

Australian Government

National Health and Medical Research Council

Administrative Report:

Promoting social and emotional development and wellbeing of infants in pregnancy and the first year of life

This Administrative Report refers to the development of the following documents:

- Evidence Evaluation Report: Evaluation of evidence on the effectiveness of interventions for caregiving practices and behaviours for optimal social and emotional development of infants: an overview of systematic reviews (Evidence Evaluation Report)
- Technical Report: Evaluation of evidence on the effectiveness of interventions for caregiving practices and behaviours for optimal social and emotional development of infants: an overview of systematic reviews (Technical Report)
- Evidence Commentary Report: Effectiveness of interventions for caregiving practices and behaviours for optimal social and emotional development of infants (Evidence Commentary Report)
- NHMRC Report on the Evidence: Promoting social and emotional development and wellbeing of infants in pregnancy and the first year of life (Report on the Evidence)
- NHMRC Plain Language Summary of Report on the Evidence (Plain Language Summary)

Introduction

During its 2012-15 triennium, the National Health and Medical Research Council's (NHMRC) former Prevention and Community Health Committee (PCHC) identified mental health as a key project area, with a particular focus on the effectiveness of parenting practices and their role in promoting social and emotional health and wellbeing in children and later on as adults. PCHC indicated that there is considerable evidence supporting the importance of such early parenting in promoting mental health and wellbeing later in life, and that there are various effective interventions for supporting stimulation through parenting.

The subsequent overview of numerous systematic reviews revealed it was going to be difficult to translate the breadth of the evidence into any succinct guidance. As such the NHMRC Project Team decided that this advice should take the form of a report on the evidence about promoting the social and emotional development and wellbeing of infants. The process involved in developing the NHMRC Report on the Evidence is outlined below.

- · Working Committee established to provide expert advice to NHMRC during the development process
- Overview of systematic literature reviews undertaken by specialists in evaluating evidence (the Evidence Evaluation)

- Professional technical writer documented the Working Committee's analysis of the evidence in the Evidence Commentary Report¹
- Professional technical writer translated the Evidence Evaluation into the NHMRC Report on the Evidence, based on advice of the Working Committee (documented in the Evidence Commentary Report)
- Draft NHMRC Report on the Evidence (and completed Evidence Evaluation Report) released for targeted consultation
- Draft NHMRC Report on the Evidence revised by the technical writer based on advice of the Working Committee, incorporating consultation feedback
- Draft NHMRC Report on the Evidence released for a second targeted consultation (with focus on jurisdiction health departments)
- Draft Plain Language Summary developed by the technical writer and released for targeted consultation
- Draft NHMRC Report on the Evidence and Plain Language Summary revised by the technical writer based on advice of the Working Committee
- Draft NHMRC Report on the Evidence and Plain Language Summary underwent independent expert review
- Draft NHMRC Report on the Evidence and Plain Language Summary considered by the Council of NHMRC who made a recommendation to the Chief Executive Officer (CEO) of NHMRC to release
- Final NHMRC Report on the Evidence and Plain Language Summary published on the NHMRC website and disseminated

Contributors

Mental Health and Parenting Working Committee

Appointment process

The Mental Health and Parenting Working Committee (Working Committee) was established by a CEO delegate, under section 39 of the *National Health and Medical Research Council Act 1992* (NHMRC Act).

The Working Committee was selected to ensure appropriate expertise in the key areas of child health and wellbeing, family/community health, migrant and refugee health, child abuse and neglect, Aboriginal and Torres Strait Islander health and public health evidence. It was tasked with guiding the development of advice aimed at supporting parents of young children as a means of promoting the child's social and emotional development and wellbeing.

Some members of PCHC were also members of the Working Committee. Representatives from the Department of Health and the Department of Social Services joined the committee in an observer capacity.

Terms of Reference

The Mental Health and Parenting Working Committee will:

- In consultation with a subgroup of the former PCHC (in its 2012-15 triennium), finalise the project scope including the child's age, target audience, intervention/parenting practices, key outcomes and format of advice
- Consider current Australian and international evidence and initiatives in this area, including gaps, and advise
 on where NHMRC could best invest its efforts
- Advise on a commissioned evidence evaluation to underpin the NHMRC guidance
- Consider the findings of the evidence evaluation to inform the development of NHMRC guidance
- Advise on consultation activities and how to effectively engage relevant stakeholders
- Seek feedback from the Council of NHMRC
- Consider comments received through consultation on the draft guidance and subsequent revisions required

¹ The Evidence Commentary Report is not publically available as it contains only the Working Committee's deliberations in developing the NHMRC Report on the Evidence. The final decisions are documented in the NHMRC Report on the Evidence. Copies of the Evidence Commentary Report may be obtained from NHMRC upon request.

- Advise on implementation and promotion strategies/activities to ensure consideration and uptake of the guidance
- Advise on how to assess/evaluate the effectiveness of the guidance.

Declarations of interest process

Members of NHMRC Committees provide high quality, expert and independent advice that allows NHMRC to fulfil its functions under the NHMRC Act. Members are appointed for their expertise and experience across a diverse range of professions and fields. Appointments are also made with consideration of balancing the benefit of having persons with expertise against the risks of their interests biasing a process.

Appointees to committees of NHMRC are required to disclose their interests consistent with section 42A of the NHMRC Act and section 29 of the *Public Governance, Performance and Accountability Act 2013.* Prior to appointment decisions being made, NHMRC asked each prospective member of the Working Committee to disclose their interests to NHMRC in writing. Prospective members were specifically asked to identify, to the best of their ability, interests including:

- relevant financial activities (e.g. employment, ownership, board membership, honoraria, consultancies, or research grants in parenting and child health)
- professional and organisational experience (e.g. publications, speeches, expert testimony, involvement in the development of guidelines, standards, education material or fact sheets, related to parenting and child health)
- other relationships or activities.

The then Acting Group Head, NHMRC Research Translation Group, reviewed each disclosure and determined that there were no conflicts that precluded an appointment to the Working Committee or required a member's interests to be managed.

Throughout the project, members were reminded of their obligation to consider any interest that may have arisen since the last meeting or with any particular agenda items. All disclosures and determinations about interests were recorded in the minutes of the Working Committee meetings. A summary of the disclosed interests was accessible on the NHMRC website throughout the duration of the project.

There were no instances in the development process where members of the Working Committee determined that a disclosed interest warranted a member being absent from a discussion or decision.

Membership

Appointments to the Working Committee were effective from 8 May 2014 to 7 May 2017. The Members were:

- Professor Jane Fisher (Chair)² Jean Hailes Professor of Women's Health and Director Jean Hailes Research Unit, School of Public Health and Preventive Medicine, Monash University; Consultant Clinical Psychologist Masada Private Hospital Mother Baby Unit
- Dr Carmel Loughland Senior psychologist, Faculty of Medicine and Population Health, University of Newcastle
- Dr Charlene Smith³ Senior Project Manager, Australian Research Alliance for Children and Youth (ARACY)
- Professor Graham Vimpani Head of Paediatrics and Child Health, University of Newcastle
- Associate Professor Harriet Hiscock Senior research fellow and paediatrician, The Royal Children's Hospital Melbourne

² Professor Elizabeth Waters was the Chair of the Working Committee until September 2015. NHMRC acknowledges the significant contribution that Professor Waters made to the work of this committee and to public health more broadly.

³ Dr Smith replaced Dr Dianne Jackson, CEO of ARACY in December 2015.

- Professor Helen Herrman Research Director, Orygen Youth Health Research Centre; Professor of Psychiatry, Centre for Youth Mental Health, The University of Melbourne; Director, WHO Collaborating Centre in Mental Health, Melbourne; Member of NHMRC's former PCHC
- Associate Professor Julie Green Executive Director, Raising Children Network
- Professor Mark Harris Foundation Professor of General Practice and Director of the Centre for Primary Health Care and Equity at the University of NSW; Member of NHMRC's former PCHC
- Ms Michal Morris Director, Mental Health and Alcohol and other Drugs Reform, Melbourne Primary Care Network (North West Melbourne Primary Health Network)
- Dr Shanti Raman Paediatrician, Sydney South West Area Health Service and South Western Sydney Clinical School
- Dr Sue Packer Community Paediatrician, ACT Health
- Ms Tina Hourigan Nurse Educator, Sustaining NSW Families Advanced Nurse Practice Course, Tresillian Family care Centres
- Dr Rebecca Armstrong⁴ Associate Director of the Jack Brockhoff Child Health and Wellbeing Program, University of Melbourne; Editorial and Methods Advisor, Cochrane Public Health Group
- Ms Adele Cox⁵ Consultant

Observers

Two observers were appointed to the Working Committee to ensure alignment and relevance of the project with government initiatives. The observers were appointed to 'represent' their respective organisations and provide factual information about relevant work in their departments as required by the Chair. The observers were from the Department of Health and the Department of Social Services.

NHMRC Project Team

The project was managed by the Public Health team of the Evidence, Advice and Governance Branch.

Governance

Meetings

The Working Committee met in person in May 2014 and advised on the scope of a) the project and b) an evidence evaluation required to underpin the final report.

In November 2015 the Working Committee met in person to critically appraise the completed evidence evaluation and consider feedback from independent methodological review. At this meeting the Working Committee also started the process for formulating and grading recommendations using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.⁶ These deliberations continued during a series of subgroup videoconferences held in December 2015 and January 2016 and through out-of-session comments by members. The Working Committee's assessment of the evidence was finalised at a videoconference of the full Committee on 19 February 2016. At this meeting the Working Committee also advised on the scope of the final Report on the Evidence in light of the findings from the evidence evaluation and the NHMRC's Project Team consultation with Government departments. A fourth meeting of the full Committee was held via videoconference on 5 April 2016 where members finalised the Evidence Commentary Report and provided the technical writer with sufficient advice to prepare the next draft of the Report on the Evidence for the Council of NHMRC in July 2016.

Following release of the draft NHMRC Report on the Evidence for targeted consultation from 4 August to 11 September 2016, the Working Committee met via videoconference on 6 October 2016 to consider comments

⁴ Dr Armstrong was appointed on 1 November 2015.

⁵ Ms Adele Cox was a member of the Working Committee until late March 2016.

⁶ http://www.gradeworkinggroup.org and the GRADE Handbook (http://gradepro.org)

received and advise on any revisions required. The Working Committee also advised on implementation and promotion strategies for the NHMRC Report on the Evidence and how to evaluate its effectiveness. At this meeting, Members suggested that another opportunity be granted to stakeholders and jurisdiction health departments to provide feedback on the draft Report on the Evidence. Subsequently, the NHMRC Project Team sought additional feedback from key stakeholders (as advised by the Committee) and Chief Health Officers in all jurisdictions. A sixth and final meeting of the Committee was held on 9 February 2017 via videoconference. At this meeting, Members considered additional comments received from targeted consultation as well as feedback from the independent expert reviewer, and advised on revisions required to the draft Report on the Evidence and Plain Language Summary.

All discussions of the Working Committee were robust and open, and decision-making was consensus-based. Minutes from all Working Committee meetings and videoconferences were recorded by NHMRC's Project Team.

Evidence Evaluation

The Australian Research Centre for Health of Women and Babies (ARCH), the University of Adelaide, was commissioned by NHMRC to undertake an evaluation of the evidence. The evaluation focused on the effectiveness of interventions and messages for parenting practices and behaviours that are delivered at a population level to infants up to 12 months of age and which aim for optimal social and emotional development. ARCH was contracted by NHMRC following a competitive procurement process using the NHMRC Health Evidence Panel.

The independent evaluation was undertaken in accordance with a research protocol that was approved by the NHMRC Project Team, based on advice from the Working Committee, before the evidence evaluation started.

The independent reviewers conducted extensive searches of electronic databases for literature published from January 1994 to October-December 2014. 8,095 citations were identified in the literature search for systematic reviews (the overview) and 532 citations were reviewed in full-text. Fifty-one systematic reviews met both the inclusion criteria and criteria for review prioritisation.

Full details of the evaluation are provided in the Evidence Evaluation Report and Technical Report undertaken by ARCH. This includes the research questions (and sub-questions) using the PICO approach (population, intervention, comparator, outcomes), the methods used to identify, select, appraise and summarise the evidence, and evidence statements.

Independent Methodological Review

Independent reviewers completed a methodological appraisal of the draft Research Protocol to provide NHMRC with assurance of the proposed methodology for the evidence evaluation prior to ARCH commencing its review. Menzies School of Health Research successfully tendered to complete this activity through a competitive process using the NHMRC Health Evidence Panel. The methodologists comments were provided to ARCH who revised the protocol accordingly, based on advice of the Working Committee, prior to commencing the evaluation of the evidence.

Once the evidence evaluation was complete, independent reviewers were commissioned to assess the methodological quality of the evaluation and ensure the systematic and rigorous approach prescribed in the review protocol had been followed, and the interpretation and reporting of the evidence was transparent and complete. This methodological review was undertaken by the University of Sydney, who was selected from the NHMRC Health Evidence Panel, following a competitive process. The methodologist suggested that the evidence reviewers should:

- clarify that the prioritisation criteria 'did not include primary studies in infants <12 months of age'
- include in the 'Differences between protocol and review' section a paragraph about the databases and other sources of literature mentioned in the protocol that were ultimately not searched for the review
- add explicit statements about how quality of the evidence was rated where one or more aspect of the GRADE assessment was not reported
- clarify the interpretation of the evidence where the p-value was reported as 0.06 and 0.07

- clarify the decisions made to exclude 'Day care interventions' and 'Interventions for preventing maltreatment' from the list of effective interventions
- clarify distinctions between intervention/population categories shown not to be effective and those with insufficient information to determine effectiveness.

The Working Committee were satisfied with the methodologist's appraisal. In subsequent drafts of its reports, ARCH addressed the issues raised to further clarify its procedures and processes.

Governance

The draft Evidence Evaluation Report and Technical Report were discussed at a meeting of the Working Committee held in November 2015, with the content further refined and the evidence statements finalised using a consensus approach.

Development of the NHMRC Report on the Evidence

Evidence Commentary Report⁷

This activity was included as a required deliverable in preparing to draft the NHMRC Report on the Evidence. Meducation Australia Pty Ltd. successfully tendered to complete this activity through a competitive process using the NHMRC Health Evidence Panel.

The Evidence Commentary Report documents the deliberations and decisions of the Working Committee in:

- appraising the evidence presented in the Evidence Evaluation Report and Technical Report,
- applying the GRADE approach⁸ to assess the body of evidence, and
- considering the broader implications of the findings relevant to the Australian context.

In applying the GRADE approach to assess the body of evidence, the Working Committee drafted conclusions through informal consensus based on their interpretation of the evidence evaluation and by considering the following GRADE⁹ domains for determining the direction and strength of recommendations:

- overall confidence in the estimates (how confident are we in the estimate of effect?)
- balance of benefits versus harms and burdens (on balance, does the evidence demonstrate that the intervention is effective or is it inconclusive?)
- values and preferences of relevant stakeholders (is there important uncertainty about how parents/caregivers, policy makers, other guideline panels, health professionals or welfare professionals) value the main outcomes?)
- resource implications (are the required resources small? If the intervention is implemented, is the incremental cost small relative to *the net benefit?*)
- equality, acceptability and feasibility (is the evidence acceptable to the target groups and applicable in an Australian context? What would be the impact on health inequalities? Is the option feasible to implement?)

Further information about the GRADE approach used by the Working Committee can be found in the Report on the Evidence.

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⁸ http://www.gradeworkinggroup.org and the GRADE Handbook (http://gradepro.org/)

⁹ For more information on each of the GRADE domains refer to GRADE Handbook at http://gradepro.org

The Working Committee followed the GRADE approach to develop recommendations and determine their strength as it assessed the evidence with the intent of developing guidance for parents. However, given the breadth and quality of evidence found, NHMRC and the Working Committee later agreed that a more suitable end product was advice for governments in the form of an NHMRC Report on the Evidence that contained Working Committee Conclusions.

The development of the Evidence Commentary Report commenced at the Working Committee's meeting held in November 2015 and continued through to March 2016 via a series of subgroup videoconferences, a face to face meeting in February 2016 and out-of-session comments by members. As the purpose of the Evidence Commentary Report was to detail the comprehensive deliberations and decisions of the Working Committee in assessing the evidence, it was not intended to be a public document. The content and wording of the draft recommendations within the report reflect the Working Committee's initial deliberations and were superseded by the content of the final NHMRC Report on the Evidence.

NHMRC Report on the Evidence

The NHMRC Report on the Evidence aims to provide information to governments and other policy makers, researchers and service providers who work with parents of young children to promote children's social and emotional development and wellbeing. Meducation Australia Pty Ltd. successfully tendered to complete this activity through a competitive process using the NHMRC Health Evidence Panel.

The NHMRC Report on the Evidence:

- summarises the methods and findings of the Evaluation of evidence on the effectiveness of interventions for caregiving practices and behaviours for optimal social and emotional development of infants (Evidence Evaluation Report)
- provides the Working Committee's assessment of each intervention reported in the evaluation using the GRADE approach
- contains the conclusions reached by the Working Committee on the potential of each intervention to promote infant and child social and emotional development and wellbeing among Australian parents/caregivers, and the systematic approach used to develop these statements.

The Working Committee guided the development of the NHMRC Report on the Evidence via videoconferences and out-of-session comments. The Technical writer (Meducation Australia Pty Ltd) attended all Working Committee videoconferences and commenced drafting the report in February 2016. In August-December 2016, the NHMRC Report on the Evidence underwent targeted consultation.

Plain Language Summary

Through discussions at the 6 October 2016 Working Committee meeting, Members agreed that a supporting document to the Report, such as a plain language summary, would be very useful. Subsequently, Meducation (Technical Writer), together with the NHMRC Project Team and Working Committee, drafted a plain language summary to accompany the Report on the Evidence.

Targeted consultation

On 14 July 2016, the Council of NHMRC discussed the draft NHMRC Report on the Evidence ahead of its release for targeted consultation. The Evidence Evaluation Report authored by ARCH was released at the same time as background information.

Targeted consultation on the NHMRC Report on the Evidence was undertaken from 4 August to 11 September 2016. This consultation was advertised on the NHMRC Public Consultation website. Invitations were sent to more than one hundred stakeholders. Due to the small number of submissions received, Committee Members suggested that another opportunity be granted to stakeholders and jurisdiction health departments to provide feedback on the draft Report on the Evidence. Subsequently, the NHMRC Project Team sought additional feedback from key stakeholders (as advised by the Committee) and Chief Health Officers in all jurisdictions during November-December 2016. The draft Plain Language Summary also underwent consultation during this period with stakeholders who provided feedback in Round One consultation on the draft Report on the Evidence.

A total of 27 submissions were received on the Report on the Evidence from a variety of stakeholders including jurisdiction health and child/family government departments, professional colleges, national mental health associations and researchers.

The Working Committee met on 6 October 2016 to consider the submissions received from the Round One consultation and again on 9 February 2017 to consider submissions received from the Round Two targeted consultation.

Apart from many positive comments from stakeholders and jurisdictions remarking on the utility of the report for policy makers and service providers, issues raised during targeted consultation included:

- Ensuring consistency of Working Committee summary statements and reporting of the primary and secondary outcomes
- Clarifying intervention categories (some interventions are broad and inclusive, whilst others are specific and focused) and structuring the presentation of the evidence accordingly.
- Clarifying the term 'Insufficient evidence' and distinguishing between interventions not supported due to lack of evidence and interventions not researched.
- Structure, format and readability of the Report

The draft NHMRC Report on the Evidence was subsequently revised by the technical writer based on the advice of the Working Committee.

Independent Expert Review

The draft NHMRC Report on the Evidence and Plain Language Summary underwent expert review from 6 December 2016 to 29 January 2017. The purpose of expert review was to gain independent advice, primarily on the Working Committee's translation of the evidence and its application of the GRADE framework. The expert reviewer was selected on the basis of her expertise in GRADE, with the remit for her to:

- · provide any views or comments on how the Working Committee applied GRADE to the overview
- advise on the 'appropriateness' of the final product the Report on the Evidence in regards to its readability and usefulness, given the articulated target audience/s
- provide comments on the Plain Language Summary to accompany the Report on the Evidence

The expert reviewer was required to sign a *Deed of Confidentiality* and declare any potential interests as per the process outlined for Working Committee members.

Independent expert review participant

 Ms Miranda Cumpston, Head of Learning and Support, Cochrane Central Executive — expertise in in evidence-based decision making and systematic review methodology, health policy, and public health

Key issues raised by the reviewer included the use of the decision tool to ensure standardised language in the Committee's conclusion statements, and distinguishing between 'no evidence of an effect' and 'uncertainty of an effect'. Expert review feedback was addressed by the Working Committee and the NHMRC Project Team at the meeting on 9 February 2017.

Governance

Following targeted consultation and independent expert review, the final NHMRC Report on the Evidence and Plain Language Summary were provided to the Council of NHMRC on 16 March 2017. The Council of NHMRC was satisfied with the content and the process undertaken to develop both documents and advised the NHMRC CEO to release them. The CEO of NHMRC accepted Council's advice and agreed to issue the NHMRC Report on the Evidence and Plain Language Summary under Section 7(1a) of the NHMRC Act in May 2017.