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## **NHMRC requirements for approval of evidence-based clinical practice guidelines**

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Draft for consultation  
February 2010

Third party guideline developers should read this document in conjunction with  
*NHMRC procedures for third party development of clinical practice guidelines*

## About this document

This document outlines the mandatory and desirable requirements for NHMRC approval of evidence-based clinical practice guidelines. NHMRC will only approve guidelines that meet all the mandatory requirements. The desirable requirements are likely to improve the quality of a guideline however some may not always be applicable.

This list encompasses existing NHMRC Guidelines for Guidelines, incorporates dimensions from internationally validated guideline appraisal instruments (AGREE and GLIA) and draws on Australian and international best practice. These requirements are for paper based guidelines developed de novo. It does not apply to guidelines being adapted, updated or which are electronic only.

Third party guideline developers should read this document in conjunction with *NHMRC procedures for third party development of clinical practice guidelines* (version 1.1).

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

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## **1. Governance and Stakeholder Involvement**

### ***Mandatory***

- 1.1.** The agency responsible for developing and publishing the guideline is identified.
- 1.2.** There is an explicit statement about the source of funds for the guideline development and publication.
- 1.3.** The guideline has been developed by a multidisciplinary group and the mechanisms employed to convene this group are described.
- 1.4.** The guideline has been developed with consumer participation and the mechanisms employed to involve consumers are described (including the recruitment process and role within the group).
- 1.5.** NHMRC processes for identifying and dealing with competing interests are followed. Details are recorded, including how any competing interests identified were addressed and published in the guideline.
- 1.6.** Names of organisations who will be asked to formally endorse the guideline are provided.

### ***Desirable***

- 1.7.** Details of the amount of funding from each funding source are described in the document.
- 1.8.** The process and criteria used for inviting the group members to participate is described.
- 1.9.** The guideline has been developed with participation from Aboriginal and Torres Strait Islander peoples and the mechanisms employed to involve these groups are described.

## **2. Scope and Purpose**

### ***Mandatory***

- 2.1.** The scope of the guideline is described (including whether the guideline covers prevention, screening/ assessment, treatment, rehabilitation and monitoring).
- 2.2.** The purpose of the guideline and the underlying questions/issues/problems/ motivating the guideline are stated.
- 2.3.** The intended target audience of people who should and should not use the guideline is described.
- 2.4.** The population group for whom the guideline recommendations will apply is defined (e.g. elderly, children, and adults) and groups that may be particularly affected are identified and described.
- 2.5.** Issues of special importance for Aboriginal and Torres Strait Islander peoples are described.

### ***Desirable***

- 2.6.** The draft scope has been reviewed by potential users of the guideline.

### **3. Evidence Review**

#### ***Mandatory***

- 3.1.** Clinical questions to be answered by the guideline are identified and described.
- 3.2.** The inclusion and exclusion criteria used to select studies for appraisal are described.
- 3.3.** Systematic searches for evidence are undertaken and described. The dates covered by the searches are included.
- 3.4.** The tools used to critically appraise the included studies are explicitly stated.
- 3.5.** Evidence tables which summarise and appraise the quality of each study are prepared and provided to the NHMRC for those studies that informed the recommendations of the guideline.
- 3.6.** Studies that met the inclusion criteria for the systematic review but were not used to inform the recommendations are tabulated with reasons why they were not considered e.g. low quality. NB. Full evidence tables are not required for these studies.
- 3.7.** NHMRC recommended levels of evidence or GRADE are applied and listed in the evidence tables.
- 3.8.** The strengths and limits of the body of evidence reviewed are described in the text. Areas of uncertainty are acknowledged.

#### ***Desirable***

- 3.9.** Search strategies for each clinical question are available as an appendix to the full guideline.
- 3.10.** The systematic searches include consumers' perceptions and experiences. The details of these searches are recorded.
- 3.11.** Search strategies are retained for the period of the NHMRC approval to assist the updating process.
- 3.12.** Completed critical appraisal documents are retained for the period of the NHMRC approval and the contact details of the person responsible for holding these documents is provided.
- 3.13.** Evidence tables are publicly available.

## **4. Guideline Content/Recommendations**

### ***Mandatory***

- 4.1.** Body of evidence tables are prepared for each clinical question/recommendation.
- 4.2.** The clinical impact of the recommendations are described.
- 4.3.** Harms/risks and benefits of all interventions are described in the formulation of recommendations.
- 4.4.** Recommendations are linked with the references to the evidence that supports them.
- 4.5.** Recommendations based on expert opinion or best practice are labelled as such.
- 4.6.** A summary of all recommendations and their grade is provided.
- 4.7.** Methods used to arrive at recommendations e.g. voting or formal methods such as Delphi are described.
- 4.8.** The wording of recommendations is specific, consistent, action orientated and unambiguous throughout the guideline.
- 4.9.** Areas of major debate about the evidence and the recommendations (even when eventually a unanimous decision has been reached) are highlighted and described.
- 4.10.** Gaps in the evidence identified during the evidence review are described.
- 4.11.** Recommendations that specify the use of interventions not currently available or restricted in Australia should be clearly highlighted.
- 4.12.** Issues of relevance in the recommendations for Aboriginal and Torres Strait Islander peoples are identified.
- 4.13.** Safety, legal and potential misuse issues are described.
- 4.14.** Ethical issues are identified and considered.
- 4.15.** There is an identified recommended date for future review of the guideline.
- 4.16.** The guideline contains an appendix that lists the people involved in the guideline development process, their profession or discipline, their organizational affiliation and their role in the guideline development process. A declaration of the competing interests of every team member is recorded in an appendix to the guideline.
- 4.17.** Details about where to find all the evidence review documentation is specified in the guideline.
- 4.18.** Details of the process of guideline development are published as an appendix to the guideline.
- 4.19.** An AGREE rating of the draft guideline by 2 reviewers independent of the guideline development process is available.

## ***Desirable***

- 4.20.** Dependent on the scope, the guideline considers the different options for screening, prevention, diagnosis or treatment of the condition it covers. These options are presented in the guideline.
- 4.21.** Numbers Needed to Treat (NNT), Numbers Needed to Screen (NNS) and Numbers Needed to Harm (NNH) are described for each alternative treatment option (where they are available).
- 4.22.** A strategy for incorporating new evidence during the life of the guideline is described.
- 4.23.** A strategy for updating the guideline is described.
- 4.24.** Ineffective current practices are identified and alternatives are proposed.
- 4.25.** Complementary therapies are described (and risks and benefits of these are outlined) if evidence is available or state that there is a lack of rigorous evidence.
- 4.26.** Areas where changes in service delivery would be beneficial are described.
- 4.27.** The resource implications and cost effectiveness of any recommended practice versus current/established practice, are explicitly considered.
- 4.28.** Evidence of socio-economic differences (including ethnicity, gender, age, disability and location) in prevention or treatment outcomes is explicitly considered in the formulation of the recommendation/s.
- 4.29.** Options for patient/consumer self management are actively considered and described.
- 4.30.** Recommendations for areas requiring further research are described.
- 4.31.** Areas where the evidence is likely to change and effect the recommendations, e.g. a major trial is underway, are identified.
- 4.32.** Recommendations should emphasise the involvement of the patient (and/or their carers if needed) in decisions on treatment and care.
- 4.33.** Recommendations should be displayed in a way suitable for electronic implementation.

## 5. Format

### *Mandatory*

- 5.1. The guideline is easy to navigate and has a clear table of contents.
- 5.2. The period of NHMRC approval is clearly stipulated in the introductory pages.
- 5.3. A summary of the recommendations is available as a separate document.
- 5.4. Recommendations are easily identifiable.
- 5.5. Chapter and heading levels are consistent and assist with the navigation throughout each topic of the guideline.
- 5.6. The sequencing of the information in the guideline is logical from a readers' perspective.
- 5.7. The guideline is internally consistent.
- 5.8. A website address which has copies of all the relevant guideline documents is provided.
- 5.9. References in the text are clearly identified and the reader is able to easily find which references were used. Electronic references should provide URL and date accessed.
- 5.10. The date of publication, authorship, copyright information and addresses for permissions is clearly detailed at the beginning of the document. An ISBN number is provided for each document.
- 5.11. The approved NHMRC disclaimer is provided at the beginning of the document.
- 5.12. A glossary of technical terms, acronyms and abbreviations is provided.
- 5.13. Where medications are described in the guideline, generic names are used.
- 5.14. Brand names should not be used, give the recommended international non-proprietary name (rINN).
- 5.15. A clear statement is made if the recommended use of a drug is outside its licensed indication ('off label').
- 5.16. A preferred citation for the guideline is specified.

### *Desirable*

- 5.17. Plain English is used wherever possible.
- 5.18. The guideline has an index.
- 5.19. The format (in hard or soft copy) is suitable for people with visual impairment and where possible, online versions can be magnified electronically.
- 5.20. Accompanying consumer information is provided.
- 5.21. Versions of the consumer summaries in different languages are available, if appropriate.

## **6. Consultation**

### ***Mandatory***

- 6.1.** The process for public consultation on the draft guideline complies with Section 13 or 14A (guidelines for third parties) of the NHMRC Act 1992 and accompanying regulations.
- 6.2.** Details of submissions arising from the consultation process and the response of the guideline team to the submissions, including whether, why and how the guideline has altered as a result are provided as a separate document to the NHMRC.

### ***Desirable***

- 6.3.** Details of submissions arising from the consultation process and the response of the guideline team to the submissions, including whether, why and how the guideline has altered as a result are publicly available.

## **7. Implementation Considerations**

### ***Mandatory***

- 7.1.** Priority recommendations for implementation are identified and described.
- 7.2.** A plan for the dissemination of the guideline is provided as a separate document to the NHMRC.

### ***Desirable***

- 7.3.** An implementation plan is provided.
- 7.4.** Suggestions for local adaptation and adoption of the guideline are provided.
- 7.5.** Barriers and enablers to the application of the guideline are described.
- 7.6.** User specific summaries and other tools for different health care professionals are provided.
- 7.7.** The wording of guideline recommendations has been externally reviewed by potential users for their clarity and capacity for implementation.
- 7.8.** An evaluation strategy and framework for uptake is prepared and described.
- 7.9.** Indicators that can be used to measure the extent to which key guideline recommendations have been implemented are provided.