WORKING TO BUILD A HEALTHY AUSTRALIA
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NHMRC standards and procedures for externally developed guidelines

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1. Introduction

The National Health and Medical Research Council (NHMRC) has statutory responsibilities to raise the standard of individual and public health throughout Australia and to foster the development of consistent health standards. As part of this role, the NHMRC encourages the development of evidence-based guidelines by expert bodies.

It is now widely recognised that guidelines should be based, where possible, on the systematic identification and synthesis of the best available scientific evidence. The NHMRC requirements for developing clinical practice guidelines are rigorous so as to ensure that this standard is upheld. As such, guidelines with NHMRC approval are recognised in Australia and internationally as representing best practice in health and medical knowledge and practice.

To achieve NHMRC approval, externally developed guidelines must meet certain NHMRC requirements and standards as set out in legislation, and in a series of NHMRC publications on the development, implementation and evaluation of clinical practice guidelines. These requirements and standards are designed to ensure that the end product is based on the best available scientific evidence and presented in creative, innovative and, most importantly, effective ways.

This paper aims to inform external persons and organisations of the procedures to be followed in developing guidelines that are intended for submission to the NHMRC for approval. Organisations or individuals intending to submit guidelines to the NHMRC for approval should obtain an undertaking, before the guideline development process has begun, that the NHMRC will consider the proposed guidelines for approval, once completed. Not all externally developed guidelines will be appropriate for consideration by the NHMRC.

2. Key principles for developing guidelines

The key principles underpinning the development of evidence-based guidelines are listed in the NHMRC publication *A guide to the development, implementation and evaluation of clinical practice guidelines* (1999).

The nine key principles are:

1. The guideline development and evaluation process should focus on outcomes;
2. The guidelines should be based on the best available evidence and include a statement concerning the strength of recommendations. Evidence can be graded according to its level, quality, relevance and strength;
3. The method used to synthesise the available evidence should be the strongest applicable;
4. The process of guideline development should be multidisciplinary and include consumers early in the development process. Involving a range of generalist and specialist clinicians, allied health professionals and experts in methodology and consumers has the potential to improve quality and continuity of care and assists in ensuring that the guidelines will be adopted;
5. Guidelines should be flexible and adaptable to varying local conditions;

6. Guidelines should consider resources and should incorporate an economic appraisal, which may assist in choosing between alternative treatments;
7. Guidelines are developed for dissemination and implementation with regard to their target audiences. Their dissemination should ensure that practitioners and consumers become aware of them and use them;
8. The implementation and impact of the guidelines should be evaluated; and
9. Guidelines should be updated regularly.

These key principles should also underpin the development of any companion documents to guidelines and any other types of health advice.

3. Processes for submitting guidelines for NHMRC approval

Organisations or individuals intending to submit guidelines to the NHMRC for approval should obtain an undertaking, before the guideline development process has begun, that the NHMRC will consider the proposed guidelines for approval once completed. This undertaking should not be taken to imply that approval will be guaranteed on completion of the guidelines.

A request for agreement to consider proposed guidelines for approval should be made in writing to the Chief Executive Officer (CEO) of the NHMRC and signed by a senior member of the organisation proposing to develop the guidelines. The proposal must address the following issues to assist the NHMRC in making a decision on the request:

1. The significance of the problem, i.e.
   - size (if relatively small, is it an emerging issue?);
   - burden of illness;
   - benefits (including opportunities for effective clinical and/or public health intervention) and/ or harms;
   - degree of urgency; and
   - socio-economic, demographic and cultural issues;
2. Consistency of the issue with current Government health priority areas;
3. Incorporation of priority issues, e.g. issues with significant clinical practice variations, contradictory evidence or where the health costs and/or burdens are high;
4. The level of community concern, i.e. the degree of support or debate for advice or intervention from the relevant clinical, public health and consumer bodies and communities;
5. The availability of suitable processes and infrastructures within the community to facilitate and support the proposed intervention;
6. The definition and purpose of the guidelines, including their scope and target audience;
7. Confirmation that the guidelines are not duplicating existing material, given that they may build on or adapt existing Australian or overseas guidelines;
8. A proposed timeframe and timeline for development of the guidelines. Note that the final draft of the guidelines will need to be submitted to Council which sits quarterly and which will make a recommendation to the CEO regarding their approval;

9. Strategies for updating the guidelines;
10. Development under the auspices of a person or body of recognised professional standing that will attract multidisciplinary participation at a high level;
11. Consumer participation in the development process; and
12. Accessibility of the developing body to the financial and other resources required to complete the guidelines in accordance with NHMRC standards, including completing systematic reviews of the literature, as well as writing, printing, implementation and dissemination of the guidelines.

Applications for the NHMRC's support will be assessed by NHMRC project officers against the above criteria and NHMRC's priorities and strategic plan, which can be found at: http://www.nhmrc.gov.au/publications/synopses/nh80syn.htm

This advice will be referred to the CEO who will make the final decision as to whether an application is approved 'in principle' or declined. Any undertaking should not be taken to imply that approval will be guaranteed on completion of the guidelines.

If the CEO gives approval 'in principle', the project will be added to the NHMRC's workplan and the developer informed of the NHMRC's Guideline Assessment Register (GAR) (refer to part seven of this document). An officer from the NHMRC will liaise with the developer over the course of the project. However, the guideline developer is responsible for the guideline's development, publication and dissemination (refer to section 6 of this document).

The completed guidelines should be submitted in draft form, not in final printed form. This is to allow for all amendments that may be requested by the NHMRC to be incorporated before publication.

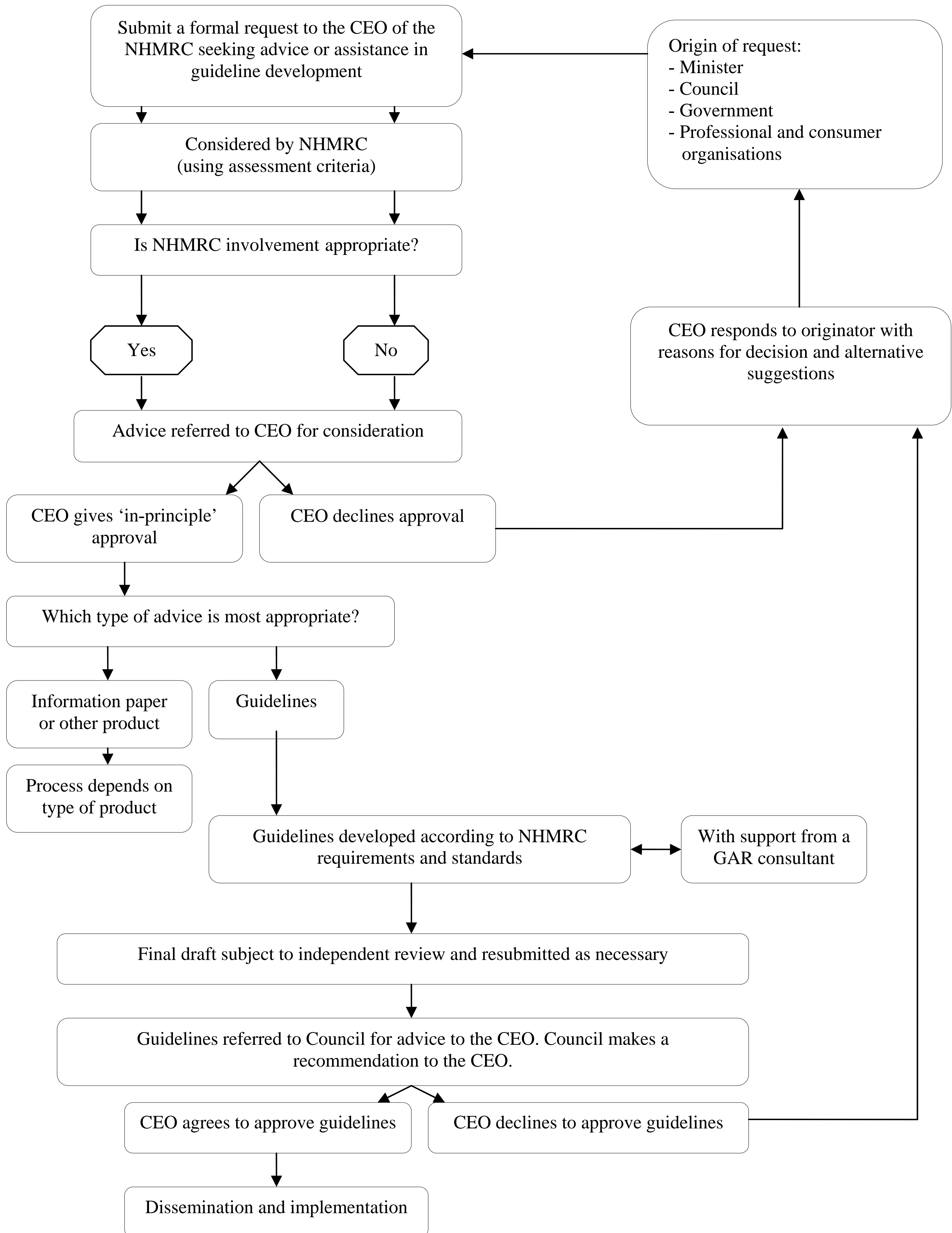
The NHMRC will seek independent review of the guidelines submitted for approval (refer to section 9 of this document). This review is separate to the GAR consultant, who will be engaged to assist developers in ensuring that the NHMRC's processes for guideline development are upheld.

Guideline developers will be given an opportunity to comment on the independent review report and revise the draft document, if appropriate, prior to it being submitted for consideration by the NHMRC. If necessary, the NHMRC may seek further clarification from the developer. Once the NHMRC is satisfied that the document meets NHMRC requirements it will then refer the guidelines, with its recommendation, to Council for consideration. Based on advice from Council, the CEO will make the final decision as to whether the guidelines are approved or not.

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

Diagram 1 outlines the key steps in seeking NHMRC approval of externally developed guidelines.

Diagram 1: Key steps in seeking NHMRC approval of externally developed guidelines



4. NHMRC requirements and standards for guideline development

Externally developed guidelines must meet certain NHMRC requirements and standards before final approval from the NHMRC is sought. These requirements and standards are set out in a series of NHMRC publications on the development, implementation and evaluation of clinical practice guidelines.

The key documents setting a 'gold standard' for the development of evidence-based guidelines are the NHMRC *A guide to the development, implementation and evaluation of clinical practice guidelines* (1999), and the six accompanying toolkits that relate to specific areas of guidelines development:

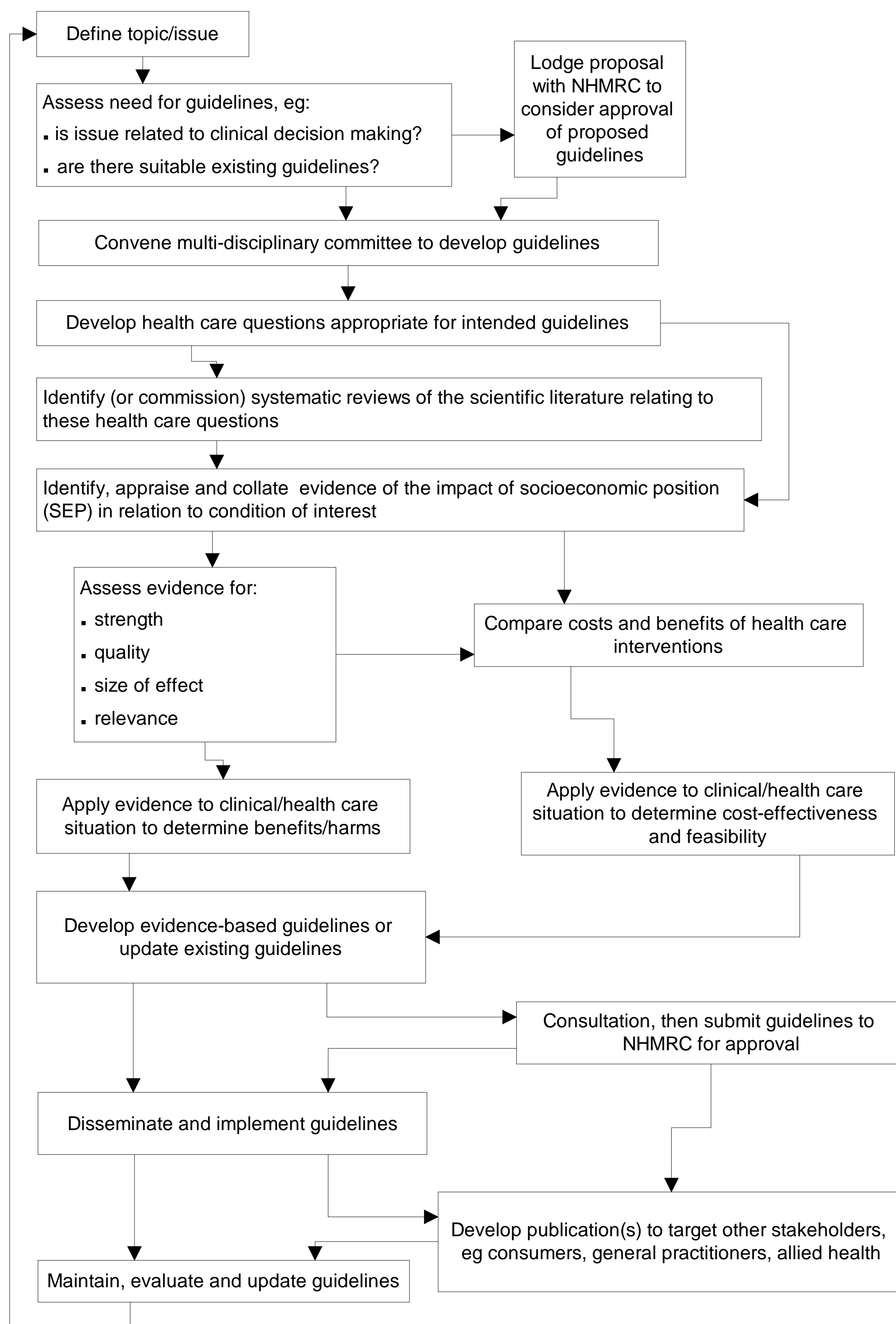
- *How to review the evidence: systematic identification and review of the scientific literature (2000)*
- *How to use the evidence: assessment and application of scientific evidence* (2000)
- *How to put the evidence into practice: implementation and dissemination strategies* (2000)
- *How to present the evidence for consumers: preparation of consumer publications* (2000)
- *How to compare the costs and benefits: evaluation of the economic evidence* (2001)
- *Using socio-economic evidence in clinical practice guidelines* (2003)

These publications are now due for review but are the most current information available at this time.

The same standards apply whether guidelines are developed from the beginning, are adapted from existing Australian or overseas guidelines, or are an update of an existing NHMRC publication.

Diagram 2 depicts a flow chart of the NHMRC's development process for evidence based guidelines.

Diagram 2: Flow chart of the NHMRC's development process for evidence based guidelines



5. Levels of evidence and grades for recommendations

Guidelines should be based on the best available current evidence and include a statement concerning the strength of recommendations. Evidence can be graded according to its level, quality, relevance and strength.

The 'level' of evidence refers to the study design used to minimise bias: the highest level involves a systematic review of randomised controlled clinical trials.

'Quality' refers to the methods used to minimise bias in the design and conduct of a study.

'Relevance' refers to the extent to which research findings can be applied in other settings.

The 'strength' of evidence refers to the magnitude and reliability of the treatment effect seen in clinical studies: strong effects are more likely to be real and more likely to be clinically important.

Ideally, recommendations would be based on the highest level of evidence. However, it has been acknowledged that the levels of evidence used by the NHMRC for intervention studies are restrictive for guideline developers, especially where the areas of study do not lend themselves to randomised controlled trials. It is proposed that this issue will be addressed when the toolkit publications are reviewed.

However, due to the importance of the issue, as an interim measure, a Pilot Program with additional levels of evidence and grades for recommendations for guideline developers has been trialled. More information on the pilot is at http://www.nhmrc.gov.au/consult/docfeedback.htm The results of the pilot are being considered as part of a review of the NHMRC Guidelines and Advisory Program.

The 'interim' levels of evidence and grading system for recommendations do not have official NHMRC status. NHMRC guidelines that are developed using the interim framework must include a statement at the front of the document explaining that the guidelines were developed using the pilot process, blending the official NHMRC levels with the 'interim' levels of evidence and grading system for recommendations.

6. Resources required for guideline development

External developers of guidelines should be mindful of the resources required for the development and implementation of evidence-based guidelines. As shown in Diagram 2 the development of a guideline according to the NHMRC protocol involves a substantial financial commitment. While costs will vary depending on the nature and extent of the guidelines, an organisation intending to develop guidelines needs to be able to fund the following aspects of the project:

- formation of a multidisciplinary panel and/or expert working party;
- administration costs (including meeting expenses) throughout the process;
- a systematic literature review;
- drafting of the document;
- technical editing at various stages of the project;
- public consultation;

- desktopping, publication and dissemination; and
- reviewing and updating the guidelines when necessary (recommended five-yearly intervals).

The only costs borne by the NHMRC associated with external guideline development are:
- consultancy fees for the Guideline Assessment Register consultant and the Independent Reviewer.

7. The Guidelines Assessment Register

In 2002, a Guidelines Assessment Register (GAR) was established to provide guideline developers with support from a fully-funded expert in evidence-based medicine.

The aim of the GAR is to provide developers external to the NHMRC with support in relation to utilising evidence-based findings and applying the NHMRC criteria. Specifically, the nominated expert in evidence-based medicine provides advice on the following matters within the NHMRC context:
- evaluating and documenting the scientific evidence;
- developing evidence-based recommendations based on the scientific literature; and
- NHMRC procedures.

The GAR consultant will assist the NHMRC and stakeholder organisations to ensure that the guidelines that are developed support best practice and are based on the best available current evidence to achieve better health outcomes.

8. Public consultation requirements

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

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

> "The Council may only advise the CEO to approve the guidelines if the Council is satisfied that the person or body, before submitting the guidelines to the CEO for his or her approval:
> (a) prepared a draft of the guidelines that the person or body proposed to submit to the CEO; and
> (b) published a notice, in a manner and form acceptable to the Council:
> i) containing a summary of the draft guidelines; and
> ii) stating where copies of the draft guidelines could be obtained; and
> iii) inviting persons or bodies to make submissions relating to the draft in accordance with the procedures, and within the period, specified in the notice; and
> (c) had regard to any submissions received pursuant to the invitation referred to in subparagraph (b)(iii)".

The legislative requirements set out in section 14A of the Act must be met in full. The notice referred to in paragraph 14A(2)(b) of the Act should follow the format set out in the box below and should be published in at least one major national daily newspaper, in addition to any other media specified by the NHMRC or which the guideline developer considers appropriate.

A period of at least 30 days should be allowed from the date on which the last notice appears for submissions to be lodged. A summary table of the submissions received, together with the

justification as to why a submission comment was or was not included in the document, must be provided to the NHMRC at the time of lodging the final draft. The NHMRC may request copies of any of the submissions received.

Consultation of the kind described above represents the minimum level of consultation that must be carried out in order to satisfy the NHMRC that the requirements of section 14A of the Act have been met. Additional consultation with interested parties may be undertaken during the development of the guidelines. Further guidance on consultation strategies is contained in the NHMRC publication *A guide to the development, implementation and evaluation of clinical practice guidelines* (1999).

Suggested format for notices:

NAME/LOGO OF DEVELOPER(S) DRAFT GUIDELINES ON (SUBJECT MATTER)

Proposed for submission to the NHMRC for approval under section 14A of the *National Health and Medical Research Council Act* 1992.

The (name of developer) has prepared draft guidelines on (subject matter).

You are invited to make a submission to (name of developer) on the draft guidelines.

How to make a submission
You may make a submission in writing or on audio tape. Please send it to:
(address of developer – postal, fax and email).

Please include your name and an address or telephone number at which you can be contacted.

Closing date
Your submission must be received at the above address by (date).

Further information
A copy of the draft guidelines can be obtained from (address – may be a website address).

Summary of draft guidelines
(A brief summary of the main issues of the draft guidelines must be included.)

9. Independent review of guidelines

Independent Reviewers provide assurance to the NHMRC on process matters and act as a second point of quality control (in addition to the GAR consultant) prior to seeking Council advice on a final draft guideline.

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

Some key criteria that the Independent Reviewer can provide advice on include:

1. Whether the research question/issue/problem underpinning the publication is clearly stated and the intended audience is made explicit;

2. That the recommendations are clearly identified when they are intended to have a regulatory effect e.g. public health standards or recommended dietary intakes;
3. That the evidence on which the recommendation/s rely is reviewed to the standard of the current NHMRC toolkit publications *How to review the evidence: systematic identification and review of the scientific literature* (2000) and *How to use the evidence: assessment and application of scientific evidence* (2000);
4. That the guidelines have been developed with adequate consumer participation and the mechanisms employed to involve consumers have been detailed;
5. That the document takes into consideration the perspectives of a range of health professions;
6. That the document contains an account of the formal public consultation process and the range of views and opposing positions are overtly discussed;
7. That the product is written in plain English with a reading age appropriate to a specified target audience;
8. That the evidence of pilot or focus-group testing for companion documents will be included in the accompanying documentation;
9. That the layout is well-designed with easy reference and summary pages providing access to key information;
10. That when a computerised version of a guideline is included, the electronic documentation includes evidence that its validity has been appropriately tested;
11. That a dissemination and/or implementation plan is included as set out in the current NHMRC toolkit publication *How to put the evidence into practice: implementation and dissemination strategies* (2000);
12. That the document includes an explicit expiry date for NHMRC approval; and
13. That the document includes a process report, a list of the Working Party membership and its Terms of Reference.

10. Format of final guideline document

The minimum format requirements for final guideline documents is as follows:

- Contents page
- Summary
- Executive summary including summary of recommendations and levels of evidence
- Introduction
- Chapters
- Appendix 1 – membership and terms of reference of working/writing group
- Appendix 2 – a process report including information on literature review and consultation process and views
- Other appendices
- Abbreviations and acronyms
- Glossary
- Bibliography
- List of Tables and Figures (may be combined with contents page)

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

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

Externally developed guidelines approved by the NHMRC will be listed as such on the NHMRC website, with instructions on how copies may be obtained from the developer. The NHMRC will not assume any responsibility for the publication or dissemination of externally developed guidelines. The electronic version of the document will be available, in most instances, on the NHMRC website or on the developer's website with a link from the NHMRC website.

The NHMRC regularly reviews its own internally produced guidelines and expects external developers to do the same (a strategy for review must be included in the guidelines). While it would normally be expected that guidelines would remain current for a period of 3-5 years, unforeseen events and developments may lead to guidelines becoming out-of-date earlier than this. It must therefore be made clear that NHMRC approval of externally developed guidelines is an acknowledgment that the NHMRC considered the guidelines to be an evidence-based statement of best practice at the time of giving approval, and is valid for a maximum of five years. Precise wording for this statement should be obtained from the NHMRC.

Guideline developers may seek new approval from the NHMRC to review guidelines, either as the result of a planned revision after a set time or as the result of new evidence coming to notice. However, developers should note that such an approach will be considered through the normal process of gaining NHMRC approval to develop guidelines and cannot be assumed.

12. Approval of companion documents

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

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

It should be noted that it is not a requirement for developers to display the NHMRC logo on companion documents.

13. Declaring conflict of interest

Guideline developers should ensure against any real or perceived conflicts of interest when appointing project officers or appointing members to Advisory or Working Committees to oversee the guideline's development. Committee members are required to provide a written statement declaring any interest they may have in the matters to be considered, or activities undertaken, by the committee within one month of being appointed or engaged.

A conflict of interest arises in any situation in which a member or related person has an interest which influences, or may appear to influence, the proper performance of the members' responsibilities. The appearance of a conflict of interest may be as important as any actual conflict of interest. There are generally three types of conflict of interest: direct pecuniary interest, indirect pecuniary interest and non-pecuniary interest.

The developer should contact the NHMRC for current conflict of interest policies at the commencement and throughout the guidelines development.

14. Minimum requirements for formulating NHMRC evidence-based guidelines

It is expected that compliance with these minimum requirements will facilitate the approval of guidelines by NHMRC. These are methodological requirements only and should be used in conjunction with the process requirements set out in this document. The NHMRC toolkit publications were used as a basis to determine the minimum requirements.

1. Systematic identification and review of the scientific literature:
   - i) Structured research questions should be developed by the multidisciplinary group. The questions will vary depending on the scope of the guidelines and ideally are broad, clear, focused and closely define the boundaries of the topic, eg PICO or PECOT criteria;
   - ii) Discuss and state the inclusion criteria/basis of inclusions and exclusions, e.g. restrictions on language, study design etc;
   - iii) Clearly state which questions have been systematically reviewed and which have not, e.g. peripheral questions;
   - iv) Document the search strategy (including the search terms), searching:
     - a minimum number of databases - Medline, Clinical Evidence, Cochrane Library (CDSR, Central, HTA, DARE) - and any other databases (such as EMBASE, CINAHL, PsychLit) as appropriate to the topic;
     - search for reviews in the topic area; and
     - use at least two other forms of searching (i.e. internet, expert sources, checking of reference lists and hand searching) as appropriate for the topic;
   - v) Delineate the search period, e.g. start from when the technique/ intervention was first practised or when the database first collated citations;
   - vi) Appraise included studies using critical appraisal checklist - as set out in the NHMRC toolkit publication *How to review the evidence: systematic identification and review of the scientific literature* (2000);
   - vii) Construct tables to summarise the extraction of data (refer Attachment A). This information should be available if requested.

Note: The developer is required to keep a record of the search terms, research questions and inclusion/exclusion criteria used for the development of the guideline.

2. Assessment and application of scientific evidence:
   i) Documented approach to applying NHMRC dimensions of evidence to all primary outcomes in included studies (including NHMRC levels of evidence and quality assessment) - as set out in the NHMRC toolkit publication *How to review the evidence: systematic identification and review of the scientific literature (2000);*
   ii) Assess the applicability of the evidence - as set out in the NHMRC toolkit publication *How to use the evidence: assessment and application of scientific evidence* (2000); and
   iii) Describe the link between the evidence and the guideline recommendation in either narrative or tabular form (refer Attachment B).

3. Comparing costs and benefits - evaluation of economic evidence:
   i) Where a clinical practice guideline recommends a change in practice:
      - the cost effectiveness of the recommended practice versus current/established practice should be explicitly considered in accordance with Part 1 of the NHMRC toolkit publication *How to compare the costs and benefits: evaluation of the economic evidence* (2001);
      - if it is not possible to conduct an evaluation of cost-effectiveness, and no suitable published analysis already exists, the report should state this and the search strategy should be documented; and
      - the economic feasibility of the recommendations should be assessed as set out in Part 2 of the NHMRC toolkit publication *How to compare the costs and benefits: evaluation of the economic evidence* (2001).

   Note : The developers are not required to conduct their own economic evaluation.

4. Use of socio-economic evidence in clinical practice guidelines:
   i) Ensure evidence of socio-economic differences in prevention or treatment outcomes is explicitly considered in formulation of the recommendation/s and where no such evidence exists, the search efforts are documented to the standard of the NHMRC toolkit publication *Using socio-economic evidence in clinical practice guidelines* (2003).

5. Implementation and dissemination strategies:
   i) Include a dissemination and/or implementation plan as set out in the NHMRC toolkit publication *How to put the evidence into practice: implementation and dissemination strategies* (2000).

6. Preparation of consumer publications:
   i) Document the evidence of pilot testing or focus group testing that is undertaken for the companion documents as set out in the NHMRC toolkit publication *How to present the evidence for consumers: preparation of consumer publications* (2000).

   Note 1*:* Companion documents (e.g. for general practitioners or consumers) are not mandatory.
   Note 2: If guideline developers wish for the companion documents to display the NHMRC logo, they must seek agreement from the NHMRC within six months of the primary document being approved.

15. Summary of key issues for developers' consideration

The developer must work in consultation with the GAR consultant. It should be noted that:

- Organisations or individuals intending to develop guidelines should obtain an undertaking before the guideline development process has begun indicating that the NHMRC will consider the proposed guidelines for approval;
- The developers must demonstrate access to the necessary financial and other resources to complete the guidelines in accordance with the NHMRC's standards;
- The NHMRC will appoint an expert in evidence-based medicine from the GAR to work with the developers;
- The GAR expert in evidence-based medicine can provide advice but is not engaged to perform the work for the guideline developers;
- A multidisciplinary working group must be established and must include consumer representation;
- The guidelines must be released for a public consultation period of no less than 30 days;
- A summary table of submissions and responses must be prepared and provided to the NHMRC when forwarding the final draft;
- A process report including search strategies, methodology, details of how the document was developed and a list of submissions received is to be included as an appendix to the guidelines;
- A dissemination plan must be prepared for the guidelines and is the responsibility of the developer;
- Publishing is the responsibility of the developer. However, the incorporation of the NHMRC logo and necessary text in the document must be negotiated with the NHMRC Project Manager;
- A strategy for review must be included in the guidelines; and
- NHMRC approval of external guidelines is given for the original developed guidelines. To obtain NHMRC approval for future reviews of the guidelines, the process of gaining NHMRC approval to develop guidelines will need to be again undertaken.

Attachment A

Summary Table for Intervention Studies

This table is to be used as a guide to summarise the extraction of data. The construction of your table will depend on the inclusion/exclusion criteria being used and therefore some columns may not be relevant.

If information is not available from the study, insert ‘not recorded’. However, if the study is important for formulating a recommendation, you should contact the author to obtain the relevant data.

The numbers in square brackets refer to the explanatory notes below. If you require any assistance regarding this table, please discuss with your allocated NHMRC GAR consultant.

Note: If one study covers several outcomes relevant to different clinical questions, more that one summary table may be required (see explanatory note [19]).

<table>
<tr><td colspan="5">STUDY DETAILS</td></tr>
<tr><td colspan="5">Reference [1]</td></tr>
<tr><td colspan="5">Affiliation/source of funds [2]</td></tr>
<tr><td colspan="2">Study design [3]</td><td colspan="2">Level of evidence [4]</td><td>Location/setting [5]</td></tr>
<tr><td colspan="2">Intervention [6]

Sample size [7]</td><td colspan="3">Comparator(s) [8]

Sample size [9]</td></tr>
<tr><td colspan="5">Population characteristics [10]

Intervention group –

Comparator group(s) –</td></tr>
<tr><td colspan="2">Length of follow-up [11]</td><td colspan="3">Outcome(s) measured [12]</td></tr>
<tr><td colspan="5">INTERNAL VALIDITY</td></tr>
<tr><td>Allocation [13]</td><td>Comparison of study groups [14]</td><td>Blinding [15]</td><td>Treatment/ measurement bias [16]</td><td>Follow-up (ITT) [17]</td></tr>
<tr><td colspan="5">Overall quality assessment (descriptive) [18]</td></tr>
<tr><td colspan="5">RESULTS</td></tr>
<tr><td>Outcome [19]</td><td>Intervention group [20]</td><td>Control group [21]</td><td>Measure of effect/effect size</td><td>Benefits (NNT) [23]

95% CI [25]</td></tr>
</table>

			[22] 95% CI [25]	Harms (NNH) [24] 95% CI [25]
	Clinical importance (1-4) [26]		Relevance (1-5) [27]	
Any other adverse effects [28]				
EXTERNAL VALIDITY				
Generalisabilty [29]				
Applicability [30]				
Comments [31]				

Explanatory Notes

STUDY DETAILS

Enter the following details into the table as indicated:

[1] Full reference citation details
[2] Details of how the study was funded or other relevant affiliations of the authors (designed to expose potential conflicts of interest, such as drug company funding for the drug being trialed)
[3] The study type (eg RCT, case-control study, cohort study), with additional detail where relevant
[4] As per the NHMRC levels of evidence, provided at pg-8 of the NHMRC toolkit publication: *How to use the evidence: assessment and application of scientific evidence*
[5] Country/setting (eg hospital, primary care, hospice)
[6] Provide detail on the intervention. This will generally be a therapeutic procedure such as treatment with a pharmaceutical agent, surgery, a dietary supplement, a dietary change or psychotherapy. Some other interventions are less obviously categorised as interventions, such as early detection (screening) and patient educational materials. The key characteristic is that a person or their environment is manipulated in the hope of benefiting that person or reducing harm. Particular reference should be made to any differences from Australian current practice.

[7] Number of participants enrolled in the intervention/treatment group

[8] The intervention (eg drug, therapy, placebo) used as a comparison in the study. There may be more than one comparator. Particular reference should be made to any differences from Australian current practice.

[9] Number of participants enrolled in the comparison/control group(s)
[10] Any factors that may confound/influence the results and/or the external validity (see below) of the results (eg age, sex, comorbidities, obesity, existing medications, previous surgery)
[11] Length of follow-up of the participants
[12] The outcomes studied (list all outcomes in terms of primary and secondary outcomes). Indicate which outcomes are relevant to the review/guidelines inclusion criteria

INTERNAL VALIDITY (QUALITY ASSESSMENT)

Enter the following details about the study:

[13] The method used to assign patients to treatment or control groups (eg coin toss, random number table, computer-generated random numbers, sealed envelopes). Also indicate whether the allocation list was concealed (eg computerised random number generation, administered from a central trial office, assigned locally)
[14] The results of the group analysis, noting any clinically or statistically significant differences between the groups at study inception

[15] Whether the participants, outcome assessors and (if different) investigators were blinded to the group allocation
[16] Indicate whether, aside from the experimental treatment, the groups were treated and measured the same
[17] The proportion of participants that were followed up and whether all participants were analysed according to the group to which they were initially allocated, regardless of whether or not they dropped out, fully complied with the treatment, or crossed over and received the other treatment ('intention to treat analysis' - ITT)
[18] Describe your assessment (in words) of the overall quality of the study. Is the study quality good enough that you have confidence in the results?

RESULTS
Allowing one row for each relevant outcome, enter the following data from the results of the trial:
[19] The outcome relevant for this entry in the database (Note: more than one table may be required if there are several outcomes relevant to different clinical questions/guidelines)
[20] For binary outcomes, show numbers of patients with the outcome. For continuous outcomes, show means ± standard deviations; or medians and interquartile ranges
[21] For binary outcomes, show numbers of patients with the outcome. For continuous outcomes, show means ± standard deviations; or medians and interquartile ranges. Add number of columns as needed , e.g. 3-arm trials
[22] Absolute and relative measures of effect and measure of variability eg risk differences (absolute risk reduction or absolute risk increase), mean differences, relative risk, odds ratio
[23] A measure of benefit, when the treatment increases the probability of a good event. The number needed to treat to benefit (NNT) = the number of participants who must receive the treatment to create one additional improved outcome in comparison with the control treatment; calculated as 1/absolute benefit increase, rounded up to the next highest whole number

[24] A measure of harm, when the treatment increases the risk of specified adverse outcomes of a condition or reduces the probability of a good event. The number needed to treat to harm (NNH) = the number of patients who, if they receive the treatment, would lead to one additional person being harmed compared with patients who receive the control treatment; calculated as 1/absolute risk increase, rounded up to the next highest whole number

[25] 95% confidence interval (CI) for all measures, if available, otherwise use P-value (be explicit on what comparison the P-value relates to)

[26] Insert the words corresponding to the appropriate rating from the scale provided at pg-23 of the NHMRC toolkit publication: *How to use the evidence: assessment and application of scientific evidence*
[27] Insert the words corresponding to the appropriate rating from the scale provided at pg-28 of the NHMRC toolkit publication: *How to use the evidence: assessment and application of scientific evidence*
[28] Information on any adverse events mentioned in the study

EXTERNAL VALIDITY
Include a brief discussion of the following questions:
[29] Are the patients in the study so different from those being considered for the guideline that the results may not be applicable to them?
[30] Will the potential benefits outweigh any potential harms of treatment in the guideline population?
[31] Add your overall comments regarding the interpretation or implications of this study

Attachment B

Use of Evidence – Summary of included studies table

This table is an example of what can be used in the body of the guideline text to show 'at a glance' a evidence summary of the included studies for a specific guideline. Inclusion of such tables is not an NHMRC minimum requirement but if they are not used the guideline text should include a description of the same information for the included studies. If the descriptive method in the text is preferred, summary tables can also be included as an appendix.

Note: The numbers in square brackets refer to the explanatory notes below. If you require any assistance regarding this table, please discuss with your allocated NHMRC GAR consultant.

Reference [1]	Type of study [2] (Level [3])	Intervention/ comparator [4]	*N* [5]	Population/study information [6]	Quality [7]	Results [8]	Clinical importance [9] / relevance [10]

Explanatory Notes

[1] Authors, eg Smith et al (1999)
[2] Type of study (RCT, case-control, etc)
[3] As per the NHMRC levels of evidence, provided at pg-8 of the NHMRC toolkit publication: *How to use the evidence: assessment and application of scientific evidence*
[4] Intervention (eg treatment with a pharmaceutical agent, surgery, a dietary supplement, psychotherapy) and comparator(s)
[5] Number of participants in each group
[6] Brief information relevant to the particular study (eg participants, methods, outcomes, length of follow up)
[7] Assessment (in words) of the overall quality of the study. Is the study quality good enough that you have confidence in the results?
[8] Size of the summary measure (or point estimate) plus the 95% CI (confidence interval) and/or P-value

[9] The words corresponding to the appropriate rating from the scale provided at pg-23 of the NHMRC toolkit publication: *How to use the evidence: assessment and application of scientific evidence*

[10] The words corresponding to the appropriate rating from the scale provided at pg-28 of the NHMRC toolkit publication: *How to use the evidence: assessment and application of scientific evidence*