Antenatal care guidelines review

Public consultation draft

22 May 2017
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Summary

This consultation draft provides a summary of recent reviews of the evidence on selected topics relevant to antenatal care. Developed with input from an expert committee (see Appendix A), it includes:

- topics reviewed for Module I of the Antenatal Care Guidelines — weight and body mass index (weight monitoring reviewed), family violence, hepatitis C, vitamin D status, chromosomal anomalies (cell-free DNA testing reviewed)
- topics reviewed for Module II of the Guidelines — fetal growth and well-being (based on new guidelines), risk of pre-eclampsia (risk factors and prediction reviewed), risk of preterm birth, diabetes (early testing reviewed), thyroid dysfunction
- new topic — illicit substance use.

In addition, narrative review of the literature on models of care for Aboriginal and Torres Strait Islander women was undertaken and the chapter from Module I revised to highlight emerging models that are improving outcomes.

Changes or additions to guidance since the previous reviews are as follows.

- **Substance use** — Consensus was that women be assessed for use of illicit substances and misuse of pharmaceuticals in early pregnancy and that advice be provided about the associated harms.
- **Routine weighing** — Consensus was that routine weighing does not have significant effects on pregnancy complications but provides an opportunity to engage women in important conversations about weight gain, diet and exercise.
- **Family violence** — Routine enquiry is likely to identify additional women experiencing family violence. Consensus was that consistent approaches be used to screening and that training programs improve the confidence and competency of health professionals.
- **Fetal growth** — Previous guidance was that fetal growth be assessed at each antenatal visit using abdominal palpation and/or symphysis-fundal height. However, there is evidence that fetal growth should not be assessed based solely on abdominal palpation; and that symphysis-fundal height be measured from 24 weeks.
- **Fetal movements** — Consistent with the previous recommendation, there was consensus that all women be provided with information about normal fetal movements and advised to contact their health professional promptly if they have concerns about decreased or absent fetal movements.
- **Risk of pre-eclampsia** — The evidence identifies a range of factors associated with risk of pre-eclampsia. Early assessment is recommended so that women at risk can be identified and given advice on prevention and symptoms as soon as possible.
- **Risk of preterm birth** — The evidence identifies a range of factors that are associated with risk of preterm birth. If women at risk are identified, advice on modifiable risk factors can be provided.
- **Hepatitis C** — Previous guidance was that routine testing for hepatitis C was not recommended. However, routine testing is supported by the evidence that avoiding certain interventions among women who test positive reduces risk of mother-to-child transmission and that direct-acting antiviral therapy used postpartum (or post breastfeeding) is highly curative and removes the risk of transmission in subsequent pregnancies.
- **Diabetes** — Previous guidance was to test women with risk factors for diabetes early in pregnancy using fasting plasma glucose or 2-hour plasma glucose. However, some evidence supports an increased risk of poorer pregnancy outcomes among women with glycated haemoglobin ≥41 mmol/mol and consensus was that this test is also suitable for use in the first trimester.
- **Vitamin D status** — The evidence found no clear benefit or harms associated with supplementing vitamin D during pregnancy and therefore the recommendation against routine testing of vitamin D status in low-risk women was retained.
- **Thyroid dysfunction** — Previous guidance on using targeted rather than universal screening was retained as it is supported by the current evidence
- **Chromosomal anomalies** — The chapter was revised to incorporate new evidence on cell-free DNA testing.
Summary of recommendations

This section lists the recommendations and practice points included in this consultation draft, some of which have been carried over from previous reviews of the evidence. Four types of guidance are included:

- **evidence-based recommendation (EBR)** — a recommendation formulated after a systematic review of the evidence, with a clear linkage from the evidence base to the recommendation using GRADE methods (shaded in purple)
- **qualified evidence-based recommendation (QEBR)** — an evidence-based recommendation where there is lower certainty about the effects of the recommended course of action (shaded in purple)
- **consensus-based recommendation (CBR)** — a recommendation formulated in the absence of quality evidence, after a systematic review of the evidence was conducted and failed to identify sufficient admissible evidence on the clinical question (shaded in blue)
- **practice point (PP)** — advice on a subject that is outside the scope of the search strategy for the systematic evidence review, based on expert opinion and formulated by a consensus process (shaded in green).

The table below includes commentary on when the supporting evidence was reviewed (ie for Module I [2010–2011], Module II [2013] or as part of the current review [2016–2017]) and whether revisions have been made due to findings from the current review. The recommendations and practice points for which the supporting evidence was not reviewed in the current review are not under consideration in this consultation and are shaded in grey in the comments column.

Recommendations from Modules I and II that were graded ‘A’ under the previous grading system have been retained as evidence-based recommendations. Recommendations that were graded lower than ‘A’ have been included as qualified evidence-based recommendations or consensus-based recommendations depending on the quality of the supporting evidence. Recommendations adapted from other guidelines are included as consensus-based recommendations.

<table>
<thead>
<tr>
<th>Guidance</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Substance use</strong></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>CBR</td>
</tr>
<tr>
<td>A</td>
<td>PP</td>
</tr>
<tr>
<td><strong>Routine weighing</strong></td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>CBR</td>
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<tr>
<td>III</td>
<td>CBR</td>
</tr>
<tr>
<td>IV</td>
<td>CBR</td>
</tr>
<tr>
<td>V</td>
<td>CBR</td>
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<tr>
<td>Guidance</td>
<td>Comments</td>
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<td>-------------------------------------------------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td><strong>Guidance</strong></td>
<td></td>
</tr>
<tr>
<td><strong>B PP</strong> Taking a respectful, positive and supportive approach and</td>
<td>Evidence reviewed 2010</td>
</tr>
<tr>
<td>providing information about healthy eating and physical activity in an</td>
<td></td>
</tr>
<tr>
<td>appropriate format may assist discussion of weight management.</td>
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<tr>
<td><strong>Comments</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Family violence</strong></td>
<td></td>
</tr>
<tr>
<td><strong>1 EBR</strong> Explain to all women that asking about family violence is a</td>
<td>Evidence reviewed 2010 and 2016 (no change)</td>
</tr>
<tr>
<td>routine part of antenatal care and enquire about each woman’s exposure</td>
<td></td>
</tr>
<tr>
<td>to family violence.</td>
<td></td>
</tr>
<tr>
<td><strong>VI CBR</strong> Ask about family violence when alone with the woman,</td>
<td>Evidence reviewed 2016 (new questions)</td>
</tr>
<tr>
<td>utilising the tool used in your state/territory, specific questions</td>
<td></td>
</tr>
<tr>
<td>or a validated screening tool (eg Humiliation, Afraid, Rape, Kick</td>
<td></td>
</tr>
<tr>
<td>[HARK], Hurt, Insult, Threaten, Scream [HITS]).</td>
<td></td>
</tr>
<tr>
<td><strong>VII CBR</strong> As training programs improve confidence and competency</td>
<td>Evidence reviewed 2010 and 2016 (revised)</td>
</tr>
<tr>
<td>in identifying and caring for women experiencing family violence,</td>
<td></td>
</tr>
<tr>
<td>undertake and encourage training of health professionals.</td>
<td></td>
</tr>
<tr>
<td><strong>C PP</strong> Be aware of family and community structures and support</td>
<td>Evidence reviewed 2010 and 2016 (revised)</td>
</tr>
<tr>
<td>and of community family violence services that can be called for</td>
<td></td>
</tr>
<tr>
<td>urgent and ongoing support.</td>
<td></td>
</tr>
<tr>
<td><strong>D PP</strong> Responses to assisting Aboriginal and Torres Strait Islander</td>
<td>Evidence reviewed 2010 and 2016 (no change)</td>
</tr>
<tr>
<td>women who are experiencing family violence need to be appropriate to</td>
<td></td>
</tr>
<tr>
<td>the woman and her community.</td>
<td></td>
</tr>
<tr>
<td><strong>Fetal growth restriction</strong></td>
<td></td>
</tr>
<tr>
<td><strong>E PP</strong> Early in pregnancy, assess women for risk factors for having</td>
<td>Adapted from RCOG*</td>
</tr>
<tr>
<td>a small-for-gestational-age fetus/newborn.</td>
<td></td>
</tr>
<tr>
<td><strong>VIII CBR</strong> When women are identified as being at risk of having a</td>
<td>Adapted from RCOG*</td>
</tr>
<tr>
<td>small-for-gestational-age fetus/newborn, provide advice about</td>
<td></td>
</tr>
<tr>
<td>modifiable risk factors.</td>
<td></td>
</tr>
<tr>
<td><strong>IX CBR</strong> Consider referring women who have a significant risk factor</td>
<td>Adapted from RCOG*</td>
</tr>
<tr>
<td>for having a small-for-gestational-age fetus/newborn for serial</td>
<td></td>
</tr>
<tr>
<td>ultrasound measurement of fetal size and assessment of wellbeing with</td>
<td></td>
</tr>
<tr>
<td>umbilical artery Doppler from 26–28 weeks of pregnancy.</td>
<td></td>
</tr>
<tr>
<td><strong>F PP</strong> Consider referring women who have three or more minor risk</td>
<td>Adapted from RCOG*</td>
</tr>
<tr>
<td>factors for having a small-for-gestational-age fetus/newborn for</td>
<td></td>
</tr>
<tr>
<td>uterine artery Doppler at 20–24 weeks of pregnancy.</td>
<td></td>
</tr>
<tr>
<td><strong>X CBR</strong> Do not assess fetal growth based solely on abdominal</td>
<td>Adapted from RCOG*</td>
</tr>
<tr>
<td>palpation.</td>
<td></td>
</tr>
<tr>
<td><strong>XI CBR</strong> At each antenatal visit from 24 weeks, measure symphysis-</td>
<td>Adapted from RCOG*</td>
</tr>
<tr>
<td>fundal height.</td>
<td></td>
</tr>
<tr>
<td><strong>G PP</strong> If plotting symphysis-fundal height, use a customised chart</td>
<td>Adapted from RCOG*</td>
</tr>
<tr>
<td>rather than a population–based chart.</td>
<td></td>
</tr>
<tr>
<td><strong>H PP</strong> Women with a single symphysis fundal height which plots below</td>
<td>Adapted from RCOG*</td>
</tr>
<tr>
<td>the 10th centile or serial measurements that demonstrate slow or</td>
<td></td>
</tr>
<tr>
<td>static growth by crossing centiles should be referred for ultrasound</td>
<td></td>
</tr>
<tr>
<td>measurement of fetal size.</td>
<td></td>
</tr>
<tr>
<td>Guidance</td>
<td>Comments</td>
</tr>
<tr>
<td>----------</td>
<td>----------</td>
</tr>
<tr>
<td>I PP</td>
<td>Women in whom measurement of symphysis fundal height is inaccurate (for example: BMI &gt;35, large fibroids, polyhydramnios) should be referred for serial assessment of fetal size using ultrasound.</td>
</tr>
</tbody>
</table>

**Fetal movements**

<table>
<thead>
<tr>
<th>XII CBR</th>
<th>Routinely provide women with verbal and written information about normal fetal movements.</th>
</tr>
</thead>
<tbody>
<tr>
<td>XIII CBR</td>
<td>Advise women to contact their health care professional if they have any concern about decreased or absent fetal movements and not to wait until the next day to report decreased fetal movements.</td>
</tr>
<tr>
<td>J PP</td>
<td>Emphasise the importance of maternal awareness of fetal movements at every antenatal visit.</td>
</tr>
<tr>
<td>XIV CBR</td>
<td>Advise women to monitor fetal movements but do not advise formal fetal movement counting as part of routine antenatal care.</td>
</tr>
<tr>
<td>XV CBR</td>
<td>Advise a woman who is unsure whether fetal movements are decreased to count while lying down on her side and to contact her health care professional if there are less than 10 movements in 2 hours.</td>
</tr>
<tr>
<td>K PP</td>
<td>Maternal concern about decreased fetal movements overrides any definition of decreased fetal movements based on counting and women with a concern about decreased fetal movements should be encouraged to contact their health professional.</td>
</tr>
</tbody>
</table>

**Fetal heart rate**

<table>
<thead>
<tr>
<th>XVI CBR</th>
<th>If auscultation of the fetal heart rate is performed, a Doppler may be used from 12 weeks and a Pinard stethoscope from 28 weeks.</th>
</tr>
</thead>
<tbody>
<tr>
<td>XVII CBR</td>
<td>Do not routinely use electronic fetal heart rate monitoring (cardiotocography) for fetal assessment in women with an uncomplicated pregnancy.</td>
</tr>
</tbody>
</table>

**Risk of pre-eclampsia**

<table>
<thead>
<tr>
<th>2 EBR</th>
<th>Early in pregnancy, assess all women for risk of pre-eclampsia.</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 EBR</td>
<td>Advise women at high risk of developing pre-eclampsia that calcium supplementation is beneficial if dietary intake is low.</td>
</tr>
<tr>
<td>L PP</td>
<td>If a woman has a low dietary calcium intake, advise her to increase her intake of calcium-rich foods.</td>
</tr>
<tr>
<td>4 EBR</td>
<td>Advise women at moderate–high risk of pre-eclampsia that low-dose aspirin from early pregnancy may be of benefit in its prevention.</td>
</tr>
<tr>
<td>5 EBR</td>
<td>Advise women that vitamins C and E are not of benefit in preventing pre-eclampsia.</td>
</tr>
</tbody>
</table>
### Guidance

<table>
<thead>
<tr>
<th>XVIII</th>
<th>CBR</th>
<th>Routinely measure blood pressure to identify new onset hypertension.</th>
<th>Evidence reviewed 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>XIX</td>
<td>CBR</td>
<td>Recommend testing for proteinuria at each antenatal visit if a woman has risk factors for or clinical indications of pre-eclampsia, in particular, raised blood pressure.</td>
<td>Evidence reviewed 2013 and 2016 (revised)</td>
</tr>
<tr>
<td>M</td>
<td>PP</td>
<td>Women should be given information about the urgency of seeking advice from a health professional if they experience: headache, visual disturbance, such as blurring or flashing before the eyes, epigastric pain (just below the ribs), vomiting and/or rapid swelling of the face, hands or feet.</td>
<td>Evidence reviewed 2013</td>
</tr>
</tbody>
</table>

**Risk of preterm birth**

| XX    | CBR | When women are identified as being at risk of giving birth preterm, provide advice about modifiable risk factors. | Evidence reviewed 2013 and 2017 (revised) |

### Hepatitis C

<table>
<thead>
<tr>
<th>X XI</th>
<th>CBR</th>
<th>At the first antenatal visit, recommend testing for hepatitis C.</th>
<th>Evidence reviewed 2010 and 2016 (revised)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>PP</td>
<td>For women who have not previously been tested and who are having a planned invasive procedure (eg chorionic villus sampling), recommend testing for hepatitis C before the procedure.</td>
<td>Evidence reviewed 2010 and 2016 (revised)</td>
</tr>
</tbody>
</table>

### Diabetes

<table>
<thead>
<tr>
<th>6</th>
<th>EBR</th>
<th>In the first trimester, assess a woman’s risk of diabetes — including her age, body mass index, previous gestational diabetes or high birth weight baby, family history of diabetes, presence of polycystic ovarian syndrome and whether she is from an ethnic group with high prevalence of diabetes, such as Aboriginal and Torres Strait Islander peoples.</th>
<th>Evidence reviewed 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>QEBR</td>
<td>Advise women that physical activity and healthy eating during pregnancy help to reduce excessive weight gain, but do not appear to directly reduce the risk of diabetes in pregnancy.</td>
<td>Evidence reviewed 2013</td>
</tr>
<tr>
<td>XXII</td>
<td>CBR</td>
<td>When a woman has risk factors for diabetes in the first trimester, suitable tests are glycated haemoglobin (HbA1c) or fasting blood glucose.</td>
<td>Evidence reviewed 2016 (new question)</td>
</tr>
<tr>
<td>XXIII</td>
<td>CBR</td>
<td>Between 24 and 28 weeks gestation, advise testing for diabetes to all women who have not previously been tested in the current pregnancy. Advise repeat testing to women who were tested early in pregnancy due to risk factors and had a normal result on an initial test.</td>
<td>Evidence reviewed 2013</td>
</tr>
<tr>
<td>XXIV</td>
<td>CBR</td>
<td>Use the World Health Organization/International Association of Diabetes and Pregnancy Study Groups tests and criteria to diagnose diabetes in pregnancy.</td>
<td>Evidence reviewed 2013</td>
</tr>
</tbody>
</table>

### Vitamin D status

| 8     | EBR | Do not routinely recommend testing for vitamin D status to pregnant women. | Evidence reviewed 2010 and 2016 (revised) |
### Guidance and Comments

<table>
<thead>
<tr>
<th>Guidance</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>0</strong> PP</td>
<td>An understanding of local geography and ethnicity may direct the decision to test for vitamin D status in pregnancy.</td>
</tr>
<tr>
<td><strong>XXV</strong> CBR</td>
<td>In women considered to be at risk of vitamin D deficiency, advise vitamin D supplementation for women with vitamin D levels lower than 50 nmol/L.</td>
</tr>
</tbody>
</table>

**Thyroid dysfunction**

| 9 EBR | Do not routinely test pregnant women for thyroid dysfunction. |
| **XXVI** CBR | Recommend thyroid testing to pregnant women who are at increased risk of thyroid dysfunction. |

**Fetal chromosomal anomalies**

| **XXVII** CBR | In the first trimester, give all women/couples information about the purpose and implications of testing for chromosomal anomalies to enable them to make informed choices. |
| **P** PP | Provide information about testing for chromosomal anomalies in a way that is appropriate and accessible to the individual woman, using neutral language and considering the woman’s level of literacy. |
| **XXVIII** CBR | If a woman chooses to have the combined test (nuchal translucency thickness, free beta-human chorionic gonadotrophin, pregnancy-associated plasma protein-A), make arrangements so that blood for biochemical analysis is collected between 9 weeks to 13 weeks 6 days gestation and ultrasound assessment takes place between 11 weeks and 13 weeks 6 days gestation. |
| **10** EBR | If a woman chooses to have a diagnostic test for chromosomal anomaly, base the choice of test on gestational age (chorionic villus sampling before 14 weeks pregnancy and amniocentesis after 15 weeks) and the woman’s/couple’s preferences. |
| **XXIX** CBR | Offer rapid access to appropriate counselling and ongoing support by trained health professionals to women who receive a diagnosis of fetal chromosomal anomaly. |
| **Q** PP | Women with a high-probability screening test result but negative diagnostic test should be referred for further specialist assessment because of an increased risk of other fetal anomalies. |
| **R** PP | Support all women to access testing for chromosomal anomalies in a timely manner. |

**Notes:**
- Recommendations adapted from the RCOG and PSANZ guidelines have been reworded for consistency with other recommendations in these Guidelines.
Introduction

Australian Clinical Practice Guidelines on Antenatal Care were released in two stages in 2012 (Module I) (Australian Health Ministers' Advisory Council 2012) and 2014 (Module II) (Australian Health Ministers' Advisory Council 2014). The Guidelines provide evidence-based recommendations to support high quality, safe antenatal care and contribute to improved outcomes for all mothers and babies.

In 2015–16, the Maternity Services Inter-Jurisdictional Committee (MSIJC) received funds through the Australian Health Ministers’ Advisory Council (AHMAC) to review the Guidelines. A multidisciplinary Expert Working Group (EWG) — the membership of which included a range of health professionals with expertise in providing, developing and researching antenatal care, a consumer representative with experience of antenatal care and a methodology expert — was established to guide the review (see Appendix A). The EWG identified seven topics from Modules I and II as particularly high priority topics for review (domestic violence, hepatitis C, vitamin D, fetal growth and wellbeing, risk of pre-eclampsia, risk of preterm birth and thyroid dysfunction) and it was agreed that evidence on cell-free DNA testing, illicit substance use, monitoring of weight gain and early testing for diabetes should also be examined in this review. Three key professional colleges (Australian College of Midwives, Royal Australian and New Zealand College of Obstetricians and Gynaecologists and Royal Australian College of General Practitioners) were invited to provide feedback on the selected topics and research questions, which resulted in the addition of one additional review topic (antenatal care for Aboriginal and Torres Strait Islander women) and some additional research questions.

The evidence for these topics was reviewed and recommendations developed using GRADE methods (see Appendix C). The new recommendations will be submitted to the National Health and Medical Research Council (NHMRC) for approval under Section 14A of the NHMRC Act 1992 following public consultation. Relevant chapters from Modules I and II have been revised and chapters on the new topics developed — these are presented in this consultation draft.

The development of this document has followed the key principles and processes outlined in Procedures and Requirements for Meeting the 2011 NHMRC Standard for Clinical Practice Guidelines (NHMRC 2011). More detail on the development process is included in Appendices B and C.

Application of the Guidelines

Objective of the Guidelines

The Guidelines aim to improve the health of women and babies by promoting consistency of care and providing a summary of the current evidence on aspects of antenatal care.

Scope

The Guidelines cover the antenatal care of healthy pregnant women (ie those who do not have identified pre-existing conditions or complications, such as multiple pregnancy). They are intended for use in all settings where antenatal care is provided, including primary care, obstetric and midwifery practice and public and private hospitals.

The Guidelines do not include information on the additional care that some women will require (eg while they discuss tests to identify clinical signs of pre-eclampsia, they do not give information about its management) — resources providing guidance in these areas are listed where relevant.

Intended audience

The Guidelines are intended for all health professionals who contribute to antenatal care, including midwives, general practitioners (GPs), obstetricians, maternal and child health nurses, Aboriginal and Torres Strait Islander health practitioners: Aboriginal and Torres Strait Islander health workers, multicultural health workers, practice nurses, allied health professionals, childbirth and parenting educators and sonographers. The way in which different professionals use these Guidelines will vary depending on their knowledge, skills and role, as well as the setting in which care is provided.

1 Also referred to as child and family health nurses in some jurisdictions.
These Guidelines will be of interest and relevance to pregnant women in Australia. In addition, it is expected that policy makers will be able to draw on the Guidelines in the development of policy and delivery of health services.

Dissemination and review

Following NHMRC approval of the new recommendations, the two original modules will be combined with the chapters included in this consultation draft. The revised Guidelines will be uploaded as a searchable PDF to the Maternity Services section of the Australian Government Department of Health’s website. This will be accessible to health professionals and the broader community. The Guidelines will also be listed on the NHMRC portal and accessible by searching the portal.

A range of strategies will be used to promote the Guidelines (eg formal launch of the Guidelines, promotion through stakeholder networks) and to support implementation (eg development of summary materials for health professionals and consumers).

The EWG has identified topics for future review and it is anticipated that the online version of the Guidelines will be updated as revised or new chapters are developed.

References


1 Optimising antenatal care

1.1 Antenatal care for Aboriginal and Torres Strait Islander women

While the diversity of circumstances and experiences is acknowledged, this chapter highlights general considerations in providing antenatal care for Aboriginal and Torres Strait Islander women. Many Aboriginal and Torres Strait Islander women experience healthy pregnancies. However, poor health and social disadvantage contribute to worse overall perinatal outcomes than those experienced by non-Indigenous women.

1.1.1 Background to culturally safe antenatal care

"Cultural Respect is achieved when the health system is a safe environment for Aboriginal and Torres Strait Islander peoples and where cultural differences are respected." (AHMAC 2004)

History and politics have shaped and continue to shape the lives and health of Aboriginal and Torres Strait Islander people. Social disadvantage and family disruption are continuing effects of government policies that have contributed to Aboriginal and Torres Strait Islander peoples having by far the worst health status of any identifiable group in Australia and the poorest access to services (Couzos & Murray 2008). This is reflected in the overall health of Aboriginal and Torres Strait Islander women and their babies.

In 2014, there were 16,572 births registered in Australia where one or both parents identified as Aboriginal and Torres Strait Islander peoples (5.3% of all births registered), of which 12,978 births were to women who identified as Aboriginal and Torres Strait Islander peoples (4.2% of all births registered) (AIHW 2016b). While this chapter focuses on the care of Aboriginal and Torres Strait Islander women during pregnancy, it is important to remember that pregnancies where the father is Aboriginal or Torres Strait Islander may have similar issues in terms of perinatal outcomes (Clarke & Boyle 2014). There is a disproportionate burden of adverse perinatal outcomes for Aboriginal and Torres Strait Islander mothers and their babies, including increased maternal mortality (13.8 versus 6.6 deaths per 100,000 women who gave birth in 2008–2012) (Humphrey et al 2015), pre-term birth (140 versus 80 per 1,000 births), low birth weight (118 versus 62 per 1,000 births) and perinatal deaths (14 versus 9 per 1,000 births) (AIHW 2016a). All health professionals need to be aware of this disparity and have a role in optimising the care of Aboriginal and Torres Strait Islander pregnant women to aid in ‘closing the gap’ in health outcomes between Aboriginal and Torres Strait Islander and other peoples (Clarke & Boyle 2014).

1.1.2 Providing woman-centred care

"Have a good chat with them, gain their trust, make 'em feel secure ... words, the way you talk to them means a lot ... especially young ones, that's what they're looking for." (Older Aboriginal woman from remote community, Central Australia as quoted in Wilson 2009)

The fundamentals of providing woman-centred care discussed in Chapter 2 of Module I apply to all women. This section discusses issues specific to providing appropriate antenatal care for Aboriginal and Torres Strait Islander women. The cultural beliefs, practices and needs of Aboriginal and Torres Strait Islander women vary, both between and within culturally defined groups, and respect for the views and beliefs of individual women and of local communities is needed (Hunt 2008).

Understanding the woman's context

Many Aboriginal and Torres Strait Islander women experience healthy pregnancies. The women having babies are generally younger and, on average, have more children during their reproductive life than non-Indigenous women (Clarke & Boyle 2014). Aboriginal culture has many strengths that can provide a positive influence, such as a supportive extended family network and kinship, connection to country, and active cultural practices in language, art and music. It informs a more holistic view of wellbeing.
For women who experience adverse events in their pregnancies, the reasons are diverse and occur throughout the life course (Clarke & Boyle 2014):

- **socioeconomic factors** — lower income, higher unemployment, lower educational levels, inadequate infrastructure (e.g., housing, water supply), increased rates of incarceration
- **health factors** — diabetes mellitus, cardiovascular disease (including rheumatic heart disease), respiratory disease, kidney disease, communicable infections, injuries, poor mental health, overweight and underweight
- **lifestyle factors** — lack of physical activity, poor nutrition, harmful levels of alcohol intake, smoking, higher psychosocial stressors (deaths in families, violence, serious illness, financial pressures, contact with the justice system).

**Individual cultural awareness**

Cultural awareness among health professionals is an essential component of clinical competence and is essential to effective communication and cultural security for Aboriginal and Torres Strait Islander people seeking health care. The evidence confirms that health professionals working individually or as members of a multidisciplinary team can effectively enhance their communication skills and knowledge of cultural security. A commitment to providing culturally safe care requires a willingness to gain the knowledge, understanding, and skills to communicate sensitively and effectively with Aboriginal and Torres Strait Islander people and to acknowledge and respect cultural differences.

Gaining an understanding about one’s own cultural awareness involves:

- reflecting on one’s assumptions, attitudes, beliefs and notions of privilege; and
- considering one’s cultural knowledge of women attending for antenatal care in the community (e.g., health-related beliefs, practices, and cultural values and disease incidence and prevalence).

Cultural awareness training programs and tools for evaluating individual cultural competence have been developed and should be accessed wherever available (see Sections 1.1.7 and 1.1.9).

**Improving women’s experience of antenatal care**

**Taking an individualised approach**

Factors that may improve a woman’s experience of antenatal care include (Clarke & Boyle 2014):

- taking time to establish rapport and trust (e.g., continuity of carer)
- ensuring her privacy and confidentiality
- having some knowledge about the woman’s community
- endeavouring to have flexible scheduling of appointments.

Ideally a nominated person within a practice should be able to ensure the woman is receiving appropriate care from other healthcare team members and to assist to coordinate services if required.

**Providing information and support so that women can make decisions**

Involving women in decision-making about their health care during pregnancy has been endorsed as a key feature of good quality maternity care (Chalmers et al. 2001). However, there is indirect evidence that, in some settings, Aboriginal and Torres Strait Islander women have fewer opportunities to be involved in decision-making than non-Indigenous women, or than is desirable (Hunt 2003). This may be improved through providing information to women in a culturally appropriate way and providing strategies to help them achieve positive change (Clarke & Boyle 2014).

**Assistance from Aboriginal community workers**

Where available, assistance from Aboriginal health workers, community workers or Aboriginal liaison officers should be sought as they can facilitate understanding between the woman and her healthcare provider and provide assistance for attending appointments and coordinating care (Clarke & Boyle 2014). This may be particularly important where English is not the woman’s first language.

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2 In these Guidelines, ‘cultural awareness’ is defined as ‘a sensitivity to the similarities and differences that exist between two different cultures, and the use of (this) sensitivity in effective communication with members of another cultural group’ and ‘cultural security’ as upholding a commitment to the provision of services that do not ‘compromise the legitimate cultural rights, views, values and expectations of Aboriginal people’ (Bainbridge et al. 2015).
1.1.3 Successful models of antenatal care for Aboriginal and Torres Strait Islander women

“Aboriginal peoples and Torres Strait Islanders should access services and health care not just at a level enjoyed by other Australians (principle of equality) but at one that reflects their much greater level of health care need (principle of equity).” (Couzos & Murray 2008)

A number of programs have been implemented around the country to improve the delivery of antenatal services to Aboriginal and Torres Strait Islander women. Evaluations have shown their success in improving uptake of care earlier in the pregnancies, for the duration of the pregnancy and often postnatally, which allows other opportunistic healthcare interventions, such as family planning, cervical screening and improving breastfeeding rates (Clarke & Boyle 2014). This shows that if services cater for their needs, women will utilise them.

Evaluated programs include:

- **Midwifery group practice** — A midwifery group practice (staffed by midwives, Aboriginal Health Workers, Aboriginal midwifery students and an Aboriginal ‘senior woman’) was introduced in a regional centre in the Northern Territory to provide continuity of care for women from remote communities transferred to the centre for antenatal care and birth (Barclay et al 2014). There were improvements in antenatal care (fewer women had no antenatal care and more had more than five visits), antenatal screening and smoking cessation advice and a reduction in fetal distress in labour. The experiences of women, midwives and others during the establishment and the first year of the midwifery group practice were also reported positively and women’s engagement with the health services through their midwives improved. Cost-effective improvements were made to the acceptability, quality and outcomes of maternity care.

- **Midwifery continuity of care** — A meta-synthesis of qualitative studies undertaken in Australia and Canada found that overall the experience of midwifery services was valuable for Indigenous women, with improved cultural safety, experiences and outcomes in relation to pregnancy and birth (Corcoran et al 2017). The most positive experiences for women were with services that provided continuity of care, had strong community links and were controlled by Indigenous communities (Corcoran et al 2017). Continuity of midwifery care can be effectively provided to remote dwelling Aboriginal women and appears to improve outcomes for women and their infants (Lack et al 2016). However, there are barriers preventing the provision of intrapartum midwifery care in remote areas (Corcoran et al 2017). A study among midwives in a large tertiary hospital in South Australia found that communication and building support with Aboriginal health workers and families were important to midwives working with Aboriginal women and identified the following barriers to provision of care (Brown et al 2016):
  - time constraints in a busy hospital
  - lack of flexibility in the hospital protocols and polices
  - the system whereby women were required to relocate to birth
  - lack of continuity of care
  - lack of support 24 h a day from the Aboriginal workforce
  - the speed at which women transitioned through the service.

The midwives had some difficulty differentiating the women’s physical needs from their cultural needs and the concept of cultural safety was not well understood. The midwives also determined that women who were living in metropolitan areas had lesser cultural needs than the women who were living in rural and remote areas. Stereotyping and racism was also identified within the study.

- **Aboriginal Maternity Group Practice Program (AMGPP)** — The AMGPP employed Aboriginal grandmothers, Aboriginal Health Officers and midwives working in partnership with existing antenatal services to provide care for pregnant Aboriginal women residing in south metropolitan Perth (Bertilone & McEvoy 2015). Babies born to participants were significantly less likely to be born preterm (9.1% vs 15.9% in historical controls [aOR 0.56; 95%CI 0.35 to 0.92]; vs 15.3% in contemporary controls [aOR 0.75; 95%CI 0.58 to 0.95]); to require resuscitation at birth (17.8% vs 24.4% in historical controls [aOR 0.68; 95%CI 0.47 to 0.98]; vs 31.2% in contemporary controls [aOR 0.71; 95%CI 0.60 to 0.85]) or to have a hospital length of stay greater than 5 days (4.0% vs 11.3% in historical controls [aOR 0.34; 95%CI 0.18 to 0.64]; vs 11.6% in contemporary controls.
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1.1.4
• Aboriginal Family Birthing Program (AFBP) — The AFBP provides culturally competent antenatal, intrapartum and early postnatal care for Aboriginal families across South Australia, with women cared for by a midwife and an Aboriginal Maternal and Infant Care worker. Compared with women attending mainstream public antenatal care, women attending metropolitan and regional AFBP services were more likely to report positive experiences of pregnancy care (aOR 3.4, 95%CI 1.6 to 7.0 and aOR 2.4, 95%CI 1.4 to 4.3, respectively). Women attending Aboriginal Health Services were also more likely to report positive experiences of care (aOR 3.5, 95%CI 1.3 to 9.4) (Brown et al 2015). Even with greater social disadvantage and higher clinical complexity, pregnancy outcomes were similar for AFBP and Aboriginal women attending other services (Middleton et al 2017).
• Aboriginal Maternal and Infant Health Service (AMIHS) — the AMIHS was established in NSW to improve the health of Aboriginal women during pregnancy and decrease perinatal morbidity and mortality for Aboriginal babies (Murphy & Best 2012). The AMIHS is delivered through a continuity-of-care model, where midwives and Aboriginal Health Workers collaborate to provide a high-quality maternity service that is culturally sensitive, women-centred, based on primary health-care principles and provided in partnership with Aboriginal people. An evaluation of the AMIHS found:
  — the proportion of women who attended their first antenatal visit before 20 weeks increased (65 vs 78% in 2004, OR 1.2; 95%CI 1.01 to 1.4; p=0.03)
  — the rate of low birthweight babies decreased (13 vs 12%, not statistically significant)
  — the proportion of preterm births decreased (20 vs 11%; OR 0.5 95%CI 0.4–0.8–1.4; p=0.001)
  — perinatal mortality decreased (from 20.4 per 1,000 births in 1996–2000 to 14.4 per 1,000 births in 2001–2003; not statistically significant owing to small numbers)
  — breastfeeding rates improved (from 67% initiating breastfeeding and 59% still breastfeeding at 6 weeks in 2003, to 70% initiating breastfeeding and 62% still breastfeeding at 6 weeks in 2004).
While these programs have been identified as beneficial, not all Aboriginal and Torres Strait Islander women have access to these types of programs and many still rely on mainstream services such as GPs and public hospital clinics (Clarke & Boyle 2014). Hence, it is important that mainstream services embed cultural competence into continuous quality improvement. Participation in a continuous quality improvement initiative by primary health care centres in Indigenous communities is associated with greater provision of pregnancy care regarding lifestyle-related risk factors (Gibson-Helm et al 2016b). For example, screening for cigarette smoking increased from 73% at baseline to 95% (OR 11, 95%CI 4.3 to 29) after four cycles (Gibson-Helm et al 2016b).

1.1.4 Birthing on country

There is a strong relationship between distance to maternity services and poorer clinical and psychosocial outcomes (Kildea et al 2016). For women living in traditional communities, the social risks of not birthing on country include cultural risk (eg the belief that birthing away from country may be the cause of ill health as it breaks the link between strong culture, strong health and the land) and emotional risks (having to spend weeks removed from family and other children while awaiting birth) (Kildea et al 2016). These factors cause distress to women and families and increase clinical and medical risks (eg women not attending antenatal care, or presenting late in labour, to avoid being flown out of their community for birth).
In a study of birthing services in rural and remote areas, very remote communities were least likely to have a local birthing facility (Rolfe et al 2017). In addition, services were influenced by jurisdictional policy rather than identified need.
1.1.5 Adolescent mothers

Adolescent motherhood occurs more often within communities where poverty, Aboriginal and Torres Strait Islander status and rural/remote location intersect (Marino et al 2016). Adolescent pregnancy has been typically linked to a range of adverse outcomes for mother and child. In Australia, the proportion of births among adolescent women is higher among Aboriginal and Torres Strait Islander women than among non-Indigenous women (17 vs 2%) (AIHW 2016a) and the risk of poorer psychosocial and clinical outcomes is greater if these women are not well supported during pregnancy and beyond (Reibel et al 2016). However, a study in the NT suggests that problems usually associated with Aboriginal adolescent births (such as low birth weight) are not due to maternal age but are related to the underlying poor health, socioeconomic disadvantage and a system that is challenged to support these young women, both culturally and medically (Barclay et al 2014).

Drawing on existing literature and consultations with young Aboriginal women and health professionals supporting pregnant Aboriginal women, a West Australian study found that engagement with the health system is encouraged and health outcomes for young mothers and their babies improved through destigmatising of young parenthood and providing continuity of caregiver in culturally safe services with culturally competent health professionals (Reibel et al 2016). Another study noted the critical role of general practitioners in identifying at-risk adolescent women, preventing unintended adolescent pregnancy, clinical care of pregnant adolescents and promoting the health and wellbeing of adolescent mothers and their children (Marino et al 2016).

1.1.6 Workforce

As outlined above, an increasing number of maternity models recognise the contribution of Indigenous workers who have a variety of titles and job descriptions (Kildea et al 2016). Some recognise the importance and cultural expertise of elders and grandmothers, while others aim to provide women support through bicultural partnerships between midwives and maternal infant health workers.

In 2015 there were 230 Indigenous midwives nationally, comprising only 1% of the midwife population, while Indigenous Australians constitute 3% of the population and 6% of all Australian births (Clarke & Boyle 2014). Additionally there is a marked drop-out of Indigenous midwifery graduates from clinical roles soon after graduation, which highlights a need for ongoing support (Clarke & Boyle 2014).

1.1.7 Cultural security

Cultural security education and training is a strategy aimed at addressing health disparities, although further development and work are required to appreciate the most effective methods, the flow-on effect of training to patients, and the best tools for measuring cultural competence in individuals, organisations and in the maternity setting (Kildea et al 2016). Critically, “racism constitutes a ‘double burden’ for Indigenous Australians, encumbering their health as well as access to effective and timely health care services”. Achieving culturally safe maternity services is key to improving maternity care and good health for mothers and babies.

An emerging area in developing a culturally safe workforce is that of trauma-informed care and practice, whereby health professionals understand the ongoing impact of intergenerational trauma resulting from historical injustices, colonisation, removal from and dispossession of land, and continuing racism (Kildea et al 2016). This is particularly important given that Indigenous children are over-represented in out-of-home care compared with non-Indigenous children (9.5 times more likely), with some women encountering the child protection system during pregnancy, leading to the removal of their babies at birth.

Although maternity services in Australia are designed to offer women the best care, they largely reflect modern western medical values and perceptions of health, risk and safety. However, the Indigenous definition of health incorporates not just physical wellbeing, but also the social, emotional and cultural wellbeing of individuals and the whole community (Kildea et al 2016).

Recent studies have found that:

- ensuring cultural training is an assessable component of practice and recognition that it is as important as the physical aspects of care for the women would be a positive approach for improving the experiences of the women and supporting midwives in practice (Brown et al 2016)
• inclusion of a well-designed unit of study on indigenous culture and health that privileged Aboriginal voices in the classroom and was conceived with substantial Aboriginal input enhanced knowledge among student midwives at a West Australian university and shifted attitudes in a positive direction (Thackrah 2016).

Tools for evaluating an organisation’s current ability to provide culturally safe care have been developed (see Section 1.1.9) and provide a useful aid in reviewing the concepts, principles and processes that underpin cultural competence (Walker 2010).

1.1.8 Improving outcomes

System-wide strategies to strengthen health centre and health system attributes that support best-practice antenatal care for Aboriginal and Torres Strait Islander women are needed. Some strategies can be implemented within health centres while others need partnerships with communities, external services and policy makers (Gibson-Helm et al 2016a).

Approaches to improving the health outcomes for Aboriginal women and their babies in pregnancy include the following.

• systems-based approaches to address socio-economic disadvantage, education and health literacy (Boyle & Eades 2016)
• health services approaches to provide trusted, welcoming and culturally appropriate health services in both community-controlled and government sectors, facilitate better communication between primary and hospital-based services and utilise initiatives such as continuous quality improvement practices that lead to improved services, particularly where staff turnover is high (Boyle & Eades 2016)
• families-based approach, for example smoking prevention and quitting (Boyle & Eades 2016), drinking alcohol, social and emotional wellbeing and nutrition (Gibson-Helm et al 2016a)
• clinical guidelines addressing specific needs of Aboriginal and Torres Strait Islander women in pregnancy, for example screening for infection in young women and those in areas where risk is high (Boyle & Eades 2016)
• support for the particular needs of rural and remote women in accessing care, for example ultrasound services (Boyle & Eades 2016)
• strengthen systems for workforce support, retention and recruitment, patient-centred care, and community capacity, engagement and mobilization (Gibson-Helm et al 2016a).

1.1.9 Resources


Queensland Health Aboriginal and Torres Strait Islander Cultural Capability Framework 2010 to 2033

RACGP (2011) Cultural Awareness Education and Cultural Safety Training. The RACGP National Faculty of Aboriginal and Torres Strait Islander Health.


Walker R & Reibel T (2009) Developing Cultural Competence for Health Services and Practitioners. Background paper for the TiCHR & Women’s and Newborn Health Network antenatal services and maternal services project.


Websites

HealthInfoNet
Closing the Gap
Birthing Business in the Bush
Maternity care in the bush
1.1.10 References


Barclay L, Kruske S, Bar-Zeev S et al (2014) Improving Aboriginal maternal and infant health services in the ‘Top End’ of Australia: synthesis of the findings of a health services research program aimed at engaging stakeholders, developing research capacity and embedding change. BMC Health Serv Res 14: 241.


Thackrah RD (2016) Culturally secure practice in midwifery education and service provision for Aboriginal women. Doctor of Philosophy, University of Western Australia.

2 Lifestyle considerations

2.1 Substance use

Antenatal care provides an opportunity to ask women about substance use. Enquiring in a non-judgmental way may assist women to disclose and enable access to additional support and care, including mental health and drug and alcohol services.

2.1.1 Background

Substance use in pregnancy is an important issue in antenatal care. The use of tobacco and alcohol are common (these are addressed in the full Guidelines) but the use of illicit substances and the misuse of prescription medications is also important. The simultaneous use of several substances (polysubstance use) and comorbid mental health problems are also common.

The substances considered in this chapter include cannabis (marijuana), methylenedioxymethamphetamine (MDMA or ecstasy), meth/amphetamines (including powder/pills [speed] and crystals [crystal meth or ice]), cocaine and opioids [including heroin] and misuse of pharmaceuticals. No information relevant to lysergic acid diethylamide (LSD) was identified.

Prevalence of illicit substance use in Australia

General population

According to the 2013 National Drug Strategy Household Survey, trends in substance use ‘in the last 12 months’ among Australians aged >14 years are as follows (AIHW 2014):

- cannabis — use has remained relatively stable since 2004 (10.2%; 35% in their lifetime)
- ecstasy — use has declined (3.0% in 2010 to 2.5% in 2013)
- meth/amphetamine — use has remained stable (2.1% since 2007) but, among meth/amphetamine users, use of ice has almost doubled (22% in 2010 to 50% in 2013) and that of speed has almost halved (51% in 2010 to 29% in 2013)
- cocaine — use has remained stable (2.1% in 2010 and 2013)
- heroin — use has declined (0.8% in 1998 to 0.1% in 2013)
- misuse of pharmaceutical medications — use has increased (7.4% in 2010 to 11.4% in 2013).

The type of substance use in the last 12 months varied across jurisdictions. For example (AIHW 2014):

- cannabis was most commonly used in the Northern Territory (17.1%) — almost double the usage in Victoria (9.1%)
- meth/amphetamines were used more by people in Western Australia (3.8%) than other jurisdictions
- people in New South Wales (2.7%) and the Australian Capital Territory (2.8%) were more likely to use cocaine than people in other jurisdictions
- ecstasy use was most common in the Northern Territory (3.7%)
- people in Western Australia were more likely to misuse pharmaceuticals (5.6%) than those in any other jurisdiction.

Pregnancy

The National Drug Survey reported that in Australia in 2013 (AIHW 2014):

- regardless of whether women knew they were pregnant or not, 2.2% had used an illicit substance such as marijuana and 0.9% had misused prescription analgesics
- among pregnant women, a small minority had used illicit substances — 2.4% before knowledge of their pregnancy and 1.6% after they knew they were pregnant.
**Risks associated with substance use in pregnancy**

Systematic reviews of observational studies have identified the following maternal and perinatal risks associated with substance use.

- **Marijuana use in pregnancy** — One review [n=31] found an association with increased risk of low birth weight (RR 1.43, 95%CI 1.27 to 1.62) and preterm birth (RR 1.32, 95%CI 1.14-1.54) but, when pooled data were adjusted for tobacco use and other confounding factors, there was no statistically significant difference [birth weight RR 1.16, 95%CI 0.98 to 1.37; preterm birth RR 1.08, 95%CI 0.82 to 1.43] (Conner et al 2016). Another review that did not adjust for confounders found an increase in risk of low birth weight [OR 1.77; 95%CI 1.04 to 3.01] and maternal anaemia [OR 1.36; 95%CI 1.10 to 1.69] (Gunn et al 2016).

- **Amphetamine use in pregnancy** — Significant increases in unadjusted risks of preterm birth (OR 4.11; 95%CI, 3.05 to 5.55), low birthweight (OR 3.97; 95%CI, 2.45 to 6.43), and small for gestational age (OR 5.79; 95%CI 1.39 to 24.06) were identified and mean birthweight was significantly lower (MD –279 g; 95% CI, –485 to -74 g) (Ladhani et al 2011).

- **Cocaine use in pregnancy** — There was an association with significantly higher risk of preterm birth (OR 3.38; 95%CI 2.72 to 4.21), low birthweight (OR 3.66; 95%CI 2.90 to 4.63), and small-for-gestational-age infants (OR 3.23; 95%CI 2.43 to 4.30), as well as lower gestational age at birth (–1.47 wk; 95%CI –1.97 to –0.98 wk) and reduced birthweight (–492 g; 95%CI –562 to –421 g) (Gouin et al 2011).

- **Opioid dependence in pregnancy** — A review of neurobehavioural function in infants (mean age 14.1 months) found non-significant mean effect sizes in favour of non-opioid exposed controls for cognition (0.24, Z=1.41, p=0.16, 95%CI −0.09 to 0.58), psychomotor function (0.28, Z=1.67, p=0.09, 95%CI −0.05 to 0.61) and behaviour (corrected mean 1.21, Z=1.30, p=0.19; 95%CI −0.61 to 3.03) (Baldacchino et al 2014).

A cohort study found that births associated with maternal opioid abuse or dependence compared with those without opioid abuse or dependence were associated with an increased odds of maternal death during hospitalisation (aOR 4.6; 95%CI 1.8 to 12.1); cardiac arrest (aOR 3.6; 95% CI 1.4 to 9.1), intrauterine growth restriction (aOR 2.7; 95%CI 2.4 to 2.9), placental abruption (aOR 2.4; 95%CI 2.1 to 2.6), length of stay >7 days (aOR 2.2; 95%CI 2.0 to 2.5), preterm labour (aOR 2.1; 95%CI 2.0 to 2.3), oligohydramnios (aOR 1.7; 95%CI 1.6 to 1.9), transfusion (aOR 1.7; 95% CI 1.5 to 1.9), stillbirth (aOR 1.5; 95%CI 1.3 to 1.8), premature rupture of membranes (aOR 1.4; 95%CI 1.3 to 1.6) and caesarean section (aOR 1.2; 95%CI 1.1 to 1.3) (Maeda et al 2014). No studies were identified that investigated outcomes associated with the use of crystal methamphetamine, LSD or ecstasy in pregnancy.

### 2.1.2 Assessing substance use

The World Health Organization (WHO) recommends screening for substance use in pregnancy (WHO 2014). Periodic screening for substance use in pregnancy is also recommended in Canada (SOGC 2011). In Australia, guidelines developed nationally and revised by NSW Health (NSW Health 2014) recommend screening for substance use early in pregnancy and emphasise the importance of establishing a sound therapeutic relationship with the woman based on respect and non-judgmental attitudes, of engaging the woman into adequate antenatal care through this relationship, and of maintaining continuity of care and of care throughout the pregnancy and postnatal period.

Validated screening instruments for substance use are available (see Section 2.1.5).

#### Consensus-based recommendation

1. Early in pregnancy, assess a woman’s use of illicit substances and misuse of pharmaceuticals and provide advice about the associated harms.

#### Practice point

A. Asking about substance use at subsequent visits is important as some women are more likely to report sensitive information only after a trusting relationship has been established.

#### Referral and intervention

Australian guidelines (NSW Health 2014) recommend that pregnant women with significant problematic substance use will benefit from an appropriate referral for specialist drug and alcohol assessment (in addition to midwifery and obstetric care), appointment of a consistent and continuous case manager.
and care team who use effective communication systems, and specific treatments for their substance use, which may include counselling, pharmacotherapies and relapse prevention strategies.

**Psychosocial interventions**

Cognitive behavioural therapy compared to brief advice for pregnant women with problematic substance use had no clear effect on the risk of low birth weight (RR 0.72, 95%CI 0.36 to 1.43; 1 study; n=160; low quality); preterm birth (RR 0.5; 95%CI 0.23 to 1.09; 1 study; n=163; low quality) or maternal substance use [no significant difference at birth or 3 months postpartum] (WHO 2014).

**Pharmacological interventions**

A Cochrane review on treatments for women with opioid dependence in pregnancy (Minozzi et al 2013) did not find sufficient significant differences between methadone and buprenorphine or slow-release morphine to allow conclusions to be drawn on whether one treatment is superior to another for all relevant outcomes. While methadone seems superior in terms of retaining women in treatment, buprenorphine seems to lead to less severe neonatal abstinence syndrome.

2.1.3 Discussing substance use

Discussions with women identified as using illicit substances or misusing pharmaceuticals may include:

- the harms associated with substance use and the benefits of ceasing their use
- the availability of local support services, including mental health and drug and alcohol services
- for opioid-dependent women, the benefits and harms of methadone compared to buprenorphine or oral slow-release morphine.

2.1.4 Practice summary — substance use

**When** — Early in pregnancy and at subsequent visits

**Who** — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker

- **Explain the purpose of enquiring about substance use** — Explain that enquiry about substance use is a routine part of antenatal care and that it aims to identify women who would like assistance.

- **Take a holistic approach** — If a woman affirms that she is using illicit substances or misusing pharmaceuticals, other considerations include intervention and ongoing support. The woman’s emotional well-being, her safety and that of children in her care should be assessed and referral to other services (e.g. community services, emergency housing, police) made as required.

- **Learn about locally available support services** — Available support services for women who are using illicit substances or misusing pharmaceuticals will vary by location.

- **Document the discussion** — Document in the medical record any evidence of substance use, referrals made and any information the woman provides. If woman-held records are used, the information included in these should be limited and more detailed records kept at the health service.

- **Seek support** — Depending on your skills and experience in discussing substance use with women and assisting them, seek advice and support through training programs, clinical supervision, mentoring and/or helplines.

- **Be aware of relevant legislation** — Each state and territory has requirements about reporting the potential for harms from substance use to the unborn child as set out in its legislation.

2.1.5 Resources


2.1.6 References


NSW Health (2014) NSW Clinical Guidelines for the Management of Substance Use during Pregnancy, Birth and the Postnatal period. Sydney: Ministry of Health NSW.


3 Clinical assessments

3.1 Weight and body mass index

Pre-pregnancy weight and weight gain during pregnancy are important determinants of the health of both mother and baby.

3.1.1 Background

The worldwide prevalence of obesity has risen dramatically in the past few decades and Australia is among those countries with the highest prevalence. There is a well-documented increased risk of complications for women who are overweight or obese during pregnancy. Conversely, being underweight during pregnancy can also affect the baby’s health.

Calculating and interpreting BMI

Body mass index (BMI) is an index of weight-for-height that is commonly used to classify underweight, overweight and obesity in adults. It is calculated by dividing weight by the square of height — weight (kg)/height (m)². The WHO classification of BMI classification is given in Table 3.1.1.

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<thead>
<tr>
<th>BMI (kg/m²)</th>
<th>Classification</th>
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<tbody>
<tr>
<td>&lt;18.50</td>
<td>Underweight</td>
</tr>
<tr>
<td>18.5–24.9</td>
<td>Healthy weight</td>
</tr>
<tr>
<td>25.0–29.9</td>
<td>Overweight</td>
</tr>
<tr>
<td>≥30.0</td>
<td>Obesity</td>
</tr>
</tbody>
</table>


Weight classification during pregnancy in Australia

Among women who gave birth in Australia in 2013 (AIHW 2016):³

- 19% were obese, 24% were overweight, 46% were in the normal weight range and 3% were underweight at the beginning of their pregnancy.
- Aboriginal and Torres Strait Islander women were more likely than non-Indigenous women to be obese (25%) or underweight (7%), less likely to be in the normal weight range (37%) and had a similar likelihood of being overweight (23%).
- Compared to women born in Australia, women born overseas were less likely to be obese (13 vs 21%) or overweight (23 vs 25%) and more likely to be in the healthy weight range (51 vs 44%) or underweight (4 vs 3%).
- Compared to women in the highest socioeconomic status quintile, those in the lowest quintile were more likely to be obese (25 vs 12%) or overweight (25 vs 23%), were less likely to be in the healthy weight range (40 vs 53%) and had a similar likelihood of being overweight (both 4%).
- Obesity was most common in very remote areas (25 vs 17% in major cities), prevalence of overweight was similar across geographical regions, prevalence of healthy weight decreased with increasing remoteness (47% in major cities to 36% in very remote areas) and underweight was more common in very remote areas (6 vs 3% in major cities).

Risks associated with a low or high pre-pregnancy BMI

- Underweight — a low pre-pregnancy BMI is associated with increased risk of preterm birth, small-for-gestational-age babies and low birth weight (Liu et al 2016). A BMI <20 has been associated with an increased risk of a low birth weight baby among Aboriginal and Torres Strait Islander women (Panaretto et al 2006).

³ Data from Victoria, Queensland, Western Australia, South Australia, Tasmania and the Australian Capital Territory.
• **Overweight** — pre-pregnancy BMI >25 has been linked with stillbirth (Chu et al 2007a), congenital abnormalities (Chu et al 2007b; Oddy et al 2009; Stothard et al 2009), neural tube defects (Rasmussen et al 2008; Oddy et al 2009; Stothard et al 2009), preterm birth (Viswanathan et al 2008; McDonald et al 2010), low birth weight (Viswanathan et al 2008; McDonald et al 2010), large-for-gestational-age babies (HAPO 2010), gestational hypertension (Callaway et al 2006; HAPO 2010), pre-eclampsia (HAPO 2008), gestational diabetes (Chu et al 2007b; Callaway et al 2006), postpartum haemorrhage (CMACE & RCOG 2010) and major depressive disorders (Bodnar et al 2009).

• **Obesity** — pre-pregnancy BMI ≥30 is also linked to the above outcomes and to an inability to initiate breastfeeding (Viswanathan et al 2008), postpartum weight retention (Thornton et al 2009) and increased rate of caesarean section (Callaway et al 2006; Chu et al 2007c; HAPO 2010).

**Risks associated with low or high weight gain during pregnancy**

• **Low weight gain** in pregnancy is associated with small-for-gestational-age babies (DeVader et al 2007; Nohr et al 2008; Viswanathan et al 2008), preterm birth (Viswanathan et al 2008), low birth weight and an inability to initiate breastfeeding (Viswanathan et al 2008).

• **High weight gain** in pregnancy increases the risk of large-for-gestational-age babies (DeVader et al 2007; Nohr et al 2008; Viswanathan et al 2008; Siega-Riz et al 2009), high birth weight (Viswanathan et al 2008; Crane et al 2009) and caesarean section (DeVader et al 2007; Nohr et al 2008; Viswanathan et al 2008; Bodnar et al 2010). It is also associated with hypertension (Crane et al 2009) and pre-eclampsia (DeVader et al 2007). High weight gain in women who are obese has been associated with neonatal metabolic abnormalities (Crane et al 2009). Weight gain before and during pregnancy not only affects the current pregnancy but may also contribute to future weight retention (Nohr et al 2008; Viswanathan et al 2008; Siega-Riz et al 2009).

3.1.2 Assessing BMI and weight gain

Routine measuring women’s height and weight and calculating BMI at an early antenatal contact is recommended in New Zealand (NZ MoH 2014), the United Kingdom (NICE updated 2016), the United States (ACOG 2013) and in Australia (RANZCOG 2017).

Encouraging self-monitoring of weight is recommended in New Zealand (NZ MoH 2014), while the NICE guidelines recommend confining repeated weighing to circumstances in which clinical management is likely to be influenced (NICE updated 2016). In Canada, weight gain tracking charts have been developed for the different weight classifications (Health Canada 2010).

Guidelines on the management of obesity in pregnancy have been developed in Australia (RANZCOG 2013), the United Kingdom (CMACE & RCOG 2010) and Canada (SOGC 2010). These guidelines are consistent in recommending that women who are obese be advised of the risks associated with obesity in pregnancy.

**Summary of the evidence**

**Measuring height and weight and calculating BMI**

Routine measurement of women’s weight and height and calculation of BMI at the first antenatal contact provides a more accurate measure than pre-pregnancy BMI and allows identification of women who require additional care during pregnancy. Note that the BMI can be less accurate for assessing healthy weight in certain groups due to variations in muscle mass and fat mass (eg cut-offs lower than the WHO classifications are recommended for Asian women and higher cut-offs are recommended for women from Pacific Islands) (Duerenberg et al 2002; James et al 2004; Depres & Tchernof 2007).

**Consensus-based recommendation**

II. Measure women’s weight and height at the first antenatal visit and calculate their BMI.

**Weight gain during pregnancy**

While pre-pregnancy BMI is independently associated with pregnancy outcomes, the amount of weight gained during pregnancy is also a contributing factor (Nohr et al 2008; Viswanathan et al 2008).
The US Institute of Medicine (IOM) provides guidance on weight gain in pregnancy based on pre-pregnancy BMI (see Table 3.1.2). When pre-pregnancy BMI is not known, a weight gain of 0.5–2 kg weight gain in the first trimester may be assumed (IOM 2009).

Studies suggest that many women do not achieve the recommended amounts. In an Australian study (de Jersey et al 2012), 36% of women gained weight according to guidelines, 26% gained inadequate weight and 38% gained excess weight. Among overweight women, 56% gained weight in excess of the IOM guidelines compared with 30% of those who started with a healthy weight ($P < 0.001$).

Table 3.1.2: IOM recommendations for weight gain in pregnancy by pre-pregnancy BMI

<table>
<thead>
<tr>
<th>Pre-pregnancy BMI (kg/m$^2$)</th>
<th>Recommended weight gain (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;18.5</td>
<td>12.7–18.1</td>
</tr>
<tr>
<td>18.5 to 24.9</td>
<td>11.5–16.0</td>
</tr>
<tr>
<td>25.0 to 29.9</td>
<td>6.8–11.3</td>
</tr>
<tr>
<td>30.0 to ≥40</td>
<td>5.0–9.0</td>
</tr>
</tbody>
</table>

Source: IOM 2009.

Recent evidence on routine weight monitoring

A recent Australian RCT ($n=782$) (Brownfoot et al 2015; Brownfoot et al 2016) addressed regular weighing at antenatal care visits plus advice on weight gain versus usual care. The study found no clear difference in weight gain, proportion of women gaining more weight than IOM recommended range or secondary outcomes (Brownfoot et al 2015). Among a subset of women who provided feedback ($n=586$), 73% were comfortable with being weighed routinely (Brownfoot et al 2016).

A pilot study (Doley et al 2015) ($n=76$), combined regular weighing by midwives and advice on weight gain with self-weighing between antenatal visits. Compared to usual care, there was no clear difference in the percentage of women gaining excessive weight during pregnancy or in mean depression and anxiety scores. Feedback in a subset of participants showed support for routine weighing among participants (9/12) and midwives (7/7).

When these two trials were pooled ($n=711$), there was no clear difference in excessive gestational weight (RR 1.05 95% CI 0.95 to 1.16) or in mean weekly weight gain (0.01 kg per week 95%CI –0.03 to 0.05). Quality of evidence was low for both outcomes. There was no indication in the two trials that either excessive gestational weight gain or mean gestational weight gain differed in women of normal weight at the beginning of pregnancy compared with women who were overweight or obese.

A third study (from Australia) found that, compared to usual care, self-weighing plus advice on weight gain reduced weight gain among women who were overweight but not among women who were normal weight or obese before pregnancy. However, the intervention did not influence excessive weight gain ($n=236$) (Jeffries et al 2009).

Consensus-based recommendations

III. Give women advice about appropriate weight gain during pregnancy in relation to their BMI.

IV. If women are underweight or overweight, record and discuss their weight at every antenatal visit.

V. Although there is insufficient evidence to recommend routine weighing based on its effects on pregnancy complications, at each antenatal visit offer women the opportunity to be weighed and to discuss their weight gain since the last antenatal visit, their diet and level of physical activity.

Supporting weight management

A recent Cochrane review (Muktabhant et al 2015) found that interventions involving diet or exercise, or both, reduced the risk of excessive gestational weight gain on average by 20% overall (average risk ratio [aRR] 0.80; 95%CI 0.73 to 0.87; high quality). Interventions involving low glycaemic load diets, supervised or unsupervised exercise only, or diet and exercise combined all led to similar reductions in the number of women gaining excessive weight. Women receiving diet or exercise, or both interventions were more likely to experience low gestational weight gain than those in control groups (aRR 1.14, 95%CI 1.02 to 1.27; moderate quality).
The review found no clear difference between intervention and control groups with regard to:

- pre-eclampsia (RR 0.95, 95%CI 0.77 to 1.16; high-quality); however, hypertension was reduced in the intervention group compared with the control group overall (aRR 0.70, 95%CI 0.51 to 0.96; low quality)
- caesarean sections overall (RR 0.95, 95%CI 0.88 to 1.03; high-quality)
- preterm birth overall (aRR 0.91, 95%CI 0.68 to 1.22; moderate-quality)
- infant macrosomia (aRR 0.93, 95%CI 0.86 to 1.02; high-quality), although the effect estimate suggested a small difference (7% reduction) in favour of the intervention group
- poor neonatal outcomes including shoulder dystocia, neonatal hypoglycaemia, hyperbilirubinaemia, or birth trauma (all moderate-quality); however, infants of high-risk women in the intervention group had a reduced risk of respiratory distress syndrome (RR 0.47, 95%CI 0.26 to 0.85; moderate-quality).

Nutrition and physical activity in pregnancy are discussed in the section on lifestyle in the full Guidelines.

**Specific risk assessments required for pregnant women above and below their most healthy weight**

There is strong evidence to support assessment of risks associated with a high pre-pregnancy BMI (HAPO 2010), including monitoring fetal growth and checking for gestational diabetes (Chu et al 2007b; Callaway et al 2006) and hypertensive disorders (Callaway et al 2006; HAPO 2008; 2010), congenital abnormality (Chu et al 2007b; Oddy et al 2009; Stothard et al 2009) and neural tube defects (Rasmussen et al 2008; Oddy et al 2009; Stothard et al 2009). Individual assessment of the risk of potential complications during the birth, including anaesthetic risk, may also be necessary for women with BMI ≥40. There is also evidence to support monitoring for small-for-gestational-age babies for women with a pre-pregnancy BMI in the underweight category (Panaretto et al 2006).

**Discussing weight and weight gain with women**

Women who have a BMI that is below or above the healthy range are likely to require additional care during pregnancy. For women with a high BMI, there may be additional implications for care during pregnancy (eg the potential for poor ultrasound visualisation) and the birth (eg need for the birth to take place in a larger centre, difficulties with fetal monitoring). Relevant risks associated with a woman’s pre-pregnancy BMI should be explained and the woman given the opportunity to discuss these and how they might be minimised.

**Practice point**

B. Taking a respectful, positive and supportive approach and providing information about healthy eating and physical activity in an appropriate format may assist discussion of weight management.

**Other considerations**

- Potential for sub-optimal visualisation on second trimester ultrasounds (delaying the ultrasound until 20 to 22 weeks pregnancy may provide better results in women with BMI ≥30) (SOGC 2010).
- Antenatal consultation with an obstetric anaesthetist to identify any potential difficulties with venous access, regional or general anaesthesia for women with a BMI ≥40.
- Additional support for initiating breastfeeding for women with BMIs lower or higher than the healthy range.
- For women with a high BMI, ongoing nutritional advice following childbirth from an appropriate health professional, with a view to weight reduction and maintenance.
3.1.3 Practice summary — measuring weight and BMI

When — At first antenatal visit

Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker

- **Explain the purpose of assessing weight and weight gain during pregnancy** — For women with a BMI outside the healthy range, discuss the risks associated with a woman’s weight being below or above the healthy range.

- **Engage women in discussions about weight gain** — Offer women the opportunity to be weighed and to discuss their weight gain since the last antenatal visit. Use the IOM recommendations to give women advice about appropriate weight gain.

- **Take a holistic approach** — Provide women with advice on the benefits of a healthy diet and regular physical activity.

3.1.4 Resources

**Health professionals**


**Women and families**


3.1.5 References


3.2 Family violence

Antenatal care provides an opportunity to ask women about exposure to violence especially at home or in their family. Asking questions may assist women to disclose their experiences of violence to health professionals and enable access to additional support and care, including community, legal and police support services.

3.2.1 Background

‘Family violence’ refers to acts of violence that occur between people who have, or have had, an intimate relationship. The central element is a pattern of behaviour aimed at controlling a partner through fear, for example by using behaviour which is violent or by threatening any act that might cause harm or suffering. Family violence can include physical, sexual, emotional or psychological abuse. It is also referred to as domestic violence or intimate partner violence.

Family violence in Australia

- **Women in the general population** — The Australian Bureau of Statistics (ABS) estimates that 17% of all women aged 18 and over have experienced partner violence (from either a current or previous partner) since the age of 15 (ABS 2013). Among women who were pregnant at some time during a relationship and experienced violence with their most recent violent partner or their current partner, 54% and 22% respectively reported that they were pregnant at the time of the violence and 25% and 13% reported that violence occurred for the first time during pregnancy (ABS 2013).

- **Aboriginal and Torres Strait Islander women** — The full extent of violence against women in Aboriginal and Torres Strait Islander communities is difficult to determine due to under-reporting, lack of screening by service providers, incomplete identification of gender and Indigenous status in many datasets, and the lack of nationally comparable data on family violence available from police, courts, health or welfare sources (Olsen & Lovett 2016). Despite under-reporting, surveys show that Aboriginal and Torres Strait Islander women report higher levels of violence and suffer higher levels of injury and death as a result of family violence than non-Indigenous women (Olsen & Lovett 2016).

Risks associated with family violence in pregnancy

Women who experience family violence during pregnancy are at increased risk of miscarriage (Morland et al 2008), pre-term labour and birth (Shah et al 2010) and having low birthweight infants (El Kady et al 2005; Yost et al 2005; Silverman et al 2006; Shah et al 2010). Women physically assaulted during pregnancy also have higher risks of placental abruption, caesarean section, haemorrhage and infection than women without a history of being assaulted (El Kady et al 2005). In addition, family violence before pregnancy is a major independent risk factor for hypertension, oedema, vaginal bleeding, placental problems, severe nausea and vomiting, dehydration, diabetes, kidney infection and/or urinary tract infection, as well as premature rupture of membranes (Silverman et al 2006).

3.2.2 Assessing for family violence

Some Australian states and territories have policies in place to support routine (NSW, NT) or targeted (Victoria) screening for family violence. While most states/territories do not have a dedicated screening tool for family violence in pregnancy, these are in development (eg Queensland), a tool that is used in other settings is recommended for use (eg in WA) or there are other mechanisms that prompt questioning (eg hand-held pregnancy records in SA, public hospital computerised recording system in Tasmania) (AIHW 2015).

While the screening tools vary considerably between jurisdictions, there are some common questions in use across the tools. Questions used in at least four jurisdictions include (AIHW 2015):

- Within the last year, have you (ever) been hit, slapped or hurt in other ways by your partner or ex-partner? OR (In the last year,) has (your partner or) someone in your family or household ever pushed, hit, kicked, punched or otherwise hurt you?
- Are you (ever) afraid of your partner or ex-partner (or someone in your family)?
- (In the last year) has (your partner or) someone in your family or household ever (often) put you down, humiliated you or tried to control what you can or cannot do?
• (In the last year), has your partner or ex-partner (ever hurt or) threatened to hurt you (in any way)?
• Would you like help with any of this now?

A review of validated screening tools that have been tested within a health-care setting and used in a perinatal context (either in part or full) found that Hurt, Insult, Threaten, Scream (HITS) and Humiliation, Afraid, Rape, Kick (HARK) tools were both considered potentially useful to recommend for national use in the perinatal context (AIHW 2015). Both have been recommended for routine screening of women of childbearing age by the United States Preventative Services Task Force and cover a number of domains of family violence. Both can give health professionals a clear picture of whether a woman is experiencing family violence or not. These tools are described in more detail in Section 3.2.4.

Summary of the evidence

Effectiveness of screening

A Cochrane review (O’Doherty et al 2015) found that screening by health professionals increased identification of women experiencing family violence (OR 2.95, 95% CI 1.79 to 4.87, moderate quality evidence). Face-to-face screening was not clearly more effective than written/computer-based techniques (OR 1.12, 95% CI 0.53 to 2.36, moderate quality evidence).

Acceptability to women

Studies found that they were largely supportive of routine enquiry:
• being asked was considered acceptable (Roelens et al 2008; Roelens 2010; Spangaro et al 2011b; Lutgendorf et al 2012; Baird et al 2013; Stockl et al 2013; Salmon et al 2015)
• was considered an important domain of enquiry for health professionals (Rietveld et al 2010; Ben Natan et al 2011; Salmon et al 2015)
• women would be willing to disclose if asked (Decker et al 2013).

However, women may not always feel able to disclose immediately (Salmon et al 2015). Reasons for not disclosing include not considering the violence serious enough, fear of the offender finding out and not feeling comfortable with the health professional (Spangaro et al 2010). Beneficial encounters are characterised by familiarity with the health professional, acknowledgement of the violence, respect and relevant referrals (Liebschutz et al 2008) and direct asking and care (defined as showing interest and a non-judgemental attitude) (Spangaro et al 2016). Multiple assessments for family violence during pregnancy increase reporting (O’Reilly et al 2010).

As women should be assessed for family violence without the partner present, strategies need to be developed that are sensitive to involving the partner in the other areas of psychosocial assessment (Rollans et al 2016).

Recommendation

1. Explain to all women that asking about family violence is a routine part of antenatal care and enquire about each woman’s exposure to family violence.

Evidence reviewed 2016

Consensus-based recommendation

VI. Ask about family violence when alone with the woman, utilising the tool used in your state/territory, specific questions or a validated screening tool (eg HARK, HITS).

Acceptability to health professionals

While studies reported that many health professionals think that screening is important (DeBoer et al 2013), some are reluctant to ask women about family violence (Roelens 2010; Ben Natan et al 2011; Shamu et al 2013). Factors increasing a health professional’s likelihood of screening women for family violence included having previously screened women (Ben Natan et al 2011), having a therapeutic relationship with the woman (LoGiudice 2015), knowledge of a history of prior abuse (Lutgendorf et al 2010), recognising silent cues from women experiencing family violence (LoGiudice 2015), having scripted questions (Spangaro et al 2011a), interdisciplinary collaboration (Chang et al 2009; Kulkarni et al 2011; Mauri et al 2015) and access to resources (Chang et al 2009) and referral services (Spangaro et al 2011a).
**Barriers to screening**

The most commonly recognised barrier to screening was lack of training (Garcia & Fisher 2008; Chang et al 2009; Lazenbatt et al 2009; Lutgendorf et al 2010; Roelens 2010; Kulkarni et al 2011; Spangaro et al 2011a; DeBoer et al 2013; Shamu et al 2013; Salcedo-Barrientos et al 2014; Baird et al 2015; Infanti et al 2015; Mauri et al 2015). Other barriers identified included:

- variations in timing and the manner in which screening takes place (LoGiudice 2015)
- lack of peer support (Garcia & Fisher 2008), confidence (Lazenbatt et al 2009) or continuity of care (Lauti & Miller 2008)
- presence of the woman’s partner (LoGiudice 2015)
- women’s unwillingness to disclose (Mauri et al 2015)
- time constraints (Chang et al 2009; Lutgendorf et al 2010; Roelens 2010)
- cultural taboos (Mauri et al 2015)
- health professional attitudes to violence (Ben Natan et al 2011; Salcedo-Barrientos et al 2014)
- concerns about privacy and confidentiality (Lauti & Miller 2008)
- uncertainty regarding management and referral options (Lutgendorf et al 2010; LoGiudice 2015)
- the need for debriefing (Lauti & Miller 2008), guidelines and employer support (Finnbogadottir & Dykes 2012)

**Consensus-based recommendation**

VII. As training programs improve confidence and competency in identifying and caring for women experiencing family violence, undertake and encourage training of health professionals.

**Interventions**

There is insufficient evidence to assess the effectiveness of interventions for family violence on pregnancy outcomes (Jahanfar et al 2014). However, brief advocacy interventions may provide small short-term mental health benefits and reduce overall abuse (Rivas et al 2015). Home visits from nurses or community health workers may also reduce episodes of physical abuse (Prosman et al 2015; Sharps et al 2016). Women who are counselled about safety planning and given a referral card may be more likely to make plans to avoid abuse by adopting safety behaviours (Cripe et al 2010). In the context of antenatal care in Australia, referral to relevant support services (eg women’s refuges and resource centres) is an appropriate response to disclosure of family violence.

**Discussing and responding to family violence**

Discussion of family violence requires rapport between the health professional and the woman. Women experiencing abuse may not speak up when the subject is first raised but may choose to open up later when they feel sufficient trust and confidence in the health professional, possibly at a subsequent visit with the same person. It is important for health professionals to enquire about family violence in private and in a sensitive manner and provide a response that takes into account the complexity of women’s needs.

If a woman discloses that she is experiencing family violence, an immediate response is needed, with the woman’s safety a primary consideration.

**Table 3.2.1: Key considerations in discussing and responding to family violence**

<table>
<thead>
<tr>
<th>Consideration</th>
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<tbody>
<tr>
<td>Enquire about family violence when alone with the woman</td>
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<tr>
<td>Explain that the woman’s responses will be kept confidential</td>
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<tr>
<td>Actively listen to what the woman tells you</td>
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<tr>
<td>Do not blame or judge the woman or her partner</td>
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<tr>
<td>Inform the woman that she is not alone, there are other women experiencing family violence</td>
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<tr>
<td>Affirm that the woman has made an important step by discussing her experiences</td>
</tr>
<tr>
<td>Reinforce that family violence is against the law</td>
</tr>
<tr>
<td>Reinforce that the woman should not self-blame</td>
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</tbody>
</table>
- Affirm to the woman that the decision to discuss family violence is a major step to enhance her safety
- Assist the woman to assess her safety and that of children in her care
- Discuss options for safe temporary accommodation if needed and available (e.g., women’s refuge, safe house, family or friends, hospital)
- Encourage the woman to access specialist support services (e.g., women’s health centre, social worker, counsellor, mental health service)
- Inform the woman of her legal right to protection and provide information on legal support services
- Inform the woman that disclosure of family violence may require further discussion and possible reporting in relation to child protection issues
- Be aware of available security supports that can be used to protect the woman and yourself if needed
- Report any incidents of violence according to organisational policy and jurisdictional legislation

Sources: Adapted from (Eastern Perth Public and Community Health Unit 2001) and (NHMRC 2002).

Health professionals with limited experience in responding to family violence can enhance their practice by:
- seeking training and support (e.g., clinical supervision) where available (see Section 3.2.4)
- planning a response to disclosure of violence, including considerations of safety, confidentiality, sensitivity, and informed support
- being familiar with specialised counselling services, emergency housing agencies, and legal support services in the local area.

Practice point
C. Be aware of family and community structures and support and of community family violence services that can be called for urgent and ongoing support.

Considerations in Aboriginal and Torres Strait Islander communities
In Indigenous communities, violence against women is conceptualised within extended families and the wider community (Olsen & Lovett 2016). Family violence is understood to be the result of, and perpetuated by, a range of community and family factors, rather than one individual’s problematic behaviour within an intimate partnership.

No one causal factor can explain violence against Aboriginal and Torres Strait Islander women (Olsen & Lovett 2016). Instead, a number of interrelated factors have been identified, highlighting the complex and cumulative nature of violence and victimisation including colonisation and the breakdown of culture, intergenerational patterns of violence, alcohol and other drugs, and socioeconomic stressors (Olsen & Lovett 2016). These factors also influence responses to disclosure of family violence by Aboriginal and Torres Strait Islander women. Confidentiality and privacy are important considerations. Women should be asked about who they would like involved in their care and offered a clear choice about referral options, including both Aboriginal-specific services and mainstream services.

It is important to respect and understand that, despite the disproportionate burden of violence against Aboriginal and Torres Strait Islander women, violence is not normal or customary in these communities (Olsen & Lovett 2016). Indigenous Australians are diverse peoples who, while having a number of areas of commonality, differ in their languages, culture, and history. Not all Aboriginal and Torres Strait Islander women are subjected to violence, and not all communities have high rates of violence.

Practice point
D. Responses to assisting Aboriginal and Torres Strait Islander women who are experiencing family violence need to be appropriate to the woman and her community.

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The legislation around mandatory reporting to police and child protection in relation to disclosure of domestic violence varies across Australia and health professionals need to be aware of the relevant laws and their requirements in their jurisdiction.
Approaches to addressing factors underlying family violence in Aboriginal and Torres Strait Islander communities are beyond the scope of these Guidelines. Some relevant resources are identified in Section 3.2.4.

Conclusions among migrant and refugee women

Small studies have noted the need to focus on the individual woman beyond ethnicity and cultural differences (Byrskog et al 2015) and to consider different definitions of violence (Byrskog et al 2015), cultural factors influencing disclosure (Wellock 2010) and the need for involvement of independent interpreters (Wellock 2010).

Considerations in rural and remote areas

Assisting women experiencing family violence in rural and remote areas may be complex due to:

- limited resources to call on for advice or an immediate response
- limited specialised services to assist in the woman’s ongoing care
- difficulties ensuring confidentiality in smaller towns and communities
- difficulties when the health professional has a relationship with the woman (eg through family, kinship or friendship), particularly if mandatory reporting is required.

3.2.3 Practice summary — assessing for family violence

When — At the first and subsequent antenatal visits

Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker

☐ Discuss assessment for family violence — Explain that enquiry about family violence is a routine part of antenatal care and that it aims to identify women who would like assistance. Explain confidentiality and provide opportunities for the woman to discuss family violence in privacy (eg without her partner present).

☐ Take a holistic approach — If a woman affirms that she is experiencing family violence, other considerations include counselling and ongoing support. The safety of the woman and children in her care should be assessed and referral to other services (eg police, emergency housing, community services) made as required.

☐ Learn about locally available support services — Available support services for women who are experiencing family violence will vary by location.

☐ Document the discussion — Document in the medical record any evidence of injuries, treatment provided because of injuries, referrals made and any information the woman provides. If woman-held records are used, the information included in these should be limited and more detailed records kept at the health service.

☐ Seek support — Depending on your skills and experience in discussing family violence with women and assisting them if they are experiencing family violence, seek advice and support through training programs, clinical supervision, mentoring and/or helplines.

☐ Be aware of relevant legislation — Each state and territory has requirements about reporting violence as set out in its legislation.

3.2.4 Resources

Training

DV-Alert DV-alert offers nationally recognised training and non-accredited training across all states and territories in Australia. DV-alert is funded by the Department of Social Services and is free for front-line community and health workers.

Guidance


Assessment tools

**Humiliation, Afraid, Rape, Kick (HARK) Screen**

1. Within the last year, have you been humiliated or emotionally abused in other ways by your partner or ex-partner?
2. Within the last year, have you been afraid of your partner or ex-partner?
3. Within the last year, have you been raped or forced to have any kind of sexual activity by your partner or ex-partner?
4. Within the last year, have you been kicked, hit, slapped or otherwise physically hurt by your partner or ex-partner?

Response categories: Yes/no for all questions

**Scoring procedure:** If any questions on the screen are answered affirmatively, the HARK is considered positive for abuse.

**Hurt, Insult, Threaten, Scream (HITS) Screen**

1. How often does your partner physically hurt you?
2. How often does your partner insult you or talk down to you?
3. How often does your partner threaten you with harm?
4. How often does your partner scream or curse at you?

Response categories: Each question is answered on a 5-point scale:
- 1 = never
- 2 = rarely
- 3 = sometimes
- 4 = fairly often
- 5 = frequently

**Scoring procedure:** Responses are summed to form a total HITS score which can range from 4 to 20. For female patients, a HITS cut-off score of 10 or greater can be used to classify participants as victimised.

Indigenous communities


References


3.3  Fetal growth restriction and well-being

Antenatal visits provide an opportunity to assess fetal growth, auscultate the fetal heart (although this cannot predict pregnancy outcomes) and encourage women to be aware of the normal pattern of fetal movements for their baby.

3.3.1 Fetal growth restriction

Monitoring growth aims to identify small-for-gestational age babies, who are at increased risk of associated morbidity and mortality.

Perinatal deaths associated with small-for-gestational age in Australia

In Australia in 2014, intrauterine growth restriction was the cause of 5.4% of perinatal deaths among singleton babies (AIHW 2016). Perinatal deaths associated with intrauterine growth restriction among singleton babies were most common at 28–31 weeks gestation (13.2%).

Risk factors for small-for-gestational age

Significant risk factors for having a small-for-gestational age fetus or newborn include (RCOG 2014):

- maternal diabetes with vascular disease ([OR 6.0, 95%CI 1.5 to 2.3]), renal impairment (aOR 5.3, 95%CI 2.8 to 10) chronic hypertension ([ARR 2.5, 95%CI 2.1 to 2.9]) or antiphospholipid syndrome ([RR 6.22, 95%CI 2.43 to 16.0]).
- having a previous small-for-gestational age baby ([OR 3.9, 95%CI 2.14 to 7.12]) or stillbirth ([OR 6.4, 95%CI 0.78 to 52.56])
- daily exercise leading to being very out of breath ([aOR 3.3, 95%CI 1.5 to 7.2])
- maternal age >40 years ([OR 3.2, 95%CI 1.9 to 5.4])
- using cocaine in pregnancy ([OR 3.23, 95%CI 2.43 to 4.3])
- smoking 11 or more cigarettes a day in pregnancy ([OR 2.21, 95%CI 2.03 to 2.4]).

Maternal ([OR 2.64, 95%CI 2.28 to 3.05]) or paternal ([OR 3.47, 95%CI 1.17 to 10.27]) history of being a small-for-gestational age baby is also a significant risk factor but may not be ascertainable.

Other risk factors include nulliparity, low fruit intake pre-pregnancy, in vitro fertilisation (IVF) singleton pregnancy, smoking up to 10 cigarettes a day, history of pre-eclampsia, pregnancy interval of <6 months or ≥60 months and BMI ≥30 (RCOG 2014).

Practice point

E. Early in pregnancy, assess women for risk factors for having a small-for-gestational-age fetus/newborn.

Consensus-based recommendations

VIII. When women are identified as being at risk of having a small-for-gestational-age fetus or newborn, provide advice about modifiable risk factors.

IX. Consider referring women who have a significant risk factor for having a small-for-gestational-age fetus/newborn for serial ultrasound measurement of fetal size and assessment of wellbeing with umbilical artery Doppler from 26–28 weeks of pregnancy.

Practice point

F. Consider referring women who have three or more minor risk factors for having a small-for-gestational age fetus/newborn for uterine artery Doppler at 20–24 weeks of pregnancy.
Summary of the evidence

Abdominal palpation
Low-level evidence from cohort and case-control studies performed in low-risk populations has consistently shown abdominal palpation to be of limited accuracy in the detection of a small-for-gestational age newborn (sensitivity 19–21%, specificity 98%) and severely small-for-gestational age newborn (<2.3rd centile, sensitivity 28%) (Kean & Liu 1996; Bais et al 2004). In mixed-risk populations, the sensitivity increases to 32–44% (Hall et al 1980; Rosenberg et al 1982). In high-risk populations sensitivity is reported as 37% for a small-for-gestational age newborn and 53% for severely small-for-gestational age newborn (Bais et al 2004) (low quality evidence).

Consensus-based recommendation
X. Do not assess fetal growth based solely on abdominal palpation.

Measurement of symphysis-fundal height
A systematic review highlighted the wide variation of predictive accuracy of symphysis-fundal height measurement for a small-for-gestational age newborn (Morse et al 2009). Although early studies reported sensitivities of 56–86% and specificities of 80–93% for symphysis-fundal height detection of small-for-gestational age (Belizan et al 1978; Cnattingius et al 1984; Mathai et al 1987), a large study (n= 2,941) reported symphysis-fundal height to be less predictive with a sensitivity of 27% and specificity of 88% (LR+ 2.22, 95% CI 1.77 to 2.78; LR− 0.83, 95% CI 0.77 to 0.90) (Persson et al 1986). Maternal obesity, abnormal fetal lie, large fibroids, polyhydramnios and fetal head engagement contribute to the limited predictive accuracy of symphysis-fundal height measurement. Symphysis-fundal height is associated with significant intra- and inter-observer variation (Bailey et al 1989; Morse et al 2009) and serial measurement may improve predictive accuracy (Pearce & Campbell 1987).

The impact on perinatal outcome of measuring symphysis-fundal height is uncertain. A systematic review found only one trial (n=1,639), which showed that symphysis-fundal height measurement did not improve any of the perinatal outcomes measured (Nelson 2000).

Consensus-based recommendation
XI. At each antenatal visit from 24 weeks, measure symphysis-fundal height.

Customised charts
A customised symphysis-fundal height chart is adjusted for maternal characteristics (maternal height, weight, parity and ethnic group). No trials were identified that compared customised with non-customised symphysis-fundal height charts and thus evidence for their effectiveness on outcomes such as perinatal morbidity/mortality is lacking (RCOG 2014).

However observational studies suggest that customised symphysis-fundal height charts may improve the detection of a small-for-gestational age newborn. In one study, use of customised charts, with referral when a single symphysis-fundal height measurement fell below the 10th centile or the last two measurements were above 10th centile but the slope was flatter than the 10th centile line, resulted in improved sensitivity for a small-for-gestational age newborn (48% vs 29%, OR 2.2, 95% CI 1.1 to 4.5) compared to abdominal palpation (Gardosi & Francis 1999). Use of customised charts was also associated with fewer referrals for investigation and fewer admissions. An audit study also showed that use of customised symphysis-fundal height charts detected 36% of small-for-gestational age newborns compared with only 16% when customised charts were not used (Wright et al 2006).

Practice points
G. If plotting symphysis-fundal height, use a customised chart rather than a population-based chart.
H. Women with a single symphysis fundal height which plots below the 10th centile or serial measurements that demonstrate slow or static growth by crossing centiles should be referred for ultrasound measurement of fetal size.
I. Women in whom measurement of symphysis fundal height is inaccurate (for example: BMI >35, large fibroids, polyhydramnios) should be referred for serial assessment of fetal size using ultrasound.
3.3.2 Fetal movements

Fetal movement assessment is widely used to monitor fetal wellbeing (Froen et al 2008a; O’Sullivan et al 2009) and is most commonly undertaken through subjective maternal perception. Fetal movement counting is a more formal method to quantify fetal movements (Mangesi & Hofmeyr 2007). Maternal perception rather than formal fetal movement counting is recommended in Australia (Gardener et al 2016) and in the United Kingdom (NICE 2008b; RCOG 2011). Maternal reporting of decreased fetal movement occurs in 5–15% of pregnancies in the third trimester (Froen 2004a; Heazell et al 2008; Flenady et al 2009).

Risks associated with decreased fetal movement

Stillbirth, which affects over 2,700 families in Australia and New Zealand (Hilder et al 2014), is often preceded by maternal perception of decreased fetal movement (Froen 2004b; Erlandsson et al 2012). Decreased fetal movement is also strongly linked to other adverse perinatal outcomes such as neurodevelopmental disability, infection, feto-maternal haemorrhage, umbilical cord complications, low birth weight and fetal growth restriction (Froen 2008b; Heazell & Froen 2008). Decreased fetal movements for some women may be associated with placental dysfunction or insufficiency, which could lead to fetal growth restriction and/or stillbirth (Warrander et al 2012).

Summary of the evidence

Information on fetal movements

Antenatal education about fetal movement has been shown to reduce the time from maternal perception of decreased fetal movements to health-seeking behaviour (Tveit et al 2009). A reduction in stillbirth rates has been associated with increased awareness of decreased fetal movements among women and health professionals in both the overall study population (OR 0.67, 95% CI: 0.49-0.94) and in women with decreased fetal movements (aOR 0.51, 95% CI: 0.32 to 0.81) (Tveit et al 2009; Saastad et al 2010). However, many women do not receive adequate information about fetal movements (Saastad et al 2008; Peat et al 2012). A recent study found that more than one-third of women at 34 weeks gestation or later did not recall receiving information from their healthcare professional about fetal movement (McArdle et al 2015). Another study found that information provided by midwives was not always consistent with evidence-based guidelines (Warland & Glover 2017). Pregnant women preferred to be given as much information as possible about fetal movements and cited health professionals as a trustworthy source (McArdle et al 2015).

Consensus-based recommendations

XII. Routinely provide women with verbal and written information about normal fetal movements.

XIII. Advise women to contact their health professional if they have any concern about decreased or absent fetal movements and not to wait until the next day to report decreased fetal movements.

Practice point

J. Emphasise the importance of maternal awareness of fetal movements at every antenatal visit.

Monitoring fetal movements

A Cochrane review assessed the effect of formal fetal movement counting and recording on perinatal death, major morbidity, maternal anxiety and satisfaction, pregnancy intervention and other adverse pregnancy outcomes (5 RCTS; n=71,458) (Mangesi et al 2015). The review did not find sufficient evidence to inform practice. In particular, no trials compared fetal movement counting with no fetal movement counting. Only two studies compared routine fetal movements with standard antenatal care. Indirect evidence from a large cluster-RCT (Grant et al 1989) suggested that more babies at risk of death were identified in the routine fetal monitoring group but this did not translate to reduced perinatal mortality.
**Consensus-based recommendations**

XIV. Advise women to monitor fetal movements but do not advise formal fetal movement counting as part of routine antenatal care.

XV. Advise a woman who is unsure whether fetal movements are decreased to count while lying down on her side and to contact her health care professional if there are less than 10 movements in 2 hours.

**Practice point**

K. Maternal concern about decreased fetal movements overrides any definition of decreased fetal movements based on counting and women with a concern about decreased fetal movements should be encouraged to contact their health professional.

**Discussing fetal movement**

Information given to women should include that:

- most women are aware of fetal movements by 20 weeks of gestation, and although fetal movements tend to plateau at 32 weeks of gestation, there is generally no reduction in the frequency of fetal movements in the late third trimester
- patterns of movement change as the baby develops, and wake/sleep cycles and other factors (eg maternal weight and position of the placenta) may modify the mother’s perception of movements
- most women (approximately 70%) who perceive a single episode of decreased fetal movements will have a normal outcome to their pregnancy (RCOG 2011)
- if a woman does report decreased fetal movement, a range of tests can be undertaken to assess the baby’s wellbeing.

**3.3.3 Fetal heart rate assessment**

Auscultation of the fetal heart has traditionally formed an integral part of a standard antenatal assessment.

**Summary of the evidence**

**Auscultation**

Routine auscultation of the fetal heart rate is not recommended in the United Kingdom (NICE 2008a). Although successful detection of a fetal heart confirms that the baby is alive, it does not guarantee that the pregnancy will continue without complications (Rowland et al 2011) and is unlikely to provide detailed information on the fetal heart rate such as decelerations or variability (NICE 2008a).

The sensitivity of Doppler auscultation in detecting the fetal heart is 80% at 12+1 weeks gestation and 90% after 13 weeks (Rowland et al 2011). Attempts to auscultate the fetal heart before this time may be unsuccessful, and lead to maternal anxiety and additional investigations (eg ultrasound) in pregnancies that are actually uncomplicated (Rowland et al 2011). It is unlikely that a fetal heart rate will be audible before 28 weeks if a Pinard stethoscope is used (Wickham 2002)

Although there is no evidence on the psychological benefits of auscultation for the mother, it may be enjoyable, reduce anxiety and increase mother-baby attachment.

**Consensus-based recommendation**

XVI. If auscultation of the fetal heart rate is performed, a Doppler may be used from 12 weeks and a Pinard stethoscope from 28 weeks.

**Cardiotocography**

Electronic fetal heart rate monitoring is not recommended as a routine part of antenatal care in the United Kingdom (NICE 2008a) or Canada (Liston et al 2007).

A Cochrane review found no evidence to support the use of cardiotocography in women at low risk of complications (Grivell et al 2010).
Anxiety levels in women who undergo routine cardiotocography are increased. This reaction seems to be influenced by the perception of fetal movement during the examination and is more evident in women whose pregnancies are affected by obstetric complications (Mancuso et al 2008).

**Consensus-based recommendation**

XVII. Do not routinely use electronic fetal heart rate monitoring (cardiotocography) for fetal assessment in women with an uncomplicated pregnancy.

### 3.3.4 Practice summary: Fetal growth restriction and wellbeing

**Fetal growth restriction**

**When:** At all antenatal visits.

**Who:** Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander Health Practitioner; Aboriginal and Torres Strait Islander Health Worker; multicultural health worker.

- **Discuss fetal growth:** Early in pregnancy, give all women appropriate written information about the measurement of fetal growth and an opportunity to discuss the procedure with a health professional.

- **Take a consistent approach to assessment:** When measuring symphysis-fundal height, start measuring at the variable point (the fundus) and continue to the fixed point (the symphysis pubis) using a non-elastic tape measure with the numbers facing downwards so that an objective measurement is taken. Document measurements in a consistent manner, using a customised fetal growth chart.

- **Take a holistic approach:** Abdominal palpation provides a point of engagement between the health professional and mother and baby.

**Fetal movements**

**When:** At antenatal visits from 20 weeks.

**Who:** Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander Health Practitioner; Aboriginal and Torres Strait Islander Health Worker; multicultural health worker.

- **Discuss fetal movement patterns:** Emphasise the importance of the woman’s awareness of the pattern of movement for her baby and factors that might affect her perception of the movements.

- **Advise early reporting:** Women should report perceived decreased fetal movement on the same day rather than wait until the next day.

- **Take a holistic approach:** Support information given with appropriate resources (eg written materials suitable to the woman’s level of literacy, audio or video) and details of whom the woman should contact if decreased fetal movements are perceived.

**Fetal heart rate**

**When:** At antenatal visits between 12 and 26 weeks gestation.

**Who:** Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander Health Practitioner; Aboriginal and Torres Strait Islander Health Worker; multicultural health worker.

- **Discuss fetal heart rate:** Explain that listening to the fetal heart does not generally provide any information about the health of the baby and that other tests (such as ultrasound) are relied upon for identification of any problems with the pregnancy.

- **Take a holistic approach:** Some women may be reassured by hearing the fetal heart beat.
3.3.5 Resources

**Fetal growth**


**Fetal movements**


3.3.6 References


3.4 Risk of pre-eclampsia

Identifying women with risk factors for or clinical signs of pre-eclampsia allows timely provision of advice on prevention and symptoms that may indicate a need for additional care. Antenatal care also provides an opportunity to discuss long-term preventive strategies with women who develop pre-eclampsia.

3.4.1 Background

Hypertensive disorders in pregnancy

Hypertensive disorders during pregnancy include (Lowe et al 2015):

- **chronic hypertension** — blood pressure ≥140 mmHg systolic and/or ≥90 mm diastolic confirmed before pregnancy or before 20 completed weeks pregnancy, without a known cause (essential hypertension), associated with a secondary cause such as existing kidney disease (secondary hypertension) or associated with measurement in a healthcare setting (white coat hypertension)

- **gestational hypertension** — new onset hypertension (defined as a blood pressure ≥140 mmHg systolic and/or ≥90 mm diastolic) after 20 weeks pregnancy without any maternal or fetal features of pre-eclampsia, followed by return of blood pressure to normal within 3 months after the birth

- **pre-eclampsia** — a multi-system disorder characterised by hypertension and involvement of one or more other organ systems and/or the fetus, with raised blood pressure after 20 weeks pregnancy commonly the first manifestation and proteinuria a common additional feature (although not required to make a clinical diagnosis)

- **superimposed pre-eclampsia** — development of one or more of the systemic features of pre-eclampsia after 20 weeks pregnancy in a woman with chronic hypertension.

Features of pre-eclampsia

In pre-eclampsia, hypertension is accompanied by one or more of the following features (Lowe et al 2015):

- impaired kidney or liver function

- haematological involvement

- neurological symptoms (persistent headache, visual disturbances, stroke, convulsions)

- pulmonary oedema

- fetal growth restriction and/or

- placental abruption.

Pre-eclampsia is a progressive disorder that worsens if pregnancy continues (Lowe et al 2015). Birth of the baby is the definitive treatment and is followed by resolution, generally over a few days but sometimes much longer (Lowe et al 2015). Decisions about management (eg induction/caesarean section or continuation of the pregnancy) are based on maternal and fetal factors (eg gestational age).

Prevalence of pre-eclampsia

Australian studies in a range of settings estimated the incidence of any pre-eclampsia as 3.0–3.3% (Thornton et al 2013; Thornton et al 2016), early onset (<34 weeks) pre-eclampsia as 0.4% (Park et al 2013; Park et al 2015) and late-onset (≥34 weeks) pre-eclampsia as 2.4% (Park et al 2013). Studies were consistent in noting a decrease in prevalence and incidence of pre-eclampsia in Western Australia (Hammond et al 2013; Diouf et al 2016) and New South Wales (Thornton et al 2013; Roberts et al 2015) (no studies from the other states and territories were identified).

The prevalence of pre-eclampsia among specific population groups was influenced by:

- **mental health** — a diagnosis of schizophrenia or bipolar disorder conferred a five-fold increased likelihood of having pre-eclampsia [OR 5.28; 95%CI 2.79 to 9.98; p<0.001] (Judd et al 2014) in one study and a three-fold increase in another (9% v 3%; P < 0.0001) (Nguyen et al 2012)

- **body mass index** — prevalence was increased among women with BMI >25 [OR 1.97; 95%CI 0.93 to 4.16] (Vanderlelie et al 2016), BMI >30 [OR 2.86; 95%CI 2.54 to 3.22; p=0.001] (Davies-Tuck et al 2016), BMI 30–34.9 [OR 2.01; 95%CI 1.48 to 2.73; p<0.001], BMI 35–39.9 [OR 2.41; 95%CI 1.68 to 3.47; p<0.001], BMI 40–44.9 [OR 3.32; 95%CI 2.18 to 5.08; p<0.001], BMI ≥45 [OR 3.98; 95%CI 2.56 to 6.19; p<0.001] (Magann et al 2013) or BMI >50 (AOR 3.43; 95%CI 1.72 to 6.84) (Sullivan et al 2015)
• country of birth — compared with women born in Australia prevalence was lower among women from Western Europe (OR 0.91; 95%CI 0.85 to 0.97), Eastern Europe (OR 0.79; 95%CI 0.67 to 0.94), South Asia (OR 0.58; 95%CI 0.55 to 0.62), East-Southeast Asia (OR 0.64; 95%CI 0.58 to 0.71), North Africa and Middle East (OR 0.69; 95%CI 0.63 to 0.77) and similar among those from Sub-Saharan Africa (OR 0.95; 95%CI 0.85 to 1.07) and Latin America and the Caribbean (OR 1.06; 95%CI 0.90 to 1.26) [Urquia et al 2014].

Prevalence did not appear to be influenced by:
• maternal age > 45 years — there was no significant difference in prevalence between women aged >45 years and <45 years though some suggestion of increase with age (OR 1.86; 95% CI 3.6; p=0.052) [Carolan et al 2013]

• refugee background — there was no clear difference in prevalence between refugee background and migration for non-humanitarian reasons among women from North Africa (age-adjusted OR 1.4: 95%CI 0.4 to 4.6; p=0.79), Middle and East Africa (crude OR 1.1; 95%CI 0.2 to 4.9; p=0.71) and West Africa (4.9% vs 0%) [Gibson-Helm et al 2014]

• conception by assisted reproductive technology — after stratification by plurality, the difference in gestational hypertension/pre-eclampsia rates between ART and non-ART mothers was not statistically significant, with AOR 1.05 (95% CI, 0.98-1.12) for mothers of singletons [Wang et al 2016]

• vaginal bleeding in pregnancy — prevalence of pre-eclampsia was not associated with the presence or absence of bleeding (aOR 0.96; 95% CI 0.67 to 1.38) [Smits et al 2012].

**Risks associated with pre-eclampsia**

• Significant pre-eclampsia is associated with serious maternal morbidity and, very rarely, with death. There were nine maternal deaths related to hypertensive disorders of pregnancy between 2008 and 2012 in Australia (Humphrey et al 2015), all of which were due to pre-eclampsia and its complications.

• Women with complicated pre-eclampsia are more likely to have a caesarean section, stillbirth or neonatal death (Bhattacharya & Campbell 2005). In 2012, hypertension or pre-eclampsia were the reasons for 9.0–13.2% of labour inductions in New South Wales, Queensland, South Australia, Tasmania and the Northern Territory and 1.3–2.4% of caesarean sections in Queensland, South Australia, Tasmania and the Northern Territory. Data collection methods varied and, for other states and territories, were unavailable or unpublished [Hilder et al 2014].

• Neonatal complications associated with pre-eclampsia in a large cross-sectional study (n=647,392) (Schneider et al 2011) were small for gestational age, low Apgar scores, acute respiratory distress syndrome and postpartum neonatal hypoglycaemia.

• Women who have had pre-eclampsia are at increased long-term risk of chronic hypertension, ischaemic heart disease, cerebrovascular disease, kidney disease, diabetes mellitus, thromboembolism, hypothyroidism and impaired memory [Williams 2012].

3.4.2 Assessing risk of pre-eclampsia

**Summary of the evidence**

Whether a woman will require additional care (eg more frequent antenatal visits) is based on the presence of risk factors for and clinical features of pre-eclampsia.

**Identifying women with risk factors for pre-eclampsia**

Factors with an established association with a high risk of pre-eclampsia include (Bartsch et al 2016):
• a history of pre-eclampsia (RR 8.4; 95%CI 7.1 to 9.9)
• chronic hypertension (RR 5.1; 95% CI 4.0 to 6.5)
• pre-existing diabetes (RR 3.7; 95%CI 3.1 to 4.3)
• autoimmune disease such as systemic lupus erythematosus (RR 2.5; 95%CI 1.0 to 6.3) or antiphospholipid syndrome (RR 2.8; 95%CI 1.8 to 4.3)
• pre-existing kidney disease (RR 1.8; 95%CI 1.5 to 2.1).

Other factors that are associated with increased risk of pre-eclampsia are maternal family history of pre-eclampsia (eg among mother and sisters) (115% increase in risk) [Boyd et al 2013] and increasing maternal
glucose levels ([aOR for 1 SD increase 1.19; 95% CI 1.11 to 1.28 for 1-hour plasma glucose; 1.21; 95% CI 1.13 to 1.30 for 2-hour plasma glucose]) [HAPO Study Cooperative Research Group 2010].

**Recommendation**

2. Early in pregnancy, assess all women for risk of pre-eclampsia.

*Evidence reviewed 2017*

Findings from systematic reviews provided information on associations with additional factors:

- **cardiovascular factors** — women with pre-eclampsia had higher levels of total cholesterol ([MD 20.20 mg/dL; 95% CI 8.70 to 31.70; p=0.001]), non-HDL-C ([MD 29.59 mg/dL; 95% CI 12.13 to 47.06; p=0.001]) and triglycerides ([MD 80.29 mg/dL; 95% CI 51.45 to 109.13; p<0.0001]) in the third trimester ([Gallos et al 2013; Spracklen et al 2014]). Lower levels of HDL-C in the third trimester ([MD –8.86 mg/dL; 95% CI –11.50 to –6.21; p<0.0001]) ([Spracklen et al 2014]) and were more likely to have arterial stiffness ([SMD 1.62; 95% CI 0.73 to 2.50]) ([Hausvater et al 2012]) than women without pre-eclampsia.

- **body mass index** — there was a clear association between overweight ([aOR 1.70; 95% CI 1.60 to 1.81, P<0.001]), obesity ([aOR 2.93; 95% CI 2.58 to 3.33, P<0.001]) and severe obesity ([aOR 4.14; 95% CI 3.61 to 4.75, P<0.001]) and risk of pre-eclampsia ([Wang et al 2013]).

- **mental health** — there were significant associations between mental stress ([OR 1.49; 95% CI 1.27 to 1.74; P<0.001]), work stress ([OR 1.50; 95% CI 1.15 to 1.97; P=0.003]), anxiety or depression ([OR 1.88; 95% CI 1.08 to 3.25; P=0.02]) ([Zhang et al 2013]) and depression alone ([OR 1.63; 95% CI 1.32 to 2.02]) and pre-eclampsia ([Hu et al 2015]).

- **blood group** — AB versus non-AB blood group increased risk in women overall ([OR 2.42; 95% CI 1.63 to 3.58]) and in primigravid women ([OR 2.44; 95% CI 1.46 to 4.07]) ([Alpoim et al 2013]).

- **assisted reproductive technology** — in contrast to the findings on prevalence above, systematic reviews suggested that risk was increased in women receiving donor oocytes ([OR 4.34; 95% CI 3.10 to 6.06; P<0.0001]) ([Blázquez et al 2016; Masoudian et al 2016]) or donor sperm ([OR 1.63; 95% CI 1.36 to 1.95]) ([Gonzalez-Comadran et al 2014]).

- **immunological factors** — interferon-gamma levels were higher in women with pre-eclampsia than in controls ([SMD 0.93; 95% CI 0.07 to 1.79]) ([Yang et al 2014]).

- **micronutrient levels** — levels of vitamin C and E were lower in women with pre-eclampsia than in controls but not when levels in mild and severe subtypes were analysed ([Cohen et al 2015]). Risk was lower among women with vitamin D level >50 nmol/L vs <50 nmol/L ([OR 0.58; 95% CI 0.32 to 1.07]) ([Hypponen et al 2013]) and levels of copper were higher ([Fan et al 2016]) and levels of zinc ([SMD –0.587; 95% CI –0.963 to –0.212]) ([Ma et al 2015]) and selenium ([MD –6.47 mug/L; 95% CI –11.24 to –1.7; p = 0.008]) ([Xu et al 2016]) lower among women with pre-eclampsia than among controls.

- **gynaecological and obstetric factors** — there was no significant association between risk of pre-eclampsia and fetal sex ([RR 1.01; 95% CI 0.97 to 1.05]) ([Jaskolka et al 2016]) or interpregnancy interval 2–4 vs <2 years ([aOR 1.01; 95% CI 0.95 to 1.07]) or 2–4 vs >2 years ([aOR 1.10; 95% CI 1.02 to 1.19]) ([Cormick et al 2016]) but a higher risk following chorionic villus sampling compared to amniocentesis ([OR 2.47; 95% CI 1.14 to 5.33]) ([Basaran et al 2016]).

- **periodontal disease** — while reviews of observational studies showed an effect on risk ([Golastra et al 2013; Wei et al 2013; Huang et al 2014]), a review of RCTs found no significant effect ([OR 1.00; 95% CI 0.78 to 1.28]) ([Kunnen et al 2010]).

Smoking ([RR 0.67; 95% CI 0.60 to 0.75]) ([Wei et al 2015]) and exposure to environmental carbon monoxide ([aOR 0.63; 95% CI 0.55 to 0.71]) ([Zhai et al 2012]) appeared to reduce risk of pre-eclampsia but are associated with other negative health effects. There was insufficient evidence to assess the relationship between pre-eclampsia and shift work ([Palmer et al 2013]).
Preventive measures

Preventive treatment with low-dose aspirin in women at high risk and calcium supplementation in women with low dietary intake is recommended in the United Kingdom (NICE updated 2011), Canada (SOGC 2014) and Australia (Lowe et al 2015) and by the WHO (WHO 2011).

Calcium

There is strong evidence that calcium supplementation is of benefit for women at risk of pre-eclampsia if dietary intake is low (Patrelli et al 2012; Hofmeyr et al 2014). The WHO defines low dietary intake as <900 mg per day and the Australian and New Zealand Nutrient Reference Values recommend an intake of 1,000 mg per day in pregnant women, 1,300 mg if they are younger than 18 years (NHMRC 2005). In Australia, calcium intake is low in relation to recommendations for some girls and women of reproductive age (NHMRC 2011). The sources and recommended number of serves of calcium-rich foods during pregnancy are discussed in the section on nutrition in the full Guidelines.

Recommendation

3. Advise women at high risk of developing pre-eclampsia that calcium supplementation is beneficial if dietary intake is low.

Evidence reviewed 2014

Practice point

1. If a woman has a low dietary calcium intake, advise her to increase her intake of calcium-rich foods.

Effectiveness of aspirin in preventing pre-eclampsia

Systematic reviews and meta-analyses have found that:

- low-dose aspirin has moderate benefits when used for prevention of pre-eclampsia (RR 0.78; 95% CI: 0.67 to 0.90) (Duley et al 2010);
- there was a reduction in risk among women at risk (i.e. with previous pre-eclampsia) (RR 0.79; 95% CI: 0.65 to 0.97) but not those with low risk (Trivedi 2011);
- the effect was only significant for preterm pre-eclampsia (RR 0.11 95% CI: 0.04 to 0.33) (Roberge et al 2012).

Recommendation

4. Advise women at moderate–high risk of pre-eclampsia that low-dose aspirin from early pregnancy may be of benefit in its prevention.

Evidence reviewed 2013

Vitamins

There is insufficient evidence that the risk of pre-eclampsia is reduced by supplementing vitamin B2 (Neugebauer et al 2006) or vitamins C and E (Sales et al 2012). A meta-analysis found associations between supplementation with vitamins C (1,000 mg) and E (400 IU) in women at risk of pre-eclampsia and some adverse effects — gestational hypertension (RR 1.11; 95% CI 1.05 to 1.17) and premature rupture of the membranes (RR 1.73; 95% CI 1.34 to 2.23) (Conde-Agudelo et al 2011).

Recommendation

5. Advise women that vitamins C and E are not of benefit in preventing pre-eclampsia.

Evidence reviewed 2013

Physical activity

Systematic reviews found a trend towards a protective effect from leisure time or recreational physical activity during pregnancy in case-control studies (RR 0.65, 95% CI 0.47 to 0.89 or OR 0.77, 0.64 to 0.91, p < 0.01) (Kasawara et al 2012; Aune et al 2014) but not in cohort studies (OR 0.99, 0.93 to 1.05, p= 0.81) (Kasawara et al 2012). Physical activity during pregnancy has general health benefits (see section on physical activity in the full Guidelines).

Salt intake

Reducing salt intake is unlikely to reduce the risk of pre-eclampsia (Duley 2011). However, avoiding foods with added salt has other health benefits (NHMRC 2013).
Identifying women with clinical signs of pre-eclampsia

Routine measurement of blood pressure and testing for proteinuria at each antenatal visit are recommended in the United Kingdom (NICE updated 2016). However, routine testing for proteinuria is not recommended internationally (Tranquilli et al 2014), in the United States (ACOG 2013) or Australia (Lowe et al 2015; RANZCOG 2015).

- **Hypertension**: Women with new onset hypertension (defined as a blood pressure ≥140 mmHg systolic and/or ≥90 mmHg diastolic) that occurs after 20 weeks pregnancy should be assessed for signs and symptoms of pre-eclampsia (Lowe et al 2015).

- **Proteinuria**: Routine testing for proteinuria is not helpful in predicting pre-eclampsia and should be confined to women with increased blood pressure or sudden weight gain. Proteinuria should not be considered mandatory in making a diagnosis of pre-eclampsia (Lowe et al 2015).

Measurement of blood pressure and testing for proteinuria is discussed in the full version of the Guidelines.

### Consensus-based recommendations

| XVIII. Routinely measure blood pressure to identify new onset hypertension. |
| XIX. Recommend testing for proteinuria at each antenatal visit if a woman has risk factors for or clinical indications of pre-eclampsia, in particular, raised blood pressure. |

Where possible, women with clinical signs of pre-eclampsia (hypertension, proteinuria, fetal growth restriction) should be referred for specialist assessment and management. Section 3.4.5 includes resources on the management of hypertensive disorders in pregnancy.

### Predicting pre-eclampsia

A range of measures has been used to further predict risk of pre-eclampsia, including biophysical (eg mean arterial pressure, uterine artery pulsatility) and biochemical (eg pregnancy-associated placent protein-A [PAPP-A], free beta-human chorionic gonadotrophin [β-hCG], placental growth hormone [PIGF] and soluble fms-like tyrosine kinase-1 [sFlt-1]:PIGF ratio) markers, both individually and in combination with maternal characteristics.

While it is clear that maternal characteristics combined with biochemical and biophysical markers are more sensitive in predicting pre-eclampsia than maternal characteristics alone, there is currently insufficient evidence to support a recommendation on any particular approach. Existing algorithms are more effective in predicting early onset pre-eclampsia (which has very low prevalence), have low sensitivity in predicting late onset pre-eclampsia and have a false positive rate of 5–10%. A systematic review noted that the reliability and validity of models may be limited by methodological deficiencies (Brunelli & Prefumo 2015) and an external validation study found lower performance than was reported (Oliveira et al 2014). An analysis of the cost-effectiveness of screening for and diagnosing pre-eclampsia found that routine use of biomarkers will be feasible only when accuracy is significantly increased (Zakiyah et al 2015).

### 3.4.3 Discussing risk of pre-eclampsia

It is important that women are given information about the symptoms of pre-eclampsia from early pregnancy.

### Practice point

M. Women should be given information about the urgency of seeking advice from a health professional if they experience: headache, visual disturbance, such as blurring or flashing before the eyes, epigastric pain (just below the ribs), vomiting and/or rapid swelling of the face, hands or feet.
3.4.4 Practice summary: pre-eclampsia

<table>
<thead>
<tr>
<th>When: Early in pregnancy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Who:</strong> Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander Health Practitioner; Aboriginal and Torres Strait Islander Health Worker; multicultural health worker.</td>
</tr>
</tbody>
</table>

- **Discuss risk factors for pre-eclampsia early in pregnancy:** Explain that the likelihood of pre-eclampsia is increased if a woman has certain risk factors.

- **Discuss pre-eclampsia screening:** Explain that if a woman has high blood pressure and/or proteinuria, she will require additional care during the rest of her pregnancy.

- **Discuss symptoms of pre-eclampsia with women at high risk:** Explain the importance of seeking medical advice immediately if symptoms occur.

- **Take a holistic approach:** Ask women at risk of pre-eclampsia about how many serves of calcium-rich foods they eat each day (see section on Nutritional Supplements in full Guidelines). Discuss low cost and culturally appropriate strategies for increasing calcium intake. Advise women who develop pre-eclampsia of the increased risk of developing hypertension and the need for ongoing surveillance.

- **Document and follow-up:** Note risk factors and the results of blood pressure measurement and proteinuria testing in the woman’s antenatal record. Further investigations may be warranted if increases in blood pressure or new proteinuria are identified at subsequent visits.

3.4.5 Resources


RANZCOG (2015) Screening in Early Pregnancy for Adverse Perinatal Outcomes. Melbourne: Royal Australian and New Zealand College of Obstetricians and Gynaecologists. Available at:


3.4.6 References


3.5 Risk of preterm birth

While there are many known and unknown causes of preterm birth, women identified as being at risk may benefit from advice about risk and protective factors.

3.5.1 Background

Preterm birth is defined as birth before 37 completed weeks of pregnancy (WHO 2012). Sub-categories of preterm birth are based on weeks of gestational age: early preterm (<34 weeks), very preterm (28 to <32 weeks) and extremely preterm (<28 weeks). This section is concerned with spontaneous preterm birth as opposed to planned preterm birth.

Incidence of preterm birth

In Australia in 2014 (AIHW 2016):
- overall, 8.6% of babies were born preterm, with most of these births occurring at gestational ages between 32 and 36 completed weeks
- the average gestational age for all preterm births was 33.3 weeks
- babies whose mothers smoked during pregnancy were more likely to be born preterm (13%) than those whose mothers did not smoke during pregnancy (8%).
- other characteristics associated with increased likelihood of preterm birth included:
  - babies born in multiple births — 63% of twins and all (100%) of other multiples (triplets and higher) were preterm, compared with 7% of singleton babies
  - babies born to mothers usually residing in more remote areas — 13% in very remote areas compared with 8% in major cities
  - babies of younger (<20 years) and older (40 years and over) mothers — 11% and 12% were preterm, compared with 8% of babies with mothers aged 20–39 years.

Nationally in 2014, around 14% of babies of Indigenous mothers were born preterm, compared with 8% of babies of non-Indigenous mothers (AIHW 2016); similar rates were found in an earlier West Australian study (14.8 and 7.6%) (Langridge et al 2010). However, a study in a Melbourne hospital found no significant difference in risk of preterm birth between Indigenous and non-Indigenous babies and mothers (Indigenous babies aOR 1.19, 95%CI 0.77 to 1.87, Indigenous mothers aOR 0.97 95%CI 0.52 to 1.80) (Whish-Wilson et al 2016).

Risks associated with preterm birth

Preterm birth is associated with perinatal mortality, long-term neurological disability (including cerebral palsy), admission to neonatal intensive care, severe morbidity in the first weeks of life, prolonged hospital stay after birth, readmission to hospital in the first year of life and increased risk of chronic lung disease (WHO 2012). Preterm birth can have a serious emotional impact on the family. In Australia in 2014 (AIHW 2016):
- preterm babies were more likely to be admitted to a special care nursery or neonatal intensive care unit (72%) than babies born at term (10%) or post-term (13%)
- spontaneous preterm birth accounted for 14% of all perinatal deaths and one third (33%) of perinatal deaths of babies of Indigenous mothers.
3.5.2 Identifying women at increased risk of giving birth preterm

Summary of the evidence

A range of risk and protective factors influence the likelihood of preterm birth. While many risk factors are not modifiable during a woman’s current pregnancy, addressing modifiable risk factors may reduce risk of preterm birth. It should also be noted that many women who experience preterm birth have no risk factors.

Significant risk factors

There is a significant association between preterm birth and:

- social disadvantage (OR 1.27, 95%CI: 1.16 to 1.39) (Ncube et al 2016) and lower levels of maternal education (RR 1.48, 95%CI: 1.29 to 1.69) (Ruiz et al 2015)
- previous preterm birth (absolute recurrence rate among women with a singleton pregnancy and previous preterm singleton birth 20%, 95% CI 19.9–20.6) (Kazemier et al 2014)
- pre-existing (p=0.002) (Kock et al 2010) or gestational diabetes (AIHW 2010)
- current urogenital infections — eg chlamydia (OR 1.60; 95%CI 1.01 to 2.5) (John Hopkins Study Team 1989), bacterial vaginosis (OR 1.85; 95%CI 1.62 to 2.11) (Flynn et al 1999)
- alcohol consumption (OR 1.34; 95%CI 1.28 to 1.41) (Aliyu et al 2010), in a dose-response fashion (Sokol et al 2007; Patra et al 2011)
- smoking at the first antenatal visit (aOR 1.42, 95%CI 1.27 to 1.59) (Bickerstaff et al 2012) and active smoking during pregnancy (aOR 1.53, 95%CI 1.05 to 2.21) (Fantuzzi et al 2007), with risk further increased among women smoking more than 10 cigarettes a day compared to those smoking 1–9 cigarettes per day (aOR 1.69 vs 1.54) (Fantuzzi et al 2007).

Other factors

Systematic reviews of RCTs found:

- women who were overweight and obese who participated in aerobic exercise for 30–60 minutes three to seven times per week had a lower risk of preterm birth <37weeks (RR 0.62, 95% CI 0.41 to 0.95) compared to controls (Magro-Malosso et al 2016)
- no significant reduction of preterm birth with periodontal treatment (RR 0.89; 95% CI: 0.73 to 1.08; substantial heterogeneity), however daily use of chlorhexidine mouthwash was associated with a reduction of preterm birth (RR 0.69; 95% CI 0.50 to 0.95, moderate heterogeneity) (Boutin et al 2013).

Systematic reviews of observational studies show the following associations with preterm birth:

- country of origin/ethnicity — odds of very preterm birth among East African immigrants were higher than among Australian-born women (aOR 1.55, 95%CI 1.27 to 1.90) (Belihu et al 2016) and higher among African American women than among Caucasian women (pooled OR 2.0; 95%CI 1.8 to 2.2), with no significant association for Asian or Hispanic ethnicity (Schaaf et al 2013)
- weight: risk was increased among women who were obese and gained more than the IOM recommendations (aOR 1.54; 95% CI 1.09 to 2.16) (Faucher et al 2016)
- emotional health and well-being — increased risk was associated with low social support compared to high social support (OR 1.22, 95%CI 0.84 to 1.74); stress (OR 1.52, 95%CI 1.18 to 1.97) (Hetherington et al 2015); untreated depression (OR 1.56; 95%CI 1.25 to 1.94) and anxiety (RR 1.50, 95%CI 1.33 to 1.70) (Ding et al 2014), (OR 1.70, 95%CI 1.33 to 2.18) (Rose et al 2016) but not with but not maternal personality traits (Chatzi et al 2013)
- exposure to antidepressants — risk was increased among women exposed to antidepressants during pregnancy compared to women with depression but without antidepressant exposure (OR 1.17, 95%CI 1.10 to 1.25) (Eke et al 2016), (RR 2.85, 95%CI 2.00 to 4.07) (Huang et al 2014a); and risk was significantly increased with exposure in the third trimester (aOR 1.96, 95%CI 1.62 to 2.38) but not in the first trimester (aOR 1.16, 95%CI 0.92 to 1.45) (Huybrechts et al 2014)
• environmental factors — increased risk was associated with high environmental temperature (Beltran et al. 2013), especially heat stress (Carolan-Oolah & Frankowska 2014); exposure to passive smoke in any place (OR 1.20, 95%CI 1.07 to 1.34) or at home (OR 1.16, 95%CI 1.04 to 1.30) (Cui et al. 2016); risk associated with exposure to fine particulate matter was unclear due to significant heterogeneity between studies (Sun et al. 2015).

• pre-existing conditions — risk of preterm birth was increased among women with hepatitis C (OR 1.62, 95%CI 1.48 to 1.76, P < 0.001) (Huang et al. 2015), human papilloma virus (OR 2.12, 95%CI 1.51 to 2.98, P < 0.001) (Huang et al. 2014c); thyroiditis (OR 1.19, 95%CI 1.12 to 1.26; P < 0.00001) and hyperthyroidism (OR 1.24, 95%CI 1.17-1.31; P < .0001) (Sheehan et al. 2015) but not hepatitis B (OR 1.12, 95%CI 0.94 to 1.33) (Huang et al. 2014b).

• lifestyle factors — incidence of preterm birth (4.5% vs 4.4%; RR 1.01, 95%CI 0.68 to 1.50) were similar among women in the normal BMI category undertaking aerobic exercise during pregnancy and controls (Di Mascio et al. 2016); risk was increased among women with serum vitamin D levels lower than 50 nmol/L (OR 1.29, 95%CI 1.16 to 1.45) (Qin et al. 2016); and there was no clear or statistically significant relationship between preterm birth and shift work (van Melick et al. 2014), multivitamin use (Johnston et al. 2016) or influenza vaccination during pregnancy (Fell et al. 2015).

• history of gynaecological procedures — risk was increased among women with a history of dilatation and curettage (D&C) (OR 1.29, 95%CI 1.17 to 1.42) or multiple D&Cs (OR 1.74, 95%CI 1.10 to 2.76) (Lemmers et al. 2016); surgically induced termination of pregnancy (OR 1.52, 95%CI 1.08 to 2.16); surgically managed miscarriage (OR 1.19, 95%CI 1.03 to 1.37) (Saccone et al. 2016); loop electrosurgical excision procedure compared to women with no history of cervical dysplasia (pooled RR 1.61, 95%CI 1.35 to 1.92); and treatment for cervical intraepithelial neoplasia before (OR 1.4, 95%CI 0.85 to 2.3) or during pregnancy (OR 6.5, 95%CI 1.1 to 37) (Danhof et al. 2015).

Consensus-based recommendation

XX. When women are identified as being at risk of giving birth preterm, provide advice about modifiable risk factors.

3.5.3 Prediction and prevention

Cervical length measurement

Systematic reviews of randomised controlled trials found:

• among women with threatened preterm labour, those whose cervical length had been measured had a significantly lower rate of preterm birth <37 weeks (22.1 vs 34.5%; RR 0.64; 95%CI 0.44 to 0.94; 3 studies) — management of women with a cervical length lower than the study threshold differed between studies (further observation in one study and administering tocolytics and antenatal corticosteroids in the other studies) (Berghella et al. 2016);

• no difference in incidence of maternal and neonatal infection among women with preterm premature rupture of the membranes who did or did not undergo transvaginal ultrasound of cervical length measurement (Berghella et al. 2013).

Systematic reviews of observational studies were heterogeneous in terms of population and cut-off thresholds used but suggest that preterm birth is better predicted at 14 to 20 weeks rather than later, using a shorter cervical length as the cut-off threshold (Crane & Hutchens 2008; Domin et al. 2010; Honest et al. 2012; Conde-Agudelo & Romero 2015).
Holistic preventive strategies

Systematic reviews that evaluated holistic models of care and their effect on preterm birth found:

• a significant effect in reducing risk of preterm birth among women receiving midwifery-led care compared to other models of care for childbearing women and their infants (average RR 0.76, 95%CI 0.64 to 0.91; n=13,238; 8 studies; high quality) (Sandall et al 2016)

• no significant difference among:
  — women receiving group antenatal care compared to those receiving standard care (RR 0.87, 95%CI 0.70 to 1.09; 11 studies) (Carter et al 2016) and (RR 0.75, 95%CI 0.57 to 1.00; 3 studies; n=1,888, moderate quality) (Catling et al 2015)
  — women randomised to specialist preterm birth programs compared to those receiving standard care (RR 0.92, 95%CI 0.76 to 1.12; 15 RCTs) (Fernandez Turienzo et al 2016)
  — low risk women receiving a reduced number of antenatal visits (RR 1.02, 95%CI 0.94 to 1.11; 7 studies, n=53,661, moderate quality) (Dowswell et al 2015)
  — women receiving additional social support compared to those receiving standard care (RR 0.92, 95%CI 0.83 to 1.01; 11 RCTs; n=10,429) (Hodnett et al 2010), including adolescent women (RR 0.67; 95%CI 0.42 to 1.05; 4 studies; n=684) (Sukhato et al 2015)
  — women receiving telephone support during pregnancy compared to women receiving routine care or other support (RR 0.91; 95%CI 0.77 to 1.08; 4 RCTs; n=3,992) (Lavender et al 2013)
  — women in preterm labour using relaxation techniques compared to those not using relaxation techniques (RR 0.95; 95%CI 0.57 to 1.59; 11 RCTs; n=833) (Khianman et al 2012)

• successful approaches to increasing access to antenatal care and reducing preterm birth among Aboriginal and Torres Strait Islander women include community-based collaborative antenatal care and community-based support (Rumbold & Cunningham 2008) and partnership between Aboriginal grandmothers, Aboriginal Health Officers, midwives and existing antenatal care services (Bertilone & McEvoy 2015).

3.5.4 Discussing risk of giving birth preterm

When risk of preterm birth is increased, modifiable risk factors should be addressed (Freak-Poli et al 2009; Kiran et al 2010; Carter et al 2011). Based on the evidence discussed in Section 3.5.2, discussion with women at risk of preterm birth can include the benefits of:

• having adequate social and emotional support
• quitting tobacco smoking and avoiding exposure to passive smoke
• not drinking alcohol during pregnancy
• having tests for urogenital infections
• participating in regular exercise, particularly if they are overweight or obese.

Women can also be advised that risk is not reduced by supplementing with Vitamins C or E (Rumbold et al 2015a; Rumbold et al 2015b) or probiotics (Othman et al 2007; Hauth et al 2010).
3.5.5 Practice summary: risk of preterm birth

**When:** A woman has identified risk factors for giving birth preterm.

**Who:** Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander Health Practitioner; Aboriginal and Torres Strait Islander Health Worker; multicultural health worker.

**Discuss lifestyle factors associated with preterm birth**
- Explain that smoking during pregnancy makes it more likely that the baby will be born preterm and also causes other serious risks to the pregnancy.
- Explain that not drinking alcohol during pregnancy is the safest option.
- Offer testing for urogenital infection if the woman has risk factors for preterm birth. If results are positive, consider counselling, contact tracing, partner testing and treatment, and repeat testing.

**Discuss protective factors**
- Explain that moderate physical activity during pregnancy has a range of health benefits, particularly for women who are overweight or obese.

**Take a holistic approach**
- Provide information on relevant community supports (eg smoking cessation programs, drug and alcohol services, physical activity groups).
- Consider whether a woman may be at increased risk if she has recently arrived from a country with a high prevalence of preterm birth.
- Provide social and emotional support and access to continuity of carer, where possible.

3.5.6 References


4 Maternal health screening

4.1 Hepatitis C

While there is currently no way of preventing mother-to-baby transmission of hepatitis C, identifying women who have hepatitis C during pregnancy means that interventions that increase the risk of transmission to the baby can be avoided and effective treatments commenced after the birth or cessation of breastfeeding.

4.1.1 Background

Hepatitis C is a blood-borne virus that is one of the major causes of liver cirrhosis, hepatocellular carcinoma and liver failure. Perinatal transmission is the main source of hepatitis C in Australian children. Babies with hepatitis C are mostly born to mothers who used intravenous drugs, had invasive procedures overseas or have tattoos (Ridley et al 2010).

Hepatitis C in Australia

The Australian Annual Surveillance Report (The Kirby Institute 2016) reported the following.

- The overall notification rate of hepatitis C notification in Australia has remained stable in the last four years (2012–2015), following a 22% decline between 2006 and 2011. A similar trend has been seen in all age groups. The primary route of transmission is sharing injecting equipment, a practice that primarily starts in late adolescence or early adulthood.

- In contrast, the age standardised rate of hepatitis C notification in the Aboriginal and Torres Strait Islander population (based on data from the Northern Territory, South Australia, Tasmania and Western Australia) increased by 43% in the past 5 years, from 115 per 100,000 in 2011 to 165 per 100,000 in 2015. The 2015 rate is four times greater than in the non-Indigenous population (40 per 100,000). The difference in overall notification rates may reflect differences in injecting risk behaviours, rates of incarceration and higher case detection among Aboriginal and Torres Strait Islander peoples.

Observational studies conducted in Australia also identified people who inject drugs (Liu et al 2009; Iversen et al 2010; Islam et al 2013; Graham et al 2016) and people in prison (van der Poorten et al 2008; Miller et al 2009; Teutsch et al 2010; Reekie et al 2014; Graham et al 2016) as at higher risk of testing positive for hepatitis C antibodies or infection.

Risks associated with hepatitis C in pregnancy

The clearest risk associated with maternal hepatitis C in pregnancy is transmission of the infection to the baby. There are several factors that influence the risk of mother-to-infant transmission:

- if the mother has antibodies for hepatitis C but is not infected, the risk of transmission is approximately 1 to 3%; if the mother is infected, the risk is approximately 4 to 6% (Panda et al 2010)

- the highest reported transmission rates occur in infants born to mothers who are both hepatitis C and HIV positive, with rates as high as 36% (Panda et al 2010; Benova et al 2014)

- risk of transmission is increased with a higher maternal viral load of hepatitis C (Panda et al 2010; Valladares et al 2010), with a threshold of >615 copies/mL (OR 9.3; 95%CI 1.11 to 78.72) (Garcia-Tejedor et al 2015)

- risk is increased with intrapartum invasive procedures (fetal scalp blood sampling or internal electronic fetal heart rate monitoring via scalp electrode) (OR 10.1; 95% CI 2.6 to 39.02) and episiotomy (OR 4.2; 95%CI 1.2 to 14.16) (Panda et al 2010; Gagnon et al 2014; Rac & Sheffield 2014; Garcia-Tejedor et al 2015)

- transmission does not appear to be influenced by mode of birth (Panda et al 2010; Ghamar Chehreh et al 2011; Cottrell et al 2013; Rac & Sheffield 2014) or gestational age at birth (Panda et al 2010)

- prolonged rupture of membranes may increase the risk of transmission (Panda et al 2010; Cottrell et al 2013), however this could be related to maternal viral load and length of membrane rupture (Rac & Sheffield 2014)
• amniocentesis in women infected with hepatitis C does not appear to significantly increase the risk of vertical transmission but very few studies have properly addressed this possibility (Panda et al 2010; Gagnon et al 2014; Rac & Sheffield 2014)

• there is no evidence that breastfeeding is associated with an increased risk of hepatitis C transmission to the newborn (Panda et al 2010; Valladares et al 2010; Cottrell et al 2013; ASHM 2015), unless the nipples are cracked and/or bleeding (Rac & Sheffield 2014; ASHM 2015).

4.1.2 Testing for hepatitis C infection in pregnancy

Internationally, routine testing of pregnant women for hepatitis C has not been recommended (CPS 2008; ACOG reaffirmed 2016; NICE updated 2016). In Australia, RANZCOG suggests that all pregnant women be tested for hepatitis C (RANZCOG 2016).

Summary of the evidence

Targeted versus universal testing

Studies were largely consistent in finding that hepatitis C seropositivity was associated with the following risk factors:

• receipt of blood transfusion or organ transplant (Diab-Elschahawi et al 2013; Wilson & Beckmann 2015)
• history of tattooing or body piercing (Diab-Elschahawi et al 2013; Lambert et al 2013)
• use of intranasal cocaine (Diab-Elschahawi et al 2013; Lambert et al 2013)
• incarceration (Diab-Elschahawi et al 2013)
• origin from a country of high prevalence (Diab-Elschahawi et al 2013; Lambert et al 2013); these include Africa and central and east Asia (WHO 2016).

Additional findings were:

• only high severity risk factors (exposure to intravenous drug use or to the blood of an hepatitis C-positive individual) were significantly associated with testing positive for hepatitis C antibodies (P=0.002) (McDermott et al 2010)
• age, history of prior pregnancy and healthcare employment were additional considerations (El-Kamary et al 2015).

However, studies have estimated that, compared to universal testing, targeted testing would fail to identify 2.5 to 27% of seropositive women (Diab-Elschahawi et al 2013; Lambert et al 2013; El-Kamary et al 2015; Wilson & Beckmann 2015).

Clinical utility of testing

The clinical utility of testing for hepatitis C in pregnancy is limited by the lack of effective treatment options to avoid mother-to-child transmission during pregnancy or childbirth (Dunkelberg et al 2014; Rac & Sheffield 2014; Poliquin et al 2015; Aebi-Popp et al 2016).

However, new treatment options (direct-acting antiviral agents) for people living with hepatitis C have become available and were recently listed on the Australian Pharmaceutical Benefits Scheme (PBS). While these treatments have not been proven to be safe in pregnancy or during breastfeeding (Rac & Sheffield 2014; Aebi-Popp et al 2016), women who are diagnosed with hepatitis C during pregnancy could commence such curative treatment after completion of breastfeeding (or immediately after the birth if the infant is not breastfed), thus reducing their risk of significant liver disease and the risk of perinatal infection for subsequent pregnancies.

In addition, knowledge of a woman’s hepatitis C status means that interventions that may increase the risk of mother-to-baby transmission (fetal scalp blood sampling, internal electronic fetal heart rate monitoring via scalp electrode, episiotomy) can be avoided.

Costs of testing

No cost-effectiveness studies relevant to the Australian context were identified. A study in the Netherlands found a modest cost-effective outcome for testing first-generation non-Western women (Coretti et al 2015) and a study conducted in the United States (Hahne et al 2013) found that neither
universal testing with or without elective caesarean section were cost-effective. However, a study in the United Kingdom found that antenatal testing and postnatal treatment was feasible and effective at an acceptable cost (Selvapatt et al 2015).

**Consensus-based recommendation**

XXI. At the first antenatal visit, recommend testing for hepatitis C.

**Planned invasive procedures**

Testing of women who are to have a planned invasive procedure has been recommended, due to the risk of hepatitis C transmission to the baby.

**Practice point**

N. For women who have not previously been tested and who are having a planned invasive procedure (eg chorionic villus sampling), recommend testing for hepatitis C before the procedure.

**Testing process**

If an initial test for hepatitis C antibodies is positive, a confirmatory hepatitis C ribonucleic acid (RNA) test will allow assessment of the potential implications and associated risks for the woman and her baby (ASHM 2015).

**Other considerations**

For a woman with a diagnosis of hepatitis C during pregnancy, referral to an infectious diseases specialist or hepatologist, as well as to hepatitis support groups for information and advice, should be made during the pregnancy (ASHM 2015). This will facilitate provision of accurate information, counselling and linkages for follow-up and treatment if desired after the birth.

4.1.3 **Practice summary — hepatitis C testing**

**When** — In the antenatal period

**Who** — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker

- **Discuss hepatitis C testing** — Explain that if hepatitis C is identified during pregnancy, interventions that increase the risk of transmission can be avoided and that effective treatment can be started after pregnancy/breastfeeding.

- **Document and follow-up** — If hepatitis C testing is undertaken, note the results in the woman’s record and advise the woman of her result. Have a system in place so that women who test positive receive education about further transmission (eg to family members) and ongoing support and their babies are followed up after birth.

- **Take a holistic approach** — If a woman is found to have hepatitis C, specialist advice on management may be required depending on the severity of disease and the health professional’s expertise. Other considerations include counselling and follow-up.

4.1.4 **Resources**


**Websites**

- Hepatitis C Council of NSW
- Hepatitis C Council of SA
- Hepatitis C Victoria
- Hepatitis Queensland
- Hepatitis WA
- Northern Territory AIDS and Hepatitis C Council
- ACT Hepatitis C Council
- Tasmanian Council on AIDS, Hepatitis C and Related Diseases
4.1.5 References


4.2 Diabetes

Identifying the risk or presence of diabetes in pregnancy enables women to receive early testing if risk factors are present and lifestyle advice, education, blood glucose monitoring and appropriate treatment if diabetes is identified.

4.2.1 Background

Hyperglycaemia (raised blood glucose level) in pregnancy includes impaired fasting glucose and impaired glucose tolerance (pre-diabetes), pre-existing type 1 diabetes, pre-existing type 2 diabetes (either previously diagnosed or diagnosed during pregnancy) and gestational diabetes (developing during pregnancy). Gestational diabetes can recur in subsequent pregnancies. Women who develop gestational diabetes are at high risk of developing type 2 diabetes in later life.

Diabetes identified during pregnancy is primarily managed with changes to diet and exercise but insulin and/or oral agents may be required if blood glucose levels are not adequately controlled by lifestyle measures.

This section addresses diabetes identified during pregnancy. It does not address the care of women diagnosed with Type 1 or type 2 diabetes before pregnancy as the Guidelines cover the antenatal care of healthy pregnant women (ie those who do not have identified pre-existing conditions). For women with diagnosed type 1 or type 2 diabetes, preconception counselling is advisable.

Prevalence of diabetes in Australia

In 2014–15, around 5.1% of the Australian population had diagnosed diabetes (excluding gestational diabetes) based on self-reported data (ABS 2015). However, self-reported data is likely to underestimate prevalence as it cannot include people with undiagnosed diabetes. The 2011–12 Australian Health Survey, which included both measured and self-reported data, showed that for every four adults with diagnosed diabetes, there was one who was undiagnosed (ABS 2013).

In the 2014–15 survey, higher prevalence of diabetes was found in some population groups (AIHW 2016a):
- compared with non-Indigenous Australians, Aboriginal and Torres Strait Islander people were 3.5 times as likely to have diabetes
- compared with those living in the highest socioeconomic areas, people living in the lowest socioeconomic areas were 3.6 times as likely to have diabetes.

Prevalence of diabetes among people born outside Australia was not reported in the 2014–15 Survey. However, in 2005–07 prevalence of diabetes among people born in specific regions was higher than among those born in Australia — 7% among people born in North Africa and the Middle East, 6% among people born in South-East Asia or Oceania (excluding Australia) and 5% for people born in Southern and Eastern Europe (AIHW 2010).

Prevalence of diabetes in pregnancy

The prevalence of diabetes in pregnancy varies with the characteristics of the population being tested and the diagnostic criteria used. Population-based studies have estimated prevalence ranging from 1% to 50% (Hartling et al 2012). The prevalence of diabetes in pregnancy has increased over the past decades in parallel with the increase in rates of obesity (BMI > 30 kg/m²) and type 2 diabetes and this trend is expected to continue (Aljohani et al 2008; Hartling et al 2012). The proportion of first-time mothers aged over 35 years in Australia is also increasing (Li et al 2013), which may increase the prevalence of gestational diabetes.

Among women who gave birth in Australia in 2009–11, 0.7% had pre-existing diabetes and 5.8% had gestational diabetes (AIHW 2014).

In 2013, rates of pre-existing diabetes were (AIHW 2016b):
- lowest among women aged <20 years (0.4%) and highest among women aged ≥40 years
- lower among nulliparous women (1.0%) than among women of higher parity (ie 1.9% for parity of four)
• higher among Aboriginal and Torres Strait Islander women (4.4%) than among non-Indigenous women (1.1%)(age-standardised)
• higher among women born overseas (1.2%) than among women born in Australia (0.9%).

Risks associated with diabetes in pregnancy

Cohort studies have found an independent relationship between hyperglycaemia during pregnancy and adverse outcomes for mother and baby (Sacks et al 1995; Serrner et al 1998; Schmidt et al 2001; HAPO Study Cooperative Research Group 2008). The most comprehensive of these studies, the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study, showed a continuum of risk across maternal glucose levels for adverse pregnancy outcomes, including pre-eclampsia, caesarean section, birth trauma, high birth weight (>90th centile) and percentage of body fat as well as premature birth (HAPO Study Cooperative Research Group 2008). High birth weight babies are at risk of birth complications (eg shoulder dystocia) (Crowther et al 2005; Falavigna et al 2012), jaundice (Nold & Georgieff 2004) and of long-term effects including childhood overweight (Li et al 1987; Langer et al 1989) and metabolic factors that may increase risk of type 2 diabetes and cardiovascular disease (Garner et al 1997).

In Australia in 2005–07 (AIHW 2010):
• women with pre-existing type 1 or type 2 diabetes were more likely to have preterm birth, induced labour, caesarean birth, hypertension and hospital stay longer than 7 days than women with gestational diabetes or without diabetes in pregnancy and their babies had higher rates of stillbirth, high birth weight, low Apgar score and admission to special care nursery/neonatal intensive care unit
• women with gestational diabetes had a higher risk of induced labour and were more likely to have a preterm birth, caesarean section, hypertension and longer hospital stay than women without diabetes, and their babies were more likely to be admitted to a special care nursery/neonatal intensive care unit
• Aboriginal and Torres Strait Islander mothers with pre-existing diabetes or gestational diabetes were at the greatest risk of preterm birth, induced labour, caesarean section and hypertension and their babies had higher rates of stillbirth, low Apgar score and admission to neonatal intensive care unit than non-Indigenous babies.

While hyperglycaemia is the principal concern of diabetes in pregnancy, hypertension and dyslipidaemia associated with diabetes contribute to the risk of adverse outcomes.

4.2.2 Assessing risk of diabetes

Summary of the evidence

Identifying women at risk of diabetes during pregnancy

The risk factors for undiagnosed type 2 diabetes are similar to those for gestational diabetes. There is a considerable body of evidence supporting an independent association between increased risk of gestational diabetes and the following factors.


• **Polycystic ovary syndrome** — The glucose metabolism alterations associated with polycystic ovary syndrome lead to an increased risk of gestational diabetes (Boomsma et al 2006; Touli et al 2009; Hartling et al 2012; Reynolds et al 2012).

• **Previous obstetric history** — Risk is increased among women with previous gestational diabetes (Gonzalez-Clemente et al 2007; Radesky et al 2008; Getahun et al 2010; Ogonowski & Miazgowski 2010; Waugh et al 2010; Nanda et al 2011; Teede et al 2011; Teh et al 2011; Hartling et al 2012), a previous high birth weight baby (Cypryk et al 2008; Ogonowski & Miazgowski 2010; Waugh et al 2010; Nanda et al 2011; Hartling et al 2012) or previous pregnancy losses, including spontaneous miscarriage and unexplained stillbirth (Hartling et al 2012).


• **Ethnic origin** — Risk of gestational diabetes is increased among women who originate from an ethnic group with a high prevalence of type 2 diabetes (Waugh et al 2010). These include Aboriginal and Torres Strait Islander peoples (Porter et al 2012) and people who are of Hispanic, African, Native American, South or East Asian or Pacific Island origin (Scott et al 2002; Nanda et al 2011; Teede et al 2011; Teh et al 2011; Hartling et al 2012; Makgoba et al 2012; Singh et al 2012).

• **Migration** — Being a migrant (including entering another country as a refugee) rather than being native to the country is associated with increased risk (Hedderson et al 2010a; Gagnon et al 2011; Schneider et al 2011).

A recent systematic review (NZ MoH 2014) had similar findings and noted that it is likely that interactions between risk factors, rather than any single risk factor, predispose a woman to gestational diabetes.

**Recommendation**

6. In the first trimester, assess a woman’s risk of diabetes — including her age, BMI, previous gestational diabetes or high birth weight baby, family history of diabetes, presence of polycystic ovarian syndrome and whether she is from an ethnic group with high prevalence of diabetes, such as Aboriginal and Torres Strait Islander peoples.

**Lifestyle interventions for preventing gestational diabetes**

• **Physical activity** — A Cochrane review (Han et al 2012) concluded that exercise programs had no clear effect on preventing gestational diabetes among healthy pregnant women. An RCT found that a physical activity intervention did not reduce the risk of healthy pregnant women developing gestational diabetes but did reduce maternal weight gain and the risk of caesarean section and having a high birth weight newborn (Barakat et al 2013).

• **Dietary interventions** — A systematic review of RCTs found that a low glycaemic index diet reduced the risk of a high birth weight baby, that any dietary counselling was effective in reducing the incidence of gestational diabetes compared to standard care and that dietary counselling with probiotics was more effective in reducing incidence of gestational diabetes than dietary counseling alone (Oostdam et al 2011). An RCT found that a low glycaemic index diet during pregnancy did not reduce the risk of a high birth weight baby among women at risk of gestational diabetes but had a beneficial effect on maternal weight gain and glucose intolerance (Walsh et al 2012).

• **Combined interventions** — RCTs into the effect of advice on diet and physical activity in preventing gestational diabetes have inconsistent results. In some studies, intervention did not reduce the risk of gestational diabetes among women at high risk but resulted in lower weight gain among women at high risk and healthy pregnant women (Korpi-Hyovali et al 2011; Phelan et al 2011; Vinter et al 2011; Hui et al 2012). Other studies found that combined interventions reduced the risk of gestational diabetes and weight gain among women who were overweight or obese (Petrella et al 2013) and the incidence of high birth weight newborns among women at high risk (Luoto et al 2011).

• **Management plans** — An Australian study reported that a four-step management plan aiming to reduce maternal weight gain among women who were obese reduced the incidence of gestational diabetes and maternal weight gain (Quinlivan et al 2011).
Qualified recommendation

7. Advise women that physical activity and healthy eating during pregnancy help to reduce excessive weight gain, but do not appear to directly reduce the risk of diabetes in pregnancy.

The full Guidelines include specific advice on nutrition and physical activity. See Section 3.1 for information on weight and body mass index.

4.2.3 Testing for diabetes

There is no agreement among current guidelines on whether testing for diabetes should be offered to all women or only to women with risk factors. However, a number of major international guidelines recommend universal testing for gestational diabetes at 24–28 weeks gestation, including the Australasian Diabetes in Pregnancy Society (ADIPS) (Nankervis et al 2013), the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG 2014), the Endocrine Society (USA) (Blumer et al 2013), the International Association of Diabetes and Pregnancy Study Groups (IADPSG) (Metzger et al 2010), the United States Preventive Services Task Force (USPSTF 2014), the World Health Organization (WHO 2013), the International Federation of Gynecology and Obstetrics (Hod et al 2015) and the International Diabetes Federation (IDF 2015).

The decision whether to test all pregnant women or only those with risk factors depends on the background frequency of abnormal glucose metabolism in the population and on local circumstances (Metzger et al 2010). The WHO guidelines leave it to local health authorities to specify the testing coverage according to local burden, resources and priorities (WHO 2013). Whether testing is universal or risk factor based, it is important that organisational protocols are consistently followed and outcomes audited.

A technical report from the United Kingdom concluded that testing for diabetes in pregnancy is worthwhile due to the costs of managing pregnancies complicated by diabetes (Waugh et al 2010). An Australian study suggested that treating mild gestational diabetes involved additional costs to hospitals and women but resulted in reductions in perinatal mortality and serious perinatal complications (Moss et al 2007).

These Guidelines recommend a two-stage approach to testing, with women at risk of diabetes identified and tested early in pregnancy and women who are not part of this group tested at 24–28 weeks gestation.

Early testing for previously undiagnosed type 2 diabetes

Detection and treatment of undiagnosed diabetes in early pregnancy has the potential to reduce immediate and long-term harm to the baby and have a positive effect on maternal health (Hughes & Moore 2013). For these reasons, it has been recommended that women with risk factors for type 2 diabetes be tested for hyperglycaemia at the first antenatal visit (Simmons & Campbell 2007; ADA 2013).

In New Zealand, it is recommended that all women are offered glycated haemoglobin (HbA1c) testing at the first antenatal visit (NZ MoH 2014). Prospective cohort studies in New Zealand since the introduction of the recommendation have found that:

- HbA1c ≥41 mmol/mol had a sensitivity of 100% (95%CI 91.8 to 100) and specificity of 97.4% (95%CI 95.5 to 99.2) for detecting diabetes and that women with HbA1c of 41–46 mmol/mol (n=200) had poorer pregnancy outcomes than those with HbA1c <41 mmol/mol (n=7,897) (Hughes et al 2014)
- earlier treatment (<24 weeks) for women with an HbA1c of 41–49 mmol/mol was associated with a reduced risk of pre-eclampsia (but not other pregnancy or neonatal outcomes) compared with treatment ≥24 weeks (1.5 vs 8.0%, adjusted P=0.03) (Rowan et al 2016).

However, the evidence on HbA1c as a test in early pregnancy is limited and it is not currently included in the Medicare Benefits Schedule as a diagnostic test in pregnancy. Further research is needed to evaluate the benefit of early treatment for hyperglycaemia in pregnancy.

Consensus-based recommendation

XXII. When a woman has risk factors for diabetes in the first trimester, suitable tests are glycated haemoglobin (HbA1c) or fasting blood glucose.
Table 4.2.1: Suggested thresholds for glycated haemoglobin and fasting plasma glucose in early pregnancy

<table>
<thead>
<tr>
<th>Test</th>
<th>Suggested threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c</td>
<td>≥41 mmol/mol</td>
</tr>
<tr>
<td>Fasting plasma glucose</td>
<td>6.1 to 6.9 mmol/L</td>
</tr>
</tbody>
</table>

Sources: (NZ MoH 2014; McIntyre et al 2016).

Testing for gestational diabetes

A lack of an agreed gold standard for diagnosing gestational diabetes creates challenges for assessing the accuracy of tests, making comparisons between them and establishing clear thresholds (Hartling et al 2012). There is currently no universally accepted testing or diagnostic regimen. A Cochrane review concluded that, although gestational diabetes was more likely to be detected when all women were tested, the effects of subsequent management on health outcomes are unclear (Tieu et al 2014). A large retrospective cohort study concluded that selective testing would miss one third of women with gestational diabetes (Cosson et al 2013). As the condition is prevalent, asymptomatic and benefits from treatment, universal testing is generally recommended. However, at present, the benefits of treating early onset gestational diabetes are uncertain.

International consensus guidelines recommend the use of fasting plasma glucose or plasma glucose 1 hour and 2 hours after 75 g glucose loading for testing for gestational diabetes (Metzger et al 2010; WHO 2013). HbA1c is not recommended as a test for gestational diabetes due to a lack of sensitivity (NZ MoH 2014).

Consensus-based recommendation

XXIII. Between 24 and 28 weeks gestation, advise testing for diabetes to all women who have not previously been tested in the current pregnancy. Advise repeat testing to women who were tested early in pregnancy due to risk factors and had a normal result on an initial test.

Diagnostic thresholds

The optimal diagnostic threshold for diabetes in pregnancy is uncertain and difficult to determine based on the available evidence.

After review of the findings of the HAPO Study, the IADPSG defined diagnostic values on the basis of an odds ratio of 1.75 for adverse neonatal outcomes. These criteria use a one-step approach to testing for gestational diabetes and have been adopted by the WHO (WHO 2013) and the American Diabetes Association (ADA 2013). Recent ADIPS guidelines on diagnosis of gestational diabetes also include these criteria (Nankervis et al 2013). Other documents, including the RACGP/Diabetes Australia Diabetes Management in General Practice (RACGP/Diabetes Australia 2013) and a US National Institutes of Health consensus development conference statement (VanDorsten et al 2013) support the use of a two-step approach to testing and higher thresholds.

Table 4.2.2: WHO/ IADPSG criteria for diagnosis of diabetes in pregnancy

<table>
<thead>
<tr>
<th>Diabetes in pregnancy — one or more of the following criteria are met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting plasma glucose ≥ 7.0 mmol/l (126 mg/ dl)</td>
</tr>
<tr>
<td>2-hour plasma glucose ≥ 11.1 mmol/l (200 mg/dl) following a 75g oral glucose load</td>
</tr>
<tr>
<td>Random plasma glucose ≥ 11.1 mmol/l (200 mg/ dl) in the presence of diabetes symptoms</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gestational diabetes — one or more of the following criteria are met at any time during pregnancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting plasma glucose 5.1–6.9 mmol/l (92 -125 mg/dl)</td>
</tr>
<tr>
<td>1-hour plasma glucose ≥ 10.0 mmol/l (180 mg/dl) following a 75g oral glucose load</td>
</tr>
<tr>
<td>2-hour plasma glucose 8.5–11.0 mmol/l (153 -199 mg/dl) following a 75g oral glucose load</td>
</tr>
</tbody>
</table>

Source: WHO 2013.

Consensus-based recommendation

XXIV. Use the WHO/IADPSG tests and criteria to diagnose diabetes in pregnancy.
The WHO criteria for diagnosing pre-existing diabetes are based on the risk of developing microvascular complications, predominantly retinopathy. There are no data available to assess diagnostic accuracy of current diabetes diagnostic criteria if used in pregnancy in untreated women (WHO 2013). The WHO grade the quality of the evidence supporting the criteria for diagnosing gestational diabetes as very low (WHO 2013). The criteria are not based on diagnostic accuracy because there is no reference test to define disease status.

A systematic review found evidence to support a positive association between increasing plasma glucose on a 75 g or 100 g oral glucose tolerance test and high birth weight and primary caesarean section but clear thresholds for increased risk were not identified (Hartling et al 2012). Another systematic review found that the risk of these adverse events was similar between the WHO/IADPSG and former WHO criteria (Wendland et al 2012). Cohort studies have found that women classified as having gestational diabetes under the WHO/IADPSG criteria but not under former criteria had a significantly increased risk of caesarean section (Lapolla et al 2011; O'Sullivan et al 2011), hypertensive complications (O'Sullivan et al 2011) and having a high birth weight baby (Morikawa et al 2010; O'Sullivan et al 2011). However, no RCTs have compared the outcomes of management following diagnosis under the two criteria.

While a full cost-effectiveness analysis has not been published, two studies that modelled the cost effectiveness of the WHO/IADPSG criteria concluded that they would only be cost effective if detection of gestational diabetes reduced the rate at which type 2 diabetes subsequently developed (Werner et al 2012) or if the rate of caesarean section was reduced (Mission et al 2012).

It is acknowledged that using the WHO/IADPSG criteria has the potential to increase the diagnosis of gestational diabetes in Australia, with resource implications. However, calculations of the prevalence in particular populations may increase or decrease with changes to both testing criteria and uptake, as well as changes in population demographics. For example:

- a prospective study in Wollongong comparing the use of the previous ADIPS criteria with the WHO/IADPSG criteria found that prevalence varied between the public and private sectors — 8.6% vs 9.1% (public sector), 10.5% vs 16.2% (private sector) and 9.6% vs 13.0% (overall) (Moses et al 2011)

- an analysis of the HAPO sites in Australia using the WHO/IADPSG criteria found a prevalence of gestational diabetes of 13.2% in Brisbane and 13.6% in Newcastle (Sacks et al 2012)

- an analysis of oral glucose tolerance test results from women in two Area Health Services in the Sydney area found that using the WHO/IADPSG criteria rather than the previous ADIPS criteria would increase rates of diagnosis and therefore affect the health service workload for management of gestational diabetes (Flack et al 2010)

- in a cohort of Aboriginal and Torres Strait Islander women in Far North Queensland, gestational diabetes prevalence increased threefold over 2 years due to enhanced testing practices, but prevalence would have been lower if the WHO/IADPSG criteria had been in place at the time (Davis et al 2013).

Increased diagnosis also has implications for women. Gestational diabetes occurs across a continuum with a variety of potential threshold points. The risk of labelling a woman with gestational diabetes needs to be weighed against any potential benefits to the woman and baby, particularly if lifestyle advice is likely to be the first treatment option. There is a need for evidence on the risks and benefits of testing at different thresholds.

### 4.2.4 Discussing diabetes in pregnancy

Discussion to inform a woman’s decision-making about testing for diabetes should take place before testing and include that:

- undetected and uncontrolled diabetes during pregnancy is associated with risks to the mother (eg high blood pressure, pre-eclampsia) and to the baby in the short term (eg stillbirth, preterm birth, high birth weight, birth complications) and the longer term (childhood overweight and development of diabetes)

- a diagnosis of diabetes in pregnancy may lead to increased monitoring and interventions during pregnancy and labour (eg induced labour, caesarean section).
If diabetes is diagnosed during pregnancy, points for discussion include:

- the role of diet, physical activity and body weight in managing diabetes
- the role of insulin or oral hypoglycaemic agents in the management of diabetes (ie if diet and physical activity do not adequately control blood glucose levels)
- the importance of monitoring and controlling blood glucose levels during pregnancy, labour, birth and early feeding of the baby to reduce the likelihood of the baby having low blood glucose levels after the birth and the associated risks
- the possibility of the baby having low blood glucose levels in the period after the birth, which may require admission to a special care nursery/neonatal intensive care unit
- the risk of the baby developing obesity, heart disease and/or diabetes in the future
- the woman’s increased risk of developing type 2 diabetes and the importance of regular assessment for glucose tolerance and maintaining a healthy weight
- the benefits of registering with the National Gestational Diabetes Register (eg annual reminders for glucose tolerance assessment)
- whether the woman understands the information she has been given.

4.2.5 Practice summary: diabetes in pregnancy

**When**: Assess risk of undiagnosed diabetes or prediabetes at the first antenatal visit and offer testing to women with risk factors. At 24–28 weeks offer testing to women not already tested and repeat testing to women with risk factors with a previous normal blood glucose level.

**Who**: Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander Health Practitioner; Aboriginal and Torres Strait Islander Health Worker; multicultural health worker; accredited dietitian, diabetes educator; endocrinologist; accredited exercise physiologist.

- **Discuss the reasons for testing blood glucose levels**: Explain that diabetes in pregnancy can have effects on the pregnancy and the baby and that early identification and taking steps to manage raised blood glucose as soon as possible can reduce the risk of these effects.

- **Take a holistic approach**: Provide women with practical advice on healthy eating and physical activity (this information is available in the full Guidelines), taking into account the availability of foods and ways of being physically active that are appropriate to the woman’s cultural practices and preferences. Consider a health promotion program to improve community understanding of the effects of diabetes in pregnancy and the importance of healthy lifestyle patterns.

- **Consider referral**: Where possible, women diagnosed with pre-existing diabetes should be referred for specialist assessment and education on nutrition, monitoring and management (eg to a multidisciplinary team involving an accredited dietitian, diabetes educator, endocrinologist). Where specialist allied health professionals are not available, other sources of information (eg written information, video or audio resources, telehealth services) may be useful.

- **Document and follow-up**: When a woman’s blood glucose level is tested, tell her the results and note them in her antenatal record. Have a system in place so that women diagnosed with diabetes receive ongoing follow-up, including further testing of blood glucose levels after pregnancy. Postnatal education and support are important in preventing or delaying the onset of diabetes in the future.

4.2.6 Resources

- NHMRC (2011) *National Evidence-Based Clinical Care Guidelines for Type 1 Diabetes for Children, Adolescents and Adults*. Canberra: National Health and Medical Research Council.
4.2.7 References


Walsh JM, McGowan CA, Mahony R et al (2012) Low glycaemic index diet in pregnancy to prevent macrosomia (ROLO study); randomised control trial. BMJ 345: e5605.


4.3 Vitamin D status

There is limited evidence to support testing of all women for vitamin D status in pregnancy and the benefits and harms of vitamin D supplementation in pregnancy remain unclear.

4.3.1 Background

Vitamin D is essential for bone development in children and skeletal health in adults. It regulates calcium and phosphate absorption and metabolism. Vitamin D is obtained through the direct action of sunlight on the skin (90%) or through dietary nutrients (10%), in particular dairy products, eggs and fish. Definitions of vitamin D sufficiency vary, with Australian organisations generally considering levels lower than 50 nmol/L as suboptimal (Nowson et al 2012; Paxton et al 2013; ABS 2014b; RANZCOG 2015).

**Vitamin D status in Australia**

The Australian Health Survey 2011–12 (ABS 2014b) found that most Australian adults had Vitamin D levels above 50 nmol/L, with 23% having lower levels. Prevalence of vitamin D levels lower than 50 nmol/L was:

- lower in summer (14%) and higher in winter (36%)
- relatively low across all the States and Territories in summer, ranging from 6% in Queensland to 19% in NSW
- particularly high in winter for those living in the south-eastern states of Australia, such as Victoria and ACT (49% compared with only 16% and 13% respectively in summer) but remained relatively low in winter for those in Queensland and the Northern Territory.

Differences were seen across geographical areas, with vitamin D levels lower than 50 nmol/L more common in major cities (27%) than in inner regional (16%), outer regional (13%) and remote areas (9%). Vitamin D levels lower than 50 nmol/L were much more common among people born in Southern and Central Asia, North-East Asia, South-East Asia, North Africa and the Middle East.

The Australian Aboriginal and Torres Strait Islander Health Survey (ABS 2014a) found that, in 2012–13, 26.5% Aboriginal and Torres Strait Islander adults had a vitamin D level lower than <50 nmol/L. This pattern was similar for both men and women. Vitamin D levels lower than 50 nmol/L were more common in remote areas (38.7%) than in non-remote areas (23.0%) and vitamin D levels varied considerably by season.

Observational studies in Australia have reported vitamin D status in a range of populations:

- at two antenatal clinics in NSW and ACT, the prevalence of levels lower than 50 nmol/L was 35% in Canberra and 25.7% in Campbelltown (Perampalam et al 2011)
- in a largely low-risk antenatal population in rural Victoria, around 5% had levels lower than 25 nmol/L (Teale & Cunningham 2010) and, at a Victorian metropolitan maternity service, 55% of women had vitamin D levels lower than 50 nmol/L (Davies-Tuck et al 2015)
- among women booking for antenatal care in Cairns, there were no significant differences overall in women’s vitamin D levels based on Indigenous status and all women had levels higher than 50 nmol/L (Bendall et al 2012)
- among women attending for antenatal care in Kalgoorlie, 56% of Aboriginal women and 20% of non-Aboriginal women had vitamin D levels lower than 50 nmol/L (Wilix et al 2015)
- among Indigenous women receiving antenatal care in the Northern Territory, mean maternal vitamin D level was 104 nmol/L during pregnancy (mean 32 weeks gestation) and 80 nmol/L at birth and mean cord blood level was 54 nmol/L (Binks et al 2016)
- compared to migrant women without a refugee background, vitamin D levels lower than 75 nmol/L were generally more common among refugee women (Gibson-Helm et al 2014; Gibson-Helm et al 2015)
- risk-based testing for vitamin D status in pregnancy (South Australian Perinatal Practice Guidelines, in which ‘high-risk’ groups are defined as veiled, dark-skinned and house-bound women) failed to detect over half of women with vitamin D levels lower than 60 nmol/L (De Laine et al 2013).
**Vitamin D status and maternal and pregnancy outcomes**

Recent studies have explored possible associations between vitamin D status in pregnancy and subsequent outcomes. This evidence is generally of low quality and heterogeneous (i.e., in definition of optimal level, timing of serum testing) and findings are inconsistent.

- **Gestational diabetes and glucose tolerance** — One cohort study (Burris et al 2012) suggested that women with vitamin D levels lower than 25 nmol/L may be more likely to experience gestational diabetes (OR 2.2; 95% CI 0.8 to 5.5), while another found no clear difference (OR: 1.08; 95% CI: 0.74 to 1.56) [Schneuer et al 2014]. A cross-sectional study suggested that, compared to vitamin D levels higher than 74 nmol/L in early pregnancy, levels lower than 50 nmol/L (p=0.008) or 50–74 nmol/L (p=0.005) increased the risk of gestational diabetes (Davies-Tuck et al 2015). Another cross-sectional study found that increases in maternal vitamin D were associated with decreases in fasting glucose (p=0.012) [McLeod et al 2012].

- **Pre-eclampsia** — The evidence was largely consistent in finding no association between vitamin D level and the risk of pre-eclampsia in cohort studies (Bomba-Opon et al 2014; Schneuer et al 2014; Gidlof et al 2015) and a case series (Davies-Tuck et al 2015).

- **Preterm birth** — No significant association between vitamin D level and preterm birth was found in a cohort study (p=0.09) [Schneuer et al 2014] and a case series (p=0.11) [Davies-Tuck et al 2015].

- **Small for gestational age** — The frequency of small-for-gestational-age newborns in cohort studies was similar in women with vitamin D levels below or above 20 nmol/L (Bomba-Opon et al 2014) or was increased with levels below 29.9 nmol/L (OR 1.9 95% CI 1.4 to 2.7) [Leffelaar et al 2010] or below 25 nmol/L (OR 1.58 95% CI 1.06 to 2.35, compared to 50–75 nmol/L) [Schneuer et al 2014].

- **Birth weight** — A cohort study (Bomba-Opon et al 2014) and a case series [Davies-Tuck et al 2015] found no association between maternal first trimester vitamin D levels and neonatal birth weight. Another cohort study (Leffelaar et al 2010) found an association between maternal vitamin D levels below 29.9 nmol/L and lower birth weights (−44.0 g, 95% CI −107.1 to −20.9).

- **Macrosomia and infant growth** — A cohort study (Morales et al 2015) found that maternal vitamin D levels lower than 50 nmol/L were associated with increased risk of fetal macrosomia (abdominal circumference 90th centile; p=0.041) but not with rapid growth (p=0.11). Other cohort studies found an association between maternal vitamin D level below 29.9 nmol/L and accelerated growth (Leffelaar et al 2010) or risk of overweight at age 1 year (p=0.03), but not at 4 years (p=0.721) [Morales et al 2015].

### 4.3.2 Vitamin D status in pregnancy

Current guidance in Australia (Paxton et al 2013; RANZCOG 2015), New Zealand (NZ MoH 2013) and the United States [ACOG 2011] suggests that testing be considered for women at high risk of suboptimal vitamin D levels and supplementation advised for pregnant women with levels lower than 50 nmol/L. Guidance in Australia and New Zealand also suggests consideration of a daily dose of 400 IU for pregnant women at lower risk (without testing) (NZ MoH 2013; RANZCOG 2015). In the United Kingdom, it is recommended that all women be advised early in pregnancy to take a supplement of 400 IU daily [NICE updated 2016].

### Summary of the evidence

**Determinants of vitamin D status in pregnancy**

The recent evidence on the determinants of vitamin D status is largely observational and of varying quality. While the definitions used varied across studies, the evidence was consistent that lower vitamin D levels in pregnancy are associated with:


- increasing body mass index (BMI) [Perampalam et al 2011; Bartoszewicz et al 2013; McAree et al 2013; Davies-Tuck et al 2015; Karlsson et al 2015]

Recommendation

8. Do not routinely recommend testing for vitamin D status to pregnant women.

Evidence reviewed 2016

Practice point

O. An understanding of local geography and ethnicity may direct the decision to test for vitamin D status in pregnancy.

Benefits and harms of vitamin D supplementation

While numerous studies have investigated vitamin D supplementation with and without calcium compared to placebo or no treatment, the evidence on the harms and benefits of vitamin D supplementation remains unclear (Harvey et al 2014; De-Regil et al 2016).

- **Serum vitamin D levels** — Studies were consistent in finding that vitamin D supplementation increased vitamin D levels in women (Perumal et al 2015; Rodda et al 2015; De-Regil et al 2016) and newborns (Perumal et al 2015; Rodda et al 2015). However, a Cochrane review noted that the clinical significance of increased maternal vitamin D concentrations remains unclear (De-Regil et al 2016).

- **Maternal outcomes** — Evidence from the Cochrane review (De-Regil et al 2016) suggests a reduced risk of pre-eclampsia (RR 0.52; 95% CI 0.25 to 1.05; low quality) and gestational diabetes (RR 0.43; 95% CI 0.05 to 3.45; very low quality) among women supplemented with vitamin D compared to those receiving placebo or no treatment, though neither result was statistically significant. Among women supplemented with vitamin D plus calcium, there was a reduced risk of pre-eclampsia (RR 0.51; 95% CI 0.32 to 0.80; moderate quality) and the data suggest a reduced risk of gestational diabetes (data from a single study) (RR 0.33; 95% CI 0.01 to 7.84; low quality).

- **Birth outcomes** — The Cochrane review found a reduced risk of preterm birth compared to no treatment or placebo with vitamin D alone (RR 0.36; 95% CI 0.14 to 0.93; moderate quality) but an increased risk with vitamin D plus calcium (RR 1.57; 95% CI 1.02 to 2.43; moderate quality) (De-Regil et al 2016), while a later RCT found no significant effect on gestational age at birth among women receiving vitamin D plus calcium (p=0.37) (Asemi et al 2016).

The Cochrane review of studies comparing vitamin D supplementation alone with no supplement found a reduced risk of low birth weight (RR 0.4; 95% CI 0.24 to 0.67; moderate quality), a possible increase in infant length (mean difference [MD] 0.70; 95% CI −0.02 to 1.43) and head circumference (MD 0.43; 95% CI 0.03 to 0.83) and no clear difference in rates of caesarean section (RR 0.95; 95% CI 0.69 to 1.31), stillbirths (RR 0.35; 95% CI 0.06 to 1.99) or neonatal deaths (RR 0.27; 95% CI 0.04 to 1.67) (De-Regil et al 2016). Another systematic review found that the evidence to support a relationship between maternal vitamin D status and birth weight is limited by its observational nature (Harvey et al 2014). A later RCT found no clear differences in birth weight (p=0.88), length (p=0.94), head circumference (p=0.13) or mode of birth (p=0.26) among newborns of women receiving vitamin D plus calcium and those receiving no intervention (Asemi et al 2016).

- **Infant outcomes** — A systematic review (Harvey et al 2014) found that the evidence to support an association between maternal vitamin D status and infant bone mass was limited by its observational nature and that evidence on serum calcium concentrations was limited by risk of bias. RCTs found that, compared to women receiving no supplement, there was no clear difference in bone mineral content in newborns of mothers receiving vitamin D alone (p=0.21) (Cooper et al 2016) or with calcium (p=0.63) (Diogenes et al 2015).

- **Vitamin D dosage** — Studies were consistent in finding that vitamin D level increased with dose (Dawodu et al 2013; Wagner et al 2013; Mutlu et al 2014; March et al 2015; Wall et al 2016). Studies comparing doses of 1000–1200 to 2000 IU daily found no difference in birth weight (p=0.8) (Mutlu et al 2014) or adverse effects (p=0.5) (March et al 2015). One study comparing 4,000 IU to 2,000 IU daily (Wagner et al 2013) found no clear difference in risk of hypertensive disorders of pregnancy (RR 2.16; 95% CI 0.68 to 6.90), gestational diabetes (RR 1.53; 95% CI 0.71 to 3.28) or preterm birth (RR 0.86; 95% CI 0.51 to 1.45) between groups. Adverse effects were not reported.
Consensus-based recommendation
XXV. In women considered to be at risk of vitamin D deficiency, advise vitamin D supplementation for women with vitamin D levels lower than 50 nmol/L.

4.3.3 Practice summary — vitamin D status

When — In the antenatal period

Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker; pharmacist

☐ Take a holistic approach — Give women advice on the risks and benefits of sun exposure (see Section 4.3.4: Resources) and the dietary sources of vitamin D (dairy products, eggs and fish), taking cultural considerations into account.

☐ Document and follow-up — If a woman’s vitamin D deficiency status is tested, note the results in her record. Have a system in place so that women who are found to be deficient in vitamin D are given ongoing follow-up and information about supplementation.

4.3.4 Resources

Australian and New Zealand Bone and Mineral Society, the Australasian College of Dermatologists, Cancer Council Australia, Endocrine Society of Australia and Osteoporosis Australia (2016) Risks and Benefits of Sun Exposure.


4.3.5 References


4.4 Thyroid dysfunction

There is currently insufficient evidence to support routine testing for thyroid dysfunction. As there is an association between thyroid dysfunction and adverse pregnancy and fetal outcomes, the focus is on identifying and treating women at high risk of the condition.

4.4.1 Background

Thyroid dysfunction in pregnancy often results from a pre-existing condition but may arise during pregnancy. Thyroid dysfunction involves either over or under activity of the thyroid gland.

- **Hyperthyroidism**, in which thyroid hormone levels are raised, is most commonly caused by Graves’ disease, an autoimmune disorder (Marx et al 2008) but may also be induced by excessive exposure to iodine (de Benoist et al 2008). Symptoms include weight loss, heat intolerance and hypertension. It is generally diagnosed and treated before conception (Mestman 2004; Marx et al 2008).

- **Hypothyroidism** is a thyroid hormone deficiency, which may be overt (with symptoms including cold sensitivity, fatigue and dry skin) (Le Groot et al 2012), or subclinical with few or no symptoms but abnormal levels of thyroid hormones (Reid et al 2013). It is most commonly caused by endemic iodine deficiency (Lazarus et al 2011). Autoimmune thyroid disease (eg Hashimoto’s disease) is the most common cause when iodine intake is adequate (Reid et al 2013). Detection of thyroid autoantibodies (to thyroid peroxidase or thyroglobulin) confirms the autoimmune origin of hypothyroidism, or in euthyroid women may indicate increased risk of thyroid dysfunction (Reid et al 2013).

### Incidence

- Thyroid dysfunction is the second most common endocrine condition (after diabetes mellitus) affecting women of reproductive age (Reid et al 2013).
- The incidence of hyperthyroidism in pregnancy is in the range of 0.1–0.4% (Le Groot et al 2012).
- Studies in relatively iodine-sufficient populations estimate an incidence of 0.3–0.5% for overt hypothyroidism and 3–5% for subclinical hypothyroidism (Le Groot et al 2012). It is likely that incidence would be higher in areas of iodine insufficiency.
- The Australian National Health Survey (ABS 2014) found that, in 2011–2012, iodine levels were relatively low among women of childbearing age. Although women aged 16–44 years had sufficient iodine levels overall, around 18% had iodine levels considered moderately deficient (compared to the national average of 13%) and nearly two thirds (62%) had an iodine level below that recommended by WHO for pregnant and breastfeeding women.
- The WHO Global Database on Iodine Deficiency identifies moderate iodine deficiency in some African countries (Algeria, Chad, Senegal), Afghanistan, Belarus and Vietnam (de Benoist et al 2008). Urinary iodine levels associated with a high risk of iodine-induced hyperthyroidism or autoimmune thyroid disease were identified in Brazil, Chile, Ecuador, Liberia and Uganda.
- Thyroid autoantibodies are present in 5–15% of women of childbearing age (Le Groot et al 2012).

### Risks associated with thyroid dysfunction in pregnancy

- Overt hypothyroidism and hyperthyroidism are associated with a range of adverse obstetric outcomes (miscarriage, pre-eclampsia, placental abruption, preterm birth and post-partum haemorrhage) and risks to the baby (low birth weight, increased neonatal respiratory distress and decreased cognitive function) (Lazarus 2011; Lazarus et al 2012).
- Studies are now focusing on the potential effect of subclinical thyroid dysfunction and autoimmune disease. A systematic review found that subclinical hypothyroidism in pregnancy is associated with pre-eclampsia (OR 1.7; 95%CI 1.1 to 2.6) and perinatal mortality (OR 2.7; 95%CI 1.6 to 4.7) and the presence of maternal thyroid autoantibodies is associated with miscarriage (OR 3.73; 95%CI 1.8 to 7.6) and preterm birth (OR 1.9; 95%CI 1.1 to 3.5) (van den Boogaard et al 2011). A meta-analysis of cohort studies had similar findings for miscarriage (OR 3.90; 95%CI 2.48 to 6.12) (Thangaratinam et al 2011) and another for preterm birth (RR 1.41; 95%CI 1.08 to 1.84) (He et al 2012).
4.4.2 Testing for thyroid dysfunction

Summary of the evidence
Routine testing for thyroid dysfunction is not recommended by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG 2015) or in the United States (ACOG 2015) and is not addressed in the United Kingdom antenatal guidelines (NICE 2015).

Benefits and harms of testing for thyroid dysfunction
More evidence is needed to assess the benefits or harms of different approaches to testing for thyroid dysfunction in pregnancy on maternal, infant and child health outcomes. A recent Cochrane review (Spencer et al 2015) found that:

- compared to case finding, universal testing increased diagnosis and subsequent treatment of thyroid dysfunction but there were no clear differences in outcomes reported (pre-eclampsia, preterm birth, miscarriage, fetal or neonatal death)
- compared to no testing, universal testing similarly increased diagnosis and subsequent treatment but there was no clear difference in neurosensory disability for the infant as a child (IQ<85 at 3 years) and other outcomes were not reported.

A subsequent RCT reported that the risk of miscarriage (3.1 vs 8.5%, RR 0.36, 95%CI 0.23 to 0.58, p<0.001) was lower and the risk of caesarean section higher (41.0 vs 33.5%, RR 1.22, 95%CI 1.08 to 1.39, p<0.001) in the testing group than in the control group (Ma et al 2016). The difference in risk of preterm birth did not reach significance (p=0.772).

Recommendation
9. Do not routinely test pregnant women for thyroid dysfunction.
Evidence reviewed 2016 (no change)

Identifying women at high risk of thyroid dysfunction
While this is an evolving area of practice, the American Thyroid Association considers that women with the following are at high risk of thyroid disease (Alexander et al 2017):

- history of thyroid dysfunction
- symptoms or signs of thyroid dysfunction,
- presence of a goiter
- known thyroid antibody positivity.

Other risk factors for thyroid disease include (Alexander et al 2017):

- age >30 years
- history of type 1 diabetes or other autoimmune disorders
- history of pregnancy loss, preterm birth or infertility
- history of head or neck radiation or prior thyroid surgery
- family history of autoimmune thyroid disease or thyroid dysfunction
- BMI ≥40 kg/m²
- use of amiodarone, lithium, or recent administration of iodinated radiologic contrast
- two or more prior pregnancies
- residing in area of moderate to severe iodine deficiency.

Assessment of risk factors at the first antenatal visit is recommended (Le Groot et al 2012). However, onset of thyroid dysfunction can occur later in pregnancy (Moleti et al 2009).

Consensus-based recommendation
XXVI. Recommend thyroid testing to pregnant women who are at increased risk of thyroid dysfunction.

Timing of testing
Low-level evidence was inconsistent regarding the timing of testing for thyroid dysfunction. One study found that first trimester testing identifies mainly minor elevations in TSH, which do not predict adverse
pregnancy outcomes (Ong et al 2014), while another found that testing in the second and third trimesters was of limited value (Ekinci et al 2015).

**Interpreting thyroid function test results**

Thyroid function is initially assessed through testing of thyroid-stimulating hormone (TSH), with measurement of serum thyroxine if maternal TSH is either elevated or reduced.

Diagnosis of thyroid dysfunction in pregnancy is complicated by the fact that normal TSH levels differ from the non-pregnant state (Stagnaro-Green 2011). Applying the general laboratory reference range for TSH to pregnant women can result in misclassification of thyroid status (Dashe et al 2005; Stricker et al 2007; Gilbert et al 2008; Lee et al 2009). TSH levels vary with gestational age and between single and twin pregnancies (Dashe et al 2005). Pregnancy-specific reference ranges that take into account gestational age and fetal number (e.g., Panesar et al 2001) should therefore be used. A recent Australian study (Ekinci et al 2013) established the following reference ranges.

### Table 4.4.1: Reference ranges for thyroid function in pregnancy by trimester

<table>
<thead>
<tr>
<th>Trimester (wk)</th>
<th>TSH median (2.5th–97.5th centile)</th>
<th>Free thyroxine (pmol/L) mean (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (9–13)</td>
<td>0.77 (0.03–3.05)</td>
<td>10.7 (5.9–15/5)</td>
</tr>
<tr>
<td>2 (22–26)</td>
<td>1.17 (0.42–3.36)</td>
<td>8.1 (4.9–11.3)</td>
</tr>
<tr>
<td>3 (35–39)</td>
<td>1.35 (0.34–2.83)</td>
<td>7.8 (4.5–11.0)</td>
</tr>
</tbody>
</table>

**Effectiveness and safety of treatments**

For women with pre-existing thyroid disease, hormone levels are monitored throughout pregnancy and medications adjusted to maintain a euthyroid state. Regular monitoring and adjustment of medication dosage is also needed when thyroid dysfunction is detected during pregnancy.

**Economic analysis**

A review of the cost implications of routine testing for thyroid dysfunction was undertaken to inform the development of Module II of these Guidelines in 2014 (included in an appendix to the full Guidelines). The review found insufficient clinical evidence to show that treatment reduces adverse obstetrical and neonatal outcomes. Additionally, there were no economic evaluations relevant to Australia to enable an assessment of the impact of a routine testing program for thyroid dysfunction to detect women with hypothyroidism who have not already been diagnosed. Further research is needed before a comprehensive economic analysis can be conducted.

### 4.4.3 Discussing thyroid dysfunction

Discussion to inform a woman’s decision-making about thyroid function testing should take place before testing and include that:

- thyroid function can be affected by autoimmune disorders or inadequate or excessive exposure to iodine in the diet
- a family history of thyroid dysfunction means that a woman is more likely to be at risk
- an under-active or over-active thyroid can cause complications to the pregnancy and risks to the baby
- as some symptoms of an over-active thyroid may be part of normal pregnancy (e.g., heat intolerance) and under-active thyroid may not cause symptoms, it is important to test thyroid function in women who have symptoms or are at high risk of thyroid problems (e.g., if they have recently arrived from a country with a high prevalence of iodine deficiency)
- consultation with a specialist may be necessary if thyroid problems are identified.
4.4.4 Practice summary: thyroid dysfunction

When: A woman has symptoms or risk factors for thyroid dysfunction.

Who: Midwife; GP; specialist obstetrician; Aboriginal and Torres Strait Islander Health Practitioner; Aboriginal and Torres Strait Islander Health Worker; multicultural health worker; endocrinologist.

- Discuss the reasons for thyroid function testing: Explain that it is important to check a woman’s thyroid hormone levels because of the effects that thyroid problems can have on the pregnancy and the baby.

- Use pregnancy specific ranges: If interpreting thyroid function test results, use pregnancy-specific reference ranges that take into account gestational age and fetal number.

- Take a holistic approach: While iodine fortification of bread in Australia means that women will likely enter pregnancy with adequate iodine intake, supplementation (150 micrograms a day) is still recommended during pregnancy and breastfeeding. Women who have recently arrived in Australia may have previous exposure to inadequate or excessive iodine, depending on their country of origin.

- Document and follow-up: If a woman’s thyroid function is tested, tell her the results and note them in her antenatal record. Also, note whether thyroid dysfunction is newly diagnosed or was previously treated. Have a follow-up system in place to facilitate timely referral and treatment.

4.4.5 Resources


4.4.6 References


The availability of tests enables women to choose to identify whether there is a probability of them of having a baby with a chromosomal anomaly. The level of decision-making needed requires sensitive engagement with women, partners and family members.

5.1 Background

In recent years, an increasing number of biochemical tests and ultrasound techniques have been developed that can significantly increase the identification of pregnancies with a high probability of chromosomal anomalies such as trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome) and trisomy 13 (Patau syndrome) (see Glossary). These conditions may result in the death of the fetus or baby, some are associated with long-term serious morbidity and some require neonatal investigation or treatment. A high probability test result leads to the offer of a diagnostic test (chorionic villous sampling or amniocentesis). If an anomaly is diagnosed, the woman and her partner may, after counselling, choose to continue with or terminate her pregnancy.

The suitability of any test depends on the gestational stage. Extensive pre- and post-test information and counselling are required, with consideration also being given to the woman’s preferences, availability of testing facilities, costs to the woman and, for ultrasound, operator expertise.

Current practice in Australia is that testing for chromosomal anomalies is done in the first trimester. The combined tests are:

- ultrasound measurement of fetal nuchal translucency thickness between 11 weeks and 13 weeks 6 days gestation (when the fetus has a crown-rump length of 45-84 mm) combined with
- maternal serum testing of pregnancy-associated placental protein-A (PAPP-A) and free beta-human chorionic gonadotrophin (β-hCG) between 9 weeks and 13 weeks, 6 days gestation.

An emerging practice is the use of cell-free deoxyribonucleic acid (cfDNA) testing (also referred to as non-invasive prenatal testing [NIPT]). DNA of placental origin is detectable in maternal serum from 10 weeks gestation. The test involves sequencing DNA fragments in maternal serum, mapping each DNA sequence to a reference genome to determine its chromosome of origin, and counting the number of fragments arising from each chromosome. If the fetus is affected by trisomy, a greater than expected number of the relevant chromosome will be present in maternal serum. Cell-free DNA testing has been used as a primary test (in combination with ultrasound), as a secondary test (with women with increased probability on first trimester screening offered cfDNA or diagnostic testing [chorionic villous sampling or amniocentesis]) or as a contingent test (with women with an intermediate probability on first trimester screening offered cfDNA testing and those with a very high probability offered diagnostic testing). Evaluations of the implementation of contingent cfDNA testing in national screening programs have found improved performance of the program (Chitty et al 2016; Gil et al 2016; Oepkes et al 2016).

Later in pregnancy (14 to 20 weeks), the triple test (maternal serum testing of α-fetoprotein [AFP], free β-hCG [or total hCG] and unconjugated estriol) or the quadruple test (which also includes inhibin A) is used to assess the risk of fetal chromosomal anomaly. The evidence for these tests, along with the integrated test (triple/quadruple test result combined with the nuchal translucency result) has not been reviewed as part of the development of these Guidelines.

5.1.1 Chromosomal anomalies in Australia

The National Perinatal Statistics Unit last reported on congenital anomalies in Australia in 2002–03 (Abeywardana & Sullivan 2008). Trisomy 21 was the most commonly reported chromosomal condition at birth (1.11 per 1,000 births) but there was a high proportion (60%) of fetal deaths and terminations. When terminations were included, the estimated rate was 2.63 per 1,000 pregnancies. Trisomies 18 and 13 were associated with a large number of fetal deaths or terminations. All conditions were more common among women aged 40 years or older. More recent state-based data (with terminations included) gives rates of trisomies 21, 18 and 13 per 1,000 pregnancies of 1.7, 0.3 and 0.2 in Victoria in 2013–14 (CCOPMM 2017) and 1.4, 0.5 and 0.1 in Queensland in 2010 (Howell et al 2011). NSW data from 2010 gives rates per 1,000 births (i.e without terminations included) of
0.5 for trisomy 21 and 0.1 for trisomies 18 and 13 (CEE 2012). The number of reported terminations of pregnancy associated with chromosomal anomalies rose from 246 in 2004 to 323 in 2009 (CEE 2012).

5.2 Discussing tests with women

At the first antenatal visit or as early as possible in pregnancy, the availability of testing for chromosomal anomalies should be discussed and women given relevant written information or other appropriate materials (eg video, DVD) (see Section 5.6). Providing information is particularly important, due to the complexity of the process and the level of decision-making that may be required. A systematic review found that levels of knowledge adequate for decision-making were at times not being achieved despite information leaflets and video having some effect (Green et al 2004). Studies in which knowledge about genetic testing is increased have not observed any corresponding increase in anxiety (Green et al 2004).

In discussing the tests, it is important to use neutral language (ie talk in terms of ‘probability’ or ‘chance’ rather than ‘risk’) and to explain:

- that it is the woman’s/couple’s decision whether any testing takes place;
- the chromosomal anomalies for which testing is available
- the testing pathway, the decisions that need to be made at each point and their consequences (see Figure 5.1)
- the need for accurate assessment of gestational age so that tests are conducted at the appropriate time
- that results of testing alone indicate a probability of fetal chromosomal anomaly but do not give a definitive diagnosis of any anomalies
- the sensitivity and specificity of the test and a full explanation of the reporting format of the test (eg high probability/low probability, 1 in 10, 1 in 300, 1 in 1,000)
- the options for women who receive a high-probability result, including information about chorionic villus sampling and amniocentesis (see Section 5.4)
- a large nuchal translucency associated with normal chromosomes may indicate other anomalies which may be structural (eg diaphragmatic hernia, cardiac anomaly) or genetic (eg Smith-Lemli-Opitz syndrome, Noonan syndrome)
- factors that increase the probability of fetal chromosomal anomalies (advanced maternal age, family history of chromosomal anomalies)
- where and how tests can be accessed if the woman chooses to have them
- the availability of evaluated decision aids (eg the Ottawa Decision Framework) (Arimori 2006; Nagle et al 2006; 2008) (see Section 5.6)
- the costs involved for the woman and the timeframe for receiving results.

Women may choose not to have a test for ethical, religious or personal reasons or may elect to have a diagnostic procedure instead (eg due to a preference to receive definitive information and/or concerns about the sensitivity of available tests). The choice a woman and her partner make about testing should not influence the subsequent care she receives.

Consensus-based recommendation

XXVII. In the first trimester, give all women/couples information about the purpose and implications of testing for chromosomal anomalies to enable them to make informed choices.

Practice point

P. Provide information about testing for chromosomal anomalies in a way that is appropriate and accessible to the individual woman, using neutral language and considering the woman’s level of literacy.
Figure 5.1: Possible pathways of testing for and diagnosis of chromosomal anomalies in the first trimester

Women offered testing for chromosomal anomalies
Purpose: Identify women with a high probability of having a baby with a chromosomal anomaly
Offer counselling from informed professional

- Woman chooses not to have test
- Woman chooses to have test
  - Combined first trimester screening (blood test at 9–13 wk 6 d plus nuchal translucency ultrasound at 11–13 wk 6 d)
  - cfDNA test as primary test (from 10 wk onwards)
  - Increased probability
    - Contingent cfDNA test (intermediate probability)
    - Secondary cfDNA test (high probability)
    - High probability of chromosomal anomaly

- Referral to an appropriately trained health professional offered

Women offered diagnostic test
Purpose: To enable the woman to have further testing to make an informed decision about the pregnancy

- Woman chooses not to have diagnostic test
- Woman chooses to have diagnostic test
  - Diagnostic test: chorionic villus sampling at >11 wk amniocentesis at >15 wk
  - Abnormal result
    - Woman is offered counselling and preparations are made for additional care required during and after the pregnancy or for termination
  - Normal result
    - Individualised follow-up
  - Test failure

*The circumstances in which termination of pregnancy is permissible vary between States/Territories. Health professionals should be aware of relevant legislation in their State/Territory.
5.3 Tests for chromosomal anomalies

5.3.1 Effectiveness of tests

Offering testing for fetal chromosomal anomalies to all women in the first trimester — regardless of maternal age — is recommended in the United Kingdom (NICE 2008), the United States (ACOG 2007) and Australia (RANZCOG 2015).

Summary of the evidence

Combined first trimester tests

Combined first trimester tests identify factors that are known to be associated with fetal chromosomal anomalies and that are independent of each other.

The probability of chromosomal and other anomalies and fetal and postnatal death increases with nuchal translucency thickness. Favourable outcomes have been observed in 92% of babies with nuchal translucency of 3.4 mm (95th centile) compared to 18% of those with nuchal translucency of ≥6.5 mm (Ayras et al 2013). In some situations, the ultrasound component of first-trimester testing may be difficult or impossible (eg due to high BMI, fetal positioning).

Combining nuchal translucency assessment with testing of maternal serum increases the predictive value (Alexioy et al 2009). Recent evidence on the sensitivity of the combined test had the following findings.

- A systematic review (65 studies) found detection rates of 91.9% for trisomy 18 (false positive rate 3.5%), 83.1% for trisomy 13 (false positive rate 4.4%) and 70.1% for monosomy X (false positive rate 5.4%) (Metcalfe et al 2014).
- Cohort studies found detection rates of:
  - 92.2% for trisomy 21 (false positive rate 8.0%) (n=675,332) (Kagan et al 2015b).
  - 91.3% for trisomy 21, 97.1% for trisomy 18, 92.3% for trisomy 13, 80% for sex chromosome aneuploidies and 87% for atypical aneuploidies (n=21,052) (Kagan et al 2015a).
  - 87% for trisomy 21, 91.8% for trisomies 13 and 18, 86.0% for monosomy X, 8.1% for other sex chromosome aneuploidies, 89.3% for triploidy and 13.0% for other high-risk outcome (n=14,684) (Syngelaki et al 2014).

The pooled rate of invasive procedures was 59 per 1,000 pregnancies tested (Susman et al 2010; Syngelaki et al 2014; Kagan et al 2015a).

As fetal nuchal translucency thickness increases with crown-rump length (Pandya et al 1995; Edwards et al 2003) and the detection rate in serum is influenced by maternal age (Grati et al 2010), these factors are included in assessment algorithms. The inclusion of age in the calculation, either alone or in combination with serum test results, increases identification of the probability of chromosomal anomalies (Wapner et al 2003; Scott et al 2004; Centini et al 2005; Soergel et al 2006; Gebb & Dar 2009; Hagen et a 2010; Schmidt et al 2010). The maternal serum variables are also influenced by gestational age, maternal weight, ethnicity, smoking, in vitro fertilisation, parity and diabetes, the background risk for each being calculated and then included in the algorithm with nuchal translucency and maternal age. A history of a previous trisomy 21 pregnancy increases the chance of an abnormal screening test result for trisomy 21.

Offering the combined ultrasound and biochemistry tests reduces the number of women offered diagnostic testing (Saltvedt et al 2005; Mark et al 2006; Philipson et al 2008; Zournatzi et al 2008; Nadel & Likhite 2009; Lo et al 2010), although some women still opt to have diagnostic testing following a normal result (Caughey et al 2007; Hagen et al 2010) and others choose to go directly to the diagnostic test. The combined test may lead to fewer losses of normal pregnancies (Chasen et al 2004) and is cost-effective (Chou et al 2009).

Consensus-based recommendation

XXVIII. If a woman chooses to have the combined test (nuchal translucency thickness, free beta-human chorionic gonadotrophin, pregnancy-associated plasma protein-A), make arrangements so that blood for biochemical analysis is collected between 9 weeks to 13 weeks 6 days gestation and ultrasound assessment takes place between 11 weeks and 13 weeks 6 days gestation.
**Cell-free DNA testing**

As a replacement for combined first trimester testing, cfDNA testing would have a higher detection rate for the more common trisomies — relative risk of detection 1.13 (1.08 to 1.18) for trisomy 21 and 1.22 (1.18 to 1.26) for trisomies 18 and 13 (Petersen et al 2014; Syngelaki et al 2014; Gyselaers et al 2015; Kagan et al 2015a; Kagan et al 2015b; McLennan et al 2016). Fewer invasive procedures would be required (10 per 1,000 women tested) (Susman et al 2010; Syngelaki et al 2014; Kagan et al 2015a) and rates of procedure-related miscarriage would be lower (Morris et al 2014; Gyselaers et al 2015; Mersy et al 2015).

However, cfDNA testing may not detect less common chromosomal anomalies identified through ultrasound assessment — relative risk of detection 0.23 (0.16 to 0.33) for sex chromosome aneuploidies (Syngelaki et al 2014; Kagan et al 2015a; McLennan et al 2016) and 0.01 (0.00 to 0.04) for atypical aneuploidies (Petersen et al 2014; Syngelaki et al 2014; Kagan et al 2015a). As well, the economic costs of incorporating cfDNA testing for trisomy 21 into practice in Australia are currently higher than those for combined first trimester testing (costs associated with cfDNA testing for other chromosomal anomalies have not been investigated in Australia) (O’Leary et al 2013; Ayres et al 2014).

As cfDNA testing is available in Australia, it is important that health professionals counsel women who request the test. The following points are of importance in ensuring informed consent:

- the test may be conducted from 10 weeks onwards (Gil et al 2013)
- the test is not diagnostic — a positive result requires confirmation by invasive procedures (Gil et al 2015; Meck et al 2015; Neufeld-Kaiser et al 2015; McLennan et al 2016)
- while, the test has a higher detection rate for common chromosomal anomalies than combined first trimester testing, it may not detect other, less common, chromosomal anomalies (see above)
- diagnosis of fetal structural or genetic anomalies may be delayed or missed if the 11–13 week ultrasound is not performed in conjunction with cell-free DNA testing (RANZCOG 2015)
- although the false positive rate is lower than for combined first trimester testing, both false positives and false negatives occur (Gil et al 2015b; Mackie et al 2016; Taylor-Phillips et al 2016)
- low fetal fraction of DNA in the maternal circulation (Benachi et al 2015, Gil et al 2015b, Neufeld-Kaiser et al 2015, McLennan et al 2016), which is common among women with a BMI >30 kg/m² (Benachi et al 2015, Gil et al 2015b, Neufeld-Kaiser et al 2015, McLennan et al 2016) may be reported as a failed test or increase the false negative rate of the result — depending on the timing of the test, this may mean that women with a test failure miss the window for combined first trimester testing
- in rare circumstances, the test may raise suspicions of maternal or fetal conditions other than the fetal anomalies for which the test is being performed (Sachs et al 2015)
- the test is not currently covered by Medicare or private health insurance — costs to women are $400–$500, depending on location.

### 5.4 Supporting women who receive a high-probability result

#### 5.4.1 Referral of women with a high probability of having a baby with a chromosomal anomaly

Following a result that suggests a higher probability of having a baby with a chromosomal anomaly, the offer of referral to a health professional (e.g., a genetic counsellor) to discuss their options is an important consideration (see below). When a woman has a diagnostic test and fetal chromosomal anomaly is detected, follow-up with an appropriate health professional should occur at the earliest opportunity. Appropriate health professionals include obstetricians, midwives experienced in genetic counselling, genetic counsellors and clinical geneticists.
5.4.2 Discussing diagnostic testing with women

The suitability of diagnostic tests is determined by gestational stage. The tests are invasive and have previously been associated with a 1% increased risk of miscarriage. However, recent studies suggest that the additional risk is not significant (Akolekar et al 2015; Wulff et al 2016) and is related to the skill and experience of the person carrying out the test (Bakker et al 2016).

Diagnostic tests are based on chromosomal analysis of cells collected using:

- chorionic villus sampling (tissue from the villi of the chorion [part of the placenta]) — testing takes place any time after 11 weeks pregnancy or
- amniocentesis (to sample fetal skin cells in the amniotic fluid) — testing takes place after 15 weeks pregnancy.

In discussing diagnostic tests, it is important to explain:

- the chromosomal anomalies that may be diagnosed
- the available tests, the gestational stage at which they should be undertaken, the process of the procedure and the risks involved
- the possibility that the procedure may not be successful or the result may not accurately reflect the fetal status
- the possibility of other fetal anomalies that are not identified by the test
- the timeframe for receiving results and making further decisions if necessary
- options to consider if a chromosomal anomaly is identified (e.g., continuation of the pregnancy or termination where this is permitted under jurisdictional legislation) and the need for additional care if the pregnancy continues (e.g., specialist management of the pregnancy and the baby)
- long-term implications for the woman and her family of having an affected baby and the health and development issues for children with the condition
- the impact on a woman and her family of a false negative or false positive result (e.g., anxiety among women receiving false positives may remain [Green et al 2004])
- costs involved and how they are to be met.

Timing of diagnostic tests

There is high quality evidence from a Cochrane review (Alfirevic et al 2003) and a subsequent randomised trial (n=3,775) (Philip et al 2004) that amniocentesis before 15 weeks pregnancy increases the risk of miscarriage and procedure-related indicated terminations and the incidence of talipes equinovarus compared to chorionic villus sampling at that time. Transabdominal chorionic villus sampling is the method of choice for diagnosis of fetal chromosomal anomalies before 14 weeks pregnancy (Philip et al 2004).

Some women may not have the option of chorionic villus sampling (e.g., if it is not feasible for the test to be conducted before 14 weeks pregnancy or due to placental positioning) and others may choose to wait for amniocentesis after 15 weeks gestation.

**Recommendation**

10. If a woman chooses to have a diagnostic test for chromosomal anomaly, base the choice of test on gestational age (chorionic villus sampling before 14 weeks pregnancy and amniocentesis after 15 weeks) and the woman’s/couple’s preferences.

**Discussing diagnostic test results**

Careful consideration should be given to the way diagnostic test results are conveyed and experienced interpreters should be used when this is necessary to enable effective communication.

Women receiving a diagnosis of fetal chromosomal anomaly may be unable to absorb information for some time and follow-up support may require several consultations. Counselling should be sensitive to the nature of decisions to be taken, should respect individual decisions and allow time to reach decisions (NSW Health 2007). Appropriate follow-up when an anomaly is detected may require referral to genetic counselling services, other professional services or support networks (see Section 5.6).
If a woman has a normal diagnostic test result, she should be advised of the residual probability of having a baby with a chromosomal anomaly as the diagnostic tests have a sensitivity of less than 100%.

Consensus-based recommendation
XXIX. Offer rapid access to appropriate counselling and ongoing support by trained health professionals to women who receive a diagnosis of fetal chromosomal anomaly.

Practice point
Q. Women with a high-probability screening test result but negative diagnostic test should be referred for further specialist assessment because of an increased risk of other fetal anomalies.

5.5 Other considerations in testing for fetal chromosomal anomalies

5.5.1 Availability and uptake of testing
The range of tests available, policies for testing and uptake by women vary regionally (O’Leary et al 2006). Overall, approximately 50% of pregnant women participated in nuchal translucency ultrasound in 2007–08 (Nisbet et al 2010). A Victorian study found the uptake of combined first trimester screening to be 70–80% in recent years (Hui et al 2016).

Studies in Victoria and Queensland have shown higher uptake of testing in metropolitan areas and in private health care and lower rates of diagnosis of Down syndrome in urban areas and public health care (Muggli et al 2006; Coory et al 2007). Lower rates of access to testing in rural areas may reflect lack of transport, low levels of support and income in these areas and women’s attitudes. However, it has been suggested that low uptake of testing among women from low socioeconomic groups reflects lower rates of informed choice rather than women’s attitudes (Dormandy et al 2005).

No data have been reported on the uptake of chromosomal anomaly testing among Aboriginal and Torres Strait Islander women. However, a study at Royal Darwin Hospital in 1999 suggested that tests were rarely offered to Aboriginal women, including those in older age groups (Hunt 2004). A more recent study into testing for chromosomal anomalies among Aboriginal and Torres Strait Islander women (MSHR 2010) has highlighted the importance of providing information about testing and identified challenges involved in offering testing, particularly in remote areas. These included late presentation in pregnancy, difficulties establishing accurate gestational age, limited consultation time to discuss the testing process, competing priorities in antenatal care, confusion about what needs to be done and when, and organisational logistics (eg women’s travel, where to send blood, referral procedures).

Practice point
R. Support all women to access testing for chromosomal anomalies in a timely manner.

Education
Health professionals caring for pregnant women should undertake continuing education regarding options available for testing for chromosomal anomalies and be aware of current tests available and the settings in which they can be implemented (RANZCOG 2015).

Accreditation of ultrasound operators
The ability to achieve a reliable measurement of nuchal translucency depends on appropriate training and adherence to a standard technique to achieve uniformity of results among different operators (Nicolaides 2004). Accreditation of ultrasound operators to conduct nuchal translucency measurement should be through the Nuchal Translucency – Ultrasound, Education and Monitoring Program administered through RANZCOG.

Quality assurance
All laboratories must be accredited by the National Association of Testing Authorities (NATA). External and internal quality control measures should be in place.
5.6 Practice summary — testing for chromosomal anomalies

**When** — At the first antenatal visit

**Who** — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker; genetic counsellor

- Discuss the process of testing for chromosomal anomalies — Explain the purpose, the process involved and that it is the woman’s choice whether any tests are carried out.

- Consider timing — For women who choose to have combined first trimester testing, make arrangements for the tests to be carried out before 13 weeks and 6 days pregnancy. If a woman elects to have cfDNA testing, this may be conducted from 10 weeks.

- Offer women with a high-probability result referral to an appropriately trained health professional — This may assist women in considering options and making decisions about diagnostic testing. If a diagnostic test is carried out and chromosomal anomaly diagnosed, referral for counselling should occur at the earliest opportunity.

- Learn about locally available resources — Available testing services and support organisations will vary by location.

5.6.1 Resources

**Health professional resources**

Resources available to health professionals include websites and professional organisations, seminars, courses and printed materials, which are regularly revised and updated so that they reflect current practice. Some examples are given below. Pamphlets and other information are available from local genetic services and obstetric ultrasound/radiology practices.

- MSHR (2010) Resources developed as a result of *Screening for Fetal Anomalies: Views of Indigenous People and their Health Care Providers* project.
- Nuchal Translucency Online Learning Program

**Resources for women and their families**

- Association for Genetic Support of Australasia
- Centre for Genetics Education’s *Prenatal Testing – Overview*.
- Decision Aid for Prenatal Testing for Fetal Abnormalities — *Your Choice: Screening & Diagnostic tests in Pregnancy*. Murdoch Children’s Institute
- Ottawa Personal Decision Aid
- Prenatal Testing – *Special tests for your baby during pregnancy*.

5.6.2 References


## Appendices

### A: Membership and terms of reference of the Expert Working Group

<table>
<thead>
<tr>
<th>Expert Working Group Members</th>
<th>Discipline/expertise/special interest</th>
<th>Position and organisation</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Co-chairs</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Professor Jeremy Oats</td>
<td>Obstetrics &amp; Gynaecology</td>
<td>Obstetrician</td>
<td>VIC</td>
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<tr>
<td></td>
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<td>Professorial Fellow</td>
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<td></td>
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<td>Melbourne School of</td>
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<td></td>
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<td>Population &amp; Global Health,</td>
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<tr>
<td></td>
<td></td>
<td>University of Melbourne</td>
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</tr>
<tr>
<td>Professor Caroline Homer</td>
<td>Midwifery</td>
<td>President, Australian</td>
<td>NSW</td>
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<td></td>
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<td>College of Midwives</td>
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<tr>
<td></td>
<td></td>
<td>Distinguished Professor</td>
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<td></td>
<td></td>
<td>of Midwifery, University</td>
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<td>of Technology Sydney</td>
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<tr>
<td><strong>Members</strong></td>
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<tr>
<td>Dr Martin Byrne</td>
<td>GP Obstetrics</td>
<td>GP &amp; Chair, GP Obstetric</td>
<td>QLD</td>
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<td></td>
<td></td>
<td>Advisory Committee, RANZCOG</td>
<td></td>
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<tr>
<td>Ms Ann Catchlove</td>
<td></td>
<td>Consumer representative</td>
<td>VIC</td>
</tr>
<tr>
<td>Ms Lisa Clements</td>
<td>Midwifery, Migrant &amp; Refugee Women</td>
<td>Practice Nurse/Midwife &amp;</td>
<td>ACT</td>
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<td></td>
<td></td>
<td>Primary Health Care</td>
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<td></td>
<td>Manger; Companion House</td>
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<td></td>
<td>Medical Service</td>
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<tr>
<td>Dr Anthony Hobbs</td>
<td>GP Obstetrics</td>
<td>Commonwealth Deputy Chief</td>
<td>ACT</td>
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<td></td>
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<td>Medical Officer, Department</td>
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<td>of Health</td>
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<tr>
<td>Ms Tracy Martin</td>
<td>Midwifery</td>
<td>Chair, Maternity Services</td>
<td>WA</td>
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<td>Inter-Jurisdictional</td>
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<td>Committee, Principal</td>
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<td>Midwifery Advisor, Nursing</td>
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<td>and Midwifery Office, WA</td>
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<tr>
<td>Professor Sue McDonald</td>
<td>Midwifery, Perinatal Health</td>
<td>Professor of Midwifery,</td>
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<td>La Trobe University</td>
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<tr>
<td>Dr Sarah Jane McEwan</td>
<td>Obstetrics &amp; Gynaecology, Indigeneous</td>
<td>District Medical Officer,</td>
<td>WA</td>
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<td>Health</td>
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<td></td>
<td></td>
<td>South Hedland, WA</td>
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<tr>
<td>Assoc Prof Philippa Middleton</td>
<td>Perinatal Epidemiology</td>
<td>Principal Research Fellow</td>
<td>SA</td>
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<td>SA Health and Medical</td>
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<td>Research Institute/The</td>
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<tr>
<td></td>
<td></td>
<td>University of Adelaide</td>
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<tr>
<td>Professor Michael Permezel</td>
<td>Obstetrics &amp; Gynaecology</td>
<td>President RANZCOG (15</td>
<td>VIC</td>
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<td>November 2016)</td>
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<tr>
<td>Adjunct Professor Debra Thoms</td>
<td>Midwifery</td>
<td>Commonwealth Chief Nursing</td>
<td>ACT</td>
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<td></td>
<td></td>
<td>and Midwifery Officer,</td>
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<td></td>
<td></td>
<td>Department of Health</td>
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</tr>
</tbody>
</table>
The Department of Health and the Expert Working Group would also like to acknowledge the following people who contributed their expertise to the review:

- Professor Greg Dore, Head, Viral Hepatitis Clinical Research Program, Kirby Institute for infection and immunity in society, The University of New South Wales;
- Associate Professor Lisa Hui, Department of Obstetrics and Gynaecology, University of Melbourne, Department of Perinatal Medicine, Mercy Hospital for Women, Public Health Genetics group, Murdoch Childrens Research Institute;
- Associate Professor Janet Vaughan, Consultant Obstetrician and Obstetrics and Gynaecology Ultrasound Subspecialist, Obstetrics Plus, Sydney.
Terms of reference

The Expert Working Group will oversee the review and revision of the National Evidence-based Clinical Practice Guidelines — Antenatal Care (incorporating both Modules I and II of the Guidelines). The role of the Expert Working Group will include:

- providing advice, expertise and direction in relation to the combining of the two modules, and the review of the Guidelines to promote optimal care for pregnant women across Australia;
- reviewing the existing Guidelines to identify topics and guidelines that require updating;
- advising on the review of national and international literature on antenatal care to inform amendments required to the existing Guidelines;
- identifying any new topics and drafting new evidence-based guidelines for inclusion in the Guidelines;
- developing a plan and strategies to promote and disseminate the finalised Guidelines to ensure clinical uptake of the Guidelines;
- advising on the development of a consultation strategy (in the event that the review results in major changes to the existing Guidelines or the inclusion of new guidelines); and
- ensuring the review is conducted in accordance with the National Health and Medical Research Council’s (NHMRC) protocols and submitted to the NHMRC for approval.
B: Administrative report

Australian Clinical Practice Guidelines on Antenatal Care were released in two stages in 2012 (Module I) (Australian Health Ministers’ Advisory Council 2012) and 2014 (Module II) (Australian Health Ministers’ Advisory Council 2014). NHMRC approval of clinical practice guidelines is valid for up to 5 years and it was therefore considered critical that Module 1 be reviewed and updated prior to NHMRC approval again being sought.

Process of guideline development

The development of the draft Guidelines has followed the key principles and processes outlined in Procedures and Requirements for Meeting the 2011 NHMRC Standard for Clinical Practice Guidelines (NHMRC 2011) and the 2016 NHMRC Standards for Guidelines.

Funding and management of the project

The Maternity Services Inter-Jurisdictional Committee (MSIJC) received funds through the 2015–16 Australian Health Ministers’ Advisory Council (AHMAC) cost-shared budget to fund a review of the Guidelines and develop a revision and evaluation framework. The Commonwealth Department of Health provided additional funding and agreed to project manage the review on behalf of the MSIJC.

Establishment of the Expert Working Group

An Expert Working Group (EWG) was established to provide expert guidance to the review. The Department of Health approached the Australian College of Midwives (ACM) and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) and invited their Presidents to be on the EWG. The Chief Nursing and Midwifery Officer (CNMO) and Deputy Chief Medical Officer for the Commonwealth Department of Health and the Chair of the MSIJC were also included in the EWG, along with the consumer representative who had been involved in the development of Module 1 and 11. Where possible, it was considered desirable to include EWG members involved in the development of the Module 1 and 11 Guidelines on the EWG as this would provide continuity to the project. A consumer representative and a range of academics and practitioners working in obstetrics and midwifery who were previously involved in the project were therefore contacted and accepted invitations to be on the EWG.

Following the first meeting of the EWG late in 2015, EWG members felt it would be useful to include a rural midwifery or obstetric practitioner, and representatives for Aboriginal and Torres Strait Islander women and migrant and refugee women. EWG members were invited to suggest potential nominees and the Department contacted the nominees to invite them to join the EWG. A rural GP obstetrician from the Royal Australian College of General Practitioners, an Aboriginal District Medical Officer with obstetrics experience, and a midwife working with migrant and refugee women were recruited to the EWG from this process.

A list of the EWG members and the Terms of Reference for the EWG is included in Appendix A.

Capturing consumer perspectives

The establishment of the EWG with dedicated consumer representation was considered fundamental to the inclusion of consumer perspectives in the development of the Guidelines. Ms Ann Catchlove, the consumer representative for the review, has four children and was also involved in the development of the Modules I and II of the Guidelines. She was originally recruited through advertisements placed in Consumer Health Forum publications for consumers with an interest in national guidelines.

In addition, the perspectives of consumers will be facilitated through the consultation process.

Capturing perspectives of specific population groups

At the first meeting of the EWG, members recognised that Aboriginal and Torres Strait Islander women and migrant and refugee women often experience poorer maternity outcomes than those among the general population. It was agreed that representatives for these two groups of women should be included on the EWG.

Dr Sarah-Jane McEwan joined the EWG as a representative for Aboriginal women, following a recommendation from an existing EWG member. Dr McEwan is from the Wiradjuri Aboriginal people in central NSW and has a strong interest in Indigenous health. She is currently the District Medical Officer in obstetrics and
gynaecology and emergency at Port Hedland Hospital, Western Australia. Throughout her career she has worked with remote Indigenous communities such as Wirraka-Mya Aboriginal Medical Service/Royal Flying Doctors Service WA and the Danila Dilba Aboriginal Medical Service in Darwin.

Ms Lisa Clements joined the EWG as a representative for migrant and refugee women following an approach from the Department. Ms Clements is currently the Practice Nurse/Midwife and Primary Health Care Manager at Companion House, ACT. She works with women and their families who have sought safety in Australia from persecution, torture and war related trauma.

Processes used for declaration and management of competing interests
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 were as follows.

- All EWG members were required to complete a Declaration of Interest Form (as per the NHMRC requirements). These signed and scanned forms were reviewed and held by the the Department.
- At the beginning of each meeting, EWG members were informed of the arising agenda items and asked to declare any potential conflicts of interest.
- Any arising conflicts of interest and strategies for managing these (if required) were adjudicated by the Co-Chairs and documented in meeting minutes. A conflict of interest held by a Co-Chair was managed by the other Co-Chair and the area of conflict clearly stated.

Identification of topics for review
The EWG met for the first time on 26 October 2015. Members agreed that Module I and II of the Guidelines should be combined, and identified seven topics (domestic violence, hepatitis C, vitamin D, fetal growth and wellbeing, risk of pre-eclampsia, risk of preterm birth and thyroid dysfunction) from Modules I and II for review. Members also agreed that four new topics (cell-free DNA testing or non-invasive prenatal testing (NIPT), illicit substance use, monitoring of weight gain and early testing for diabetes) should be examined. The list of proposed review topics and research questions was then sent out to three key professional colleges (Australian College of Midwives, Royal Australian and New Zealand College of Obstetricians and Gynaecologists and Royal Australian College of General Practitioners) for comment. This consultation process resulted in the addition of one additional review topic (antenatal care for Aboriginal and Torres Strait Islander women) and some additional research questions.

Development of recommendations and practice points
Methodologists were engaged to conduct searches of the literature and evaluate the evidence (see Appendix C). Each evidence evaluation report and associated chapter was then reviewed by the Co-Chairs and draft recommendations and practice points developed in consultation with the methodologists. Documents were then circulated for comment from the EWG by email and comments collated by the Department. On 5 December 2016, the editorial subgroup (Co-Chairs, methodologists/technical writer and representatives of the Department) reviewed comments provided by the EWG and how these had been incorporated by the technical writer.

A discussion paper was then developed that included commentary on changes since EWG review and a summary of the evidence supporting the recommendations (evidence statements and GRADE summary of findings tables). A face-to-face meeting was held on 27–28 February 2017 and the wording of recommendations (evidence-based and consensus-based), practice points and the content of the Guidelines agreed by the EWG.

The EWG was guided by the methodologists and technical writer in the approach to developing recommendations and practice points (ie wording was to be in plain English, specific, unambiguous, clearly describe the action/s to be taken by users and match the strength of the body of evidence). An iterative approach was taken to finalising the wording. As each recommendation or practice point was reviewed, the technical writer noted suggested changes and read the revised wording to the Group. This was repeated until the Co-Chairs were satisfied that each member of the EWG agreed with the wording (ie members were asked individually). Members who did not attend the meeting had input via email.
Consultation

**Preliminary consultation with key stakeholders**

Prior to public consultation, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists and the Australian College of Midwives were identified as key stakeholders and their feedback on a preliminary consultation draft sought. The input from these Colleges was incorporated into the consultation draft. These bodies will also be invited to comment on the consultation draft during public consultation.

**Public consultation**

The draft guidelines have been released for a 30-day public consultation, as required in the NHMRC Act 1992 and accompanying regulations. The public consultation began on 27 May 2017 and will formally end on 27 June 2017.

Before the consultation period commenced, the Department contacted representatives of each State and Territory health department to inform them of the consultation and invite their comments. These comments will be documented and addressed as part of the process of summarising and incorporating submissions post-consultation.

Following public consultation, a submission report documenting details of public consultation submissions and guideline developer responses will be prepared.

**Summary of issues raised through the consultation process**

To be developed following public consultation

**Anticipated process post-consultation**

**Independent review**

The revised Guidelines will be critically appraised by two independent reviewers using the AGREE II instrument and revised as required. Peer review will also be sought from clinicians with expertise in antenatal care.

**Endorsement**

Endorsement of the Guidelines will be sought from key stakeholder organisations (eg RANZCOG and ACM).

**Dissemination, implementation and review**

**Dissemination**

Following NHMRC approval of the new recommendations, the two original modules will be combined with the chapters included in this consultation draft. The revised Guidelines will be uploaded as a searchable PDF to the Maternity Services section of the Department’s website. This will be accessible to health professionals and the broader community. The Guidelines will also be listed on the NHMRC portal and accessible by searching the portal.

**Promotion**

At the first meeting of the EWG, members agreed that a letter from the Commonwealth Chief Medical Officer and Chief Nursing and Midwifery Officer should accompany the Guidelines. There was also agreement that the Minister for Health be invited to launch the Guidelines in Canberra and the presidents of RANZCOG and the ACM be invited to attend. Members felt it would be ideal to have the Guidelines endorsed by RANZCOG and ACM and suggested that, once the Guidelines are finalised, the Department could write to the Australian Commission on Safety and Quality in Health Care (ACSQHC) regarding embedding the guidelines into standards.

Following the launch, the Department will email key stakeholders to inform them of the revised Guidelines and advise how they can be accessed. This may include requesting stakeholder organisations, including those that fund or provide healthcare services or that represent groups of individual stakeholders, to inform their members or networks of the revised Guidelines via their usual communication avenues (ie e-newsletters,
conferences) and to encourage health professionals and service providers to implement the recommendations in their everyday practice.

The Department also reports to AHMAC on this project and will ensure that all jurisdictions are informed once the updated recommendations have been approved by the NHMRC.

**Implementation**

The EWG considered methods of providing supporting materials related to the Guidelines. Development of a user-friendly ‘app’ for use on phones and tablets and summary documents for health professionals and consumers are amongst the strategies being considered. Discussions with the key professional colleges and funding will inform decisions relating to implementation.

**Review**

The EWG has identified topics for future review and it is anticipated that the online version of the Guidelines will be updated as revised or new chapters are developed.

**References**


C: Overview of evaluation of the evidence

Separate systematic literature reviews were conducted for each topic in this consultation draft. As outlined in Appendix B, the review included seven topics that were previously reviewed for Modules I and II of the Guidelines (Australian Health Ministers’ Advisory Council 2012; Australian Health Ministers’ Advisory Council 2014) and an additional five topics, of which four provided additional information for existing chapters (cell-free DNA testing, monitoring of weight gain, early testing for diabetes and models of care for Aboriginal and Torres Strait Islander women) and one (illicit substance use) required development of a new chapter. This appendix provides a brief summary of the process of reviewing the evidence for these topics. The full evidence tables, GRADE summaries of the evidence and evidence statements are included in the Technical Reports.

Approach to evaluation of the evidence

The evaluation of the evidence used GRADE methods for critical analysis of the literature and aimed to provide a robust assessment of the relevance and quality of the evidence in a format that met the requirements of the Procedures and Requirements for Meeting the 2011 NHMRC Standard for clinical practice guidelines (2011) (NHMRC 2011).

Research questions

For topics previously reviewed, the original research questions were used, with some additional questions developed by the EWG to capture evidence on emerging practices. Questions for new topics were developed by the EWG. All questions were reviewed by three professional colleges (Australian College of Midwives, Royal Australian and New Zealand College of Obstetricians and Gynaecologists and Royal Australian College of General Practitioners) and some additional questions added by them.

Search strategies

Searches were conducted in Medline, EMBASE, PsycInfo, Informit, Australian Medical Index and the Cochrane Database of Systematic Reviews. Search terms were searched for as keywords, exploded where possible, and as free text within the title and/or abstract, in the EMBASE and Medline databases, with modifications to suit the keywords and descriptors of other search platforms. The reference lists of included papers were reviewed to identify any peer-reviewed evidence that may have been missed in the literature search.

Abstracts of identified studies were screened by two methodologists (PM and ES) and full text articles were reviewed by a third methodologist (JR). Exclusion criteria applied to studies were:

- does not answer research question
- not specific to target population (eg specific to non-pregnant women or high-risk women) or health care setting
- does not meet criteria for grading (eg no outcomes reported or reporting too limited to establish risk of bias, conference abstract, study protocol)
- not a systematic review (in those evaluations that were limited to systematic reviews)
- overlap with higher quality systematic review
- included in high quality systematic review
- relevant to research not practice
- beyond scope of guidelines
- narrative review or opinion paper (editorial, letter, summary, comment, interview)
- background information (eg guidelines, statements)
- duplicate
- not in English.

Data extraction

Data extraction tables were created for each research question and listed the study design; evidence level (based on NHMRC levels of evidence [see Table C.1]); sample size; aim/population/methods/outcomes reported; result and limitations (as assessed using adapted NHMRC criteria for quality assessment of systematic
reviews [see Table C.22] and GRADE criteria for quality assessment of randomised controlled trials and observational studies [see Table C.3]).

Table C.1: Designations of levels of evidence according to type of research question

<table>
<thead>
<tr>
<th>Level</th>
<th>Intervention</th>
<th>Diagnostic accuracy</th>
<th>Prognosis</th>
<th>Aetiology</th>
<th>Screening intervention</th>
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<tbody>
<tr>
<td>I</td>
<td>Systematic review of level II studies</td>
<td>A systematic review of level II studies</td>
<td>A systematic review of level II studies</td>
<td>A systematic review of level II studies</td>
<td>A systematic review of level II studies</td>
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<tr>
<td>II</td>
<td>A randomised controlled trial</td>
<td>A study of test accuracy with an independent, blinded comparison with a valid reference standard, among consecutive persons with a defined clinical presentation</td>
<td>A prospective cohort study</td>
<td>A prospectiv e cohort study</td>
<td>A randomised controlled trial</td>
</tr>
<tr>
<td>III-1</td>
<td>Pseudo-randomised trial</td>
<td>A study of test accuracy with independent, blinded comparison with a valid reference standard, among non-consecutive persons with a defined clinical presentation</td>
<td>All or none</td>
<td>All or none</td>
<td>Pseudo-randomised controlled trial (ie alternate allocation or some other method)</td>
</tr>
<tr>
<td>III-2</td>
<td>A comparative study with concurrent controls:</td>
<td>A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence</td>
<td>Analysis of prognostic factors amongst persons in a single arm of a randomised controlled trial</td>
<td>A retrospectiv e cohort study</td>
<td>A comparative study with concurrent controls:</td>
</tr>
<tr>
<td></td>
<td>• Non-randomised experimental trial</td>
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<td>• Non-randomised, experimental trial</td>
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<td>• Cohort study</td>
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<td>• Cohort study</td>
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<td>• Case-control study</td>
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<td>• Case-control study</td>
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<td></td>
<td>• Interrupted time series with control group</td>
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<td>III-3</td>
<td>A comparative study without concurrent controls:</td>
<td>Diagnostic case-control study</td>
<td>A retrospective cohort study</td>
<td>A case-control study</td>
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<td>• Historical control study</td>
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<td>Historical control study</td>
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<td></td>
<td>• Two or more single arm study</td>
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<td>Two or more single arm study</td>
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<td></td>
<td>• Interrupted time series without parallel control</td>
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<tr>
<td>IV</td>
<td>Case series with either post-test or pre-test/post-test outcomes</td>
<td>Study of diagnostic yield (no reference standard)</td>
<td>Case series, or cohort study of persons at different stages of disease</td>
<td>A cross-sectional study or case series</td>
<td>Case series</td>
</tr>
</tbody>
</table>

Source: [NHMRC 2009].

Table C.2: Assessment of quality of systematic literature reviews

<table>
<thead>
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<th>Considerations in assessing quality of systematic reviews</th>
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<tbody>
<tr>
<td>Questions and methods clearly stated</td>
</tr>
<tr>
<td>Search procedure sufficiently rigorous to identify all relevant studies</td>
</tr>
<tr>
<td>Review includes all the potential benefits and harms of the intervention</td>
</tr>
<tr>
<td>Review only includes randomised controlled trials</td>
</tr>
<tr>
<td>Methodological quality of primary studies assessed</td>
</tr>
<tr>
<td>Data summarised to give a point estimate of effect and confidence intervals</td>
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</tbody>
</table>
Differences in individual study results are adequately explained.

Examination of which study population characteristics (disease subtypes, age/sex groups) determine the magnitude of effect of the intervention is included.

Reviewers’ conclusions are supported by data cited.

Sources of heterogeneity are explored.

Source: Adapted from [NHMRC 2000a; NHMRC 2000b; SIGN 2004].

### Table C.3: Assessment of limitations of randomised controlled trials

<table>
<thead>
<tr>
<th>Study limitation</th>
<th>Explanation</th>
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<tbody>
<tr>
<td>Lack of allocation concealment</td>
<td>Those enrolling patients are aware of the group (or period in a crossover trial) to which the next enrolled patient will be allocated (a major problem in “pseudo” or “quasi” randomised trials with allocation by day of week, birth date, chart number, etc.).</td>
</tr>
<tr>
<td>Lack of blinding</td>
<td>Patient, caregivers, those recording outcomes, those adjudicating outcomes, or data analysts are aware of the arm to which patients are allocated (or the medication currently being received in a crossover trial).</td>
</tr>
<tr>
<td>Incomplete accounting of patients and outcome events</td>
<td>Loss to follow-up and failure to adhere to the intention-to-treat principle in superiority trials; or in noninferiority trials, loss to follow-up, and failure to conduct both analyses considering only those who adhered to treatment, and all patients for whom outcome data are available. The significance of particular rates of loss to follow-up, however, varies widely and is dependent on the relation between loss to follow-up and number of events. The higher the proportion lost to follow-up in relation to intervention and control group event rates, and differences between intervention and control groups, the greater the threat of bias.</td>
</tr>
<tr>
<td>Selective outcome reporting</td>
<td>Incomplete or absent reporting of some outcomes and not others on the basis of the results.</td>
</tr>
<tr>
<td>Other limitations</td>
<td>Stopping trial early for benefit. Substantial overestimates are likely in trials with fewer than 500 events and large overestimates are likely in trials with fewer than 200 events. Empirical evidence suggests that formal stopping rules do not reduce this bias. Use of unvalidated outcome measures (e.g. patient-reported outcomes) Carryover effects in crossover trial Recruitment bias in cluster-randomised trials</td>
</tr>
</tbody>
</table>

Source: [Schünemann et al 2013].

### Table C.3: Assessment of limitations of observational studies

<table>
<thead>
<tr>
<th>Study limitation</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to develop and apply appropriate eligibility criteria (inclusion of control population)</td>
<td>Under- or over-matching in case-control studies Selection of exposed and unexposed in cohort studies from different populations</td>
</tr>
<tr>
<td>Flawed measurement of both exposure and outcome</td>
<td>Differences in measurement of exposure [e.g. recall bias in case-control studies] Differential surveillance for outcome in exposed and unexposed in cohort studies</td>
</tr>
<tr>
<td>Failure to adequately control confounding</td>
<td>Failure to accurate measurement of all known prognostic factors Failure to match for prognostic factors and/or adjustment in statistical analysis</td>
</tr>
<tr>
<td>Incomplete or inadequately short follow-up</td>
<td>Especially within prospective cohort studies, both groups should be followed for the same amount of time.</td>
</tr>
</tbody>
</table>

Source: [Schünemann et al 2013].

**Selection of outcomes for GRADE analysis**

The methodologists identified outcomes reported in the evidence for each topic. These were then reviewed and agreed upon by the Co-chairs and weighted by the EWG.

**Assessing the evidence**

For many research questions, the evidence was observational and heterogeneous and did not allow meta-analysis. For these questions, findings were tabulated and summarised in the text of the reviews and, generally, consensus-based recommendations were then developed by the EWG.

For research questions where comparable outcomes were reported, these were pooled using Revman 5 and the pooled results transferred to GRADE evidence tables, which take into account the risk of bias [the degree
to which included studies have a high likelihood of protection against bias), inconsistency (the degree to which included studies find the same direction or magnitude of effect), imprecision (the confidence in the estimates of effect), indirectness (degree to which the evidence can be linked to important health outcomes) and the potential for publication bias (degree to which non-reporting or selective analysis of results may influence interpretation of study results). The evidence tables provided a basis for GRADE Summary of Findings tables, which give anticipated absolute effects (in terms of numbers per 1,000) and relative risk, and provide a summation of the quality of the evidence. Any recommendations developed were graded based on this summation.

**Synthesising the evidence**

A plain English summary of the evidence was developed for each research question for which studies were identified. This noted the quality of the studies that contributed to the body of evidence, listed the studies of greatest relevance and provided advice to the EWG on implications for the guidelines and whether the evidence was sufficient to support a recommendation or would inform the narrative.

**Grading recommendations**

Grading of recommendations was based on the GRADE summation of the evidence and key factors influencing the direction and the strength of a recommendation as outlined below.

**Table C.4: Domains that contribute to the strength of a recommendation**

<table>
<thead>
<tr>
<th>Domain</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance between desirable and undesirable outcomes (trade-offs) taking into account:</td>
<td>The larger the differences between the desirable and undesirable consequences, the more likely a strong recommendation is warranted. The smaller the net benefit and the lower certainty for that benefit, the more likely a qualified recommendation is warranted.</td>
</tr>
<tr>
<td>• best estimates of the magnitude of effects on desirable and undesirable outcomes</td>
<td></td>
</tr>
<tr>
<td>• importance of outcomes (estimated typical values and preferences)</td>
<td></td>
</tr>
<tr>
<td>Confidence in the magnitude of estimates of effect of the interventions on important outcomes (overall quality of evidence for outcomes)</td>
<td>The higher the quality of evidence, the more likely a strong recommendation is warranted</td>
</tr>
<tr>
<td>Confidence in values and preferences and their variability</td>
<td>The greater the variability in values and preferences, or uncertainty about typical values and preferences, the more likely a qualified recommendation is warranted</td>
</tr>
<tr>
<td>Resource use</td>
<td>The higher the costs of an intervention (the more resources consumed), the less likely a strong recommendation is warranted</td>
</tr>
</tbody>
</table>

The GRADE method supports two types of evidence-based recommendation — ‘strong’ and ‘weak’. The EWG agreed that preferable terminology was ‘recommendation’ and ‘qualified recommendation’, using the following definitions:

- **Recommendation**
  - implies that most/all individuals will be best served by the recommended course of action
  - used when confident that desirable effects clearly outweigh undesirable effects
  - used when confident that undesirable effects clearly outweigh desirable effects

- **Qualified recommendation**
  - implies that not all individuals will be best served by the recommended course of action
  - used when desirable effects probably outweigh undesirable effects
  - used when undesirable effects probably outweigh desirable effects.

The process of wording recommendations is outlined in Appendix B.
Research questions and findings

This section provides a summary of the evaluation of the evidence for each topic. Full details are available in the technical reports, which are available on the Department’s website.

Models of care for Aboriginal and Torres Strait Islander women

<table>
<thead>
<tr>
<th>Research question</th>
<th>A narrative review of studies was undertaken for this topic rather than a systematic evaluation of the evidence. No recommendations were developed.</th>
</tr>
</thead>
</table>

Illicit substance use

<table>
<thead>
<tr>
<th>Research questions</th>
<th>Outcomes analysed</th>
<th>Consensus-based recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>How can the harms associated with illicit drug use in pregnancy be reduced? (Informed narrative)</td>
<td>Retention of women in treatment, continued illicit substance use, birth weight, preterm birth, Apgar score, neonatal abstinence syndrome</td>
<td>Early in pregnancy, assess a woman’s use of illicit substances and misuse of pharmaceuticals and provide advice about the associated harms.</td>
</tr>
</tbody>
</table>

Weight and body mass index

<table>
<thead>
<tr>
<th>Research questions</th>
<th>Outcomes analysed</th>
<th>Evidence statements</th>
<th>Consensus-based recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Should women have their weight routinely monitored in pregnancy (self-monitored or otherwise)? (Informed narrative)</td>
<td>Gestational diabetes, macrosomia, excessive weight gain in pregnancy, mean weight gain (kg/week), pre-eclampsia, gestational hypertension</td>
<td>Excessive gestational weight gain, mean weekly weight gain and rates of gestational diabetes, pregnancy induced hypertension, pre-eclampsia and macrosomia do not differ significantly between women weighed regularly during pregnancy and those receiving usual care (low quality evidence).</td>
<td>If women are underweight or overweight, record and discuss their weight at every antenatal visit. Although there is insufficient evidence to recommend routine weighing based on its effects on pregnancy complications, at each antenatal visit offer women the opportunity to be weighed and to discuss their weight gain since the last antenatal visit, their diet and level of physical activity.</td>
</tr>
</tbody>
</table>
Family violence

Research questions

- What do health professionals need to do to identify women at risk from domestic violence? (Informed evidence-based recommendation)
- Should specific questions be asked as part of the process of routine enquiry? (Informed consensus-based recommendation)
- Are there validated screening tests for domestic violence that would be applicable to Australian maternity practice? (Informed consensus-based recommendation)
- Is routine enquiry about domestic violence acceptable to women? (Informed narrative)
- Is routine enquiry about domestic violence acceptable to health professionals? (Informed narrative)
- What do health professionals need to do to identify Aboriginal and Torres Strait Islander women experiencing domestic violence? (No evidence identified)
- Is routine enquiry about domestic violence acceptable to Aboriginal and Torres Strait Islander women? (No evidence identified)
- Is routine enquiry about domestic violence acceptable to health professionals caring for Aboriginal and Torres Strait Islander women? (No evidence identified)
- What interventions in a health care setting are effective for assisting women affected by domestic violence? (Informed narrative)
- What interventions in a health care setting are effective for assisting Aboriginal and Torres Strait Islander women affected by domestic violence? (No evidence identified)
- What interventions can be used to reduce the further incidence and impact of domestic violence for a woman who has disclosed she is in a violent relationship or has recently left a violent relationship? (Informed narrative)
- How can antenatal care providers enhance the immediate safety of women in or at risk of violence? (Informed narrative)
- What are the additional considerations for Aboriginal and Torres Strait Islander women? (Informed narrative)
- What are the additional considerations for women from culturally and linguistically diverse groups? (Informed narrative)

Outcomes analysed

Identification of family violence, referral, physical abuse, emotional abuse, sexual abuse and coercion, safety planning, low birth weight

Evidence statements

Universal screening for domestic violence versus usual care
- Identification of domestic violence in any health care setting and in antenatal clinics was higher when women were universally screened than with usual care (moderate quality evidence).
- There was no evidence for an effect on referrals (low quality evidence).

Face-to-face screening versus written/computer-based screening for domestic violence
- There was no significant difference in identification of domestic violence between the two approaches (moderate quality evidence).

Any intervention to prevent violence versus standard care for preventing or reducing domestic violence against pregnant women
- The total number of episodes of partner abuse in pregnancy and up to 10 weeks postpartum is lower among women who receive a psychological intervention than among controls (moderate quality evidence).
- The difference in risk of having a low birthweight baby between women participating in a psychological intervention and controls did not reach significance (low quality evidence).
- The difference in risk of episodes of partner abuse during pregnancy and in the first 3 months postpartum between women participating in a psychological intervention and controls did not reach significance (very low quality evidence).
- Women who participate in an empowerment intervention are more likely to adopt safety behaviours than controls (very low quality evidence).
- The evidence on partner abuse scores was inconsistent and differences between groups did not reach significance.

Advocacy interventions for women who experience intimate partner abuse versus usual care at up to 12-month follow-up
- The difference in overall abuse immediately post-intervention between women participating in intensive advocacy interventions and controls did not reach significance (very low quality evidence).
- Brief advocacy interventions for women experiencing domestic violence have no clear effect on physical abuse, minimal effect on sexual abuse and may have a beneficial effect on emotional abuse at 16 to 34 weeks follow-up and on overall abuse at 3–4 months follow-up (low to moderate quality evidence).
### Evidence-based recommendation

Explain to all women that asking about domestic violence is a routine part of antenatal care and enquire about each woman’s exposure to domestic violence.

### References (see Section 3.2.5)

O’Doherty et al 2015

### Implications for implementation

No implications associated with implementation of the recommendation were identified as the recommendation is consistent with the recommendation made in Module I (Australian Health Ministers’ Advisory Council 2012), with the exception that ‘at the first antenatal visit’ has been removed in acknowledgement of the facts that the time available at this visit and the number of assessments required may limit opportunities for enquiry about family violence and that women may be more inclined to disclose once more familiar with the enquiring health professional. However, it is noted that providing interventions in response to disclosure of family violence requires investment of time, funds and training.

### Consensus-based recommendation

Ask about family violence when alone with the woman, utilising the tool used in your state/territory, specific questions or a validated screening tool (eg Humiliation, Afraid, Rape, Kick [HARK], Hurt, Insult, Threaten, Scream [HITS]).

### Fetal growth and well-being

#### Fetal growth

No searches were conducted for this topic as it was agreed that the recommendations from *The Investigation and Management of the Small-For Gestational Age Fetus: Green-Top Guideline 31* (RCOG 2014) be used.

#### Research questions

- What is the predictive and diagnostic accuracy of performing abdominal palpation for determining fetal growth and wellbeing?  
  (Informed recommendation)
- What are the benefits and risks of performing an abdominal palpation at each antenatal visit?  
  (Informed recommendation)
- At what gestation is abdominal palpation effective and/or accurate? (No evidence identified)
- Do customised fundal height charts improve the detection of fetal growth restriction?  
  (Informed narrative and consensus-based recommendation)
- What are the additional considerations for Aboriginal and Torres Strait Islander women?  
  (No corresponding RCOG question)

#### Consensus-based recommendations

When women are identified as being at risk of having a SGA fetus or newborn, provide advice about modifiable risk factors.

Consider referring women who have a significant risk factor for having a SGA fetus/newborn for serial ultrasound measurement of fetal size and assessment of wellbeing with umbilical artery Doppler from 26–28 weeks of pregnancy.

Do not assess fetal growth based solely on abdominal palpation.

At each antenatal visit from 24 weeks, measure symphysis–fundal height.

#### Implications for implementation

The EWG noted that access to ultrasound and Doppler scans may be problematic as many of the risk factors for small for gestational age are prevalent among women who live in rural and remote areas or who do not readily access care.

### Fetal movements

No searches were conducted for this topic as it was agreed that the recommendations from *Clinical Practice Guidelines for Women Who Report Reduced Fetal Movements* be used.

#### Research questions

- What is considered to be a normal fetal movement pattern?  
  (Informed narrative)
- What is the diagnostic accuracy of using a fetal kick chart?  
  (Informed recommendation)
- What advice should be provided to women who report a change in fetal movement pattern?  
  (Informed consensus-based recommendation)
- What are the additional considerations for Aboriginal and Torres Strait Islander women?  
  (No corresponding question)

#### Consensus-based recommendations

Routinely provide women with verbal and written information about normal fetal movements.

Advise women to monitor fetal movements but do not advise formal fetal movement counting as part of routine antenatal care.
Advise women to contact their health care professional if they have any concern about decreased or absent fetal movements and not to wait until the next day to report decreased fetal movements.

Advise a woman who is unsure whether fetal movements are decreased to count while lying down on her side and to contact her health care professional if there are less than 10 movements in 2 hours.

**Implications for implementation**
No implications associated with implementation of the recommendation were identified.

**Fetal heart rate**
- What is the definition of routine auscultation? (No evidence identified)
- What is the predictive and diagnostic accuracy of performing auscultations? (No evidence identified)
- When is it appropriate to perform routine auscultation? (No evidence identified)
- What are the additional considerations for Aboriginal and Torres Strait Islander women? (No evidence identified)

**Risk of pre-eclampsia**

**Research questions**
- What is the prevalence and incidence of pre-eclampsia, including population specific groups? (Informed narrative)
- What are the risk factors for developing pre-eclampsia? (Informed evidence-based recommendation)
- What is the predictive and diagnostic test accuracy of screening for pre-eclampsia? (Informed narrative)
- What are the harms of not screening for pre-eclampsia? (No studies identified)
- What are the maternal and/or fetal benefits of screening for pre-eclampsia? (Informed narrative)
- When in pregnancy should screening be carried out? (Informed narrative)
- What are the benefits and risks of the predictive tests (eg PAPP-A) to identify women at risk of pre-eclampsia? (Informed narrative)
- Should every woman be tested for proteinuria at every antenatal visit if blood pressure remains normal? (No studies identified)
- What advice should women who are at risk of developing pre-eclampsia receive? (Informed narrative)
- What are the additional considerations for Aboriginal and Torres Strait Islander women? (No studies identified)

**Outcomes analysed**
Early onset pre-eclampsia (<34 wks), late onset pre-eclampsia (≥34 weeks), any pre-eclampsia

**Evidence statements**
- Women with a history of pre-eclampsia, chronic hypertension, pre-existing diabetes, chronic kidney disease or autoimmune disease (systemic lupus erythematosus, antiphospholipid syndrome) have an increased risk of pre-eclampsia in the current pregnancy (low quality evidence).
- Family history of pre-eclampsia is also associated with a high risk of pre-eclampsia (very low quality evidence).

**Evidence-based recommendation**
Early in pregnancy, assess all women for risk of pre-eclampsia.

**References** (see Section 3.4.6)
Wright et al 2015; Bartsch et al 2016

**Implications for implementation**
No implications associated with implementation of the recommendation were identified as, while prevalence is low, the risk factors for pre-eclampsia are routinely assessed as part of comprehensive history taking and clinical assessment previously recommended as routine components of the first antenatal visit.

**Consensus-based recommendation**
Recommend testing for proteinuria at each antenatal visit if a woman has risk factors for or clinical indications of pre-eclampsia, in particular, raised blood pressure.
### Risk of preterm birth

**Research questions**
- What is the definition of pre-term labour? (No specific evidence identified)
- What is the prevalence and incidence of pre-term labour? (Informed narrative)
- What are the risk factors for developing pre-term labour? (Informed narrative)
- What advice should be provided to women who are at risk of developing pre-term labour? (Informed narrative)
- Should cervical length be routinely measured as part of 17–22 week ultrasound assessment? (Informed narrative)
- What holistic preventative strategies including models of maternity care, reduce the incidence and impact of premature labour and birth? (Informed narrative)
- What are the additional considerations for Aboriginal and Torres Strait Islander women? (Informed narrative)

<table>
<thead>
<tr>
<th>Outcomes analysed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preterm birth (&lt;37 wk), very preterm birth (&lt;32 wk), low birth weight, admission to neonatal intensive care, perinatal death</td>
</tr>
</tbody>
</table>

**Consensus-based recommendation**

When women are identified as being at risk of giving birth preterm, provide advice about modifiable risk factors.

---

### Hepatitis C

**Research questions**
- What is the incidence of Hepatitis C in the general Australian child-bearing population (15–45 years)? (Informed narrative)
- What is the diagnostic value and clinical effectiveness of testing for Hepatitis C? (Informed narrative and consensus-based recommendation)
- What is the potential for transmission of Hepatitis C in labour and birth and breastfeeding? (Informed narrative)
- What is the potential for the transmission of blood borne viruses through scalp injuries (fetal scalp blood sampling or clips for heart rate monitoring)? (Informed narrative and consensus-based recommendation)
- What are the additional considerations for Aboriginal and Torres Strait Islander women? (No studies identified)

<table>
<thead>
<tr>
<th>Outcomes analysed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vertical transmission of hepatitis C, low birth weight</td>
</tr>
</tbody>
</table>

**Consensus-based recommendation**

Recommend testing for hepatitis C at the first antenatal visit.

---

### Diabetes

**Research questions**
- What is the most appropriate screening test to detect undiagnosed diabetes in early pregnancy? (Informed consensus-based recommendation)
- To whom should it be applied? (Informed narrative)
- What are the additional considerations for Aboriginal and Torres Strait Islander women? (Informed narrative)
- What are additional considerations for women from culturally and linguistically diverse backgrounds? (Informed narrative)

<table>
<thead>
<tr>
<th>Outcomes analysed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perinatal death, major congenital anomalies, preterm birth (&lt;37 wk), pre-eclampsia, induced labour, large for gestation age (&gt;90th centile), macrosomia (&gt;4,000g)</td>
</tr>
</tbody>
</table>

**Evidence statements**

- **Outcomes associated with HbA1c 41–46 mmol/mol compared to HbA1c <41 mmol/mol in early pregnancy**
  - Compared to women with HbA1c <41 mmol/mol in early pregnancy, women with HbA1c 41–46 mmol/mol had a higher risk of perinatal death, major congenital anomalies, preterm birth, pre-eclampsia, induced labour and large for gestational baby and the difference in rates of macrosomia did not reach significance (low quality evidence).

- **Outcomes associated with early treatment compared to later treatment for women with HbA1c 41–49 mmol/mol**
  - Treatment before 24 weeks was associated with a lower risk of pre-eclampsia than treatment at or after 24 weeks but the differences in other outcomes (perinatal death, preterm birth, induced labour, large for gestation age and macrosomia) did not reach significance (low quality evidence).

**Consensus-based recommendations**

When a woman has risk factors for diabetes in the first trimester, suitable tests are glycated haemoglobin (HbA1c) or fasting blood glucose.
### Vitamin D status

#### Research questions

- Who should be tested for vitamin D status? (Informed narrative and evidence-based recommendation)
- What are the benefits and risks of vitamin D supplementation in pregnancy? (Informed narrative and evidence-based recommendation)
- What are the additional considerations for Aboriginal and Torres Strait Islander women? (Informed narrative)
- What are the additional considerations for women from culturally and linguistically diverse groups? (Informed narrative)

#### Outcomes analysed

Pre-eclampsia, gestational diabetes, preterm birth, low birth weight (<2.500g), adverse effects of supplementation, maternal 25(OH)D at term

#### Evidence statements

**Vitamin D supplementation alone compared to placebo or no treatment**

- The risk of preterm birth and low birthweight (<2,500g) is lower among women who take vitamin D supplements in pregnancy than among women who do not (moderate quality evidence).
- Serum vitamin D level at term is higher in women who take vitamin D supplements in pregnancy than in women who do not (low quality evidence).
- The risk of pre-eclampsia is lower among women who take vitamin D supplements in pregnancy than among women who do not but the statistical significance is borderline (low quality evidence).
- There is no clear difference in the risk of gestational diabetes between women who take vitamin D supplements in pregnancy and those who do not (very low quality evidence).
- There is insufficient evidence for conclusions to be drawn on adverse effects associated with vitamin D supplementation in pregnancy.

**Vitamin D supplementation plus calcium compared to placebo or no treatment**

- The risk of pre-eclampsia is lower and risk of preterm birth higher among women who take supplements of vitamin D plus calcium in pregnancy than among those who do not (moderate quality evidence).
- The risk of gestational diabetes is lower among women who take supplements of vitamin D plus calcium in pregnancy than among those who do not — however, given the scarcity of data and the wide confidence interval no firm conclusions can be drawn (low quality evidence).

**2000 IU compared to 4000 IU vitamin D supplementation in pregnancy**

- Women are more likely to achieve vitamin D levels of ≥80 nmol/L with doses of 4000 IU than with doses of 2000 IU (low quality evidence).
- Differences between groups in the risk of gestational diabetes (moderate quality evidence), preterm birth (moderate quality evidence) and hypertensive disorders of pregnancy (low quality evidence) did not reach statistical significance.

#### Evidence-based recommendation

Do not routinely recommend testing for vitamin D status to pregnant women.

**References** (see Section 4.3.5)


#### Implications for implementation

The EWG noted that testing for vitamin D status among pregnant women is routinely conducted in some settings and that resource use would be reduced in these settings (for the health system, health care providers and women who would previously have been recommended supplementation). The existing MBS item 66833 for vitamin D testing can be used for the investigation of a person who: has deeply pigmented skin, or chronic and severe lack of sun exposure for cultural, medical, occupational or residential reasons (irrespective of pregnancy status) but not for people who do not meet these criteria.

#### Consensus-based recommendations

In women considered to be at risk of vitamin D deficiency, advise vitamin D supplementation for women with vitamin D levels lower than 50 nmol/L.
Thyroid dysfunction

Research questions

- What is the prevalence and incidence of thyroid dysfunction in pregnancy, including population specific groups? (Informed narrative)
- What is the diagnostic test accuracy of screening for thyroid dysfunction? (Informed narrative)
- What are the benefits and harms of routine screening for thyroid dysfunction? (Informed evidence-based and consensus-based recommendations)
- When should pregnant women be screened for thyroid dysfunction? (No evidence identified)
- What interventions or treatments for thyroid dysfunction are effective and safe in pregnancy, and what advice should women receive? (No evidence identified)
- What is the cost effectiveness of universal screening in pregnancy for hypothyroidism? (No evidence identified)
- What are the additional considerations for Aboriginal and Torres Strait Islander women? (No evidence identified)

Outcomes analysed

Fetal or neonatal death, neurosensory disability of the infant as child, diagnosis of hypothyroidism, diagnosis of hyperthyroidism, pre-eclampsia, preterm birth, miscarriage, caesarean section

Evidence statements

Universal testing vs case finding

- Universal testing for thyroid dysfunction identifies more women with hypothyroidism than case finding (high quality evidence) and more women with hyperthyroidism are identified (moderate quality evidence).
- The rate of preterm birth does not differ substantially between women who undergo case finding for thyroid dysfunction and those who are universally tested (high quality evidence).
- Rates of miscarriage, pre-eclampsia and neonatal death are not clearly different between women who undergo case finding for thyroid dysfunction and those who are universally tested (moderate quality evidence).

Universal testing vs no testing

- Universal testing for thyroid dysfunction identifies more women with hypothyroidism than no testing (moderate quality evidence)
- Prevalence of neurosensory disability of the infant is not clearly different between the two groups (moderate quality evidence).
- Rates of miscarriage are lower and caesarean section are higher among women universally tested for thyroid dysfunction compared to those not tested (low quality evidence).
- Rates of preterm birth are not clearly different between women universally tested for thyroid dysfunction and those not tested (very low quality evidence).

Evidence-based recommendation

Do not routinely test pregnant women for thyroid dysfunction.

References (see Section 4.4.6)

Spencer et al 2015; Ma et al 2016

Implications for implementation

No implications associated with implementation of the recommendation were identified as it is consistent with the recommendation given in Module II (Australian Health Ministers' Advisory Council 2014)

Consensus-based recommendations

Recommend thyroid testing to pregnant women who are at increased risk of thyroid dysfunction.

Fetal chromosomal anomalies

Research questions

- Are there additional benefits and costs associated with replacing the first trimester serum and nuchal translucency screening with non-invasive prenatal testing (cell-free deoxyribonucleic acid [cfDNA] testing)? (Informed narrative)
- Are there specific issues for Aboriginal and Torres Strait Islander women and rural and remote populations? (No evidence identified)

Outcomes analysed

Detection of trisomy 21, detection of trisomy 18, detection of trisomy 13, detection of sex chromosome anomalies, detection of atypical anomalies, rates of invasive procedures
**Evidence statements**

<table>
<thead>
<tr>
<th>Cell-free DNA testing compared to cFTS for detection of fetal chromosomal anomalies</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Cell-free DNA testing has a higher detection rate for the more common trisomies (trisomies 21, 18 and 13), lower detection rates for sex chromosome and atypical aneuploidies and a lower risk of invasive procedures compared with combined first trimester screening (low quality evidence).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Second-line cfDNA testing compared to cFTS for detection of fetal chromosomal anomalies</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Second-line cfDNA testing has a higher detection rate for the more common trisomies (trisomies 21, 18 and 13), lower detection rates for atypical aneuploidies, lower risk of invasive procedures compared with combined first trimester screening and the difference in detection of sex chromosome aneuploidies did not reach significance (low quality evidence).</td>
</tr>
</tbody>
</table>

**No new recommendations were developed**

**References**


D: Topics covered in Modules I and II

**OPTIMISING ANTENATAL CARE**

Principles of care
Providing woman-centred care
Antenatal care for Aboriginal and Torres Strait Islander women
Antenatal care for migrant and refugee women
Antenatal care for women with mental health disorders
Population groups with specific care needs

**CLINICAL CARE DURING PREGNANCY**

Core practices in antenatal care
Antenatal visits
Preparing for pregnancy, childbirth and parenthood
Preparing for breastfeeding

**Lifestyle considerations**

Nutrition
Nutritional supplements
Physical activity
Tobacco smoking
Alcohol
Medicines
Sexual activity
Travel
Oral health

**Clinical assessments**

Gestational age
Weight and body mass index
Blood pressure
Proteinuria
Psychosocial factors affecting mental health
Depression and anxiety
Domestic violence
Fetal development and anatomy
Fetal growth and wellbeing
Risk of pre-eclampsia
Risk of preterm birth

**Maternal health screening**

Diabetes
Human immunodeficiency virus
Hepatitis B
Hepatitis C
Rubella
Chlamydia
Syphilis
Gonorrhoea
Trichomoniasis
Asymptomatic bacteriuria
Asymptomatic bacterial vaginosis
Anaemia
Haemoglobin disorders
Vitamin D deficiency
Group B streptococcus
Toxoplasmosis
Cytomegalovirus
Cervical abnormalities
Thyroid dysfunction

**Screening for fetal chromosomal abnormalities**

**Common conditions**

Reflux (heartburn)
Haemorrhoids
Varicose veins
Pelvic girdle pain
Carpal tunnel syndrome
Nausea and vomiting
Constipation

**Clinical assessments in late pregnancy**

Fetal presentation
Prolonged pregnancy
Glossary

Aboriginal and Torres Strait Islander peoples: It is recognised that there is no single Aboriginal or Torres Strait Islander culture or group, but numerous groupings, languages, kinships, and tribes, as well as ways of living. Furthermore, Aboriginal and Torres Strait Islander peoples may currently live in urban, rural or remote settings, in urbanised, traditional or other lifestyles, and frequently move between these ways of living.

Amniocentesis: A diagnostic test for chromosomal anomalies, such as trisomy 21 (Down syndrome), where an ultrasound guided needle is used to extract a sample of the amniotic fluid.

Auscultation: The detection of the fetal heart using Doppler or a Pinard stethoscope.

Cardiotocography: A technical means of recording the fetal heart rate and uterine contractions.

Chorionic villus sampling (CVS): diagnostic test for chromosomal anomalies such as trisomy 21 (Down syndrome) where an ultrasound guided needle is used to extract a sample of the placenta.

Cognitive-behavioural therapy: Psychological therapy based on the assumption that faulty thinking patterns, maladaptive behaviours and “negative” emotions are all inter-related. Treatment focuses on changing an individual’s thoughts (cognitive patterns) or maladaptive behaviours in order to change emotional states. Cognitive-behavioural therapy integrates the cognitive restructuring approach of cognitive therapy with the behavioural modification techniques of behavioural therapy.

First antenatal visit: The first visit specifically for antenatal care following confirmation of the pregnancy.

Induction of labour: A procedure to artificially start the process of labour by way of medical, surgical or medical and surgical means.

Low birth weight: Birth weight of less than 2,500 g.

Macrosomia: Birth weight higher than 4,000 g.

Maternal serum screening: A blood test performed during pregnancy to detect markers of chromosomal abnormality, such as trisomy 21 (Down syndrome).

Migrant and refugee women: The term ‘migrant and refugee’ is used in these Guidelines to refer both to women who are voluntary migrants and women who come to Australia as refugees, humanitarian entrants or asylum seekers.

Miscarriage: The spontaneous end of a pregnancy at a stage where the embryo or fetus is incapable of surviving independently, generally defined in humans as before 20 weeks.

Neonatal abstinence syndrome: A withdrawal syndrome occurring among newborns exposed to opiates (and some other substances) in utero.

Nuchal translucency thickness assessment: An ultrasound scan performed between 11 and 13 weeks of pregnancy that measures the thickness of the nuchal fold behind the baby’s neck – a marker of chromosomal anomaly, such as trisomy 21 (Down syndrome).

Passive smoking: The inhalation of smoke, called second-hand smoke or environmental tobacco smoke, from tobacco products used by others.

Perinatal period: For the purposes of these guidelines, ‘perinatal’ is defined as the period covering pregnancy and the first year following pregnancy or birth. It is acknowledged that other definitions of this term are used for data collection and analysis. The definition used here broadens the scope of the term perinatal in line with understanding of mental health in pregnancy and following birth.

Placental abruption: A potentially life-threatening obstetric complication in which the placental lining separates from the uterus of the mother.

Polyhydramnios: Accumulation of excess amniotic fluid during pregnancy.

Preterm birth: Birth at less than 37 weeks gestation.

Proteinuria: The presence of an excess of serum proteins in the urine.

Stillbirth: The birth of a baby that has died in the uterus after 20 weeks of pregnancy or reaching a weight of more than 400 g if gestational age is unknown.
Trisomy 13 — A genetic disorder in which a person has three copies of genetic material from chromosome 13, instead of the usual two copies. Also referred to as Patau syndrome or trisomy D.

Trisomy 18 — A genetic disorder caused by the presence of all or part of an extra 18th chromosome. Also referred to as Edwards syndrome or trisomy E.

Trisomy 21 — Chromosomal abnormality due to an additional chromosome 21. Also referred to as Down syndrome.

Methodological terms

AGREE: A framework for assessing the quality of clinical practice guidelines, including that the potential biases of guideline development have been addressed adequately and that the recommendations are both internally and externally valid, and are feasible for practice. This process involves taking into account the benefits, harms and costs of the recommendations, as well as the practical issues attached to them. Therefore, the assessment includes judgements about the methods used for developing the guidelines, the content of the final recommendations, and the factors linked to their uptake.

Confidence interval: An interval describing the range of values within which there is reasonable certainty that the true effect lies. Uncertainty increases with the width of the interval.

Consensus-based recommendation: Recommendations based on systematic review of the literature where evidence is found to be limited or lacking.

Odds ratio: the ratio of the likelihood of an event occurring in one group to that of it occurring in another group. An odds ratio of 1 indicates that the condition or event under study is equally likely to occur in both groups. An odds ratio greater than 1 indicates that the condition or event is more likely to occur in the first group and an odds ratio less than 1 indicates that the condition or event is less likely to occur in the first group.

Practice point: For the purposes of these Guidelines, these cover areas of antenatal care that were beyond the scope of the literature reviews but where the EWG determined there was a need for advice. These points are based on best practice clinical judgement.

Mean difference: The absolute difference between the mean value in two groups in a clinical trial, which estimates the amount by which the intervention changes the outcome on average compared with the control.

Publication bias: The publication or non-publication of research findings. Small, negative trials tend not to be published and this may lead to an overestimate of results of a review if only published studies are included.

Randomised controlled trial: A study in which participants are allocated at random to receive one of several clinical interventions. One of these interventions is the standard of comparison or control. The control may be a standard practice, a placebo or no intervention at all.

Recommendation: Evidence-based action statement developed through systematic review of the literature.

Relative risk: The ratio of the risk (rate) of an outcome in an exposed group (e.g., to a specific medicine) to the risk (rate) of the outcome in an unexposed group in a specified time period.

Sensitivity: The proportion of people with the condition who have a positive test result.

Specificity: The proportion of people without the condition who have a negative test result.

Systematic literature review: A systematic review of evidence focused on a research question(s) that aims to identify, appraise, select and synthesise all high quality research evidence relevant to that question.
Acronyms and abbreviations

ABS  Australian Bureau of Statistic
ACOG  American College of Obstetricians and Gynecologists
ACSQHC  Australian Commission on Safety and Quality in Health Care
ADA  American Diabetes Association
ADIPS  Australasian Diabetes in Pregnancy Society
AFBP  Aboriginal Family Birthing Program
AFP  $\alpha$-fetoprotein
AHMAC  Australian Health Ministers’ Advisory Council
AIHW  Australian Institute of Health and Welfare
AMGPP  Aboriginal Maternity Group Practice Program
AMIHS  Aboriginal Maternal and Infant Health Service
AOM  Association of Ontario Midwives
aOR  adjusted odds ratio
aRR  adjusted relative risk
ASHM  Australasian Society for HIV Medicine
BMI  body mass index
CBR  consensus-based recommendation
CCOPMM  Consultative Council on Obstetric and Paediatric Mortality and Morbidity (Victoria)
CEE  Centre for epidemiology and Evidence (NSW)
cfDNA  cell-free deoxyribonucleic acid
CI  confidence interval
CMACE  Centre for Maternal and Child Enquiries
CPS  Canadian Paediatric Society
D&C  dilatation and curettage
DNA  deoxyribonucleic acid
DoHA  Department of Health and Ageing
EBR  evidence-based recommendation
EWG  Expert Working Group
GP  general practitioner
GRADE  Grading of Recommendations, Assessment, Development and Evaluation
HAPO  Hyperglycaemia and Adverse Pregnancy Outcome (study)
HARK  Humiliation, Afraid, Rape, Kick
HbA1c  glycated haemoglobin
hCG  human chorionic gonadotrophin
HDL  high density lipoprotein
HITS  Hurt, Insult, Threaten, Scream
IADPSG  International Association of Diabetes and Pregnancy Study Groups
IDF  International Diabetes Federation
IOM  Institute of Medicine (US)
IU  International unit
IVF  in vitro fertilisation
LSD  lysergic acid diethylamide
MD  mean difference
MDMA  methylenedioxymethamphetamine
mmHg  millimetres of mercury
mmol/mol  millimoles per mole
MSHR  Menzies School of Health Research
MSJC  Maternity Services Inter-Jurisdictional Committee
NHMRC  National Health and Medical Research Council
NICE  National Institute of Health and Clinical Excellence
NIPT  non-invasive prenatal testing
nmol/L  nanomoles per litre
NZ MoH  New Zealand Ministry of Health
OR  odds ratio
PAPP-A  pregnancy-associated placental protein-A
PBS  Pharmaceutical Benefits Scheme
PIGF  placental growth hormone
pmol/L  picomoles per litre
PP  practice point
QEBR  qualified evidence-based recommendation
RACGP  Royal Australian College of General Practitioners
RANZCOG  Royal Australian and New Zealand College of Obstetricians and Gynaecologists
RCOG  Royal College of Obstetricians and Gynaecologists (UK)
RCT  randomised controlled trial
RNA  ribonucleic acid
RR  relative risk
sFlt-1  soluble fms-like tyrosine kinase-1
SIGN  Scottish Intercollegiate Guidelines Network
SMD  standardised mean difference
SOGC  Society of Gynaecologists of Canada
TSH  thyroid-stimulating hormone
USPSTF  United States Preventive Services Task Force
WHO  World Health Organization
WSDH  Washington State Department of Health