

Guideline for Growth, Health and Developmental Follow-up for Children Born Very Preterm

Methodological Review			
	Reviewer Comment	NHMRC Comment	Developer Response
1	<p>NHMRC desirable requirement A.2.1</p> <p>There is a statement that the full amount of funding was received from the NHMRC. The total amount of funding was not stated.</p>	Please consider including the full funding information.	The funding used to develop this guideline was a subset of the NHMRC funding for the Centre for Excellence in Newborn Medicine. As the funding was not specific to this project it was not thought to be appropriate to include in the guideline.
2	<p>NHMRC mandatory requirement B.5</p> <p>It is acknowledged that Aboriginal and Torres Strait Islander people are at risk of experiencing inequitable healthcare and outcomes (Guideline, p. 22).</p> <p>It is suggested that information about the particular risk of preterm birth in Aboriginal and Torres Strait Islander people be included in section 1.1 of the Guideline or section 3.2 of the Guideline. (e.g. the relevant risk compared with non-Indigenous mothers).</p>	Please review comments and including the suggested additional information.	Thank you for your comment. Our team was unable to find evidence specific to the risk of very preterm (<32 weeks) in Aboriginal and Torres Strait Islander people and as such have included a statement 1.1 of risk of preterm birth in Aboriginal and Torres Strait Islander people for all preterm births.
3	<p>NHMRC desirable requirement B.5.1</p> <p>It is acknowledged that there are special-needs groups (Guideline, p. 22), although it could be worthwhile to provide more background information on what the specific risks are.</p>	Please consider including the additional background information.	Thank you for your comment. Additional information about the specific risks has not been provided as multifactorial that overlap between groups. No amendment has been made in response to this comment.
4	<p>NHMRC mandatory requirement C.6</p> <p>For question 2, the Technical report includes GRADE evidence profile tables per outcome, outlining the study design, and certainty of the evidence. They do not include the findings of the studies. The results are presented separately in a narrative format under 'Characteristics of included studies'. Only summary statements are provided, not the primary data, so it is difficult for the reader to determine the statistical significance or clinical importance of the findings.</p>	Please review and respond to the reviewer comments. Consider including the primary data or additional information to assist the reader determine the statistical significance or clinical importance of the findings.	Thank you for your comment. Due to the size of the systematic review for question 2, primary data report (215 pages) was included in a separate document called <i>Technical Report – Supplementary Material</i> and noted this in the Technical Report on page 68 "Evidence tables including

			<p><i>characteristics of all included studies is available upon request”.</i></p> <p>The steering committee felt it too cumbersome to include in the guideline or technical report document. The primary data report has been included with the final guideline documents for NHMRC consideration.</p>
5	<p>NHMRC mandatory requirement C.8</p> <p>Although no evidence-based recommendations were formulated, Table 6 in the Technical Report (pp. 17-18) provides the GRADE evidence to Decision criteria and judgements. Reference details provided in Table 3, p. 9 of Technical Report.</p> <p>No Evidence to Decision criteria and judgement table provided for question 2.</p>	<p>Please review comments and include consideration of question 2 in the Evidence to Decision criteria and judgement table.</p>	<p>The evidence to decision criteria were not considered appropriate to the development of question 2 as the guideline working group did not intend to make specific recommendations on individual risk factors but rather consider how the presence of various risk factors may influence structured follow-up care. This is detailed on page 57-58 of the guideline.</p> <p>To improve clarity this information has been reproduced in the Technical Report on page 64.</p>
6	<p>NHMRC desirable requirement C.3.4</p> <p>Cost effectiveness of interventions or implications on resourcing are not considered in this review. The Guidelines do not address any issues associated with cost-effectiveness or resource implications of the recommendations.</p> <p>The evidence to decision framework for question 1 discussed that attending appointments can be costly and burdensome, but this was not based on evidence.</p>	<p>Please respond to the reviewer’s comments and consider including further information about cost effectiveness and resource implications of the recommendations.</p>	<p>Thank you for your comment. This information can be found in the Technical Report on page 17.</p> <p><i>“In forming recommendations for this guideline, the GDG took on the perspective of the individual patient. GRADE guidance indicates that guideline developers such as professional societies may take an individual patient perspective, “with</i></p>

			<p><i>a view towards providing guidance to individual patients and clinicians making individual patient choices” [7]. Therefore, the GDG did not consider considerations of costs and resources when making recommendations.”</i></p> <p>and references on page 50 of the guideline:</p> <p><i>“Question 1. Using GRADE guidance, we elect to not consider resource use in forming recommendations, given a lack of reliable data.”</i></p> <p>The guideline development group acknowledges that the evidence to decision framework for question 1 discussed that attending appointments can be costly and burdensome,</p> <p><i>(e.g., may be a source of anxiety for some families; attending appointments can be costly and burdensome depending on families’ situations, but families would be free to choose whether to engage with the care that is offered)</i></p> <p>was not evidence based but provided as a clinical consensus statement due to a lack of available reliable data.</p>
--	--	--	---

			<p>This was reflected in the evidence to decision framework in the technical report on page 17 as it underpinned a clinical consensus recommendation denoted by CCR in the evidence to decision framework table. This recommendation was developed by consensus of the guideline development group.</p> <p>No amendment has been made in response to this comment.</p>
7	<p>NHMRC mandatory requirement D.9 It is not documented which questions differed between this review and the existing NICE guidelines; but in the evaluator’s view this does not stop the guideline meeting the requirement.</p>	For noting. No action required.	Thank you for your comment. No amendment has been made in response to this comment.
8	<p>NHMRC mandatory requirement D.11 It is unclear if any of the evidence identified for clinical question 2 was in Aboriginal and Torres Strait Islander or other population groups with specific risks.</p>	Please confirm if any of the evidence identified for clinical question 2 was in Aboriginal and Torres Strait Islander or other population groups with specific risks.	Thank you for your comment. Evidence identified for clinical question 2 were specific to the risk/resilience factors described and not specific to the Aboriginal and Torres Strait Islander peoples. Risk factors were developed by clinical consensus by the guideline working group as well as public consultation.
9	<p>NHMRC mandatory requirement D.15 The Guideline should note in the final version that the recommendations have been assessed by at least two reviewers, independent of the guideline development process, using the AGREE II instrument once it has been reviewed.</p>	Please confirm at final submission that the guideline has been subject to two independent AGREE II assessments	Thank you for your comment. It has been noted in the final submission of the guideline that the guideline has been subject to two independent AGREE II assessments on page 32 <i>“Two independent AGREE II assessments will also be conducted.”</i>
10	<p>NHMRC desirable requirement D.13.1 No consideration has been given to ethical issues in these guidelines and there is no justification given for the omission. Ethical issues should be considered in this population group who are more likely to experience disability, chronic illness and developmental delay.</p>	Please consider and respond to the comments.	Thank you for your comment. One of the ethical issues around a guideline is singling out the very preterm group as ‘high risk’, which may be

			interpreted as discrimination. However, this guideline was developed in response to those with lived experience and other stakeholders (clinicians caring for these children and families) that there is a need to develop evidence based guidelines for follow-up care. No amendment has been made in response to this comment.
11	NHMRC desirable requirement E.4.1 A separate document with a summary of the recommendations will be developed after public consultation.	Please ensure a summary of recommendations is included in the final guideline documents submitted to NHMRC.	Thank you for your comment. A summary of the recommendations is included in the final guideline documents submitted to the NHMRC.
12	NHMRC desirable requirement E.7.1 The evaluators have been unable to test if the design of the guideline is suitable for people with vision impairment.	For noting. Please ensure all final documents are accessible.	Thank you for your comment. The heading structure has been changed to allow the final guideline document to be more accessible for people with a vision impairment.
13	NHMRC mandatory requirement E.9 Tables in section 4.3 do not have captions.	Please check all tables in the final documents.	Thank you for your comment. Section 4.3 of the Guideline, Administrative Report and/or the Technical Report do not include tables however the captions on all tables have been checked in the final documents submitted to NHMRC.
14	NHMRC mandatory requirement F.2 A summary of public consultation comments and the response for the guideline development group to be completed after public consultation.	Please ensure this summary is included in the final guideline documents submitted to NHMRC.	Thank you for your comment. A submissions summary including all public consultation comments and the appropriate responses by the guideline development group will be provided with the final guideline documents submitted to the NHMRC.

15	<p>NHMRC mandatory requirement F.4 List of organisations that will be involved in, or affected by, the implementation of recommendations will be completed during public consultation.</p>	<p>Please ensure this information is included in the final guideline documents submitted to NHMRC.</p>	<p>Thank you for your comment. The dissemination and implementation plan which includes a list of organisations that will be involved in the implementation of recommendations is provided with the final guideline documents submitted to the NHMRC.</p>
----	---	--	---