

Australian Perinatal Mental Health Guideline Evidence Review

Technical Report Part A
Overall approach and
governance

Prepared by



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TABLE OF CONTENTS

A1	SCOPE AND PURPOSE	5
A1.1	Objectives.....	5
A1.2	Questions	5
A1.2.1	Psychosocial assessment.....	6
A1.2.2	Screening.....	6
A1.2.3	Effectiveness of interventions.....	7
A1.2.4	Harms associated with selected interventions	8
A1.3	Population	10
A2	STAKEHOLDER INVOLVEMENT.....	11
A2.1	Group membership	11
A2.1.1	Identification of key stakeholders and establishment of the Expert Working Group	11
A2.1.2	Methodologists	14
A2.1.3	Technical writer.....	14
A2.2	Target population preferences and views	14
A2.3	Target users	15
A3	RIGOUR OF DEVELOPMENT	16
A3.1	Search methods	16
A3.2	Evidence selection criteria	18
A3.2.1	Psychosocial assessment and screening	18
A3.2.2	Effectiveness of interventions.....	18
A3.2.3	Harms of interventions	18
A3.3	Strengths and limitations of the evidence	18
A3.4	Formulation of recommendations	19
A3.5	Consideration of benefits and harms	19
A3.6	Link between recommendations and evidence	20
A3.7	External review	21
A3.8	Updating procedure	21
A4	CLARITY OF PRESENTATION.....	22
A4.1	Specific and unambiguous recommendations	22
A4.2	Management options.....	22
A4.3	Identifiable key recommendations	22
A5	APPLICABILITY	23
A5.1	Facilitators and barriers to application.....	23
A5.2	Implementation advice/tools	24
A5.2.1	Resources for health professionals.....	24

A5.2.2	Consumer and carer resources	24
A5.3	Resource implications	24
A5.4	Monitoring/ auditing criteria.....	25
A6	EDITORIAL INDEPENDENCE.....	26
A6.1	Funding body.....	26
A6.2	Competing interests.....	26

TABLE OF TABLES

Table A2-1 Perinatal guideline Expert Working Group Members 11

Table A2-2 Perinatal guideline Proxy Representatives 12

Table A2-3 Members of the Expert Committees 13

Table A3-1 Literature searches 17

Table A3-2 Cross-referencing to Technical Report for Evidence Based Recommendations 20

A1 SCOPE AND PURPOSE

A1.1 OBJECTIVES

The objective of the Perinatal Mental Health Guideline is to guide best practice in the identification, prevention and treatment/management of mental health disorders that may occur during pregnancy or in the first year following the birth of a baby (the perinatal period).

Health intents

The Guideline is designed to guide health professionals in the identification of the more common disorders (depression and anxiety), together with the prevention and treatment of these conditions through a range of treatment approaches that includes psychosocial and psychological therapies, pharmacological, complementary and physical therapies.

In addition, the Guideline addresses the management of low prevalence, more severe mental illnesses - namely schizophrenia, bipolar disorder, postpartum psychosis, and borderline personality disorder (BPD). For each of these conditions the Guideline provides guidance in the provision of psychosocial and psychological therapies, pharmacological and physical therapies.

Expected benefits or outcomes

Through undertaking a review of the latest evidence, the first aim of the Guideline was to identify current and effective tools for the detection of those most at risk of perinatal mental health conditions (psychosocial assessment) as well as those likely to be experiencing symptoms of the more common conditions (screening tools). The second aim of the Guideline was to assess the evidence of interventions for managing mental health disorders, with a particular focus on the impact to the offspring of *in utero* exposure to systemically-active treatments (i.e., medications, complementary therapies and some physical therapies).

The intention is that these evidence-based findings can inform local, state and national policy surrounding the timely implementation of appropriate tools to ensure early identification of needs and timely, safe (for mother and baby) and effective intervention. Early detection and management of perinatal mental health disorders will serve to have significant health and economic benefits for the woman, her family and the broader community.

Target

The target audience for this Guideline is primary health professionals caring for women as they plan pregnancy, and throughout the perinatal period. This includes but is not limited to: midwives, Child and Family Health Nurses, Mental Healthcare Workers, General Practitioners, and obstetricians.

A1.2 QUESTIONS

There were three main topics under investigation for this Guideline:

- Identification of mental health problems during the perinatal period using psychosocial assessment and screening [assessed in **Part B** of the **Technical Report**].
- The effectiveness of treatment or prevention of mental health problems during the perinatal period using various interventions [assessed in **Part C** of the **Technical Report**]
- Harms to the offspring or mother related to the use of selected interventions [assessed in **Part D** of the **Technical Report**].

To address these three topics, eight main questions were formulated, with each question being broken down into multiple sub-questions based on population, intervention or outcome.

In addition to these clinical questions, the resource implications of perinatal mental health screening have been addressed via targeted consideration of published cost-effectiveness analyses.

A1.2.1 Psychosocial assessment

The main question relating to psychosocial assessment was broken down into five sub-questions based on different outcomes. It should be noted that each sub-question could be broken down further into individual psychological instruments/tool and outcomes.

Main question:

1. What is the most appropriate method for psychosocial assessment of women at risk of mental health problems in the perinatal period?

Sub-questions:

1a. What is the performance (defined as reliability, validity and predictive accuracy) of validated multidimensional tools for perinatal psychosocial assessment? [addressed via systematic review; see **Part B Technical Report**]

1b. What are the non-technical characteristics (defined as number of items, time to administer, complexity of scoring, training requirements, and available languages) of validated multidimensional tools for perinatal psychosocial assessment? [addressed via descriptive review; see **Part B Technical Report**]

1c. What is the acceptability to pregnant or post-partum women, health professionals, and the general public of validated multidimensional tools for perinatal psychosocial assessment? [addressed via narrative review; see **Part B Technical Report**]

1d. What is the effectiveness (defined as impact on detection, care sought or received, and mental health outcomes) of perinatal psychosocial assessment with validated multidimensional tools? [addressed via narrative review; see **Part B Technical Report**]

1e. What are the implications (for resourcing, workforce, and models of care) of implementing perinatal psychosocial assessment (via different modes of delivery) with a validated multidimensional tool? [addressed via narrative review; see **Part B Technical Report**]

A1.2.2 Screening

The two main questions relating to the depression and anxiety screening for pregnant or postpartum women were each broken down into five sub-questions based on different outcomes. It should be noted that each sub-question could be broken down further into individual tools/in and outcomes.

A1.2.2.1 Depression screening

The main question relating to depression screening was broken down into five sub-questions based on different outcomes.

Main question:

2. What is the most appropriate method for screening women for depression in the perinatal period?

Sub-questions:

2a. What is the performance (defined as reliability, sensitivity, specificity, positive likelihood ratio, and negative likelihood ratio) of validated tools for perinatal depression screening? [addressed via systematic review; see **Part B Technical Report**]

2b. What are the non-technical characteristics (defined as number of items, time to administer, complexity of scoring, training requirements, and available languages) of validated tools for perinatal depression screening? [addressed via descriptive review; see **Part B Technical Report**]

2c. What is the acceptability to pregnant or post-partum women, health professionals, and the general public of screening for perinatal depression? [addressed via narrative review; see **Part B Technical Report**]

2d. What is the effectiveness (defined as impact on detection, care sought or received, and mental health outcomes) of screening for perinatal depression? [addressed via narrative review; see **Part B Technical Report**]

2e. What are the implications (for resourcing, workforce, and models of care) of implementing perinatal depression screening (via different modes of delivery) with a validated tool? [addressed via narrative review; see **Part B Technical Report**]

A1.2.2.2 Anxiety screening

The main question relating to anxiety screening was broken down into five sub-questions based on different outcomes.

Main question:

3. What is the most appropriate method for screening women for anxiety in the perinatal period?

Sub-questions:

3a. What is the performance (defined as reliability, sensitivity, specificity, positive likelihood ratio, and negative likelihood ratio) of validated tools for perinatal anxiety screening? [addressed via systematic review; see **Part B Technical Report**]

3b. What are the non-technical characteristics (defined as number of items, time to administer, complexity of scoring, training requirements, and available languages) of validated tools for perinatal anxiety screening? [addressed via descriptive review; see **Part B Technical Report**]

3c. What is the acceptability to pregnant or post-partum women, health professionals, and the general public of screening for perinatal anxiety? [addressed via narrative review; see **Part B Technical Report**]

3d. What is the effectiveness (defined as impact on detection, care sought or received, and mental health outcomes) of screening for perinatal anxiety? [addressed via narrative review; see **Part B Technical Report**]

3e. What are the implications (for resourcing, workforce, and models of care) of implementing perinatal anxiety screening (via different modes of delivery) with a validated tool? [addressed via narrative review; see **Part B Technical Report**]

A1.2.3 Effectiveness of interventions

The two main questions relating to the effectiveness of interventions for the treatment of mental health problems in pregnant or postpartum women, or prevention of mental health problems in pregnant or postpartum women identified as being at risk of developing mental health problems, were each broken down into five sub-questions based on different intervention types. It should be noted that each sub-question could be broken down further into individual interventions and outcomes. The detailed definitions associated with these interventions and outcomes can be found in Section C2.2 of the Part C Technical Report.

A1.2.3.1 Treatment interventions

Main question:

4. What is the efficacy and safety of interventions for the treatment of mental health problems in women in the antenatal or postnatal period?

Sub-questions:

4a. What is the efficacy and safety of psychosocial interventions for the treatment of mental health problems in women in the antenatal or postnatal period? [addressed via systematic review; see **Part C Technical Report**]

4b. What is the efficacy and safety of psychological interventions for the treatment of mental health problems in women in the antenatal or postnatal period? [addressed via systematic review; see **Part C Technical Report**]

4c. What is the efficacy and safety of pharmacological interventions for the treatment of mental health problems in women in the antenatal or postnatal period? [addressed via systematic review; see **Part C Technical Report**]

4d. What is the efficacy and safety of complementary interventions for the treatment of mental health problems in women in the antenatal or postnatal period? [addressed via systematic review; see **Part C Technical Report**]

4e. What is the efficacy and safety of physical interventions for the treatment of mental health problems in women in the antenatal or postnatal period? [addressed via systematic review; see **Part C Technical Report**]

A1.2.3.2 Prevention interventions**Main question:**

5. What is the efficacy and safety of interventions for the prevention of mental health problems in women identified as being at risk of developing a mental health problem in the antenatal or postnatal period?

Sub-questions:

5a. What is the efficacy and safety of psychosocial interventions for the prevention of mental health problems in women identified as being at risk of developing a mental health problem in the antenatal or postnatal period? [addressed via systematic review; see **Part C Technical Report**]

5b. What is the efficacy and safety of psychological interventions for the prevention of mental health problems in women identified as being at risk of developing a mental health problem in the antenatal or postnatal period? [addressed via systematic review; see **Part C Technical Report**]

5c. What is the efficacy and safety of pharmacological interventions for the prevention of mental health problems in women identified as being at risk of developing a mental health problem in the antenatal or postnatal period? [addressed via systematic review; see **Part C Technical Report**]

5d. What is the efficacy and safety of complementary interventions for the prevention of mental health problems in women identified as being at risk of developing a mental health problem in the antenatal or postnatal period? [addressed via systematic review; see **Part C Technical Report**]

5e. What is the efficacy and safety of physical interventions for the prevention of mental health problems in women identified as being at risk of developing a mental health problem in the antenatal or postnatal period? [addressed via systematic review; see **Part C Technical Report**]

The detailed PICO definitions associated with these questions can be found in Section C2.2 of the Part C Technical Report.

A1.2.4 Harms associated with selected interventions

The four main questions relating to the harms associated with interventions for the treatment of mental health problems in pregnant or postpartum women, or prevention of mental health problems in pregnant or postpartum women identified as being at risk of developing mental health problems, were each broken

down into four sub-questions based on the different populations that are harmed. It should be noted that each sub-question could be broken down further into individual interventions and outcomes. The detailed definitions associated with these interventions and outcomes can be found in Section D2.2 of the Part D Technical Report.

A1.2.4.1 Pharmacological interventions

Main question:

6. What are the harms that occur as a result of perinatal exposure to pharmacological intervention used for the treatment of mental health problems?

Sub-questions:

6a. What are the harms that occur to the fetus as a result of perinatal exposure to a pharmacological intervention used for the treatment of mental health problems? [malformations; addressed via systematic review; see **Part D Technical Report**]

6b. What are the harms that occur to the infant as a result of perinatal exposure to a pharmacological intervention used for the treatment of mental health problems? [pregnancy and birth outcomes; addressed via systematic review; **Part D Technical Report**]

6c. What are the harms that occur to the child as a result of perinatal exposure to a pharmacological intervention used for the treatment of mental health problems? [neurodevelopmental outcomes; addressed via systematic review; **Part D Technical Report**]

6d. What are the harms that occur to the mother as a result of perinatal exposure to a pharmacological intervention used for the treatment of mental health problems? [postpartum haemorrhage; addressed via systematic review; see **Part D Technical Report**]

A1.2.4.2 Complementary interventions

Main question:

7. What are the harms that occur as a result of perinatal exposure to a complementary intervention used for the treatment of mental health problems?

Sub-questions:

7a. What are the harms that occur to the fetus as a result of perinatal exposure to a complementary intervention used for the treatment of mental health problems? [malformations; addressed via systematic review; see **Part D Technical Report**]

7b. What are the harms that occur to the infant as a result of perinatal exposure to a complementary intervention used for the treatment of mental health problems? [pregnancy and birth outcomes; addressed via systematic review; see **Part D Technical Report**]

7c. What are the harms that occur to the child as a result of perinatal exposure to a complementary intervention used for the treatment of mental health problems? [neurodevelopmental outcomes; addressed via systematic review; see **Part D Technical Report**]

7d. What are the harms that occur to the mother as a result of perinatal exposure to a complementary intervention used for the treatment of mental health problems? [postpartum haemorrhage; addressed via systematic review; see **Part D Technical Report**]

A1.2.4.3 Physical interventions

Main question:

8. What are the harms that occur as a result of perinatal exposure to a physical intervention used for the treatment of mental health problems?

Sub-questions:

8a. What are the harms that occur to the fetus as a result of perinatal exposure to a physical intervention used for the treatment of mental health problems? [malformations; addressed via systematic review; see **Part D Technical Report**]

8b. What are the harms that occur to the infant as a result of perinatal exposure to a physical intervention used for the treatment of mental health problems? [pregnancy and birth outcomes; addressed via systematic review; see **Part D Technical Report**]

8c. What are the harms that occur to the child as a result of perinatal exposure to a physical intervention used for the treatment of mental health problems? [neurodevelopmental outcomes; addressed via systematic review; see **Part D Technical Report**]

8d. What are the harms that occur to the mother as a result of perinatal exposure to a physical intervention used for the treatment of mental health problems? [postpartum haemorrhage; addressed via systematic review; see **Part D Technical Report**]

A1.3 POPULATION

The population to whom the Guideline applies includes all pregnant or postnatal women, with the postnatal period being defined as the 12 months following birth. As this guideline also provide an assessment of the harms associated with interventions used for the treatment or prevention of perinatal mental health issues, the population also encompasses the offspring of these women.

Attention is also given to women with a history of mental health issues who might be planning a pregnancy.

A2 STAKEHOLDER INVOLVEMENT

A2.1 GROUP MEMBERSHIP

A2.1.1 Identification of key stakeholders and establishment of the Expert Working Group

On the commissioning of this Guideline, the Executive Director of COPE wrote to all company members, inviting their respective College or Organisation to nominate a representative for the Guideline Expert Working Group (EWG). In doing so the College was asked to consider the expertise and representation of the College in the area of perinatal mental health specifically.

Company Members are as follows:

- Australian College of Mental Health Nurses (ACMHN)
- Australian College of Midwives (ACM)
- Australian Psychological Society (APS)
- Maternal Child and Family Health Nursing Association (MCaFNA)
- Post and Antenatal Depression Association (PANDA)
- Royal Australian College of General Practitioners (RACGP)
- Royal Australian New Zealand College of Obstetricians and Gynaecologists (RANZCOG)
- Royal Australian and New Zealand College of Psychiatrists (RANZCP)
- Congress of Aboriginal and Torres Strait Islander Nurses and Midwives (CATSINaM)

The role of EWG members was to provide oversight regarding the scope of the Guideline and agreement on the clinical questions, including the mental health disorders to be included and the outcomes of most relevance to women in the perinatal period and different users of the Guideline. The inclusion of two representatives from PANDA on the EWG is one way in which the Guideline captures consumer (patients') views and preferences.

The nominated members assigned to the EWG from their respective Colleges and Organisations is detailed in **Table A2-1**

Table A2-1 Perinatal guideline Expert Working Group Members

Representative	Expertise	Organisation Representing	Institutional Affiliation(s)	Geographical Location
Professor Marie-Paule Austin (Chair)	Perinatal Psychiatrist, Former Chair beyondblue Clinical Guideline, researcher and clinician working across private and public perinatal settings.	Royal Australian College of Psychiatrists (RANZCP)	University of New South Wales, St John of God Healthcare, Royal Hospital for Women, Black Dog Institute.	Sydney, NSW
Dr Nicole Highet (Co-chair)	Former Co-Chair & Director beyondblue perinatal Guideline, online training programs & resources. Expertise in consumer/carer research, advocacy, policy & implementation.	Centre of Perinatal Excellence (COPE)	Centre of Perinatal Excellence (COPE)	Flemington, Vic.
Dr James Best	General Practitioner with specialist training and expertise in perinatal mental health.	Royal Australian College of General Practitioners (RACGP)	Your Doctors (Medical Practice)	Leichhardt & Summer Hill, NSW

Representative	Expertise	Organisation Representing	Institutional Affiliation(s)	Geographical Location
Mr Andrew Davis	Carer Representative and volunteer at PANDA.	Carer Representative	None	Melbourne, Vic.
Ms Suzanne Higgins	Mental health nurse and social worker with expertise clinical and educational expertise in perinatal mental health.	Australian College of Mental Health Nurses (ACMHN)	St John of God Healthcare.	Geelong, Vic.
Dr Helen Lindner	Health psychologist and former member of the EWG for beyondblue perinatal guideline.	Australian Psychological Society (APS)	Australian Psychological Society (APS)	Melbourne, Vic.
Ms Creina Mitchell	Clinician, researcher and educator in maternal and child health with expertise and interest in perinatal mental health.	Maternal & Child Family Health Australia (McAFHNA)	Griffith University	Brisbane, Qld.
Ms Jenni Richardson	Consumer representative involved in the management of PANDA helpline with expertise in consumer needs, experiences and advocacy.	Consumer representative Perinatal Anxiety and Depression Association (PANDA)	Perinatal Anxiety and Depression Association (PANDA)	Fitzroy, Vic
Ms Terri Smith	Chief Executive Officer of PANDA	Consumer representative Perinatal Anxiety and Depression Association (PANDA)	Perinatal Anxiety and Depression Association (PANDA)	Fitzroy, Vic
Dr Vijay Roach	Obstetrician with dedicated expertise in perinatal mental health. Chair of the Gidget Foundation (perinatal mental health support organisation) and carer.	Royal Australian College of Obstetricians and Gynaecologists (RANZCOG)	Royal North Shore Hospital	Sydney, NSW
Prof. Rhonda Marriott	Midwife, researcher and specialist in Aboriginal and Torres Strait Islander perinatal mental health.	ATSI Representative	Murdoch University	Perth, WA
Dr Jan Taylor	Clinician, researcher and educator in midwifery with expertise in perinatal mental health. Former member of the beyondblue EWG.	Australian College of Midwives (ACM)	Canberra University	Canberra, ACT

In order to ensure adequate representation at all meetings, if assigned EWG members are not able to attend a meeting, they are asked to nominate a proxy for the meeting from their respective College/organisation – again reflecting the interests and expertise of the College/organisation in perinatal mental health. Proxies attending over the course of the Guideline development process are detailed below.

Table A2-2 Perinatal guideline Proxy Representatives

Representative	Expertise	Organisation Representing	Institutional Affiliation(s)	Geographical Location
Dr Anne Sved Williams	Perinatal Psychiatrist. Head, Medical Unit.	Royal Australian College of Psychiatrists (RANZCP)	Helen Mayo House	Adelaide, SA

Representative	Expertise	Organisation Representing	Institutional Affiliation(s)	Geographical Location
Julie Ferguson	Mental health nurse practitioner with expertise clinical and educational expertise in perinatal mental health.	Australian College of Mental Health Nurses (ACMHN)	St John of God Healthcare.	Geelong, Vic.
Dr Louise Roufiele	Psychologist and researcher in perinatal mental health.	Australian Psychological Society (APS)	Australian Psychological Society (APS)	Melbourne, Vic.
Ms Terri Smith	Consumer representative involved in the management of PANDA helpline with expertise in consumer needs, experiences and advocacy.	Consumer representative Perinatal Anxiety and Depression Association (PANDA)	Perinatal Anxiety and Depression Association (PANDA)	Fitzroy, Vic
Dr Agnes Wilson	Senior policy advisor, Royal Australian College of Obstetricians and Gynaecologists (RANZCOG)	Royal Australian College of Obstetricians and Gynaecologists (RANZCOG)	Royal North Shore Hospital	Sydney, NSW
Dr Catherine Chamberline	Senior Research Fellow, College of Science, Health and Engineering, School of Nursing and Midwifery Department of Public Health	ATSI Representative	La Trobe University	Melbourne, Vic

In addition to the Expert Working Group, two additional committees were formed to provide opportunity for a broader representation of specialist clinical expertise.

Expert Committee #1: Harms expert committee

The first of these pertained to with respect addressing the potential harms associated with treatment for perinatal mental health (particularly pharmacological treatments).

Expert Committee #2: Low prevalence disorder expert committee

Following the initial EWG meeting when the scope of the Guideline was discussed, there was strong support for the scope of the perinatal mental health Guideline to include a broader range of mental health disorders. As such, the scope of the Guideline was increased to include Borderline Personality Disorder and Schizophrenia. In line with this change in scope, a second committee with specialist expertise in these illness areas was also formed.

Both expert committees contained representation of recognised experts (identified by the EWG) and contained representatives from perinatal psychiatry and pharmacotherapy. A list of the members of each of these committees is detailed in **Table A2-3**.

Table A2-3 Members of the Expert Committees

Representative	Expertise	Institutional Affiliation	Geographical location	Expert committee
Professor Marie-Paule Austin (Chair)	Chair Perinatal Mental Health Unit, Professorial Fellow and Consultant Psychiatrist	University of New South Wales, Black Dog Institute, University of New South Wales.	Sydney, NSW	Harms Low prevalence disorders
Professor Phillip Boyce	Professor of Psychiatry, Perinatal Psychiatrist	University of Sydney and Westmead Hospital.	Wentworthville, NSW	Harms Low prevalence disorders
Professor Megan Gallbally	Foundation Chair in Perinatal Psychiatry & Perinatal Psychiatrist.	University of Notre Dame, Fiona Stanley Hospital.	Perth, Western Australia.	Harms

Representative	Expertise	Institutional Affiliation	Geographical location	Expert committee
Professor Anne Buist	Perinatal Psychiatrist & Director, North-East Women's Mental Health Parent Infant Program	Austin Hospital and University of Melbourne	Heidelberg West, Victoria.	Low prevalence disorders
Dr Debra Kennedy	Director, Mothersafe.	Royal Hospital for Women	Sydney, NSW.	Harms
Dr Tram Nguyen	Consultant Psychiatrist. Centre for Women's Mental Health.	The Royal Women's Hospital	Melbourne, Vic.	Harms Low prevalence disorders
Dr Anne Sved-Williams	Perinatal Psychiatrist. Head, Medical Unit.	Helen Mayo House Family Unit.	Glenside, South Australia.	Harms Low prevalence disorders
Dr Sylvia Lim-Gibson	Consultant Psychiatrist, Royal Hospital for Women. Director of Postgraduate Psychiatry Training for the South-East Sydney and Illawarra.	Royal Hospital for Women, NSW. Brain and Mind Research Institute.	NSW	Low prevalence disorders
Professor Louise Newman	Director, Centre of Women's Mental Health.	The Royal Women's Hospital	Melbourne, Vic.	Low prevalence disorders

A2.1.2 Methodologists

In addition, the Guideline developer (COPE) engaged the skills and expertise of a team of Guideline methodologists led by Dr Sarah Norris (Health Research Consulting; hereco). The methodologists were engaged by the Guideline developer due to their knowledge and experience in guideline development, and in particular, their authorship of the systematic reviews associated with the initial (Beyondblue) Guideline.

A2.1.3 Technical writer

A technical writer, Jenny Ramson (AmperSand), was also engaged to draft the Guideline. The contractor was selected due to their experience in the writing of the current National Antenatal Care Guideline as well as the writing of the development of the initial Commonwealth/beyondblue Guideline. This technical writer will also be invited to undertake the writing of the companion documents that will be produced following submission to (and approval by) the NHMRC.

A2.2 TARGET POPULATION PREFERENCES AND VIEWS

All COPE members were informed of the development of the Guideline through the COPE Annual General Meeting (November 2016). COPE collaborated with each of the professional bodies identified in Section A2.1.1 (who are members of COPE) to disseminate information and engage College members and consumer groups for consultation. This ensured widespread consultation with health professionals involved in the delivery of primary, maternity and mental health care, as well as those involved in the education, screening, identification and provision of treatment across both primary and specialist care settings. In addition, the peak bodies/leaders in perinatal mental health working with Aboriginal and Torres Strait Islander and culturally and linguistically diverse (CALD) populations will be approached in the consultation phase to provide feedback on the Clinical Guideline.

In putting the Guideline out for public consultation, individuals or organisations will be invited to provide feedback in writing to the Expert Working Group for Consideration. All information gathered from the Consultation period will be reviewed by the EWG in consultation with the Expert Committees for consideration in the formation of recommendations and finalisation of the Guideline.

On the finalisation of the Guideline, companion documents will be developed for consumers, carers and health professionals. Feedback on drafted documents will be obtained through consultation with

representatives from all professional bodies as well as consumers and carers to ensure relevance and appropriate presentation of information.

A2.3 TARGET USERS

The target populations for this guideline can be considered threefold:

1) Primary healthcare professionals

In order to ensure inclusion of views and preferences from each target group, health professionals were identified through approaching their respective colleges and asking them to nominate a representative (as per Section A2.1.1). This approach to the Colleges (as opposed to selecting individuals) ensured a transparent approach to nomination onto the expert working group. In addition to seeking representatives from each professional body, a representative from the Aboriginal and Torres Strait Islander community was selected through an approach to the Congress of Aboriginal and Torres Strait Islander Nurses and Midwives, and inclusion of a representative and proxy onto the EWG.

2) Consumers of health services

In order to ensure the views of consumers and carers are reflected in the development of the Guideline, the Perinatal Anxiety and Depression Association (PANDA) was approached to nominate a consumer representative to the Expert working group.

3) Carers

Perinatal mental health conditions can have a significant impact upon carers and family members, and this was reflected in the inclusion of a carer representative on the Expert Working Group, also identified through PANDA.

The Guideline will be used by each of the professional groups in accordance with their role in the management of perinatal health. For example, those involved at the front-end of maternity care provision (GPs, midwives and obstetricians) will be informed about best practice screening and assessment tools to identify and respond to identified mental health problems in pregnancy, whilst those professionals involved in the provision of treatment for mental health conditions (psychiatrists, psychologists, GPs) will likely refer to the information surrounding safe and effective treatments for perinatal mental health conditions. Consumers and carers will also refer to the Guideline to obtain information surrounding the assessment of risk and symptom detection, as well as the recommended safe and effective treatments for perinatal mental health. Specifically, this will include the development of tailored factsheets and resources for consumers and carers as well as health professionals (see **Section A5**).

A3 RIGOUR OF DEVELOPMENT

A3.1 SEARCH METHODS

A summary of the searches performed, databases used and search dates is presented in **Table A3-1**; further details are provided below. Full details of all searches can be found in the Appendices for Part B (**Section B8.1**), Part C (**Section AppC1**) and Part D (**Section AppD1**) of the Technical Report.

Searches were conducted in the MEDLINE, Embase and PsychINFO databases, and also in CINAHL for psychosocial assessment and screening (via the OVID and/or Embase.com interfaces), various databases of the Cochrane Library, and included examination of the reference lists of included SRs and individual studies. Searches were conducted between June 2016 and April 2017.

It should be noted that the searches did not specifically aim to identify or limit retrieval of articles to studies that addressed socioeconomic, Aboriginal or Torres Strait Islander populations. However, the reviewers were required to document any papers addressing these populations for specific consideration by the EWG. Implications for rural and remote areas, and the Indigenous population, have been considered and documented in the clinical guidance.

A3.1.1.1 *Psychosocial and screening searches*

A two-tiered search strategy was undertaken as follows:

1. An initial systematic review search (SR search) identified systematic reviews that assessed various treatments for the main mental health disorders seen during the perinatal period; these included depression, anxiety, puerperal psychosis, bipolar disorder and schizophrenia. It should be noted that this search was conducted to identify studies not only for the assessment of effectiveness and harms, but also for screening.

From this search, an initial list was assembled of SRs that reported on various aspects of psychosocial assessment and screening (as well as effectiveness and harms of interventions used for the treatment or prevention of mental health problems in pregnant or postpartum women). The individual studies included in each SR were identified and, where possible, a 'foundation review' was identified. The foundation review was defined as the SR that included the most recent and comprehensive set of data for a particular psychosocial assessment or screening tool, and if suitable could be included in the evidence review; if not suitable for inclusion, the foundation review could be used to identify relevant individual studies.

2. Supplementary searches for individual studies were then conducted as required. Circumstances for supplementary searches included updating literature searches from foundation reviews that were more than 3 years old (for psychosocial assessment) or re-specifying literature searches from foundation reviews because they did not completely align with the questions within the current Guideline (anxiety screening).

A3.1.1.2 *Intervention searches*

A two-tiered search strategy was also undertaken as follows:

3. An initial SR search identified systematic reviews that assessed various treatments for the main mental health disorders seen during the perinatal period; these included depression, anxiety, puerperal psychosis, bipolar disorder and schizophrenia. It should be noted that this search was conducted to identify studies not only for the assessment of effectiveness and harms, but also for screening.

From this search, an initial list was assembled of SRs that assessed effectiveness (and harms for the systemically-active interventions) associated with the psychosocial, psychological, pharmacological, complementary and physical therapies included in the review. The individual studies included in each SR were identified and, where possible, a 'foundation review' was identified. The foundation review was defined as the SR that included the most recent and comprehensive set of data for a particular intervention and outcome, and if suitable could be included in the evidence review; if not suitable for inclusion, the foundation review could be used to identify relevant individual studies.

4. Based on the findings of the SR search, a second series of literature searches were carried out for the systemically-active interventions¹ and online interventions ('updated searches'). These searches aimed to identify additional SRs, and individual RCTs and observational studies, and were based on the interventions of interest as follows:
 - Where a suitable foundation review was identified, the search was limited from the year of the foundation review's literature search up to October 2016. Date-limited searches were conducted for all pharmacological agents except z-drugs, and the complementary therapy omega-3 fatty acids.
 - Where no suitable foundation review was identified, no initial date limit was set, and the search was conducted up to October 2016. Extended date searches were conducted for z-drugs, the complementary therapies St John's Wort and Gingko biloba, and the physical therapies electroconvulsive therapy (ECT) and transcranial magnetic stimulation (TMS).

Table A3-1 Literature searches

Search	Question type	Study type/s	Databases	Date
Psychosocial assessment	Psychosocial risk factor assessment	SR search	MEDLINE, Embase and PsychINFO (via OVID) CDSR, DARE and HTA (via Cochrane Library)	01 Jun 16
		Supplementary search	Medline, EMBASE, PsychInfo, CINAHL (via OVID)	15 Dec 16
Depression screening	Screening	SR search	MEDLINE, Embase and PsychINFO (via OVID)	01 Jun 16
Anxiety screening	Screening	SR search	MEDLINE, Embase and PsychINFO (via OVID)	01 Jun 16
		Supplementary search	Medline, EMBASE, PsychInfo, CINAHL (via OVID)	21 Dec 16
Psychosocial and psychological interventions	Effectiveness	SR search SR (RCTs)	MEDLINE and Embase (via Embase.com) CDSR, DARE and HTA (via Cochrane Library)	01 Jun 16 29 Jul 16
Online interventions	Effectiveness	SR search SR (RCTs)	MEDLINE and Embase (via Embase.com) CDSR, DARE and HTA (via Cochrane Library)	01 Jun 16 29 Jul 16
		Updated search SR (RCTs), RCT	MEDLINE, Embase and PsychINFO (via OVID) All Cochrane databases (Cochrane Library)	12 Apr 17 12 Apr 17
Pharmacological agents Omega-3 fatty acids St John's Wort and Gingko biloba ECT and TMS	Effectiveness and harms	SR search SR (RCTs)	MEDLINE and Embase (via Embase.com) CDSR, DARE and HTA (via Cochrane Library)	01 Jun 16 29 Jul 16
		Updated search SR (RCTs/OBS), RCT, OBS	MEDLINE (PubMed) Embase and PsychINFO (OVID) All Cochrane databases (Cochrane Library)	11 Oct 16 12 Oct 16 13 Oct 16

Abbreviations: ECT, electroconvulsive therapy; OBS, observational studies; RCT, randomised control trial; SR, systematic review; TMS, transcranial magnetic stimulation.

¹ Includes pharmacological therapies (antidepressants, antipsychotics, anticonvulsants, benzodiazepines and z-drugs, and lithium), complementary therapies (omega-3 fatty acids, St John's Wort and Gingko biloba) and selected physical therapies (electroconvulsive therapy and transcranial magnetic stimulation).

A3.2 EVIDENCE SELECTION CRITERIA

Inclusion/exclusion criteria were formulated based on the PICO (Population, Intervention, Comparator, Outcome) criteria used to define the research questions. The PICO criteria for each question type can be found in the following sections of the Technical Report:

- Psychosocial assessment – **Section B3.1.2** in Part B of the Technical Report.
- Depression screening and anxiety screening – **Section B3.1.1** in Part B of the Technical Report.
- Effectiveness of interventions – **Section C2.2** in Part C of the Technical Report
- Harms of interventions – **Section D2.2** in Part D of the Technical Report.

The main inclusion/exclusion criteria for each of the research question types were as follows:

A3.2.1 Psychosocial assessment and screening

- Target population – all pregnant or postnatal women (psychosocial assessment), or pregnant or postnatal women with no known diagnosis of depression or anxiety (screening)
- Study design – prospective, controlled studies reporting predictive accuracy (psychosocial assessment) or diagnostic accuracy (screening)
- Comparisons – subsequent manifestation of mental health issues (psychosocial assessment), or any standard clinical/diagnostic interview as a reference standard (screening)
- Language – limited to English.

A3.2.2 Effectiveness of interventions

- Target population – pregnant or postnatal women diagnosed with a mental health problem, or considered to be at risk of developing a mental health problem.
- Study design – SRs of RCTs, or individual RCTs if no SR or SR out of date.
- Interventions – Psychosocial, psychological, pharmacological, complementary or physical therapies used to treat or prevent mental health problems in pregnant or postnatal women.
- Comparisons – no treatment/placebo/treatment as usual or active treatment
- Language – limited to English.

A3.2.3 Harms of interventions

- Target population – pregnant or postnatal women diagnosed with a mental health problem, or considered to be at risk of developing a mental health problem, or a fetus, infant or child of a mother exposed to a pharmacological, complementary or physical therapy.
- Study design – SRs of RCTs (if available), SRs of observational studies, or individual observational studies if no SR or SR out of date or unsuitable.
- Comparisons – no treatment/exposure or active treatment
- Language – limited to English.

A3.3 STRENGTHS AND LIMITATIONS OF THE EVIDENCE

The strengths and limitations of the evidence have been considered from the perspective of the individual studies and the body of evidence aggregated across all the studies. Wherever possible validated methods have been used to assess:

- Study design(s)
- Study methodology limitations (sampling, blinding, allocation concealment, analytical methods)
- Appropriateness/relevance of primary and secondary outcomes considered
- Consistency of results across studies
- Direction of results across studies

- Magnitude of benefit versus magnitude of harm
- Applicability to practice context

GRADE methodology was used to determine the quality of the evidence available for each intervention/outcome. The majority of the evidence for fetal harms was considered generally to be of very low (●○○○) or inadequate (○○○○) quality. It should be noted that the category 'inadequate' was added for this review to better reflect the broad range of quality that would have been considered very low if GRADE methods had been adhered to. A discussion of this adaptation of GRADE methodology can be found in **Part D Technical Report Section D2.5.1**.

In addition, no GRADE methods could be identified for the assessment of psychometric instruments. Consequently, a hybrid method was developed for quality appraisal of psychosocial assessment instruments. This method was based on accepted psychometric properties and QUADAS-2 principles and is described in detail in **Part B Technical Report Sections B4.1 and B5.2**.

A3.4 FORMULATION OF RECOMMENDATIONS

As groups of evidence reviews were completed they were considered by the EWG and the relevant Expert Committee(s) as appropriate. General discussion of the interpretation and implications of the review findings were discussed, and then Evidence Based Recommendations developed once consensus was reached. The strength of the EBRs was agreed at this point. Once a group of related EBRs and CBRs was developed, the EWG then deliberated on the need for Practice Points to highlight important aspects of care.

The Expert Committees were engaged to provide specific expertise to support the EWG. The Harms Expert Committee were the first to review the Harms systematic reviews. This Committee then drafted proposed Recommendations, for consideration and approval by the EWG.

Once Recommendations had been developed across all types of intervention, the Low Prevalence Expert Committee then used their expertise to apply the Recommendations to perinatal women with bipolar disorder, postpartum psychosis, schizophrenia or borderline personality disorder. This process involved explicit consideration of relevant, recent Australian Guidelines for mood disorder, schizophrenia, and borderline personality disorder in general populations.

A3.5 CONSIDERATION OF BENEFITS AND HARMS

The evidence reviews present an explicit consideration of health benefits and harms. The trade-off between benefits and harms is articulated in the rationale for each Recommendation.

Recommendations regarding the use of psychosocial and psychological interventions were based primarily on evidence of the effectiveness, because they do not cause direct harm to the fetus, infant or child.

Recommendations regarding the use of pharmacological, complementary and selected physical interventions were to be based on a trade-off between effectiveness and harm; however, there was very little evidence of effectiveness for these interventions in the pregnant and postpartum population. The only evidence available was for antidepressants (suggesting it may improve postnatal depression) and omega-3 fatty acids (where it appeared to have no effect on depression).

The harms most likely to impact on recommendations were major and cardiac malformations, and neurodevelopmental harms. Due to its strong association with major and cardiac malformation, and adverse cognitive outcome, as well as a lack of evidence of effectiveness in pregnant or postpartum women with, or at risk of developing, a mental health problem, the prescribing of sodium valproate in all women of childbearing age, was strongly recommended against. The evidence of harm associated with

carbamazepine, and the lack of evidence for lamotrigine led to a consensus-based recommendation to prescribe anticonvulsants with great caution during pregnancy.

While there were a number of pregnancy and birth outcomes found to be associated with pharmacological therapies (including miscarriage, preterm birth, poor neonatal adaptation syndrome, respiratory distress, convulsions and persistent pulmonary hypertension), these were not directly captured in any recommendations; instead, a Practice Point notes that the potential risks of treatment (including the risk of relapse), as well as the benefits, should be discussed with women.

There was little evidence available of the side effects experienced by the mother of pharmacological, complementary and physical interventions assessed; these treatments are all used regularly in clinical practice and as such their side effect profiles are well established. However, based the known side effect of clozapine, agranulocytosis, a Consensus-based Recommendation states that its use should not be initiated during pregnancy due to a theoretical potential harm to the infant.

A3.6 LINK BETWEEN RECOMMENDATIONS AND EVIDENCE

An explicit link has been made between the evidence and the recommendations arising from that evidence. In circumstances where evidence was sought and not found, or where evidence was relied on from other populations (e.g. a general depressed population, not a perinatal depressed population) then Consensus Based Recommendations were developed. Aspects of care that were not within scope of the evidence reviews are then captured in Practice Points.

An explicit Evidence to Decision framework was developed for psychosocial assessment and screening to capture evidence beyond related to predictive or diagnostic accuracy. Consideration of Recommendations regarding treatment options explicitly considered the effectiveness of the interventions and the harms to the fetus.

The links between the EBRs and the evidence reviews are shown in **Table A3-2**.

Table A3-2 Cross-referencing to Technical Report for Evidence Based Recommendations

Cross-Referencing to Technical Report for Evidence-based Recommendations				
Evidence-based Recommendations		Strength	Location of evidence	
			Benefit	Harm
Screening and assessment				
Screening for depression				
1	Use the EPDS to screen women for a possible depressive disorder in the perinatal period	Strong	Part B Tech Report – Table B5-20	Discussed but not formally assessed
2	Arrange further assessment of perinatal woman with an EPDS score of 13 or more.	Strong	Part B Tech Report – Table B5-20	Discussed but not formally assessed
Assessing psychosocial risk				
3	Use the ANRQ to assess the presence of psychosocial risk.	Strong	Part B Tech Report – Table B4-13	Discussed but not formally assessed
Prevention and treatment				
Depressive and anxiety disorders				
Psychosocial support and psychological approaches				
4	Provide structured psychoeducation to women with symptoms of depression in the perinatal period.	Strong	Part C Tech Report – Table C3-1	Not assessed
5	Advise women with symptoms of depression in the postnatal period of the potential benefits of a social support group.	Conditional	Part C Tech Report – Table C3-4	Not assessed
6	Recommend individual structured psychological interventions (cognitive behavioural therapy or interpersonal psychotherapy) to women with mild to moderate depression in the perinatal period.	Strong	Part C Tech Report – Table C3-19	Not assessed
7	Advise women with depression or anxiety disorder in the postnatal period of the possible benefits of directive counselling.	Conditional	Part C Tech Report – Table C3-22	Not assessed

Evidence-based Recommendations		Strength	Location of evidence	
			Benefit	Harm
Complementary therapies				
8	Advise women who enquire about omega-3 fatty acid supplementation that it does not appear to improve depression symptoms but is not harmful to the offspring when taken during pregnancy or while breastfeeding.	Conditional	Part C Tech Report – Table C3-38 and Table C4-28 to 29	Part D Tech Report – Table D3.40
Pharmacological				
9	Consider the use of SSRIs as first-line treatment for moderate to severe depression in pregnant women.	Conditional	No evidence available	Part D Tech Report – Table D3-2
10	Recommend the use of SSRIs as first-line treatment for moderate to severe depression in postnatal women	Strong	Part C Tech Report – Table C3-31	Part D Tech Report – Table D3-2
Severe mental illness				
Antipsychotics				
11	Consider the use of antipsychotics for treating psychotic symptoms in pregnant women	Conditional	No evidence available	Part D Tech Report – Tables D3-14 to 25
Anticonvulsants				
12	Do not prescribe sodium valproate to women of childbearing age	Strong	No evidence available	Part D Tech Report – Table D3-27

Abbreviations: ANRQ, antenatal risk questionnaire; EPDS, Edinburgh Postnatal Depression Scale; SSRI, selective serotonin reuptake inhibitor;

A3.7 EXTERNAL REVIEW

Methodology used to conduct external review will be completed after public consultation, and will cover:

- *Purpose and intent of the external review (e.g., to improve quality, gather feedback on draft recommendations, assess applicability and feasibility, disseminate evidence)*
- *Methods taken to undertake the external review (e.g., rating scale, open-ended questions)*
- *Description of the external reviewers (e.g., number, type of reviewers, affiliations)*
- *Outcomes/information gathered from the external review (e.g., summary of key findings)*
- *How the information gathered was used to inform the guideline development process and/or formation of the recommendations (e.g., guideline panel considered results of review in forming final recommendations)*

A3.8 UPDATING PROCEDURE

The procedure to be used to update the guidelines will be completed after public consultation, and will cover:

- *A statement that the guideline will be updated*
- *Explicit time interval or explicit criteria to guide decisions about when an update will occur*
- *Methodology for the updating procedure*

A4 CLARITY OF PRESENTATION

A4.1 SPECIFIC AND UNAMBIGUOUS RECOMMENDATIONS

In developing the Recommendations and Practice Points the developers have adhered to the following principles:

- A succinct statement of the recommended action,
- In a clearly stated relevant population (e.g., pregnant women, postnatal women, or perinatal women)
- At a specific timing, if appropriate.

The rationale for each Recommendation and Practice Point covers: the intent or purpose of the recommended action (e.g., to improve quality of life, to decrease side effects); any caveats or qualifying statements (e.g., patients or conditions for whom the recommendations would not apply); and if there is uncertainty about the best care option(s), a description of the nature of that uncertainty.

A4.2 MANAGEMENT OPTIONS

The Guideline addresses multiple management options and these are clearly articulated via the structure of the Guideline and the wording of the Recommendations and Practice Points.

A4.3 IDENTIFIABLE KEY RECOMMENDATIONS

The key recommendations are presented in a way that is easy to identify, and to differentiate between Evidence-Based Recommendations (EBRs), Consensus Based Recommendations (CBRs) and Practice Points (PPs). The strength of the EBRs is also clearly identified as either 'Strong' or 'Conditional'.

A5 APPLICABILITY

A5.1 FACILITATORS AND BARRIERS TO APPLICATION

There are a number of facilitators to guideline application which include:

- Engagement of key stakeholders in the Guideline Development
Peak bodies provide varying aspects of perinatal health and mental health care, each of whom have been involved in the development of the Guideline from the outset.
- Infrastructure of peak bodies
Each of the Colleges will play a key role in communicating the Guideline to their members and advocating for their implementation through communication with College members in newsletters, academic publications in journals and presentation at conferences.
- The infrastructure of the health system
The framework of maternity, postnatal and primary care provision provides a vehicle for all aspects of guideline implementation from consumer education through to screening and assessment and treatment provision. The health and community care landscape has been taken into account when considering the Guideline application across maternity, postnatal, general practice, public and private healthcare settings as well as the range of services available across jurisdictions.
- The history of the National Perinatal Depression Initiative (NPDI)
The Commonwealth Government's investment into the NPDI with States and Territories (2008-15) has provided some valuable history and infrastructure to implementation of the Guideline. Current investment is variable across States and Territories. For example, whilst some States (eg. NSW) have state-wide policies surrounding in relation to screening, in other states this has been discontinued in the absence of funding. Awareness of the state of play across each jurisdiction and ongoing relationships and collaboration with key Commonwealth and State Government and Policy Stakeholders since the NPDI, will serve to provide an opportunity to continue to advocate and seek support for national Guideline implementation.
- The development of a perinatal mental health website to house all information for consumers, carers and health professions
Since the release of the initial (beyondblue) Guideline, COPE (Guideline developer) has been established to provide a dedicated focus on perinatal mental health. As part of this work, an extensive website has been developed to provide best practice information for consumers, carers and health professionals (www.cope.org.au). The website will be updated to reflect the latest evidence for existing disorders, and be expanded to include the additional mental health disorders that have been specifically addressed in the current Guideline (schizophrenia and borderline personality disorder). In addition, this dedicated website will include all factsheets and screening aids (companion documents) and house the online training program (see below).
- The development of a free, online, accredited training program for health professionals
To support implementation, a free online training program will accompany the release of the Guideline. This will facilitate education for health professionals in include coverage of all guideline recommendations and good practice points. In addition, all companion document that have been developed for health professionals and consumers/carers will be embedded into the online program to direct people to specific information on each topic.
- Innovative guide for consumers and carers
In addition to the website and fact sheets for consumers and carers, as much of the Guideline focus on the need for education and information provision for consumers. In response to this, a series of

fortnightly emails for expectant and new parents will provide emotional and mental health information relative to each stage in the perinatal period, whilst providing information and links to further information and factsheets derived from the Guideline.

- Innovative technology to facilitate screening in accordance with the Guideline

As one of the greatest barriers to screening is time taken to do screening within tight maternity and postnatal appointments, the Guideline developer (COPE) has developed a Digital screening platform that allows screening to be undertaken electronically on an iPad (<http://cope.org.au/health-professionals-3/icope-digital-screening/>). The feasibility trials and subsequent implementation across a range of primary, maternity and postnatal healthcare settings demonstrates the ability of the platform (iCOPE) to save time, reduce language barriers, improve screening rates in accordance with the national guideline. Through the programming of any additional Guideline recommended scales onto the iCOPE Platform this will also facilitate their application. Furthermore, the automated production of clinical reports at the time of screening serves to guide health professional in best practice with respect to screening outcomes and referral pathways. Consumers also can also access a tailored report (via email or SMS) detailing outcomes and referring to more information on the COPE website.

Barriers to application include:

- Low screening in the private sector

The greatest barriers to implementation are likely to be found in the private system, whereby many specialist obstetricians do not prioritise perinatal mental health, but rather tend to focus on physical health. In response to this work is being led by the Royal Australian and New Zealand College of Obstetricians (RANZCOG) to include screening in accordance with the Guidelines as a Medicare item number.

- Lack of time to undertake screening and assessment

As detailed above time is a barrier and hence this is addressed through the selection of brief assessment tools and the digitisation of screening to improve screening rates, times, accuracy and inclusiveness.

A5.2 IMPLEMENTATION ADVICE/TOOLS

A5.2.1 Resources for health professionals

As part of the Guideline, an online, fully accredited training program will be developed and made free available for health professionals. This will cover all information contained in the Guideline to support their implementation in practice. This will involve evaluation in order for professionals to receive accreditation and be supported throughout the development of a series of factsheets to guide and support assessment, management and treatment of perinatal mental health disorders.

A5.2.2 Consumer and carer resources

The free e-newsletter (Ready to COPE) will be made freely available for consumers and contain within it specifically designed factsheets.

A5.3 RESOURCE IMPLICATIONS

These have been addressed in the body of the Technical Report and the Guideline. This section will be completed after public consultation and will cover:

- *Types of cost information that were considered (e.g., economic evaluations, drug acquisition costs)*

- *Methods by which the cost information was sought (e.g., a health economist was part of the guideline development panel, use of health technology assessments for specific drugs, etc.)*
- *Information/description of the cost information that emerged from the inquiry (e.g., specific drug acquisition costs per treatment course)*
- *How the information gathered was used to inform the guideline development process and/or formation of the recommendations*

A5.4 MONITORING/ AUDITING CRITERIA

As the peak body for perinatal mental health in Australia, COPE will continue to consult with service providers nationally to ensure the dissemination and application of the Clinical Guideline across the country. For those utilizing the digital screening, this will enable the monitoring of screening rates and outcomes across sites and setting in real time. Further the integration of clinical advice into the clinical reporting facilitated by the iCOPE platform will serve to inform and guide best practice by the health professionals.

Further to this, COPE will continue to liaise with representatives of all states and territories involved in the implementation of perinatal mental health initiatives.

A6 EDITORIAL INDEPENDENCE

A6.1 FUNDING BODY

The funding body was the Commonwealth Government of Australia. The Government had no direct or indirect influence on the content of the Guideline. Specifically, the Commonwealth Government were not involved in any of the committees or content reviews, rather were only engaged in reporting of progress (as opposed to the specific content).

A6.2 COMPETING INTERESTS

All group members have declared whether they have any competing interests at the outset of the Guideline development process and at each subsequent meeting.

At the outset of the Guideline development process, all representatives were informed of the importance of managing competing interests and ensuring that any potential conflicts of interest were identified in advance of any meeting (as evidenced in meeting minutes). Processes put in place to manage any potential conflicts of interest are as follows:

- All EWG members and proxies involved in the Guideline development process were required to complete a Declaration of Interest Form (as per the NHMRC requirements). These signed and scanned forms were reviewed by the Co-Chairs of the EWG and are held by the Guideline developer.
- On sending out agenda papers, EWG members were to be informed of the arising agenda items and asked to notify the Chairperson in advance of the meeting of any potential conflicts of interest that had arisen since the most recent meeting.
- Any arising conflicts of interest were to be adjudicated by the Chair and Co-Chair. In the event of a conflict of interest held by the Chair, this was to be managed by the Co-Chair and the area of conflict clearly stated. In this instance, as with other conflicts of interest declared by other EWG members, members were to be invited to take part and contribute discussions, however were asked to leave the room when forming recommendations. In the instance where the Chair has a declared conflict of interest, this will be managed by the Co-Chair.
- If a conflict of interest was deemed to be material prior to a meeting, the member was asked to continue to contribute to the committee, with the above measures taken to limit the introduction of bias.

There was only one instance of a possible competing interest, and that was the review of a clinical scale which was developed by one of the expert working group members. This was made known to all members of the expert working group at the outset of these discussions. To address this competing issue when reviewing the evidence, the member of the group was involved in the discussion, however when deciding on its inclusion the member was asked to remove him or herself from the discussion and decision-making process.