	Synthesise the identified evidence for each prioritised outcome using an appropriate method (qualitative or quantitative synthesis) for the relevant clinical question. *Documenting the assessment process in a Summary of Findings table enhances the transparency of the guideline development process.*	Report the synthesis findings in a Summary of Findings table. Detail the methods used for synthesis, the results and the level of certainty in the evidence (as per GRADE)[4].	Guidelines for Guidelines | Synthesising Evidence
C.12	Provide a brief written statement on the interpretation of the body of evidence. *This written statement aids in the interpretation of complex evidence tables and assists in the development of recommendations.*	Provide a high-level narrative summary of the body of evidence per PICO question.	Guidelines for Guidelines | Synthesising Evidence
C.13	Where evidence has been used from other guidelines (e.g. adopt/adapt methods), outline the methods used to incorporate evidence from the source guideline. *Documenting how evidence reviews were taken from other guidelines enhances the transparency of the guideline development process.*	Process used to adapt or adopt evidence reviews of others including what elements of the source guideline were used to contribute to the final guideline (as per GRADE-ADOLOPMENT).	Guidelines for Guidelines | Adopt, adapt or start from scratch

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
C.14	Identify gaps in evidence and areas that require further research. *Identifying the research gaps acknowledges the limitations of the current knowledge base and can help direct research to areas of need.*	Describe any gaps in evidence that you may find and highlight areas for further research.	

	Desirable requirements What you should do to meet the Standards, where possible	What information you should make available	How to do it
C.15	Consider including in your search strategies terms that identify evidence related to interventions' cost-effectiveness, resource implications, feasibility to implement and acceptability to intended users.	List the search terms in the Technical Report. Describe the identified issues in the guideline.	Guidelines for Guidelines | Identifying the evidence
C.16	State the absolute measures of efficacy and harm for each intervention when evidence is available.	The absolute measures of efficacy and harm are stated for each intervention using metrics such as numbers per 100 or numbers per 1000, number needed to treat (NNT), number needed to screen (NNS), or number needed to harm (NNH).	

D. Guideline recommendations

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
D.1	Write clear, actionable recommendations in plain English. *Well-written recommendations are easily understood by all users, regardless of their expertise or background.*	Recommendations should: • detail the action to be taken (start with a verb) • identify who should take the action and when • identify the target population • be worded to match the strength of the recommendation.	Guidelines for Guidelines | Implementability - Form actionable recommendations
D.2	Use the GRADE Evidence-to-Decision framework to facilitate decision making, record judgements, and document the process of going from evidence to drafting a recommendation.[4, 5] *This helps intended users understand the rationale behind each recommendation.*	The supporting GRADE Evidence-to-Decision table is available next to each recommendation.	

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
D.3	For each recommendation provide a summary of how the guideline development panel weighed up the evidence and the judgements they made to inform the recommendation. *An evidence summary allows intended users to quickly grasp the key findings that underpin the recommendation.*	A summary of the overall interpretation of the balance of benefits and harms and judgments for each recommendation is documented.	
D.4	Document where recommendations were used from other guidelines (e.g. adopt/adapt methods), and how they were incorporated into the recommendation.	Documenting how recommendations may have been adopted or adapted from other guidelines enhances the transparency of the guideline development process. See GRADE-ADOLOPMENT for advice on the process for adoption or adaptation.	Guidelines for Guidelines | Adopt, adapt or start from scratch
D.5	Label recommendations according to the strength of the recommendation and the certainty of evidence, using GRADE methods.[4] *Labelling recommendations makes it easier for intended users to understand the certainty of the evidence behind the guidance they are following.*	Recommendations are clearly labelled in the guideline.	Guidelines for Guidelines | Assessing certainty of evidence

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
D.6	Label actionable statements as good practice statements if they are deemed necessary for practice but are not based on a systematic review and an assessment of the certainty of evidence.[6, 7] *Clear labelling helps intended user distinguish between actionable statements based on systematic evidence review (i.e. formal recommendations) and those based on ethics principles, principles of care or other factors. Good practice statements are usually made when there is high certainty that the desirable effects of the action clearly outweigh the undesirable effects, but the body of supportive evidence is indirect.*	Good practice statements are clearly labelled in the guideline and supported by a structured decision-making process and rationale for their development.	
D.7	Document the method used to develop recommendations (e.g. voting or formal methods, such as Delphi). *Documenting the methods provides a clear and transparent record of how decisions were made.*	Methods used to achieve consensus amongst the guideline development group for developing recommendations and good practice statements are described in the guideline.	

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
D.8	Explain the terminology used to describe the strength of recommendations.[7] *Defining the strength (e.g. strong or conditional) and direction (e.g. for or against) of recommendations helps intended users understand whether there are specific conditions in which the recommend applies.*	Definition of the terminology used to describe the strength of recommendations is provided in the guideline.	
D.9	Where evidence shows that Aboriginal and Torres Strait Islander people require special considerations in prevention, diagnosis or treatment, this evidence is clearly identified and considered in the formulation of the recommendations. *Tailored recommendations can help to reduce inequities.*	Where evidence is available recommendations aimed to address issues specific to Aboriginal and Torres Strait Islander people are included in the guideline.	
D.10	Where evidence shows that specific population groups require special considerations in prevention, diagnosis, or treatment, based on clinical need and context, this evidence is clearly identified and considered in formulating the recommendations. *Tailored recommendations can help to reduce inequities.*	Where evidence is available, recommendations aimed to address issues specific to these populations are included in the guideline.	Guidelines for Guidelines | Equity

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
D.11	Recommendations or good practice statements that emphasise consumer and carer involvement in treatment and care decisions are included where relevant. *Recommendations or good practice statements that support consumer and carer involvement in clinical decisions ensure that treatment and care are tailored to the individual's needs.*	Recommendations supporting consumer and carer involvement in treatment and care decisions are included in the guideline.	
D.12	Indicate if any recommended intervention is unavailable or restricted in Australia and consult with relevant authorities. *Knowing the availability and restrictions of interventions helps intended users avoid delays in treatment.*	Any unavailable or restricted intervention is clearly marked as such in the guideline.	
D.13	Describe any safety, legal or potential misuse issues related to the recommendations. *Understanding the risks associated with implementing recommendations ensures they are applied in compliance with regulations and minimises patient harm.*	Safety, legal or potential misuse issues are described in the guideline.	

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
D.14	Describe the resource and cost implications of any recommended practice compared to current practice. *Knowing the resource implications aids in resources allocation and planning.*	The resource and cost implications of recommended practices compared to current practice are described in the guideline. These are usually considered as part of the GRADE Evidence to Decision (EtD).	
D.15	Describe any implementation considerations and provide suggestions to assist intended users with implementing the recommendations. *Knowing potential barriers helps intended users anticipate challenges and develop strategies to overcome them.*	Implementation considerations are described in the guideline.	
D.16	Identify recommendations likely to be affected by new evidence (e.g. ongoing major clinical trials) and explain the potential implications on the recommendations. *Knowing which recommendations may soon be updated and why fosters an adaptable approach to clinical practice.*	Recommendations likely to be affected by new evidence are identified in the guideline with corresponding explanation of the potential implications on those recommendations.	Guidelines for Guidelines | Updating
D.17	Identify a future review date for each recommendation. *Knowing which recommendations may soon be updated and why fosters an adaptable approach to clinical practice.*	A future review date is included in the guideline for each recommendation or topic.	Guidelines for Guidelines | Update

	Desirable requirements What you should do to meet the Standards, where possible	What information you should make available	How to do it
D.18	Describe the circumstances that would trigger the need to review or update the guideline or specific recommendations and how these circumstances should be monitored. *Identifying what scenarios could trigger the need to review a guideline enables users to assess the currency of information a guideline is based on.*	A section that describes specific circumstances that could trigger a review of the recommendations after they are published and how they should be monitored. For instance, new information, emerging evidence or new therapies that have substantial implications for the recommendations.	Guidelines for Guidelines | Update
D.19	Identify and describe any ethical issues and consider them when formulating the recommendations.	Ethical issues considered in formulating the recommendations are described in the guideline.	

E. Structuring your guideline

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
E.1	The guideline includes a title page listing: • the date of publication • the date of next review • the authorship • the publisher • the funder(s) • copyright information including the copyright holder • address for requesting permission to reproduce material • a preferred citation for the guideline publication. *A well-structured title page assists readers to immediately identify the basic information about the guideline.*	A title page is included in the guideline. This could be included in the guideline's introduction section. Alongside the date of publication should be a date for when the guideline should be next reviewed.	
E.2	Include a table of contents or a navigation menu. *A table of contents or a navigation menu allows readers to quickly find specific sections, improving the user experience.*	A table of contents or navigation menu is included in the guideline.	

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
E.3	Provide an executive summary, a brief plain English summary and a summary of all recommendations. *A summary of the guideline allows intended users and the public to quickly grasp the essential points and recommendations.*	An Executive Summary, a plain English summary and a summary of recommendations are included in the guideline.	
E.4	Include a glossary of technical terms, acronyms and abbreviations, and use terms consistently. *A glossary of terms ensures that all readers, regardless of their level of expertise, can understand the content.*	A glossary of terms, acronyms and abbreviations is included in the guideline.	
E.5	Use generic names for medicines and avoid brand names (unless clinically required). *Generic names remain consistent even when the same medicine is available under a different brand. This prevents any perception of bias.*	All medicines are referred to by their generic name and justification is provided to any use of brand names.	
E.6	Clearly identify references in the text and list citations with source locations and access dates for electronic references. *Clear referencing enhances the credibility of the guideline.*	References are included in the guideline.	

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
E.7	Ensure chapter and heading levels are consistent and clearly distinguishable, aiding navigation. *Clear distinctions between chapter and heading levels allow readers to quickly find the information they need without confusion.*	Chapter and heading levels are distinguishable and consistent throughout the guideline.	
E.8	The administrative and technical reports/information are provided in an accessible location which is hyperlinked in the guideline. *Providing these reports/information demonstrates transparency in the guideline development process. It is important to make this information available and accessible.*	Information related to the administrative and technical reports can be provided as part of an administrative or technical report, or as part of the guideline, or in another location (e.g. website). Links to this information should be referenced in the guideline where appropriate.	
E.9	Ensure that the content of your guideline is inclusive and accessible for all people including those with disabilities. *Accessible guidelines promote equality, enhance user experience and broaden audience reach.*	The content of the guideline must be accessible to people with disabilities.	

F. Undertaking public consultation

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
F.1	The process for public consultation on the draft guideline complies with Section 14A of the *NHMRC Act 1992* and accompanying regulations.[8] *For guidelines developed by other organisations, compliance with Section 14A is necessary for the NHMRC CEO to approve the guidelines.*	Describe the process for public consultation in the public consultation submissions summary.	Guidelines for Guidelines | Public Consultation
F.2	Promote the public consultation using a variety of strategies that consider use of social media, media releases and direct emails to stakeholders. *Utilising multiple strategies ensures that the consultation reaches a broad audience, increasing the likelihood of engaging a diverse group of stakeholders.*	Describe the strategies to promote public consultation in the public consultation submissions summary.	Guidelines for Guidelines | Public Consultation
F.3	Include question(s) in your consultation to inform the application of the guideline's recommendations. *Gathering specific feedback on practical aspects of the recommendations can help identify potential barriers and facilitators to implementation.*	List public consultation questions in the public consultation submissions summary.	Guidelines for Guidelines | Public Consultation

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
F.4	Publish a public consultation submissions summary detailing all public consultation submissions and the guideline development working group's responses including any changes made and justifications for no changes. *A detailed public consultation submissions summary demonstrates how public input has been considered and incorporated into the final guidelines.*	The public consultation submissions summary is publicly available. If respondents consent to publicising their submissions, ensure you redact their contact details and any personal information of others mentioned. Submissions may include personal stories and names of individuals who might not know they have been referenced.	Guidelines for Guidelines | Public Consultation
F.5	Consult with and document responses from government departments, key professional and consumer organisations involved in or affected by the guideline's clinical recommendations. *Consultations can ensure that the views and needs of all stakeholders are considered, leading to more comprehensive and applicable guidelines. Consultations can also provide insights into regulatory and policy frameworks, which can inform the development of guidelines that are aligned with current policies.*	Consult with key government departments in each state and territory and the Commonwealth health department. Submissions and corresponding responses are documented in the public consultation submissions summary.	Guidelines for Guidelines | Public Consultation

G. Disseminating, implementing and evaluating your guideline

	Mandatory requirements What you must do to meet the Standards and why it is necessary	What information you need to make available	How to do it
G.1	Describe the strategies you will use to disseminate the guideline. Consider using social media, media releases and local community champions. *Well-designed dissemination strategies can improve access to a guideline and lead to improvement in health outcomes.*	A dissemination plan outlining your strategies for each group of intended users and consumers is described. For each dissemination activity, you must include when it will be done and who will be responsible for it.	Guidelines for Guidelines | Dissemination and Communication
G.2	Consult with key professional and consumer organisations that are involved in or affected by the guideline's recommendations to inform your dissemination strategies. *Organisations can help disseminate the guidelines to a wider audience, ensuring that the information reaches all relevant parties.*	The consultation process and its outcomes are reported.	Guidelines for Guidelines | Dissemination and Communication
G.3	Outline potential measures of impact for the health outcomes the guideline aims to address. *Evaluation objectives provide a framework for continuous improvement of the guidelines based on the measured impact and feedback.*	Specific impact measures are listed in the guideline.	Guidelines for Guidelines | Guideline Impact

	Desirable requirements What you should do to meet the Standards, where possible	What information you should make available	How to do it
G.4	Provide an implementation plan that includes clear implementation outcomes, the resources and activities required to achieve the outcomes and who is responsible for carrying out each task.	An implementation plan is described.	Guidelines for Guidelines | Implementation
G.5	Develop resources to support implementation, such as one-page summaries, infographics and tools for healthcare professionals and indicate where to find them.	Links to resources and tools to support implementation are available in the guideline or another accessible location.	Guidelines for Guidelines | Implementation
G.6	Provide accompanying consumer information, such as one-page summaries, infographics and tools.	Links to accompanying consumer information and resources are available in the guideline.	
G.7	Offer versions of the plain English summary and consumer information in different languages.	Links to accompanying consumer information in different language are available in the guideline.	
G.8	Provide suggestions for local adaptation and adoption of the guideline.	Suggestions to local adaptation and adoption of the guideline are described in the guideline (for example, case studies).	

Companion resources to support developers

NHMRC has developed a suite of resources to assist developers in following the NHMRC approval process and meeting the requirements. These resources, which are accessible for download on the NHMRC website, include:

Guidelines for Guidelines Handbook

The Guidelines for Guidelines Handbook is a comprehensive guide designed to help guideline developers produce high-quality guidelines that meet NHMRC Standards. Guidelines for Guidelines modules are referenced throughout the Requirements to provide detailed information to guideline developers on how to address a specific requirement.

Needs analysis template

This template provides a structured approach to writing a needs analysis ensuring all relevant factors are considered. You can find the template in Appendix A of this document.

NHMRC guideline approval checklist

This checklist has been developed to assist guideline developers in ensuring that all necessary steps of the NHMRC approval process have been followed. It can be used to communicate the completion dates of key milestones with NHMRC. You can find the checklist in Appendix C of this document.

Proposed structure for Administrative and Technical reports

Guideline developers seeking NHMRC approval must prepare administrative and technical reports or provide a link to where this information can be found. The proposed structure outlines what information should be included in the administrative and technical reports.

Abbreviations and special terms used

Administrative report	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. The means by which this report can be accessed must be provided within the guideline.
Body of evidence	All studies identified for each clinical question by the systematic literature search which meet the specified inclusion criteria.
Clinical practice guideline/s	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.[9]
Clinical practice	The performance of health professionals within any health care settings.
Consumers	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 full members of a committee, steering group or similar, consumer representatives voice the consumer perspective and take part in the decision-making process on behalf of consumers.
Companion document	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.
Council	The Council of the NHMRC, as established under Section 20 of the *National Health and Medical Research Council Act 1992*. The functions of the Council are to provide advice to the NHMRC Chief Executive Officer and perform other functions conferred on it.
Desirable requirement	Requirements which developers are encouraged to meet to improve guideline quality.
Evidence summary	A summary prepared for each clinical practice guideline recommendation, which briefly summarises the body of evidence on which the recommendation was based including outcomes and reference citation of clinical studies.

Evidence to Decision (EtD) Framework	A framework that helps guideline development groups move from evidence to recommendations. It helps guideline development groups structure their discussions about the pros and cons of each intervention and ensure all important factors that determine a recommendation are considered. The NHMRC-approved framework is the seven-factor GRADE EtD framework.[4]
Executive summary	A concise overview that highlights the key points of the guideline. It is designed to provide a quick understanding of the main recommendations, evidence, limitations, and implications of the guideline without needing to read the entire document.
Final draft guideline	The draft clinical practice guideline that is submitted to NHMRC for consideration for approval after addressing issues raised at public consultation and expert review stages. 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.
Good practice statement	A good practice statement (GPS) is an actionable guideline statement that describes the population and intervention and is deemed important to issue by the guideline development group to address a healthcare need. A GPS is characterized by providing guidance for an intervention or practice where there is broad consensus among the guideline development group members that the intervention's desirable consequences unequivocally outweigh the undesirable consequences and implementing the opposite course of action is not appropriate. They are used in instances where indirect evidence is available, however conducting a formal evidence review would not be a good use of resources.[6]
GRADE	The Grading of Recommendations Assessment, Development and Evaluation (GRADE) is a systematic approach to rating the certainty of evidence in systematic reviews and other evidence syntheses.[4]
Guidelines for Guidelines	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. It is the 'how to do it' guide to NHMRC guideline approval.
Health professionals	Any suitably qualified health worker who provides health care treatment, advice and related services.
Independent clinical expert review	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.
Independent methodological review	An NHMRC-commissioned evaluation of draft clinical practice guideline and related process documentation (including technical reports and administrative reports) by experts in evidence review methodology and guideline development.

Living guideline	Living guidelines use the 'living evidence' approach, which combines rigorous, evidence-based methods and rapid updating as new research emerges. More information is available from the Australian Living Evidence Collaboration.
Mandatory requirement	Requirements that must be met to obtain NHMRC approval.
Plain English Summary	A clear and simple summary that is free of technical terms and jargon to help people (mainly consumers) to understand the scope and key health advice made by the guideline.
Procedures	A set of tasks which must be carried out by developers seeking NHMRC approval of clinical practice guidelines.
Public consultation draft guideline	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.
Requirements	The set of conditions necessary for meeting the NHMRC standards for clinical practice guidelines.
Standards for guidelines (NHMRC standards)	The NHMRC standards for high-quality clinical practice guidelines. They require 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.
Technical report	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 and NHMRC, but which is not required for inclusion in the main guideline document. This report will include information such as research questions, literature search strategies, and description of methods for evidence evaluation. The means by which this report can be accessed must be provided within the guideline.

Appendix A - Needs analysis template

Guideline developers must submit a needs analysis when registering their proposed guideline for NHMRC approval. The needs analysis should address the items listed in this form and must be supported with references.

1. What is the purpose of your guideline?

Describe the primary purpose of the guideline and state its goals and objectives.

2. Why is a guideline needed in this area? Are there alternatives to a guideline?

Explain the necessity of a guideline in this specific area and discuss why possible alternatives to a guideline are not selected for development.

3. Are there existing national guidelines on this topic? If so, list them and explain why another guideline is needed.

Identify any existing guidelines and justify the need for a new or updated guideline.

4. How does the guideline topic area relate to a national health priority area or a significant disease burden area?

Describe the current burden of disease and its impact on the targeted patient population. Explain why the issues addressed by the guideline are important.

5. What health indicators or other measures do you hope to improve?

Explain what outcomes the guideline aims to improve and any gaps or variation in current practices it aims to address.

Appendix B - Proposed structure for Administrative and Technical Reports

Guideline developers seeking NHMRC approval must prepare Administrative and Technical Reports or provide a link to where this information can be found. These reports/information must be submitted with the final draft guideline for approval and made available with the public consultation draft. The administrative and technical reports can also be included in the guideline or provided in an accessible location which is hyperlinked in the guideline.

Proposed structure for the Administrative Report

1. Governance

- Governance structure for example the developer, panels and the project management team
- Funding
- Details of all individuals and groups involved in the development of the guidelines (as per section A of the requirements)
- Selection process used to recruit the guideline development group
- Recruitment and support processes (for example, training) for consumers in the guideline development panel
- Declarations of potential conflicts of interest of all individuals involved in the development of the guideline and details of how they were identified and managed

2. Stakeholder engagement

- List of stakeholders you consulted with
- Summary of the outcomes of stakeholder consultations
- List of experts who reviewed the guideline

3. Dissemination plan

- List of dissemination strategies (including who will be responsible for each strategy and when it will be done).

Proposed structure for the Technical Report

1. Evidence review

- Inclusion and exclusion criteria used to select studies
- Search strategies
- Data extraction and synthesis methods

- Results of the search for evidence (PRISMA)
- Risk of bias assessments
- Characteristics of Included Studies table
- Summary of findings/evidence profile tables

2. Developing recommendations

- GRADE Evidence to Decision frameworks

Appendix C - NHMRC guideline approval checklist

Guideline developers seeking NHMRC approval must submit an estimated timeline of key milestones to NHMRC before starting their guideline development process. These key milestones are marked in blue and with an asterisk (*).

This checklist helps developers estimate key milestone dates and ensure important steps in the approval process are completed.

Please record the estimated date next to each key milestone before starting and update it whenever there are changes. Please email to NHMRC at clinicalguidelines@nhmrc.gov.au.

#	Activity or key milestone (highlighted in blue)	Timeline considerations	Estimate date
Meet with NHMRC to discuss your guideline and its potential eligibility for approval			
1	Register your proposed guideline with NHMRC	Allow 4 weeks for NHMRC to respond	
Meet with NHMRC to discuss the approval process and any sensitivities or risks related to your guideline			
2	Submit an estimate timeline of key milestones to NHMRC		
3	Complete recruitment of the guideline development group*		
4	Undertake a systematic search for evidence*	The latest date of the publication period covered by the searches must be within 12 months of the first day of public consultation and 20 months of the submission of the final draft guideline to NHMRC for approval.	
5	Submit a Progress Report to NHMRC	*When?* Six months before the start date of the public consultation	

#	Activity or key milestone (highlighted in blue)	Timeline considerations	Estimate date
Meet with NHMRC to discuss the requirements for public consultation			
6	Notify NHMRC of the public consultation dates	*When?* At least 2 weeks before the start date of the public consultation	
7	Provide NHMRC with the draft guideline, administrative and technical reports/information	*When?* At least one week before the start date of the public consultation	
8	Publish a notice of public consultation	This notice must specify the last day you will accept submissions: this must be at least 30 days after the notice is first published	
9	Release the guideline for public consultation*	Public consultation period must be at least 30 days	
Meet with NHMRC to discuss the final submissions of your guideline and NHMRC Council meeting requirements			
10	Confirm with NHMRC your planned submission date for consideration of NHMRC approval	*When?* At least 8 weeks prior to planned submission date	
11	Submit the draft guideline for NHMRC approval*	*When?* At least 8 weeks prior to the Council meeting at which you request the draft guideline to be considered	

#	Activity or key milestone (highlighted in blue)	Timeline considerations	Estimate date
12	Council meeting at which your draft guideline to be considered. *(You may be asked to attend the Council session at which your guideline is considered to respond to comments from members)*	Council meetings are typically held three times a year, in March, July and November	
13	Receive final decision on the approval of your guideline from NHMRC	Allow 4 weeks after Council meeting to receive the final decision	
14	Publish and disseminate your guideline	*When?* Within 16 weeks of the date of approval stated in the NHMRC official notification	

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