Public consultation

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NHMRC Standards

The following Standards apply to the Public consultation module:

1. To be relevant and useful for decision making guidelines will:
   1.1 Address a health issue of importance.
   1.2 Clearly state the purpose of the guideline and the context in which it will be applied.
   1.3 Be informed by public consultation.
   1.4 Be feasible to implement.

Overview

Public consultation gives the community the opportunity to comment on decisions and advice that may affect them. It is a common component of clinical, public and environmental health guideline development standards internationally because it can improve a guideline’s quality and legitimacy, as well as its acceptability to end users and the public.

NHMRC’s role in providing health advice includes a long standing policy of public consultation which is mandated in the legislation, as set out in the National Health and Medical Research Council Act.
1992 (NHMRC Act) (NHMRC 1992) and the National Health and Medical Research Council Regulation 1996 (NHMRC Regulation) (NHMRC 1992; NHMRC 2016). NHMRC also recognises the importance of using additional methods of stakeholder consultation early and often in the guideline development process, which is discussed further in the Engaging stakeholders module. The purpose of this module is to outline methods for how to conduct a fair and effective public consultation on guidelines, with reference to NHMRC’s legislated requirement to do so for internally developed advice. Consultation requirements also apply to those third party developers of clinical practice guidelines seeking NHMRC approval (see the ‘NHMRC requirements’ section below).

While stakeholder consultation methods enable feedback to be sought in a relatively controlled manner, one advantage of public consultation is that it can capture views from individuals or groups who might not otherwise have been planning or expected to engage. Public consultation can achieve:

• the early identification and management of controversial issues
• the incorporation of a wider range of views from target audiences, the public and patients into the guideline
• identification of gaps in the evidence and early notice of the publication of new evidence
• improvements in the wording and presentation of the guideline, and
• advice from intended users about ways to effectively disseminate and implement the guideline.

What to do

1. Prepare for public consultation

Ensure enough time, resources and expertise are allocated to conduct a rigorous public consultation process. In particular, plan for how best to communicate with the public, manage queries during the consultation period, and consider and respond to submissions as they inform the final guideline.

When notifying the community of the public consultation period, ensure they are made aware that the guideline being released is a draft only. It is important to avoid the perception that decisions have already been made, so the public understands that the consultation process will contribute to the end product.

Allow sufficient time for key stakeholders to undertake their own consultation process. For example, medical colleges or special advisory committees may need to table the guideline for discussion at committee meetings, or distribute it to their own network and collate responses before providing a submission.

Prepare a communications strategy in advance of the public consultation release date in order to:

• identify the key objectives and messages of the draft guideline
• prepare answers to questions that might be received from the public
• brief any agencies that might then be involved in responding to submissions
• consider whether the release should be timed with an event with an invited speaker (e.g. a conference)
• establish how people should be notified about the draft guideline (e.g. email, social media, television, newspaper, event launch)
• identify topic areas or questions on which you would like the community to provide specific feedback or advice
• direct the community to topical or potentially controversial areas in the guideline through ‘trigger’ questions to prompt responses focusing on those areas, and
• nominate a spokesperson from the development group or project team to respond to specific questions (e.g. questions about process, or questions about content).

It is important to articulate clearly the purpose and scope of both the guideline and the consultation process: if key messages in the guideline are misinterpreted on its first release to the community, it may be difficult to overcome these perceptions when it comes to implementation.

2. Define parameters for the consultation
Establishing clear parameters is crucial to ensure that developers follow a transparent process for deciding which submissions are relevant (i.e. in-scope) and which are not. Doing so will also help to control the volume of feedback received so that developers can give due regard to all submissions.

When developing parameters for the consultation:
• ask specific questions
• describe what type of feedback will be considered and what will not, in regards to the purpose and scope of the consultation
• describe the type of materials that are sought (e.g. comments, journal articles, guidelines, policies)
• set a maximum word limit (or request that submissions are concise) to assist the developer in considering the key points being made
• set out the information in a logical order including line items, page numbers or structured forms to assist in the collation process
• outline time frames and set a strict deadline for submissions, and
• if extensions will or will not be offered, state this in the advertising material.

For example, in preparing for public consultation on the Australian Dietary Guidelines, NHMRC outlined specific parameters for how additional studies provided would be considered. These were based on the same requirements for studies included in the supplied Evidence Report (i.e. with regard to NHMRC levels of evidence and grades for recommendations), including:

• that the study is a high quality systematic review, meta-analysis, randomised controlled trial, or intervention, cohort, or observational study, but not an editorial or opinion piece
• that the outcome of the study relates to health or chronic disease
• that the study results can be generalised to the Australian population, and
• that the study relates to foods or the total diet rather than nutrients.

NHMRC determined that if a relevant systematic review or meta-analysis was provided, the recommendations in question would be revisited to incorporate the new evidence. If relevant high quality studies of other types were provided (according to the parameters above) the new evidence would be incorporated in the surrounding text supporting the recommendations.
3. Notify the public
NHMRC uses various methods to communicate with the public, including an email subscription service, notifications of public consultation on its website, and emailing stakeholders through its stakeholder database. It is important that guideline developers collate and maintain their own list of stakeholders at the beginning of the process and ensure they are notified of public consultation.

Formal notices inviting public comment on a guideline should contain:

- the subject matter of the draft guideline
- where a copy of the draft recommendations or guideline can be obtained
- the manner in which submissions should be made, and
- the timeframe for receipt of submissions (at least 30 days).

Social media (such as Facebook, Twitter and LinkedIn) should also be considered as a means to notify the public about draft guidelines.

4. Request information
To better understand the context for comments and the motivations of respondents, the following information should be requested during public consultation:

- their name, and the city or state in which they are based
- their profession or the type of organisation in which they are employed
- whether they are responding as an individual or on behalf of an organisation
- any conflicts of interest they might have, and
- whether they agree to the publication of their submission.

5. Prepare submissions for consideration
The project team should carefully read all submissions and apply the parameters of the consultation process to determine what is relevant to the scope. If submissions are excluded from the decision making process because they do not fall within the stated parameters, the decision to exclude them, and the reason for the exclusion, should be recorded. The guideline development group should still be provided with copies of all submissions, as well as the record of decisions to exclude material.

If there is a large number of submissions, consider allocating subgroups of the guideline development group and project teams to process different sets of submissions. Exactly how this is done may vary depending on the sensitivity of the subject matter, complexity of the issue and the length of the submission (including the number of provided citations to be read).

In some cases, well-resourced stakeholders may use a public consultation period to submit multiple comments that promote their interests. For example, recent calls for evidence for public and environmental health guidelines have on some occasions resulted in NHMRC receiving over 500 submissions with near-identical content. If this situation arises, developers may find it easier to respond to submissions if duplicate or near-identical comments are grouped together. This approach should still enable the unique content of the submissions to be considered in full (while noting the potential skewing of total submission numbers), but reduces the administrative burden on the
development group of having to respond to duplicate comments. Consider also whether some members of the development group should form a subgroup to respond to such submissions.

As with all public consultation processes, it is important to be transparent about decisions made to manage lobbying campaigns if the situation arises, for example documenting the approach taken, as well as the number of duplicate submissions received in a given time period that led to the approach.

In these cases it may also help if the project team or a technical writer prepares a document that summarises submissions. Some caution is required however since brief summaries that only provide a cursory examination of relevant material will not satisfy the test of lawful administrative decision making. Where summaries of submissions are prepared for members of a guideline development group, they (and any associated cover papers) must be sufficiently detailed so as to alert the group of the contents of the submission and to the need to undertake a more thorough analysis of the material if appropriate. Full submissions should also be provided to members along with any documents summarising them.

To assist the guideline development group in their deliberations, all specific issues from the submissions should be extracted and tabulated. This could be done by a project team or a contracted technical writer. There is no designated standard for how comments should be categorised, but it is important that the end product is clearly presented for the guideline development group to help its deliberations.

One way to categorise comments into a table is in terms of:

- the issue
- the part of the guideline to which it applies, and
- the questions asked.

A public consultation table should then outline:

- whether the comment resulted in a change to the guideline and what that change was, or
- that the comment was considered but did not result in a change, and the reasons why it did not.

It is common for respondents to make editorial comments and suggestions, and in order to make best use of a guideline development group’s time it may be easier to summarise editorial comments in a separate table for project staff to consider.

An example of a public consultation table with sample content is provided in Table 1, whereby the final two columns would be filled in after the development group has considered the comments (see also step 6 Consider submissions).
Table 1. Example of public consultation summary table

<table>
<thead>
<tr>
<th>Name /ID</th>
<th>Section of guideline/issue</th>
<th>Comment</th>
<th>Guideline development group response</th>
<th>Action taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID39</td>
<td>Section 2.1 Lifestyle interventions</td>
<td>Include a, b and c in this section.</td>
<td>Agreed. While consideration of a, b, and c is out of scope for the recommendations, these should be included in the supporting text of the guideline.</td>
<td>Guideline amended in Section 2.1 and 4.2 to include a, b, and c</td>
</tr>
<tr>
<td>ID42</td>
<td>Section 5.2 Pharmaceutical interventions</td>
<td>Please note use of the word d in this section may be outdated.</td>
<td>Noted. The GDG has decided to retain current wording since it is correct in this context.</td>
<td>No change.</td>
</tr>
<tr>
<td>ID52</td>
<td>Section 6.1 and Section 6.3 Family history</td>
<td>Parameters e and f are inconsistent as listed in these two sections.</td>
<td>Noted and agreed.</td>
<td>Guideline amended as per suggestion.</td>
</tr>
</tbody>
</table>

6. Consider submissions
Public consultation offers an opportunity for any stakeholder to submit comments on the guideline. The primary role of stakeholders in guideline development is to represent their own interests, and their views should be understood in that context. Stakeholders are expected to promote the interests of their organisation, which can be straightforward to manage when their communication is open and honest.

It may be prudent to take steps to minimise the risk that a guideline will be biased by the interests of particularly well-resourced stakeholders. For example, NICE considers tobacco companies separate to other stakeholders to differentiate them from their standard procedures (NICE 2014).

The guideline development group must adhere to the parameters specified at the beginning of the process, irrespective of the volume or nature of comments received; they must not be selective in what they read. For example, if it is specified that all comments will be considered, care must be taken to consider submissions in all forms, whether they are published literature, personal stories, or images.

This requirement has been challenged once in court by the tobacco industry, who submitted a large volume of material in response to the public consultation of NHMRC’s passive smoking guidelines. The Federal Court found that NHMRC did not fulfil its obligation to give proper consideration to all materials received because the steering committee at the time elected to consider only literature published in peer reviewed journals, meaning literature published by the tobacco industry was deemed out of scope (Jamrozik, Chapman et al. 1997).
If stakeholders identify new evidence, it should be considered if it meets the specific inclusion criteria. If the evidence was published outside the timeframe of the guideline search parameters, the development group may still wish to consider its potential impact and decide how it should be referred to in the guideline. For example, developers of the Australian Dietary Guidelines determined that relevant high quality studies published after the search dates of their literature review would not be formally incorporated into the recommendations, but included in the surrounding text of the guidelines to support the recommendations and ensure currency.

The guideline development group is ultimately the decision maker for the content of a guideline and has a responsibility to maintain the scope and judge the evidence, taking into account the needs of the target audience. It is important that this judgement is applied while reviewing submissions.

7. **Write a consultation report**
All comments received by stakeholders should be documented, as well as any decisions made as a result, and the reasons for those decisions – whether a change was made to the guideline or not. It is important that the consultation report provides a clear and accurate record of this decision making.

Once the guideline is finalised and ready to be released, it is prudent to include a summary of the public consultation process and the changes made to the guideline as a result. The summary should capture the key issues and their corresponding responses (for example, see the public consultation report of the NHMRC Draft Information Paper: Evidence on Wind Farms and Human Health).

This report is usually provided as part of the process report of a guideline (either as an appendix or published separately).

8. **Feedback on the public consultation process**
Respondents to a public consultation process are likely to want to know how the guideline changed in response to their comments. When providing feedback to respondents it is important to refer to the parameters of the public consultation so it is clear how decisions were made, including in determining whether comments were in scope or out of scope.

If respondents have consented to having their individual submissions made publicly available, take care to redact any personal information of other people that may be contained in the submission before this occurs. For example, submissions may contain personal stories and experiences including the names of patients or health professionals that may be unaware they have been referred to in the submission.

9. **Acknowledge submissions**
It is important that a guideline acknowledges those individuals and organisations that have made a submission in the final published guideline. This can be provided within the process report (as an appendix) or published separately to the guideline (e.g. the NHMRC public consultation portal publishes submissions online).
NHMRC requirements

The NHMRC Act states, *inter alia*, that when it is practicable to do so, NHMRC should adopt a policy of public consultation in relation to individual and public health matters.

Section 13 of the NHMRC Act details the requirements for consultation on guidelines developed by NHMRC internally, namely that:

Before:

(a) the Council provides guidelines (other than human research guidelines) to the CEO for the purposes of subsection 9(1); or

(b) the Australian Health Ethics Committee provides human research guidelines to the Council for the purposes of subsection 10(2);

the Council or Committee must:

(c) prepare a draft of the guidelines; and

(d) publish a notice, in the manner and form specified in the regulations:

   (i) containing a summary of the draft guidelines; and

   (ii) stating where copies of the draft guidelines can be obtained; and

   (iii) inviting persons or bodies to make submissions relating to the draft guidelines in accordance with the procedures, and within the period, specified in the notice; and

   (e) have regard to any submissions received as a result of the invitation referred to in subparagraph (d)(iii).

Section 14A of the NHMRC Act details the requirements for consultation on third party guidelines seeking approval by NHMRC, namely that:

(1) The CEO may, on the advice of the Council, approve guidelines prepared by a person or body from outside the NHMRC.

(2) 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).

Note: Subsection (2) does not apply if the guidelines are of minor significance: see section 14B

In addition, regulation 7 of the NHMRC Regulation details NHMRC’s requirements regarding the manner and form of notice of such consultation, namely that:

(1) A notice under paragraph 13(d) of the Act must be published on the NHMRC website.

(2) A notice under paragraph 13(d) of the Act must include the following:

   (a) the subject matter of the draft guidelines to which the notice relates;

   (b) the last day on which the Council or the Australian Health Ethics Committee will accept submissions relating to the draft guidelines, which must be a day that is at least 30 days after the notice is published under subsection (1) of this section.

Third party developers of clinical practice guidelines seeking NHMRC approval must meet all requirements outlined in the Procedures and requirements for meeting the NHMRC standard, including the following in relation to public consultation:

• F.1 The process for public consultation on the draft guideline complies with section 14A of the NHMRC Act and the NHMRC Regulation.

• F.2 Details of submissions received during public consultation and the response of the guideline development working group to the submissions (including whether, why and how the guideline was altered) are provided as a separate document to the NHMRC.

• F.3 During the public consultation period, the developer has undertaken and documented consultation with: – the Director-General, Chief Executive or Secretary of each state, territory and Commonwealth health department – relevant authority/ies, when a guideline makes any recommendation/s specifying interventions that are not available or restricted in Australia (see Requirement D.10).

• F.4 The developer has identified and consulted with key professional organisations (such as specialty colleges) and consumer organisations that will be involved in, or affected by, the implementation of the clinical recommendations of the guideline.

Useful resources

NHMRC public consultation portal
NHMRC public consultation submission guidelines
NHMRC public consultation factsheet
GiN Public Toolkit 2015
European Commission Guidelines on stakeholder consultation
European Commission Code of Good Practice for consultation of stakeholders

Public consultation version – 30/10/2017
References