CLINICAL PRACTICE GUIDELINES

Antenatal care - Module I

Australian Government

Department of Health and Ageing

Clinical Practice Guidelines: Antenatal Care - Module I

Publication Approval

Australian Government
National Health and Medical Research Council

These guidelines were approved by the Chief Executive Officer (CEO) of the National Health and Medical Research Council (NHMRC) on 6 December 2011 (with a minor amendment approved by the CEO on 17 December 2012), under Section 14A of the *National Health and Medical Research Council Act 1992*. In approving these guidelines the NHMRC considers that they meet the NHMRC standard for clinical practice guidelines. This approval is valid for a period of 5 years. NHMRC is satisfied that they are based on the systematic identification and synthesis of the best available scientific evidence and make clear recommendations for health professionals practising in an Australian health care setting. The NHMRC expects that all guidelines will be reviewed no less than once every five years.

This publication reflects the views of the authors and not necessarily the views of the Australian Government.

Disclaimer

This is a general guide to appropriate practice, to be followed subject to the relevant clinician's judgement in each individual case. The Commonwealth has taken all reasonable steps to ensure that the Guidelines are based on, and accurately represent, the best available published evidence on key areas of antenatal care.

However, the Commonwealth does not accept any legal liability for any loss, damage costs or expenses that may result from reliance on the information and recommendations contained in these Guidelines.

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Foreword

We are pleased to issue these *Clinical Practice Guidelines: Antenatal Care — Module I* as approved by Australian Health Ministers' Advisory Council on 31 August 2012. The purpose of the Guidelines is to provide evidence-based advice on the care of pregnant women in a range of settings.

There are numerous aspects to antenatal care and reviewing the evidence in all areas is a lengthy process. For this reason, the project is being completed in stages. The clinical topics discussed in this module of the Guidelines were selected after a process of consultation designed to identify the areas where specific guidance is required. The topics discussed are generally specific to the first trimester. Some other aspects of first trimester care (eg screening for diabetes) will be included in the subsequent module of the Guidelines, which will be developed over the next two years. Module II will also include an expanded section related to care for women from culturally and linguistically diverse communities.

The Guidelines summarise published evidence and make recommendations on key areas of antenatal care. The development of the draft Guidelines has followed the key principles and processes outlined in the document *NHMRC Standards and Procedures for Externally Developed Guidelines* (2007). In areas for which there is insufficient evidence for recommendations, the Guidelines include practice points that are based on best practice clinical judgement. To provide guidance in a single resource, recommendations from evidence-based national guidelines relevant to antenatal care in the first trimester have also been included and their evidence base summarised. Specific reference is made to antenatal care for Aboriginal and Torres Strait Islander women and expert input has been included to ensure that the recommendations are relevant and culturally appropriate.

The Guidelines are not meant to be a textbook of antenatal care. The management of conditions identified through the screening procedures addressed in this module is not discussed; health professionals are directed to appropriate resources where available.

The Guidelines are intended as a resource for all health professionals working with women in the early antenatal period. They will be relevant to the work of a variety of health professionals in many different settings. Women should be at the centre of care, wherever it is provided.

Summary resources and companion documents for women and their families, and for specific groups of health professionals, will be developed from the Guidelines.

The Guidelines will be implemented within the context of significant current activity at national, jurisdictional and local levels in relation to maternity care and health reform more broadly. It is envisaged that the Guidelines will support activities and Budget initiatives arising from the National Maternity Services Plan. Monitoring the uptake of the Guidelines will assess their contribution to changes in practice and potentially to health outcomes.

It is anticipated that the Guidelines will contribute to greater consistency in antenatal care and improve the experience and outcomes of antenatal care for women and their families.

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on behalf of the Expert Advisory Committee

Dr Jenny Hunt and Dr Marilyn Clarke
on behalf of the Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care

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Summary

Antenatal care is a routine part of pregnancy for most of the 280,000 women who give birth in Australia each year. Women receive antenatal care in community and hospital-based settings and see a range of health professionals. Effective models of antenatal care have a focus on the individual woman's needs and preferences, collaboration and continuity of care. Taking a woman-centred approach also ensures that a woman's social, emotional, physical, psychological, spiritual and cultural needs and expectations are considered and respected. Throughout the pregnancy, women need to be given information in an appropriate form to support them in making choices about their care.

Within the diversity of women that make up the Australian population, some face greater disadvantage in terms of access to health services and may experience poorer outcomes. The broader context of a woman's life should be taken into account in planning antenatal care. For example, cultural competence at the individual and organisational level is essential to effective communication and cultural security for Aboriginal and Torres Strait Islander women and those from culturally and linguistically diverse backgrounds. Specific approaches may also improve the experience of antenatal care for adolescent women and women living in rural and remote areas.

Depending on when a woman first seeks pregnancy care, the initial antenatal visit may be her only contact with health services in the first trimester. This visit provides the opportunity to discuss with the woman her expectations for the pregnancy. It is also a valuable opportunity to give verbal and other forms of information, support and advice about pregnancy and the transition to parenthood, and to explain to the woman the aims of the care offered during pregnancy. This includes:

› discussing pregnancy care options;

› where there is a need, having an ultrasound examination in the first trimester to assess the gestational age of the baby, so that any tests a woman chooses to have are undertaken at the most appropriate time, the date of birth can be estimated and multiple pregnancies are identified;

› assessing for any conditions that may affect the health of the women or the unborn baby (such as existing kidney disease or infection);

› assessing the health of the woman, in particular factors that indicate additional care may be required (such as high blood pressure, high or low body mass index);

› offering screening to assess the risk of chromosomal abnormalities in the baby;

› discussing mental health and psychosocial issues that may affect the woman and her baby during pregnancy and beyond;

› providing advice on symptoms that are common during pregnancy (eg nausea and vomiting and constipation);

› discussing other issues that may affect the health and wellbeing of the woman during pregnancy (eg smoking, alcohol, prescription and over-the-counter medicines, nutritional supplements, domestic violence and oral health); and

› providing opportunities for women to raise any concerns they wish to discuss.

A planned schedule of antenatal visits should also be agreed at the first antenatal visit based on the individual woman's needs. For a woman's first pregnancy without complications, a schedule of ten visits should be adequate. For women having subsequent uncomplicated pregnancies, a schedule of

seven visits should be adequate. Assessment of a woman's risk and need for additional care continues throughout pregnancy.

The Guidelines provide a reliable and standard reference for health professionals providing antenatal care. They take a woman-centred approach, which includes considering the woman's context, ensuring cultural safety and involving family following the woman's preferences. Specific discussion of antenatal care for Aboriginal and Torres Strait Islander women is included. The Guidelines aim to promote consistency of care, provide a summary of the currently available evidence on aspects of antenatal care and improve the experience and outcomes of antenatal care for all families.

Summary of recommendations

The recommendations in these Guidelines were developed by the Expert Advisory Committee (EAC) (see Appendices A and B) based on systematic reviews of the available evidence. Where sufficient evidence was available, this was graded according to the National Health and Medical Research Council (NHMRC) *Levels of Evidence and Grades for Recommendations for Developers of Guidelines* (2009) (see below) and formulated as recommendations. For areas of clinical practice included in the systematic reviews but where evidence was limited or lacking, the EAC developed consensus-based recommendations (CBRs). Some recommendations and CBRs from other national guidelines were included, where these were based on systematic review of the evidence. For areas beyond the scope of the systematic reviews, practice points (PPs) were developed by the EAC or the Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care (see Appendices A and B).

The evidence-based recommendations and practice points focus on the clinical and physical aspects of care. This care is provided following principles that endorse the protection, promotion and support necessary for effective antenatal care outlined in Chapter 1 and expanded on in Part A. These include taking a holistic approach that is woman-centred, culturally appropriate and enables women to participate in informed decision-making at all stages of their care.

Definition of grades of recommendations and practice points

Grade	Description
A	Body of evidence can be trusted to guide practice
B	Body of evidence can be trusted to guide practice in most situations
C	Body of evidence provides some support for recommendation(s) but care should be taken in its application
D	Body of evidence is weak and recommendation must be applied with caution
CBR	Recommendation formulated in the absence of quality evidence (where a systematic review of the evidence was conducted as part of the search strategy)
PP	Area is beyond the scope of the systematic literature review and advice was developed by the EAC and/or the Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care

Source: Adapted from NHMRC (2009) *Levels of Evidence and Grades for Recommendations for Developers of Guidelines* and NHMRC (2011) *Procedures and Requirements for Meeting the 2011 NHMRC Standard for Clinical Practice Guidelines*.

Recommendations and practice points[1]

Recommendation/practice point	Grade	Section; page
Antenatal visits		
1 Determine the schedule of antenatal visits based on the individual woman's needs. For a woman's first pregnancy without complications, a schedule of ten visits should be adequate. For subsequent uncomplicated pregnancies, a schedule of seven visits should be adequate.	B	6.1; p31 App D; p218
i At the first contact with a woman during pregnancy, make arrangements for the first antenatal visit, which requires a long appointment and should occur within the first 10 weeks.	CBR	6.1; p31 App D; p218
ii Early in pregnancy, provide women with information in an appropriate format about the likely number, timing and content of antenatal visits associated with different options of care and the opportunity to discuss this schedule.	CBR	6.2; p34 App D; p218
a Antenatal care should be woman-focused, with each antenatal visit structured around specific content based on the woman's needs. Longer visits are needed early in pregnancy to allow comprehensive assessment, discussion and support. Assessments and tests should be incorporated into visits in a way that minimises inconvenience to the woman.	PP	6.3; p35
Clinical assessments		
Gestational age		
2 Provide information and offer pregnant women who are unsure of their conception date an ultrasound scan between 8 weeks 0 days and 13 weeks 6 days to determine gestational age, detect multiple pregnancies and accurately time fetal anomaly screening. Use crown–rump length (CRL) measurement to determine gestational age. If the CRL is above 84 mm, estimate the gestational age using head circumference.	B	7.1.1; p46 App D; p220
b The timeframe for ultrasound assessment of gestational age overlaps with that for assessment of nuchal translucency thickness as part of screening for fetal chromosomal abnormalities (11 weeks to 13 weeks 6 days), which may enable some women to have both tests in a single scan. This should only occur if women have been provided with an explanation of both tests and have given their consent to them both.	PP	7.1.1; p46
c The agreed due date should not be changed without advice from a health professional with considerable experience in antenatal care.	PP	7.1.1; p47
d Ultrasound assessment of gestational age should only be performed by a person who has had specific training.	PP	7.1.1; p48

1 Recommendations are numbered using Arabic numerals (eg 1, 2, 3), consensus-based recommendations using Roman numerals (eg i, ii, iii) and practice points using letters (eg a, b, c).

Recommendation/practice point		Grade	Section; page
e	Repeated ultrasound assessments should only be used when clinically indicated.	PP	7.1.1; p48
Weight and body mass index			
3	Measure women's weight and height at the first antenatal visit and calculate their body mass index (BMI).	B	7.2.2; p53 App D; p222
f	Repeated weighing during pregnancy should be confined to circumstances that are likely to influence clinical management.	PP	7.2.2; p54
4	Give women advice about appropriate weight gain during pregnancy in relation to their BMI.	B	7.2.2; p54 App D; p222
g	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.	PP	7.2.2; p55
Blood pressure			
5	Measure blood pressure at a woman's first antenatal visit to identify existing high blood pressure.	B	7.3.2; p60 App D; p224
Proteinuria			
iii	Routinely offer testing for proteinuria at the first antenatal visit, regardless of stage of pregnancy.	CBR	7.4.2; p65 App D; p226
6	For point-of-care testing, use an automated analyser if available, as visual inspection of a urinary dipstick is the least accurate method to detect true proteinuria.	B	7.4.2; p65 App D; p226
Psychosocial factors affecting mental health			
iv	As early as practical in pregnancy, ask all women questions about psychosocial factors, including previous or current mental health disorders. If a woman affirms their presence, ask whether she would like help with any of these issues.	CBR	7.5.2; p71 App D; p228
Depression and anxiety			
7	Use the *Edinburgh Postnatal Depression Scale* as a component of the assessment of all women for symptoms of depression in the antenatal period.	B	7.6.2; p77 App D; p228
v	Be aware that women who score 13 or more on the Edinburgh Postnatal Depression Scale (EPDS) may be experiencing anxiety, either alone or with depression. Base decisions about further assessment on the woman's answers to questions 3, 4 and 5 of the EPDS and her response to enquiry about 'worrying'.	CBR	7.6.2; p77 8.9.2; p228

Recommendation/practice point		Grade	Section; page
h	If a woman scores 1, 2 or 3 on EPDS question 10, assess her current safety and the safety of other children in her care and, acting according to clinical judgement, seek advice and/or refer immediately for mental health assessment.	PP	7.6.2; p78
Domestic violence			
8	At the first antenatal visit, 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.	B	7.7.2; p83 App D; p229
vi	Ask about domestic violence when alone with the woman, tailoring the approach to her individual situation and your own skills and experience (eg use open-ended questions about her perception of safety at home or use an assessment tool).	CBR	7.7.2; p83 App D; p229
vii	Be aware that training programs improve the confidence and competency of health professionals in identifying and caring for women experiencing domestic violence.	CBR	7.7.2; p84 App D; p229
i	Responses to assisting Aboriginal and Torres Strait Islander women who are experiencing domestic violence need to be appropriate to the woman and her community. Health professionals should be aware of family and community structures and support.	PP	7.7.2; p86
j	Health professionals should be aware of resources for domestic violence services in their community that can be called for urgent assistance. This may include local safe houses or the Strong Women Workers in their community.	PP	7.7.2; p87
Nausea and vomiting			
k	Women who experience nausea and vomiting in pregnancy can be advised that, while it may be distressing, it usually resolves spontaneously by 16 to 20 weeks pregnancy and is not generally associated with a poor pregnancy outcome.	PP	7.8.2; p93
l	Discontinuing iron-containing multivitamins for the period that women have symptoms of nausea and vomiting may improve symptoms.	PP	7.8.2; p93
Constipation			
9	Offer women who are experiencing constipation information about increasing dietary fibre intake and taking bran or wheat fibre supplementation.	C	7.9.2; p97 App D; p232
10	Advise women who choose to take laxatives that preparations that stimulate the bowel are more effective than those that add bulk but may cause more adverse effects such as diarrhoea and abdominal pain.	C	7.9.2; p97 App D; p232

Recommendation/practice point		Grade	Section; page
Maternal health screening			
<u>Human immunodeficiency virus</u>			
11	Routinely offer and recommend HIV testing at the first antenatal visit as effective interventions are available to reduce the risk of mother-to-child transmission.	B	8.1.2; p104 App D; p233
m	A system of clear referral paths ensures that pregnant women who are diagnosed with an HIV infection are managed and treated by the appropriate specialist teams.	PP	8.1.2; p104
<u>Hepatitis B</u>			
12	Routinely offer and recommend hepatitis B virus testing at the first antenatal visit as effective postnatal intervention can reduce the risk of mother-to-child transmission.	A	8.2.2; p110 App D; p235
<u>Hepatitis C</u>			
13	Do not routinely offer pregnant women hepatitis C testing.	C	8.3.2; p115 App D; p236
n	Hepatitis C testing may be offered to women with identifiable risk factors: › intravenous drug use or needle sharing; › tattooing or body piercing; › incarceration; › receipt of blood products or invasive procedures overseas or before 1990 in Australia; or › country of origin has a high prevalence of hepatitis C.	PP	8.3.2; p116
o	Women who are having an invasive procedure (eg chorionic villus sampling, amniocentesis) should be offered screening for hepatitis C before the procedure.	PP	8.3.2; p116
<u>Rubella</u>			
14	Routinely offer and recommend testing for rubella immunity at the first antenatal visit to identify women at risk of contracting rubella and enable postnatal vaccination to protect future pregnancies.	B	8.4.2; p120 App D; p237
15	Inform women who have been vaccinated against rubella before they were aware of the pregnancy that the baby is highly unlikely to have been affected by the vaccine.	A	8.4.2; p120 App D; p237
p	Women identified as non-immune to rubella antenatally should be advised to avoid contact with people experiencing possible symptoms of rubella.	PP	8.4.2; p120

Recommendation/practice point		Grade	Section; page
Chlamydia			
16	Do not routinely offer chlamydia testing to all women as part of antenatal care. Routinely offer chlamydia testing at the first antenatal visit to pregnant women younger than 25 years.	**C**	8.5.2; p125 App D; p238
q	Testing for chlamydia and other sexually transmitted infections regardless of age should be considered for women who live in areas where their prevalence is high. An understanding of local prevalence will inform planning for population screening when this is indicated.	PP	8.5.2; p125
Syphilis			
17	Routinely offer and recommend syphilis testing at the first antenatal visit as treating syphilis benefits both mother and baby.	**B**	8.6.2; p130 App D; p239
r	Because syphilis is a rare condition in most parts of Australia and a positive result does not necessarily mean that a woman has syphilis, expert advice regarding the care of women who test positive and their partners should be sought. Assessment/testing for other sexually transmitted infections in women with positive serology is advisable.	PP	8.6.2; p131
Asymptomatic bacteriuria			
18	Routinely offer and recommend testing for asymptomatic bacteriuria early in pregnancy as treatment is effective and reduces the risk of pyelonephritis.	**A**	8.7.2; p135 App D; p240
19	Use urine culture testing wherever possible as it is the most accurate means of detecting asymptomatic bacteriuria.	**A**	8.7.2; p135 App D; p240
s	Where access to pathology services is limited, dipstick tests may be used to exclude infection, with positive results confirmed by urine culture. Appropriate storage of dipsticks is essential to the accuracy of these tests.	PP	8.7.2; p136
Asymptomatic bacterial vaginosis			
20	Do not routinely offer pregnant women testing for bacterial vaginosis.	**B**	8.8.2; p140 App D; p242
t	Early treatment (before 20 weeks pregnancy) of proven bacterial vaginosis may be beneficial for women with a previous preterm birth.	PP	8.8.2; p140
Vitamin D deficiency			
viii	Offer vitamin D screening to women with limited exposure to sunlight (eg because they are predominantly indoors or usually protected from the sun when outdoors), or who have dark skin or a pre-pregnancy BMI of >30, as they may be at increased risk of vitamin D deficiency and benefit from supplementation for their long-term health. Base decisions about whether to offer screening on these factors, season and climate.	CBR	8.9.2; p145 App D; p243

Recommendation/practice point		Grade	Section; page
Screening for fetal chromosomal abnormalities			
Discussing screening tests			
ix	At the first antenatal visit, give women information about the purpose and implications of testing for chromosomal abnormalities to enable them to make informed choices about whether or not to have the tests.	CBR	9.2; p153 App D; p244
u	Information about testing for chromosomal abnormalities should be provided in a way that is appropriate and accessible to the individual woman, with particular regard given to language and literacy.	PP	9.2; p153
Screening tests in the first trimester			
21	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 and ultrasound assessment takes place between 11 weeks 0 days and 13 weeks 6 days.	B	9.3.1; p155 App D; p244
v	For women with a risk of 1 in 300 or greater, referral to a genetic counsellor should be considered.	PP	9.3.2; p155
22	If a woman chooses to have a diagnostic test for chromosomal abnormalities, base the choice of test on the gestation of pregnancy and the woman's preferences. Chorionic villus sampling is safer before 14 weeks pregnancy. Amniocentesis is safe after 15 weeks.	B	9.3.2; p156 App D; p244
x	Offer rapid access to appropriate counselling and ongoing support by trained health professionals to women who receive a diagnosis of fetal chromosomal abnormality.	CBR	9.3.2; p156 App D; p244
w	Women with an high-risk first trimester screening test result but negative diagnostic test should be referred for further specialist assessment because of an increased risk of other fetal abnormalities.	PP	9.3.2; p156
Other considerations in screening for fetal chromosomal abnormalities			
x	There is inadequate access to screening for chromosomal abnormalities in many rural and remote areas. Every effort should be made to support women in these areas to access screening.	PP	9.4; p157

Recommendation/practice point		Grade	Section; page
Lifestyle considerations			
<u>Tobacco smoking</u>			
23	At the first antenatal visit: › assess the woman's smoking status and exposure to passive smoking; › give the woman and her partner information about the risks to the unborn baby associated with maternal and passive smoking; and › if the woman smokes, emphasise the benefits of quitting as early as possible in the pregnancy and discuss any concerns she or her family may have about stopping smoking.	A	10.1.2; p166 App D; p247
24	Offer women who smoke referral for smoking cessation interventions such as cognitive behavioural therapy.	B	10.1.3; p167 App D; p247
y	At each antenatal visit, offer women who smoke personalised advice on how to stop smoking and provide information about available services to support quitting, including details on when, where and how to access them.	PP	10.1.3; p167
25	If, after other options have been explored, a woman expresses a clear wish to use nicotine replacement therapy, discuss the risks and benefits with her.	B	10.1.3; p167 App D; p247
z	If nicotine replacement therapy is used during pregnancy, intermittent–use formulations (gum, lozenge, inhaler and tablet) are preferred to continuous-use formulations (nicotine patches).	PP	10.1.3; p167
aa	Smoking status should be monitored and smoking cessation advice, encouragement and support offered throughout pregnancy.	PP	10.1.3; p168
bb	Health care professionals involved in the care of Aboriginal and Torres Strait Islander women should be aware of the high prevalence of smoking in some communities, and take account of this social norm when discussing smoking and supporting women to quit.	PP	10.1.4; p169
cc	Culturally appropriate smoking cessation services should be offered.	PP	10.1.4; p169
dd	In discussing smoking and supporting Aboriginal and Torres Strait Islander women to quit smoking, health professionals should draw on the expertise of anti-tobacco workers where available.	PP	10.1.4; p169
<u>Alcohol</u>			
xi	Advise women who are pregnant or planning a pregnancy that not drinking is the safest option as maternal alcohol consumption may adversely affect the developing fetus.	CBR	10.2.2; p178

Recommendation/practice point		Grade	Section; page
Medicines			
xii	Advise women that use of prescription and over-the-counter medicines should be limited to circumstances where the benefit outweighs the risk as few medicines have been established as safe to use in pregnancy.	CBR	10.3.1; p183 App D; p249
xiii	Therapeutic Goods Administration Category A medicines have been established to be safe in pregnancy.	CBR	10.3.1; p183 App D; p249
ee	Health professionals should seek advice from a tertiary referral centre for women who have been exposed to Category D or X medicines during pregnancy.	PP	10.3.1; p183
ff	Few herbal preparations have been established as being safe and effective during pregnancy. Herbal medicines should be avoided in the first trimester.	PP	10.3.3; p183
Nutritional supplements			
26	Inform women that dietary supplementation with folic acid, from 12 weeks before conception and throughout the first 12 weeks of pregnancy, reduces the risk of having a baby with a neural tube defect and recommend a dose of 500 micrograms per day.	A	10.4.1; p187 App D; p250
gg	Specific attention needs to be given to promoting folic acid supplementation to Aboriginal and Torres Strait Islander women of childbearing age and providing information to individual women at the first antenatal visit.	PP	10.4.1; p187
27	Advise women that taking vitamins A, C or E supplements is not of benefit in pregnancy and may cause harm.	B	10.4.2; p188 App D; p251
xiv	Advise women who are pregnant to take an iodine supplement of 150 micrograms each day. Women with pre-existing thyroid conditions should seek advice from their medical practitioner before taking a supplement.	CBR	10.4.3; p188
28	Do not routinely offer iron supplementation to women during pregnancy.	B	10.4.4; p188 App D; p251
Oral health			
29	At the first antenatal visit, advise women to have oral health checks and treatment, if required, as good oral health protects a woman's health and treatment can be safely provided during pregnancy.	B	10.5.2; p193 App D; p252

Introduction

Antenatal care is a routine part of pregnancy for most of the 280,000 Australian women who give birth each year. There are many aspects of antenatal care, including providing support and information through pregnancy, undertaking regular clinical assessments, screening for a range of infections and abnormalities, and offering social and lifestyle advice.

These Guidelines provide evidence-based recommendations to support high quality, safe antenatal care and contribute to improved outcomes for all mothers and babies. The Guidelines are being developed in collaboration with State and Territory governments. Development of the Guidelines is being funded by the Australian Health Ministers' Advisory Council (AHMAC) and is co-sponsored by the Child Health and Wellbeing Subcommittee (CHWS) of the Australian Population Health Development Principal Committee (APHDPC) and the Maternity Services Inter-Jurisdictional Committee (MSIJC) under the Health Policy Priorities Principal Committee.

There are numerous aspects to antenatal care and reviewing the evidence in all areas is a lengthy process. For this reason, the project is being completed in stages. This module of the Guidelines includes discussion of a range of clinical topics that are generally specific to the first trimester. Some aspects of first trimester care (eg screening for diabetes) are yet to be reviewed (see Appendix F). Module II of the Guidelines will be developed over the next two years.

The development of the draft Guidelines has followed the key principles and processes outlined in the document *NHMRC Standards and Procedures for Externally Developed Guidelines* (2007) (see Appendix C). This involved convening multidisciplinary committees in key areas relevant to antenatal care, with oversight by an Expert Advisory Committee with expertise in provision of, development of, research into and experience of antenatal care. Input was also sought from a Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care (see Appendices A and B). Formal consultation was undertaken with a wide range of experts, stakeholders and consumer representatives.

A systematic approach was used to identify existing guidelines on antenatal care and the United Kingdom National Institute for Health and Clinical Excellence (NICE) 2008 *Antenatal Care: Routine Care for the Healthy Pregnant Woman* (the NICE guidelines) were selected as reference guidelines. Systematic literature reviews in each area of clinical interest examined the evidence presented in the NICE guidelines, where included, and identified and reviewed recent evidence, with final searches for each topic conducted between November 2010 and March 2011 (see Appendix D). Based on this evidence, recommendations were formulated by the Expert Advisory Committee. Where there was insufficient evidence to support recommendations, consensus-based recommendations were formulated. For areas beyond the scope of the literature reviews, practice points were developed. Cost implications of some recommendations were also analysed (see Appendix E).

Need for the Guidelines

The need for national guidance on antenatal care has been promoted for some time. Variation in screening practice and lack of systematic assessment of tests was highlighted in 2000 (Oats 2000). A later study (Hunt & Lumley 2002) identified a lack of consistency in antenatal care in Australia, with local protocols differing from each other and from national policies and research evidence. While efforts have been made to standardise antenatal care within and between institutions (eg the Three Centres Consensus Guidelines in Victoria), no national guidance exists. An evidence-based approach is needed to facilitate national consistency in antenatal care while allowing flexibility in local service provision. It is also hoped that the Guidelines will encourage research to further inform practice (see Part C).

Service delivery

Women usually see a range of different health professionals during pregnancy. While continuity of care and carer (Hatem et al 2008; Homer et al 2008; DoHA 2009) and a multidisciplinary collaborative approach (NHMRC 2010) are recognised as improving outcomes among women in the maternity setting, this is not always available. There are significant disparities between States and Territories, metropolitan and regional or remote areas, and between private and public systems. There are also issues of access and affordability and the suitability of existing approaches to care for some Australian women. For these reasons it is particularly important that all health professionals can access consistent guidance on the different aspects of antenatal care.

Challenges faced by specific population groups

While the principles of woman-centred care apply in all cases, specific approaches may be required in providing antenatal care for groups of women who access antenatal care at lower rates than the general population (eg due to difficulties accessing the health system, distance or financial issues) or who have poorer outcomes.

Application of the Guidelines

Objective of the Guidelines

The Guidelines take a woman-centred approach, which includes considering the woman's context, ensuring cultural safety and enabling the woman to make informed decisions and choices about assessments and tests. They aim to improve the health of women and babies by promoting consistency of care and providing a summary of the currently available evidence on aspects of antenatal care. They include specific discussion of antenatal care for Aboriginal and Torres Strait Islander women, with the aim of improving the experience and outcomes of care for these women and their babies.

Scope

These Guidelines cover the antenatal care of healthy pregnant women (ie those who do not have known 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.

This module of the Guidelines presents the evidence for specific clinical assessments, screening tests and lifestyle considerations that are discussed at the first antenatal visit and may be carried out in the first trimester. However, the principles outlined in Part A apply throughout pregnancy. Much of Part B may also be useful beyond the first trimester as the timing of a woman's first antenatal contact and the availability of services may mean that some clinical assessments or screening tests are carried out later in the pregnancy. As well, some assessments are repeated throughout the pregnancy and social and lifestyle advice is beneficial at all stages of pregnancy.

The Guidelines include recommendations on baseline clinical care for all pregnant women but do not include information on the additional care that some women will require (eg while they recommend that health professionals ask women about their smoking status and provide information about which smoking cessation interventions are effective, they do not give detailed information about the delivery of these interventions). Resources that provide guidance in these areas are listed where relevant.

During the scoping process it was identified that a number of national guidelines relating to antenatal care had recently been developed or were under development. For example, the *beyondblue* (2011) *Clinical*

Practice Guidelines on Depression and Related Disorders in the Perinatal Period were in the final stages of development and the National Health and Medical Research Council (NHMRC) *Australian Guidelines to Reduce Health Risks from Drinking Alcohol* were released in 2009. To provide a single resource for health professionals, summaries of these documents are included in these Guidelines.

For topics relevant to the second and third trimesters systematic literature reviews were not conducted and any guidance included is sourced from the NICE guidelines or relevant Australian guidelines. While considerations beyond the first trimester are noted, this guidance may change as the evidence is reviewed during the development of Module II of the Guidelines.

While some consideration is given to the needs of women from culturally and linguistically diverse backgrounds, specific issues will be included in Module II of the Guidelines.

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,[2] Aboriginal and Torres Strait Islander health workers, practice nurses, allied health professionals 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.

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 health services.

Implementation and review

It is anticipated that a web-based approach be taken to dissemination, with the Guidelines being published on the Department of Health and Ageing website. A range of companion materials will be derived from the Guidelines, such as clinical summaries, a guide for health professionals in Aboriginal and Torres Strait Islander communities and educational materials for women and their families. Key messages from the Guidelines may also be implemented through a number of existing initiatives.

A multidisciplinary team has been convened to contribute to the design and execution of strategies aiming to increase the uptake of the Guidelines through liaison with professional groups and promotion of the recommendations. The team includes representation from midwifery, general practice, obstetrics, rural and remote health, Aboriginal and Torres Strait Islander health, and consumers. A range of implementation strategies will be employed, informed in some cases by an assessment of the likely barriers to uptake of the prioritised recommendations. Potential implementation strategies include: education through meetings, conferences and presentations; outreach education; and opinion leaders.

The extent to which the Guidelines have influenced practice and policy will be monitored in a number of ways, including against indicators already reported.

It is anticipated that the Guidelines will be reviewed in 5 years.

Implementation of the Guidelines is discussed in greater detail in Appendix C.

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2 Also referred to as child and family health nurses in some jurisdictions.

Cost implications of the Guidelines

Economic evaluation has been undertaken for few key aspects of antenatal care. Separate economic analyses into routine ultrasound assessment of gestational age in the first trimester and smoking cessation interventions were conducted to inform the development of these Guidelines. These are summarised in the relevant chapters and discussed in more detail in Appendix E.

Cost implications of the Guidelines will also be considered in the implementation plan (see Appendix C).

Structure of the Guidelines

›	Part A of the Guidelines discusses fundamental aspects of antenatal care. It outlines international principles and highlights key areas for action in Australia (Chapter 1); explains features that support woman-centred care for all women (Chapter 2); discusses ways to optimise the experience of antenatal care for Aboriginal and Torres Strait Islander women (Chapter 3), and other groups of women who experience poorer access to services and/or maternity outcomes (Chapter 4); and discusses antenatal care provision at the organisational level (Chapter 5).

›	Part B discusses the number of antenatal visits (Chapter 6) and the evidence on clinical care including clinical assessments (Chapter 7), maternal health screening (Chapter 8), screening for fetal chromosomal abnormalities (Chapter 9) and lifestyle considerations (Chapter 10).

›	Part C highlights areas for further research.

›	The appendices provide information on the development of the Guidelines.

References

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NHMRC (2009) *Australian Guidelines To Reduce Health Risks from Drinking Alcohol*. Canberra: National Health and Medical Research Council.

NHMRC (2010) *National Guidance on Collaborative Maternity Care*. Canberra: National Health and Medical Research Council.

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PART A —
BASICS OF ANTENATAL CARE

1.   Principles of care

In 1998 the World Health Organization (WHO) proposed a set of principles of perinatal care (WHO 1998) that endorse the protection, promotion and support necessary for effective antenatal and postnatal care (Chalmers et al 2001). These principles are embedded in the approach to care outlined in these Guidelines and are included in Table 1.1.

Table 1.1:   WHO principles of perinatal care

Care for women with a normal pregnancy and birth should be demedicalised
Pregnancy and birth should be viewed as a natural process in life and essential care should be provided to women with the minimum set of interventions necessary.
Care should be based on the use of appropriate technology
Sophisticated or complex technology should not be applied when simpler procedures may suffice or be superior.
Care should be evidence-based
Care should be supported by the best available research, and by randomised controlled trials where possible and appropriate.
Care should be local
Care should be available as close to the woman's home as possible and based on an efficient system of referral from primary care to tertiary levels of care.
Care should be multidisciplinary
Effective care may involve contributions from a wide range of health professionals, including midwives, general practitioners, obstetricians, neonatologists, nurses, childbirth and parenthood educators.
Care should be holistic
Care should include consideration of the intellectual, emotional, social and cultural needs of women, their babies and families, and not only their physical care.
Care should be woman-centred
The focus of care should be meeting the needs of the woman and her baby. Each woman should negotiate the way that her partner and significant family or friends are involved.
Care should be culturally appropriate and culturally safe
Care should consider and allow for cultural variations in meeting these expectations.

Care should provide women with information and support so they can make decisions

Women should be given evidence-based information that enables them to make decisions about care.

Care should respect the privacy, dignity and confidentiality of women

All women have the right to be treated with respect and dignity, have their privacy respected, and be assured that all their health information is confidential.

1.1.1. References

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2. Providing woman-centred care

Woman-centred care focuses on the woman's unique needs, expectations and aspirations; recognises her right to self-determination in terms of choice, control and continuity of care; and addresses her social, emotional, physical, psychological, spiritual and cultural needs and expectations (ANMC 2006). It also acknowledges that a woman and her unborn baby do not exist independently of the woman's social and emotional environment, and incorporates this understanding in assessment and provision of health care.

2.1. Understanding the woman's context

"An individualised approach to care should be offered at all times rather than routine practice. Care provision needs to be flexible, friendly and non-threatening, making it accessible to all women, including young women."
(Chalmers et al 2001)

Every woman has a right to antenatal care that takes into account her individual social and emotional situation. While many Australian women experience high levels of economic prosperity, educational attainment and good health, there are still many women living in poverty, subsisting on inadequate pensions, restricted by under-employment or low-income occupations and experiencing poor health outcomes (AWHN 2008). Gender inequalities persist, with women economically less secure, maintaining the primary carer role, and subject to violence (including physical and sexual assault, as well as emotional, psychological and financial abuse) (AWHN 2008).

The experience of pregnancy, especially in the early stages, differs for each woman. The stability of a woman's relationships and social environment will influence her experience. In addition, if the pregnancy is unplanned or results from sexual assault, the woman may experience uncertainty about whether to proceed with the pregnancy.

Although addressing all of these factors is beyond the scope of antenatal care, taking them into account will lead to a fuller understanding of an individual woman's situation and the environment for the developing baby. This provides the opportunity for early intervention to reduce any risk to the woman and her baby. Referral to other services (eg housing, social services) should also be considered, in partnership with the woman.

2.2. Cultural safety in antenatal care

"Cultural safety puts the woman at the centre of care by identifying her needs and establishing a partnership built on trust." (Phiri et al 2010)

Cultural safety is based on the basic human rights of respect, dignity, empowerment, safety and autonomy (Phiri et al 2010). The concept of 'cultural safety' comes from an approach that incorporates culture within a wider structural framework, focusing on social position to explain health status rather than on the 'values, beliefs and traditions' of a particular group (Williamson & Harrison 2010). This approach considers the dynamic nature of culture and the diversity within groups, avoids stereotyping and identifies the needs of the individual receiving care.

Cultural safety is defined by the individual attending health care. It builds on the concepts of cultural awareness (appreciating cultural, social and historical differences and reflecting on one's own culture, biases and tendency to stereotype) and cultural sensitivity (acknowledging differences and exploring self attitudes) (Thomson 2005). For example, if a woman prefers to see a female health professional, identifying this need is *culturally aware*, planning the woman's care around that need is *culturally sensitive* and ensuring that the woman is not seen by a male health professional is *culturally safe* (Phiri et al 2010). Embedding this into routine care may contribute to a *culturally responsive* service (Reibel & Walker 2010).

Strategies to ensure culturally safe care include optimising communication (eg through the use of interpreters), building sound relationships, acknowledging women's cultural preferences (Phiri et al 2010) and reflecting on and analysing how power relationships and history have affected the health of individuals (Kruske et al 2006). It is also important to acknowledge that the interaction between the 'culture' of the health professional and the culture of the woman (regardless of ethnicity) may result in a power imbalance (Kruske et al 2006). Women from vulnerable and marginalised groups may feel particularly disempowered in healthcare settings. This can be reduced through (Kruske et al 2010):

› mindfulness about symbols of power (eg uniform, stethoscope) and the way the room is structured (eg avoiding sitting behind a desk);

› positioning — sitting alongside, not opposite, quiet or shy women and families; and

› showing genuine respect for the woman — the woman will be more likely to feel trust, tell more of her experience and accept advice.

2.3. Providing information and support so that women can make decisions

"Women should be provided with evidence-based information and encouraged to participate in decisions about care." (Chalmers et al 2001)

In any health interaction, a woman has the right to (adapted from *Charter of Health Consumer Rights* [CHF 2004]):

› determine what treatment she accepts or chooses not to accept;

› be given easily understandable explanations in her first language of the details of her specific health problem, any proposed treatments or procedures and the results of any tests performed;

› have access to all health information about herself and her baby; and

› have her privacy respected, be treated with respect and dignity and know that all her own health information is confidential.

Health professionals and women need to communicate and collaborate in a team approach (Kryzanauskas 2005; NZ MOH 2008). The woman's input — and her family's when she chooses — is an important part of this process (NHMRC 2010). Consistency of information, especially if this is provided by different professionals, is very important (Jones et al 1999; Price et al 2005).

Making a choice or consenting should be an ongoing process of discussion between a woman and the health professionals involved in her care. Factors that may assist women in decision-making include:

› determining how much prior knowledge the woman has (Kruske et al 2010);

› asking open-ended questions and listening to the answers;

› attending to verbal and non-verbal cues;

› clarifying the information provided by the woman;

› clarifying the woman's understanding of the information provided to her;

› providing easy to understand verbal explanation and written or audiovisual information in the woman's preferred language (where available); and

› where appropriate, using accredited interpreters to ensure effective communication.

Women have the right to decline care or advice if they choose, or to withdraw consent at any time and have these choices respected (UNESCO 2005). It is important that the level of care provided does not alter because of this choice (FPA Health & Read 2006; Faunce 2008; NHMRC 2010).

2.3.1. Documenting discussions and decisions

Documenting discussions and decisions is important and should include clear and consistent records of (NHMRC 2010):

›   information provided to the woman and indications that the messages have been understood;

›   informed consent, responsibility and accountability for decisions; and

›   the woman's understanding of risk and her responsibility for her own choices and decisions about care, especially if these decisions are in conflict with professional advice (in such circumstances it must be clearly documented that the woman has accepted a certain level of risk[3]).

Shared and reciprocal documentation, including some form of woman-held record, ensures that all members of the collaboration are aware of essential information throughout maternity care. Several jurisdictions in Australia regularly use woman-held records, which have been found to be an excellent way to improve communication (NHMRC 2010). A woman-held record means the woman has a better chance of controlling her health information, encouraging respectful language and, as a result, enabling her to feel more in control during her maternity care (NHMRC 2010).

Electronic (eg web-based or e-health) or triplicate records allow sharing of accurate documentation and also reduce duplication of effort, enabling more streamlined care for women (NHMRC 2010).

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3 Several Australian States and Territories have schedules in their health legislation that outline health practitioners' obligations and protections if treatment is refused. These include refusal of treatment certificates, which may help in recording decisions and avoiding confusion if care is transferred.

2.4.   Involving the woman's family

"Women and their families should be assisted to prepare for pregnancy, birth and parenthood. Fathers have needs of their own as individuals and not simply as companions or supports for their partner." (Chalmers et al 2001)

Woman-centred care encompasses the needs of the baby, the woman's family, significant others and community, as identified and negotiated by the woman herself (ANMC 2006). Each woman should be asked about whom she would like to be involved in her care — some women may only want their partner involved while others may wish to involve a wider family or social network. A minority of women may have limited control over the family members who are involved in their antenatal care or the social environment in which the baby develops (eg exposure to passive smoking or domestic violence).

Involving fathers/partners in antenatal care enables them to participate in decision-making and be informed about the care pathway and environmental factors that may influence the health of the baby during pregnancy (eg maternal passive smoking) and after the birth (eg infectious diseases such as pertussis). Education and information about pregnancy and childbirth should be provided using the principles outlined in Section 2.3. Assessment and intervention for fathers/partners may also be a consideration (eg mental health, smoking cessation, immunisation).

Involvement of fathers/partners in antenatal care may also enable early intervention (eg family support) for families requiring additional assistance (COAG 2009).

2.5.   Resources

COAG (2009) *Protecting Children is Everyone's Business. National Framework for Protecting Australia's Children 2009–2020*. An initiative of the Council of Australian Governments. Commonwealth of Australia. http://www.coag.gov.au/coag_meeting_outcomes/2009-04-30/docs/child_protection_framework.pdf

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NHMRC (2004) *Communicating with Patients. Advice for Medical Practitioners*. Canberra: Commonwealth of Australia. http://www.nhmrc.gov.au/guidelines/publications/e58

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3. Antenatal care for Aboriginal and Torres Strait Islander women

While many Aboriginal and Torres Strait Islander women experience healthy pregnancies, for many, poor health and social disadvantage contribute to poorer perinatal outcomes than those experienced by non-Indigenous 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.

3.1. 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 (see Table 3.1).

Table 3.1:   Snapshot of perinatal health among Aboriginal and Torres Strait Islander women

Overall poorer perinatal outcomes than non-Indigenous women	› At least four times the rate of maternal mortality (Sullivan et al 2008) › Higher rates of preterm birth (13.3% vs 8.0%), low birth weight (12.3% vs 5.9%) and perinatal deaths (17.3 vs 9.7 per 1,000 births) (Laws et al 2010)
Risk factors for complications of pregnancy experienced in some communities	› High levels of life stressors › Limited access to affordable nutritious food › High prevalence of urinary tract infections, sexually transmitted infections and anaemia › High prevalence of chronic illness — diabetes, kidney disease and rheumatic heart disease › High prevalence of smoking › Harmful levels of alcohol consumption in pregnancy › Lack of family or social support › Pregnancy in adolescence › High rates of incarceration
Access to health services	› Limited availability of culturally appropriate services may affect attendance (eg average number of antenatal visits ranges from 5.5 in mainstream health care settings to 10.5 in community-controlled settings [Jan et al 2004; Rumbold & Cunningham 2008]) › While most Aboriginal women live in urban settings, and many live in rural towns, Aboriginal and Torres Strait Islander women are more likely to live in remote areas where there are fewer health services › Financial issues may restrict access

A holistic view of Aboriginal health includes the physical, social, emotional, spiritual and cultural wellbeing of both an individual and his or her community (NAHSWP 1989). Traditional practices around pregnancy and birth are also important to many Aboriginal and Torres Strait Islander women, particularly in remote areas (Carter et al 1987; Myles 1992; Danila Dilba Medical Service 1999). However, 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).

The development of a health service that is culturally equipped to provide holistic antenatal care is one of many important requirements to improve general health and wellbeing in Aboriginal and Torres Strait Islander communities.

## 3.2.	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 apply to all women. This section discusses issues specific to providing appropriate antenatal care for Aboriginal and Torres Strait Islander women.

### 3.2.1.	Individual cultural competence

Cultural competence 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 cultural competence. A commitment to cultural competence 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 competence 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 (eg health-related beliefs, practices and cultural values and disease incidence and prevalence).

Cultural competence training programs and tools for evaluating individual cultural competence have been developed and should be accessed wherever available (see Section 3.4). Within communities, cultural mentoring of non-Indigenous health workers by community members can also assist in increasing culturally competent practice (NHMRC 2005).

### 3.2.2.	Improving women's experience of antenatal care

Taking an individualised approach

Factors that may improve the experience of antenatal care for Aboriginal and Torres Strait Islander women include:

›	taking the time to establish rapport and trust with each woman;

›	explaining confidentiality and that the woman's privacy will be respected;

›	consulting the woman about whom she would like to be involved in her care;

›	having knowledge about the health and social wellbeing of the woman's community; and

›	if necessary, advocating on behalf of the woman so that she receives appropriate care throughout pregnancy.

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)(see Section 2.3). 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 (Hunt 2003):

› taking steps to improve communication;

› increasing available time;

› improving continuity of carer; and

› having protocols that explicitly endorse shared decision-making.

3.3. Service delivery issues 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)

In many regions of Australia, there are specific services and programs to respond to the expressed preferences of Aboriginal and Torres Strait Islander women (Hunt 2008) and several evaluations have shown their success in improving uptake of antenatal care services. However, these programs are not available for all Aboriginal and Torres Strait Islander women and many women seek antenatal care through mainstream primary health services, such as general practice, community health services, public hospitals and other settings.

Mainstream health services frequently prioritise managing physical illness over addressing a woman's social and cultural needs during pregnancy. Reasons for Aboriginal and Torres Strait Islander people not attending health services include a lack of Aboriginal and Torres Strait Islander staff, perceptions of staff as unfriendly and uncaring (including talking down and using body language suggesting Aboriginal and Torres Strait Islander people are not welcome) and long waits to see the doctor (Hayman et al 2009). Communication issues, mistrust of the system, racism and poor cultural understanding have also been identified as factors affecting uptake of services (AHMAC 2004). As well, many women have described negative experiences of hospital care (Carter et al 1987; Sutherland 1998; Daruk AMS & Western Sector Public Health Unit 1998; Ireland et al 2010) and there may be poor communication between primary and secondary care and duplication of care.

Evidence confirms that embedding cultural competence within an organisation's continuous quality improvement processes enhances Aboriginal health outcomes as well as building organisational capacity (Walker 2010). Tools for evaluating an organisation's cultural competence have been developed (see Section 3.4) and provide a useful aid in reviewing the concepts, principles and processes that underpin cultural competence (Walker 2010).

Table 3.2:   Key components in providing culturally responsive antenatal care services

There is evidence that Aboriginal and Torres Strait Islander people are welcome at the health service, such as local artwork in the waiting room and Aboriginal staff at reception, and waiting areas are family friendly

Aboriginal and Torres Strait Islander health professionals and/or Aboriginal health workers are involved in the maternal health care team

Aboriginal and Torres Strait Islander women have the option of consulting female health staff

Non-Indigenous health professionals are supported in gaining an understanding of Aboriginal 'women's business'

Women have the opportunity to involve extended family and kin (community) in decision-making

Interpreters are available

Internal roles and kinship systems within the community are not compromised (eg family members may not be appropriate interpreters)

Where possible, services are provided in a location intended for health care for women and children

There are effective partnerships between obstetricians, general practitioners, midwives and Aboriginal health workers and between primary and hospital care

In consultation with the woman, engagement of fathers and partners is encouraged and supported

Home visits and outreach activities are offered

Transport and child care or playgroups are available

Culturally appropriate education about health in pregnancy is provided (this may include local adaptation of written materials [booklets, posters] or using other media [such as video])

Feedback is invited from women and used for continuous quality improvement purposes

Attention is given to accurate reporting of Indigenous status

A community approach is taken to program development and Aboriginal and Torres Strait Islander women are involved in planning

Source: Compiled from d'Espaignet et al 2003; Carter et al 2004; NSW Health 2005; Panaretto et al 2005; 2007; Congress Alukura & Nganampa Health Council 2008; NSW Dept Community Services 2008; Hayman 2010.

3.4.   Resources

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Wilson G (2009) *What Do Aboriginal Women Think Is Good Antenatal Care? Consultation Report.* Darwin: Cooperative Research Centre for Aboriginal Health.

Rural Health Education Foundation *Aboriginal Maternal and Infant Health* (video)
http://www.rhef.com.au/programs/program-1/?program_id=188&group_id=5

Websites

HealthInfoNet: http://www.healthinfonet.ecu.edu.au/

Closing the Gap: http://www.healthinfonet.ecu.edu.au/closing-the-gap

Queensland Health *Cultural Safety Module*: http://www.health.qld.gov.au/capir/library/cultural.asp

Birthing Business in the Bush: http://www.maningrida.com/mac/bwc/index.html

Maternity care in the bush: http://courses.crana.org.au/36-page-about-crana.html

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4. Population groups with specific care needs

Within the diversity of women that make up the Australian population, some face greater disadvantage in terms of access to health services and may experience poorer perinatal outcomes (AWHN 2008). These include women from culturally and linguistically diverse backgrounds (including women from a refugee background), adolescent women and women living in rural and remote areas. This chapter discusses considerations in providing optimal antenatal care for these groups of women.

4.1. Women from culturally and linguistically diverse backgrounds[4]

"Caring for individuals from diverse backgrounds is a daily reality for nurses and midwives, who are expected to provide care which is both clinically safe and culturally sensitive" (Williamson & Harrison 2010)

Around a quarter of women who give birth in Australia were born in another country (Laws et al 2010). These women experience slightly higher rates of fetal death than Australian-born women (7.9 versus 7.1 per 1,000 total births) (Laws et al 2010).

Women bring with them the knowledge and practices from their first home countries and expectations of early antenatal attendance vary between countries. For example, more than half (57%) of women giving birth in NSW in 2004 who were originally from a developing country attended antenatal care later than 12 weeks in the pregnancy (Trinh & Rubin 2006).

Factors affecting uptake of antenatal care

Women from culturally and linguistically diverse backgrounds are diverse, and different groups have differing issues and outcomes. As well as cultural background, women's experiences differ with residential status, educational level and prior experience of pregnancy and birth. However, there are some common issues that can affect uptake of antenatal care by women from culturally and linguistically diverse backgrounds. These include (McCarthy & Barnett 1996):

› language or lack of literacy;

› inaccessibility or unacceptability of health services;

› cultural issues regarding male health professionals;

› lack of usual female family and community support systems;

› conflict between traditional practices around antenatal care and mainstream health services;

› lack of cultural competency among health professionals;

› history of grief, loss and trauma, in addition to migration;

› lack of entitlement to free health care; and

› lack of suitable resources (eg female interpreters).

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4 This section includes provisional guidance on improving the experience of antenatal care for women from culturally and linguistically diverse backgrounds. A more comprehensive approach to care for these women will be included in Module II of these Guidelines.

Women from culturally and linguistically diverse backgrounds who have no previous experience with the western health care system may lack understanding of reasons for antenatal visits, medical procedures and use of technology. They may not feel confident to ask questions or participate in discussions about their care plan or birth options. Different cultural beliefs may also influence aspects of antenatal care such as involvement of the father in pregnancy and childbirth, consent for interventions such as caesarean section, willingness to be cared for by a midwife rather than a doctor, understanding of dates and times of appointments, and knowledge about medical aspects of pregnancy.

Information needs to be explained carefully and clearly, with the assistance of an accredited interpreter, in addition to providing written information. Written material can serve as a prompt or can be shown to other health professionals who can then remind the woman or explain the information again. Video or audio resources may also be appropriate.

Issues affecting women from particular groups

Different groups of culturally and linguistically diverse women face specific issues that may affect their experience of pregnancy and birth. Increased awareness of such issues and variation between groups will promote better antenatal care of women from culturally and linguistically diverse backgrounds.

› *Women who are refugees or asylum seekers* — Many refugee women experience issues such as poor prior health (including oral health, co-existing health issues, inadequate nutrition and Post Traumatic Stress Disorder). They may feel fear of authority figures, including health professionals, due to past experiences of trauma and/or torture, and may also have financial, employment and housing issues. Women with a history of torture or trauma are at increased risk of mental disorders, including anxiety and depression; screening for these disorders and referral to appropriate counselling services should always be offered. Women in this situation will require reassurance and explanation of the care offered to them, including tests, procedures and pregnancy risks. More time may be needed, and specific strategies used (often in collaboration with other services and migrant agencies) to build necessary confidence and trust.

› *Women affected by Female Genital Mutilation (FGM)* — FGM is the collective term used to describe the cultural practice of cutting or removal of either a part, or the whole external female genitalia. Some of these procedures are minor, while others involve significant change and have an impact during the antenatal period. Some women may need to be deinfibulated to enable ongoing clinical assessment and avoid complications; this is usually performed in the second trimester but the first trimester is the optimum time to discuss the procedure. Women affected by FGM have specific care needs and should where possible be referred to an FGM team for ongoing support and management of their physical and psychological wellbeing.

› *Women in higher risk groups* — some culturally and linguistically diverse groups have higher rates of risk factors such as gestational diabetes, smoking in pregnancy and vitamin D deficiency. Lifestyle advice may need to take cultural issues into account (eg giving culturally relevant nutritional advice on managing gestational diabetes and educating both women and men about passive smoking as in many households it may be men rather than women who smoke). Domestic violence is high among some communities, and may be hidden within the family structure and or the community.

Health professionals are encouraged to develop an understanding of the issues facing mothers and babies from the culturally and linguistically diverse groups that they regularly work with and to use this information to improve the appropriateness of their care.

Improving antenatal care for women from culturally and linguistically diverse backgrounds

Experiences of antenatal care among women from culturally and linguistically diverse backgrounds, including refugee backgrounds, may be improved through (State Perinatal Reference Group 2008):

› social support, for example through ethnic-specific cultural liaison officers and women's groups, to maintain cultural connections with the traditions, birthing ceremonies and rituals of women's countries of origin;

› cultural competence among health professionals, including knowledge of cultural traditions and practices relevant to pregnancy and birth and associated expectations of women, especially of groups in the local community;

› cultural brokerage, for example through maternity liaison officers/bilingual health workers who can help women to understand and navigate the health system, provide education and resources in relation to maternity care, act as a patient advocate and liaise between women and maternity staff, or through partnerships with multicultural resource centres and English language providers;

› education, including linguistically appropriate information, parenting education workshops, education about accessing the health system, different models of care available, and education for fathers/partners on antenatal issues; and

› culturally appropriate resources, including materials available in the woman's own language, resources in spoken format for women who lack literacy in their own languages and access to interpreter services during appointments or important events.

The care needs of women from culturally and linguistically diverse backgrounds can be complex. The first point of contact (eg first antenatal visit) is important and should be undertaken with an accredited health interpreter.

4.2. Adolescent women

"While a higher risk of poor birth outcomes such as low birth weight is seen for births to teenage women, this is likely to be related more to the social circumstances of these young women, rather than their age." (Middleton 2009)

The number of births to adolescent women in Australia has decreased over the last few decades (ABS 2008) but still accounts for around 4 per cent of all births (Laws et al 2010). Around 20 per cent of births to Aboriginal and Torres Strait Islander mothers are to women aged younger than 20 (Laws et al 2010). Women younger than 20 years experience higher rates of fetal and neonatal deaths than Australian women in general (15.7 versus 7.4 total births and 4.0 versus 2.8 per 1,000 live births, respectively)(Laws et al 2010).

Adolescent women are likely to seek confirmation of pregnancy and antenatal care later in pregnancy. For example in NSW an average of only 76% of adolescent women started antenatal care before 20 weeks of pregnancy, compared with 90% of women aged between 30 and 39 years of age (CER 2008).

The high levels of social disadvantage, higher incidence of domestic violence, higher rates of smoking in pregnancy, lack of social supports and lower socioeconomic and education status of these women contribute to poorer outcomes. Young adolescent mothers still have their own developmental needs that should be addressed in addition to the needs related to the pregnancy. Whether the pregnancy is unplanned or unwanted, and the need for reporting of sex in a minor at risk, are also considerations.

Improving perinatal outcomes for adolescent women and their babies

In the context of growing recognition of young people's need for services that are sensitive to their unique stage of biological, cognitive and psychosocial transition into adulthood (Tylee et al 2007), the World Health Organization identified that youth-friendly services need to be equitable, accessible, acceptable, appropriate, comprehensive, effective and efficient (WHO 2002). Key features of youth-friendly care include (WHO 2002; Tylee et al 2007):

› health professionals and support staff who are non-judgmental and considerate, treat each young person with equal care and respect, are competent, motivated and well supported; and

› health services that have an appealing ambience, convenient working hours, offer privacy and avoid stigma, and aim for short waiting times and (when needed) swift referral.

4.3. Women in rural and remote areas

"While it is generally accepted that women should have access to safe maternity care, consistent with their assessed level of risk, as close as possible to where they live, the options available to women differ according to where they live." (DoHA 2008)

Women living in outer regional, remote or very remote areas may have difficulties accessing appropriate antenatal health care due to distance and limited availability of services. They may be required to give birth away from their communities, which can lead to extra financial costs, lack of practical and emotional support, isolation, lack of integrated care between systems, inappropriate or culturally unsafe health care, and temporary separation from older children (Perinatal Mental Health Consortium 2008).

Rates of neonatal death are significantly higher among women living in rural areas and rates of fetal death are higher among women living in remote areas (AIHW 2005). Rural and remote families also experience higher rates of maternal death. For example, the rate of direct maternal deaths is high in rural and remote areas (8% of direct maternal deaths in locations inhabited by 3% of the population) and proportionately high in outer regional areas (Sullivan et al 2008).

Providing integrated care in rural and remote areas

Care pathways in rural, remote and very remote Australia are different to those in urban settings and options can be limited. This has a particular impact on women and families living in these areas, a significant proportion of whom are Aboriginal and Torres Strait Islander women (see Chapter 3).

In rural and remote settings, care is largely provided by the local primary care health professionals — midwives, nurses, Aboriginal and Torres Strait Islander health workers, GPs, or a combination of these. It is important that these health professionals have access to specialist advice and support. Contemporary approaches including telemedicine, support lines and online services are becoming increasingly available and will be extremely valuable in rural and remote areas. Innovative models of care (eg specialist outreach services and caseload midwifery care) may also expand women's possibilities to have care as close to home as possible. It is also important for health professionals in these areas to use family and community networks where possible and explore community initiatives and existing programs to improve pathways to care for women in their region.

4.4.   Women with serious mental health disorders

"Women with a serious mental illness are just as likely to be mothers and their fertility rates are no different from the general population of women."
(Nicholson & Biebel 2002)

Mental health disorders have been identified as a leading cause of maternal morbidity and mortality in the UK (Lewis 2007) and as one of the top three causes of indirect maternal mortality in Australia (Austin et al 2007).

While specific data on the prevalence of serious mental health disorders (eg schizophrenia, bipolar disorder, severe personality disorders) in pregnant women in Australia are not available, recent studies suggest that schizophrenia is present in 1% of the population world wide, lifetime prevalence of bipolar disorder in Australia is estimated as 1.2% (University NSW 2002) and personality disorders are present in 6.5% of the Australian population (Jackson & Burgess 2000). Australian research indicates that up to one in ten (9%) women experience depression during pregnancy (Buist & Bilszta 2006) and anxiety disorders are likely to be as, or more, common (see Section 7.6).

Women with serious mental health disorders are at higher risk for pregnancy and birth complications (eg preterm birth, still birth and low birth weight [Nilsson et al 2002]) and there are increased neurological developmental risks for their children (Jablensky et al 2005). Lifestyle factors such as smoking, use of illicit drugs, poor compliance with folate supplementation, poor nutrition as well as failure to access antenatal care have been implicated in this increased risk (Hauck et al 2008; King-Hele et al 2009; Matevosyan 2011). Pregnancy can evoke many issues for women who have experienced complex traumas (eg in borderline personality disorder) and may lead to difficulties in attendance or follow-up (SA Perinatal Practice Guidelines Working Group 2011). Postnatally, many issues will present that challenge families and professionals (Mares et al 2005; Newman & Stevenson 2005).

Women with serious mental health disorders are also more likely to have had a negative early sexual experience or to have been a victim of sexual assault and therefore are more at risk of unplanned or unwanted pregnancy (Miller & Finnerty 1996). Not only are these women less likely to receive antenatal care, but they have more chance of being without partner support, separated or divorced (Rudolph et al 1990), at risk of suicide and using illicit drugs (Miller 1990).

Women who are taking psychotropic medicines may experience side effects such as nausea, breast tenderness and menstrual cycle disruption, which mask the signs of early pregnancy (Fitzgerald & Seeman 2000) and may delay diagnosis of pregnancy.

Improving outcomes for women with serious mental health disorders

While there is clear evidence of the detrimental effects of serious mental disorders on both mother and infant, there are few evaluated interventions to improve outcomes. Objectives include enabling cessation or reduction of smoking (see Section 10.1), and optimising mental health care while providing collaborative antenatal care (Hauck et al 2008).

Given the prevalence of mental health problems, the Australian Government has provided funding for screening during pregnancy for psychosocial factors that affect mental health (see Section 7.5) and for symptoms of the more common mental health problems, depression and anxiety (see Section 7.6), and for the training of health professionals to undertake this screening and understand pathways to care (see

Section 7.6.4). Assessing women for psychosocial risk factors and symptoms of distress during regular pregnancy checks gives the opportunity to link women with appropriate services (Austin et al 2008). Antenatal screening also seeks to identify whether a woman has experienced, or received treatment for, more severe mental health disorders. If this is affirmed, further understanding of current and future significance is indicated along with collaboration with relevant mental health professionals.

It is also appropriate to ensure knowledge of current psychotropic medicine use. While no recent Australian statistics are available, figures from comparable populations suggest that at least 2% of women take antidepressants in the first trimester of pregnancy (Ververs et al 2008). It is important that the risks/benefits of treatment are discussed (Lorenzo et al 2011). Women will seek information about the safety of psychotropic medicines and will also need information regarding risks of relapse if they stop taking their medicines because of pregnancy. Medicine use in pregnancy is discussed in Section 10.3. As information in this field can change rapidly, current information about specific medicines should be sought (see Section 10.3.6).

For more severe mental health issues, such as schizophrenia and drug-related psychoses, working collaboratively with trained mental health professionals is appropriate. When risk of suicide is identified (eg through question 10 of the Edinburgh Postnatal Depression Scale; see Section 7.6) referral to a psychiatrist or other mental health professional is required. Sources of information about serious mental health disorders in perinatal practice and mental health referral and advice are included in Section 4.5.

4.5. Resources

Women from culturally and linguistically diverse backgrounds

Multicultural Health (Queensland Health) — Pregnancy and postnatal topics
http://www.health.qld.gov.au/multicultural/public/pregnancy.asp

NSW Health Standards Procedures for Working with Health Care Interpreters PD2006_053.
www.health.nsw.gov.au/policies/pd/2006/PD2006_053.html

NSW Multicultural Health Communication Service — Pregnancy and postnatal topics
http://www.mhcs.health.nsw.gov.au/topics/Pregnancy_and_Post_Natal.html

Royal Women's Hospital (2010) *Female Genital Mutilation – Maternity*.
www.thewomens.org.au/FemaleGenitalMutilationMaternity

Adolescent women

SA Children, Youth and Women's Health —
http://www.cyh.com/HealthTopics/HealthTopicDetails.aspx?p=240&np=299&id=2136

Women in rural and remote areas

Rural Health Education Foundation online videos
http://www.rhef.com.au/programs/?group_id=28

Women with serious mental health disorders

beyondblue (2011) Clinical Practice Guidelines Depression and Related Disorders — Anxiety, Bipolar Disorder and Puerperal Psychosis — in the Perinatal Period. A Guideline for Primary Care Health Professionals. Melbourne: *beyondblue: the national depression initiative.* http://www.beyondblue.org.au/index.aspx?link_id=6.1246

Online training — *beyondblue* provides online training in assessing and managing mental health disorders in the perinatal period. http://thinkgp.com.au/beyondblue.

Nguyen TN, Faulkner D, Allen S et al (2010) Managing pregnant women with serious mental illness: using the Edinburgh Postnatal Depression Scale as a marker of anxiety and depressive symptoms. *Aust NZ J Psychiatric* 44(11): 1036–42.

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SA Perinatal Practice Guidelines Workgroup (2010) Chapter 144 Eating disorders in pregnancy. In: *South Australian Perinatal Practice Guidelines. Adelaide*: SA Health.
http://www.health.sa.gov.au/PPG/Default.aspx?PageContentID=1416&tabid=35

SA Perinatal Practice Guidelines Workgroup (2011) Chapter 146 Personality disorders. In: *South Australian Perinatal Practice Guidelines*. Adelaide: SA Health.
http://www.health.sa.gov.au/PPG/Default.aspx?tabid=262

WA Dept Health (2008) *Healthy Babies for Mothers with Serious Mental Illness: A Case Management Framework for Mental Health Clinicians*.
http://www.nmahsmh.health.wa.gov.au/projects/docs/Healthy_babies_clinicians_manual.pdf

Mental health referral and advice

› The *beyondblue* website (www.beyondblue.org.au) includes a directory of medical and allied health professionals in mental health, including psychologists, clinical psychologists, social workers and mental health nurses.

› The headspace Knowledge Centre provides up-to-date information about treatment interventions and models of care for young people with mental health and substance use issues.
http://www.headspace.org.au/knowledge-centre/

› The Black Dog Institute offers education and training programs, resources and online learning for health professionals with a focus on depression and bipolar disorder.
http://www.blackdoginstitute.org.au/healthprofessionals/index.cfm

› square — Suicide, Questions, Answers and Resources — is an integrated suicide prevention resource developed by General Practice SA and Relationships Australia (SA) in conjunction with the Australian and State/Territory Governments. It is part of the National Suicide Prevention Strategy and was jointly funded by the Australian Government and the Government of South Australia.
http://square.org.au/

› The Living Is For Everyone (LIFE) website is a suicide and self-harm prevention resource designed for people across the community who are involved in suicide and self-harm prevention activities.
http://www.livingisforeveryone.com.au/

› The GP Psych Support service provides GPs with patient management advice from psychiatrists within 24 hours. Phone: 1800 200 588; Fax: 1800 012 422; Email: http://www.psychsupport.com.au.

Government funding to receive treatment from psychiatrists, psychologists, appropriately trained GPs, social workers, occupational therapists and nurses can be accessed through initiatives including:

› Access to Allied Psychological Services (ATAPS)
  http://www.health.gov.au/internet/main/publishing.nsf/content/mental-boimhc-ataps

› Better Access initiative (Medicare items)
  http://www.health.gov.au/internet/main/publishing.nsf/Content/mental-ba

› Better Outcomes in Mental Health Care
  http://www.health.gov.au/internet/main/publishing.nsf/content/mental-boimhc

› Mental Health Nurse Incentive Program
  http://www.medicareaustralia.gov.au/provider/incentives/mental-health.jsp

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5.   Providing antenatal care services

Different women have different needs in relation to pregnancy and childbirth and require access to appropriate levels of care (AHMAC 2008). The level of care determines whether the woman is at the right place, at the right time, with the right health professional, for her clinical needs. Models of care should, as far as possible, provide a range of options at the same time as closely matching quality services to clinical needs (AHMAC 2008).

5.1.   Approaches to antenatal care

"A highly trained, qualified and effective primary maternity service workforce, working collaboratively, to use increasingly scarce respective skills efficiently, is the key to developing and sustaining quality primary maternity services." (AHMAC 2008)

Australian women are likely to receive antenatal care in primary and hospital settings and to see a range of health professionals. Existing models of care include:

› *public hospital care* — the woman attends the hospital for all aspects of her antenatal care and receives care from hospital doctors and midwives;

› *GP care* — the woman sees her GP throughout her pregnancy;

› *private obstetrician or private midwife care* — the woman sees her private obstetrician or midwife throughout her pregnancy;

› *private obstetrician and private GP* — the woman sees her GP regularly during the antenatal period with specific visits to an obstetrician;

› *shared care* — several health professionals are involved in the care of a woman during pregnancy, often in the context of a formal arrangement; health professionals involved may include GPs, midwives, other primary care health professionals, specialist obstetricians and hospital practitioners; and

› *midwife care* — midwives are the primary providers of care for the woman; this may be through a team of midwives sharing a caseload (team midwifery) or a woman receiving care from one midwife or his/her practice partner (caseload midwifery).

As well as these health professionals, others who may have an integral role in the antenatal care team where available include Aboriginal health workers, maternity liaison officers, bilingual or multicultural health workers and sonographers. Child and family health workers, psychologists, nutritionists and drug and alcohol workers may also play a role in a woman's antenatal care.

5.1.1. Collaborative practice

Findings from several comprehensive Australian maternity reviews have confirmed the need for maternity services to work within collaborative and consultative frameworks, in order to more closely match services to women's needs, preferences and expectations (AHMAC 2008). Midwives, obstetricians and GPs can all make valuable contributions to collaborative antenatal care (AHMAC 2008).

In maternity care, collaboration is a dynamic process of facilitating communication, trust and pathways that enable health professionals to provide safe, woman-centred care. Collaborative maternity care enables women to be active participants in their care (NHMRC 2010). It includes clearly defined roles and responsibilities for everyone involved in the woman's care, especially for the person the woman sees as her maternity care coordinator (NHMRC 2010).

Collaboration also involves working within established clinical networks and systems to facilitate timely referral and transfer to appropriate services when required (AHMAC 2008). Collaborative networks within these systems are critical for enabling access to safe effective quality services (AHMAC 2008).

5.1.2. Continuity of care and carer

The benefits of continuity of care and carer when providing maternity services are well documented (Homer et al 2008). Continuity of *care* is a common philosophy and shared understanding of care pathways by all professionals involved in a women's care, with the aim of reducing fragmented care and conflicting advice. Continuity of *carer* is when a health professional who is known by the woman provides all her care, thus enabling the development of a relationship.

Factors that may improve continuity of care include:

› sharing of information (eg through documenting of all assessments) — this reduces the need for a woman to repeatedly "tell her story";
› collaborative development of management plans — this ensures that they are matched to locally available resources;
› developing linkages and networks; and
› adapting approaches to care that are locally successful.

5.1.3. Providing antenatal care for women with complex social needs

For women with complex social needs, maternity care may be provided in partnership with other agencies including children's services, domestic violence teams, illegal substance use services, drug and alcohol teams, youth and adolescent pregnancy support services, learning disability services and mental health services (UK Dept Health 2007; cited in Homer et al 2008).

5.1.4. Antenatal groups

A model of antenatal education and support where women set the agenda (as opposed to being told what their health professionals decide they should know) can provide women with the opportunity to learn from each other and build their own support network (Homer et al 2008). Women may learn and retain knowledge more readily through hearing other women's stories or experiences.

Antenatal groups may provide a sustainable alternative to the delivery of antenatal care for health services experiencing significant demand and limited resources. Antenatal groups can also be used to meet the needs of specific groups of women, such as adolescent women, Aboriginal and Torres Strait Islander women, women from specific cultural backgrounds, refugee women and women experiencing social isolation.

5.2.   Resources

AHMAC (2008) *Primary Maternity Services in Australia: a Framework for Implementation*. Prepared by NSW Health, on behalf of the Maternity Services Inter-jurisdictional Committee. Sydney: NSW Health.

NHMRC (2010) *National Guidance on Collaborative Maternity Care*. Canberra: National Health and Medical Research Council.

5.3.   References

AHMAC (2008) *Primary Maternity Services in Australia: a Framework for Implementation*. Prepared by NSW Health, on behalf of the Maternity Services Inter-jurisdictional Committee. Sydney: NSW Health.

Homer C, Brodie P, Leap N (eds) (2008) *Midwifery Continuity of Care. A Practical Guide*. Sydney: Elsevier.

NHMRC (2010) *National Guidance on Collaborative Maternity Care*. Canberra: National Health and Medical Research Council.

UK Dept Health (2007) *Maternity Matters: Choice, Access and Continuity of Care in a Safe Service.* London: UK Department of Health.

PART B —
CLINICAL CARE IN THE FIRST TRIMESTER

6.   Antenatal visits

"The key issue is not whether there is more or less antenatal care; rather it is that antenatal care should include only those activities supported by reasonable evidence of effectiveness and safety. The frequency of visits and the content of visits can then be planned accordingly." (Dowswell et al 2010)

While antenatal visits are well established as a means of improving perinatal outcomes, the number and timing of visits has been less studied (NICE 2008). Systematic reviews and observational studies tend to show an association between number of antenatal visits and/or gestational age at first antenatal visit and pregnancy outcomes (Dowswell et al 2010), although there are many differences in sociodemographic and risk profiles of women attending for antenatal care that may contribute to these findings (Hueston et al 2003).

6.1.   Number and timing of antenatal visits

Antenatal visits in Australia

In States and Territories where data on the number of antenatal visits during pregnancy are available (Queensland, SA, NT), 98.4% of women who gave birth at 32 or more weeks pregnancy had at least one antenatal visit and 92.7% had five or more visits (Laws et al 2010). Aboriginal or Torres Strait Islander mothers attended fewer antenatal visits compared with non-Indigenous mothers, with 76.8% of women who gave birth at ≥32 weeks pregnancy attending five or more visits (Laws et al 2010). However, earlier and more regular attendance for antenatal care has been demonstrated when models of care appropriate to Aboriginal and Torres Strait Islander women are provided (eg Panaretto et al 2007; Rumbold & Cunningham 2008).

Data on gestational age at first antenatal visit are available for NSW, SA and the NT. Of women who gave birth in these jurisdictions, 78.4% attended at least one antenatal visit in the first trimester (before 14 weeks pregnancy) (Laws et al 2010).

Summary of the evidence

The NICE guidelines cited two systematic reviews that included the same randomised controlled trials (RCTs) (n=57,418) (Villar & Khan-Neelofur 2003; Carroli et al 2001) and concluded that it is likely that antenatal care for women without risk or complications can be provided with fewer visits than traditionally offered. A Cochrane review (Dowswell et al 2010), which included studies in high-, middle- and low-income countries, found no strong evidence of differences in the number of preterm births or low birth weight babies between groups receiving a reduced number of antenatal visits (eight visits in high-income countries and fewer than five visits in low-income countries) compared with standard care. However, there was some

evidence that in low- and middle-income countries perinatal mortality may be increased with reduced visits. The number of inductions of labour and births by caesarean section were similar in women receiving reduced visits compared with standard care.

Evidence concerning women's preferences about the number of antenatal visits suggests that:

› for some women, the gap between visits was perceived as too long when the number of visits was lower than that traditionally offered (Dowswell et al 2010);

› women who were satisfied with a reduced number of antenatal visits were more likely to have a caregiver who both listened and encouraged them to ask questions than women who were not satisfied with reduced schedules (Clemet et al 1996); and

› women who were over 35 years of age, had previous pregnancies, were less educated or had more than two children preferred fewer appointments, whereas women who were less than 25 years of age, single or had a prior adverse pregnancy history indicated a preference for more appointments than the standard schedule (Hildingsson et al 2002).

Recommendation	Grade B
1. Determine the schedule of antenatal visits based on the individual woman's needs. For a woman's first pregnancy without complications, a schedule of ten visits should be adequate. For subsequent uncomplicated pregnancies, a schedule of seven visits should be adequate.	

Timing of initiation of antenatal care

The NICE guidelines suggest that the first antenatal visit occur before 10 weeks pregnancy due to the high information needs in early pregnancy. This also allows arrangements to be made for tests that are most effective early in the pregnancy (eg gestational age assessment, screening for Down syndrome).

Consensus-based recommendation
i. At the first contact with a woman during pregnancy, make arrangements for the first antenatal visit, which requires a long appointment and should occur within the first 10 weeks.

Economic considerations

The NICE guidelines found inconclusive evidence regarding the cost-effectiveness of a reduced number of antenatal visits. Most of the existing research in developed countries is based on women assessed as at low risk of poor perinatal outcomes at first contact. The available evidence found that:

› providing routine antenatal care through five compared with eight visits did not affect maternal and perinatal outcomes and therefore was more cost effective (Villar et al 2001);

› reduced costs associated with six or seven versus thirteen visits were offset by the greater number of babies requiring special or intensive care, although maternal satisfaction and psychological outcomes were poorer in women attending fewer visits (Henderson et al 2000);

› although the average number of antenatal visits was lower in France than in England and Wales in 1970–80, there was no difference in pregnancy outcomes, suggesting that fewer visits would be more cost effective if only these outcomes are considered (Kaminski et al 1988); and

› there was no significant difference in the monetary value women placed on different providers of antenatal care (Ryan et al 1997).

6.2. Discussing the schedule of antenatal visits with women

The first or another early contact with a woman provides an opportunity to assess the appropriate number of visits for her pregnancy. Considerations include:

› any existing conditions that may affect the pregnancy or the woman's general health and social and emotional wellbeing;

› whether this is the first or a subsequent pregnancy; and

› the woman's preferences for how antenatal care is provided.

This initial contact should be used to provide women with much of the information they need for early pregnancy. This includes explanation and appropriate written or other form of information about the different types of maternity care available and what each option entails. Information on each option of care should include:

› who the primary carer or carers will be and how they will care for the woman (one-to-one, as part of a team etc);

› the likely number, timing and content of antenatal visits;

› place of labour and birth; and

› postnatal care and support.

Consensus-based recommendation
ii. Early in pregnancy, provide women with information in an appropriate format about the likely number, timing and content of antenatal visits associated with different options of care and the opportunity to discuss this schedule.

6.3. Planning antenatal visits

The needs of each woman should be assessed at the first appointment, reassessed at each visit, and be guided by the woman's needs if and as they change. The environment in which visits take place should facilitate discussion of sensitive issues.

Planning for antenatal care allows assessments and tests to be conducted at the appropriate stage of pregnancy. At an early contact, explanation should be given of:

› assessments and tests that are offered to all women;

› any additional assessments that are recommended, the reasons why these may be appropriate for that woman, whether referral is required and when the assessment should occur; and

› any continuing assessments that may be required or recommended during the pregnancy.

At this time, the woman's overall health and preparation for birth and parenting and care of the newborn should also be assessed. Focused antenatal visits should include time for health professionals and women to talk about important issues related to health during pregnancy, including:

› the importance of good nutrition to the health of the mother and baby;

› the risks of using tobacco, alcohol, prescription and over-the-counter medicines and illicit drugs in pregnancy;

› the risks and benefits of continuing existing medicines (eg antidepressants, hypertensives);

› the risks associated with sexually transmitted and other infections in pregnancy;

› other social and lifestyle factors that may affect the pregnancy;

› the impact of work, physical activity and travel on pregnancy outcomes;

› the danger signs of complications during pregnancy; and

› preparation for the birth and early parenthood, including breastfeeding.

Practice point
a. Antenatal care should be woman-focused, with each antenatal visit structured around specific content based on the woman's needs. Longer visits are needed early in pregnancy to allow comprehensive assessment, discussion and support. Assessments and tests should be incorporated into visits in a way that minimises inconvenience to the woman.

6.3.1. Content of antenatal visits

First antenatal visit/booking appointment

The first contact with a woman in the antenatal period may be when she attends primary care to confirm the pregnancy. Women will either start antenatal care at that point or be referred to a maternity care provider or service, for example, the local hospital, midwife, obstetrician, GP or Aboriginal health service. Women intending to give birth in hospital will attend a booking visit — this may be their first visit at the hospital if they are receiving care through this service or later in pregnancy if they are receiving care through a private provider.

The first antenatal visit should be longer than most later visits because of the large volume of information needed in early pregnancy. On occasion, two or more visits may be required to ensure there is sufficient time to cover "first visit" activities, particularly for women experiencing pregnancy for the first time. However, these extra visits should not be counted when planning the schedule for subsequent antenatal visits.

The need to discuss the many assessments and screening tests that are offered to women in the first trimester contributes to the length of the first visit. It is important to explain that no assessment or screening test is compulsory and that women have the right to make informed decisions. Considerations in discussing specific tests and available resources to assist with explanation are included in Chapter 8. Additional time may be required for the first antenatal visit for women who have:

› limited experience of the health system or a limited understanding of health care procedures — clear explanation of the reasons for antenatal visits, medical procedures and the use of technology is needed;

› difficulties communicating in English — accredited interpreters should be involved and time for interpretation taken into consideration;

› past experiences that affect their trust in authorities or health professionals — reassurance and explanation of the care being offered and collaboration with other services may be required to build necessary confidence and trust; or

› other conditions that usually require additional care (see Table 6.2).

Table 6.1: **Content of first antenatal visit**

Woman-centred care
› Seek women's thoughts, views and opinions
› Ask open-ended questions and provide an opportunity to discuss issues and ask questions
› Offer verbal information supported by written or other appropriate form of information (on topics such as diet and lifestyle, available pregnancy care services, maternity benefits, screening tests, breastfeeding)
› Discuss involvement of the woman's partner/family in antenatal care

General assessment

› Undertake a comprehensive history including:
  – current pregnancy (planned, unplanned, woman wishes to proceed with/terminate pregnancy)
  – medical (past history, medicines, family history, cervical smears, immunisation)
  – obstetric (previous experience of pregnancy and birth)
  – smoking, nutrition, alcohol, physical activity and drug use
  – expectations, partner/family involvement, cultural and spiritual issues, concerns, knowledge, pregnancy, birth, breastfeeding and infant feeding options

› Clinical assessment (see Chapter 8):
  – discuss conception and date of last menstrual period and offer ultrasound scan for gestational age assessment to be carried out between 8 and 14 weeks of pregnancy
  – measure height and weight and calculate body mass index
  – measure blood pressure
  – test for proteinuria
  – ask questions about previous mental health disorders and psychosocial factors that affect mental health
  – administer the Edinburgh Postnatal Depression Scale at this visit or as early as practical in pregnancy

› Screening:
  – check blood group and antibodies, full blood count and haemoglobin
  – offer testing for HIV, hepatitis B, rubella non-immunity, syphilis and asymptomatic bacteriuria
  – offer testing for hepatitis C to women with identified risk factors
  – offer women younger than 25 years chlamydia testing — in areas with a high prevalence of sexually transmitted infections, consider offering chlamydia and gonorrhoea testing to all pregnant women
  – consider offering testing for vitamin D deficiency
  – offer screening for chromosomal abnormalities to be carried out between 11 and 14 weeks of pregnancy

Assessment
› Estimated date of birth/gestational age
› Current problems
› Risk factors
› Need for referral

› Need for further investigation/ treatment/ preventive care

Actions
› Referral
› Further investigation
› General advice (also for the partner/family) — pregnancy symptoms, supplements, smoking, nutrition, alcohol, physical activity, drug use, dental visits
› Advice on options for antenatal care and place of birth or on access to counselling and termination where this is permitted under jurisdictional legislation
› Specific preventive interventions — folate, iodine, immunisations, cervical smear, others as needed (eg iron supplement)

* Note that testing for diabetes is not considered in these Guidelines as the evidence is being reviewed and will be discussed in Module II.

The Guidelines include recommendations on baseline clinical care for all pregnant women but do not include information on the additional care that some women will require. Pregnant women with the conditions listed in Table 6.2 usually require care additional to that detailed in these Guidelines. Some resources that may assist in providing appropriate care are listed in Section 6.5.

CLINICAL CARE IN THE FIRST TRIMESTER – PART B

Table 6.2:   Women who may require additional care

Existing conditions	Experiences in previous pregnancies
› Cardiovascular disease (eg hypertension, rheumatic heart disease) › Other conditions (eg kidney disease, diabetes; thyroid, haematological or autoimmune disorders; epilepsy, malignancy; severe asthma; HIV, hepatitis B or hepatitis C infection) › Psychiatric disorders › Obesity or underweight › Female genital mutilation	› Recurrent miscarriage › Preterm birth › Pre-eclampsia or eclampsia › Rhesus isoimmunisation or other significant blood group antibodies › Uterine surgery (eg caesarean section, myomectomy or cone biopsy) › Antenatal or postpartum haemorrhage › Puerperal psychosis › Four or more previous births › A stillbirth or neonatal death › Small or large-for-gestational-age baby › Baby with a congenital abnormality (structural or chromosomal)
Lifestyle considerations	
› History of alcohol misuse › Use of recreational drugs such as heroin, cocaine (including crack cocaine), ecstasy and cannabis	
Mental health and psychosocial factors	
› Psychosocial issues/ mental health problems › Developmental delay or other disabilities › Vulnerability or lack of social support	

Source: Adapted from NICE (2008).

Subsequent antenatal visits

Determining the pattern of visits and the activities that are undertaken at each visit requires a degree of flexibility. Care should be collaboratively planned with the woman based on the needs identified through assessments. Planning should take also into account the involvement of the woman's partner/family.

At all visits, opportunities should be provided for the woman to share her expectations and experiences as well as discuss any issues and/or concerns that may have arisen since her last visit. Women should also be offered information on aspects of health in pregnancy and early parenthood (eg nutrition, alcohol, smoking, breastfeeding), supported by antenatal education opportunities. Later in pregnancy, it may be beneficial to promote positive body image and confidence in the woman's ability to labour and give birth. The woman's needs should dictate the type of information and support provided (eg while many women will benefit from written information, other forms of information such as audio or video are sometimes more suitable). The type of issues and questions discussed should also be directed by the woman.

Further information on the schedule and content of the rest of the antenatal visits will be included in Module II of these Guidelines.

6.4. Practice summary — antenatal visits

The following table is intended to assist with planning the content of antenatal appointments to include aspects of care recommended in these Guidelines. It does not include all assessments and tests required at the first visit (see Table 6.1).

What	Who		
	All women	High-risk groups*	Symptoms present
Clinical assessments (Chapter 7)			
Gestational age	✓		
Weight	✓		
Body mass index	✓		
Blood pressure	✓		
Proteinuria	✓		
Psychosocial factors	✓		
Depression/anxiety	✓		
Domestic violence	✓		
Nausea/vomiting			✓
Constipation			✓
Maternal health screening (Chapter 8) **			
Full blood examination	✓		
Human immunodeficiency virus	✓		
Hepatitis B	✓		
Hepatitis C		✓	
Rubella	✓		
Chlamydia		✓	
Syphilis	✓		
Bacteriuria	✓		
Bacterial vaginosis		✓	

What	Who		
	All women	High-risk groups*	Symptoms present
Vitamin D deficiency		✓	
Fetal screening (Chapter 9)			
Chromosomal abnormalities	✓		
Lifestyle considerations (Chapter 10)			
Smoking	✓		
Alcohol	✓		
Medicines	✓		
Nutritional supplements	✓		
Oral health	✓		

* Women who may be at higher risk are identified in each chapter.

** Tests used for screening are listed in Table 8.1.

6.5. Resources

DoHA (1998) *An Active Way to Better Health. National Physical Activity Guidelines for Adults.* Canberra: Australian Government Department of Health and Ageing.
http://www.health.gov.au/internet/main/publishing.nsf/content/BC3101B1FF200CA4CA256F9700154958/$File/adults_phys.pdf

DoHA (1998) *Australian Guide to Healthy Eating. Background Information for Consumers.* Canberra: Australian Government Department of Health and Ageing. [under review]
http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-publicat-document-fdcons-cnt.htm

FSANZ (undated) *Thinking About Having a Baby? Important Things You Need to Know About What You Eat and Drink.* Food Standards Australia and New Zealand.
http://www.foodstandards.gov.au/_srcfiles/FSANZ%20Pregnancy_WEB.pdf

Ministerial Council on Drug Strategy (2006) *National Clinical Guidelines for the Management of Drug Use During Pregnancy, Birth and the Early Development Years of the Newborn.* Sydney: NSW Health.
http://www.health.nsw.gov.au/pubs/2006/pdf/ncg_druguse.pdf

National Health and Medical Research Council (2013) *Australian Dietry Guidelines.* Canberra*: National Health and Medical Research Council.*

NHMRC (2005) *Nutrient Reference Values for Australia and New Zealand.* Canberra: National Health and Medical Research Council. http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/n35.pdf

NHMRC (2005) *Screening to Prevent Cervical Cancer: Guidelines for the Management of Asymptomatic Women with Screen Detected Abnormalities.* Canberra: National Health and Medical Research Council.
http://www.nhmrc.gov.au/guidelines/publications/wh39

ATAGI (2009) *Australian Immunisation Handbook*. 9th edition. Australian Technical Advisory Group on Immunisation. Canberra: Department of Health and Ageing.
http://www.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook-hepatitisb#5

RANZCOG (2005) *Termination of Pregnancy. A Resource for Health Professionals.* Melbourne: Royal Australian and New Zealand College of Obstetricians and Gynaecologists.
http://www.ranzcog.edu.au/womenshealth/pdfs/Termination-of-pregnancy.pdf

6.6.   References

Carroli G, Villar J, Piaggio G et al (2001) WHO systematic review of randomised controlled trials of routine antenatal care. *Lancet* 357: 1565–70.

Clement S, Sikorski J, Wilson J et al (1996) Women's satisfaction with traditional and reduced antenatal visit schedules. *Midwifery* 12: 120–28.

Dowswell T, Carroli G, Duley L et al (2010) Alternative versus standard packages of antenatal care for low-risk pregnancy. *Cochrane Database of Systematic Reviews* 2010, Issue 10. Art. No.: CD000934. DOI: 10.1002/14651858. CD000934.pub2.

Henderson J, Roberts T, Sikorski J et al (2000) An economic evaluation comparing two schedules of antenatal visits. *J Health Services Res Pol* 5: 69–75.

Hildingsson I, Waldenstrom U, Radestad I (2002) Women's expectations on antenatal care as assessed in early pregnancy: Number of visits, continuity of caregiver and general content. *Acta Obstet Gynecol Scand* 81: 118–25.

Hueston WJ, Gilbert GE, Davis L et al (2003) Delayed prenatal care and the risk of low birth weight delivery. *J Comm Health* 28(3): 199–208.

Kaminski M, Blondel B, Breart G (1988) Management of pregnancy and childbirth in England and Wales and in France. *Paediatr Perinatal Epidemiol* 2: 13–24.

Laws PJ, Li Z, Sullivan EA (2010) *Australia's Mothers and Babies 2008*. Perinatal statistics series no 24. Cat no PER 50. Canberra: Australian Institute of Health and Welfare.

NICE (2008) *Antenatal Care. Routine Care for the Healthy Pregnant Woman*. National Collaborating Centre for Women's and Children's Health. Commissioned by the National Institute for Health and Clinical Excellence. London: RCOG Press.

Panaretto KS, Mitchell MR, Anderson L et al (2007) Sustainable antenatal care services in an urban Indigenous community: the Townsville experience. *Med J Aust* 187(1): 18–22.

Rumbold AR & Cunningham (2008) A review of the impact of antenatal care for Australian indigenous women and attempts to strengthen these services. *Mat Child Health J* 12(1): 83–100.

Ryan M, Ratcliffe J, Tucker J (1997) Using willingness to pay to value alternative models of antenatal care. *Soc Sci Med* 44(3): 371–80

Villar J & Khan-Neelofur D (2003) Patterns of routine antenatal care for low risk pregnancy. *Cochrane Database of Systematic Reviews* 2003; (1).

Villar J, Ba'aqeel H, Piaggio G et al (2001) WHO antenatal care randomised trial for the evaluation of a new model of routine antenatal care. *Lancet* 357(9268): 1551–64.

7.   Clinical assessments

A range of clinical assessments is carried out to promote and enhance the physical and emotional wellbeing of a woman and her baby during pregnancy. This chapter discusses:

› assessments that are offered to all women early in the antenatal period or whenever they first seek antenatal care — gestational age assessment, calculating body mass index (BMI), measuring blood pressure and detecting proteinuria; and

› interventions to reduce symptoms of conditions common in the first trimester — nausea and vomiting and constipation.

Recommendations are based on evidence about the accuracy of assessments in predicting complications in pregnancy and the effectiveness of interventions in reducing symptoms. The advice in the table below is derived from the systematic reviews conducted to inform these Guidelines or sourced from the NICE guidelines and relevant Australian guidelines.

Table 7.1:   Summary of advice for women about common conditions and assessments in the first trimester

Clinical assessments		Evidence
Anaemia*	Assessing haemoglobin level enables women to receive treatment if anaemia is detected.	Grade B*
Blood group	Identifying blood group and rhesus D status is important to prevent haemolytic disease of the newborn.**	Grade B*
Gestational age	Ultrasound scanning is most accurate in determining gestational age between 8 and 14 weeks of pregnancy. After 24 weeks of pregnancy, the date of the last menstrual period is used.	Grade B
Weight and height	Calculation of body mass index allows appropriate advice about nutrition and physical activity to be given early in pregnancy.	Grade B
Blood pressure	Measuring blood pressure allows identification of women who have chronic hypertension and may require additional monitoring during pregnancy.	Grade B
Proteinuria	Testing women for proteinuria identifies existing kidney disease or urinary tract infection.	Grade B
Breast examination*	Routine breast examination during antenatal care is **not** recommended.	Grade A*
Pelvic examination*	While pelvic pain can be debilitating and distressing, routine antenatal pelvic examination is **not** recommended.	Grade B*
Psychosocial factors	Assessment of psychosocial factors aims to identify women who are more vulnerable to mental health disorders during pregnancy.	CBR
Depression	Detecting symptoms of depression enables suitable follow-up.	Grade B
Anxiety	Anxiety, either alone or with depression, is common in pregnancy.	CBR

Clinical assessments		Evidence
Domestic violence	All women are asked about domestic violence during pregnancy to enable access to additional support and care.	Grade B

Common conditions		Evidence
Nausea and vomiting	Although distressing and debilitating for some women, nausea and vomiting usually resolves spontaneously by 16 to 20 weeks pregnancy and is not generally associated with pregnancy complications.	PP
	Discontinuing iron-containing multivitamins may be advisable while symptoms are present.	PP
Constipation	Increasing dietary fibre intake and taking bran or wheat fibre supplements may relieve constipation.	Grade C
	Stimulating laxatives are more effective than preparations that add bulk but are more likely to cause diarrhoea or abdominal pain	Grade C
Heartburn*	Heartburn may be improved through maintaining upright positions, especially after meals, sleeping in a propped up position, having small frequent meals, and reducing high-fat foods and irritants such as caffeine. Antacids may also be considered for relieving heartburn.	PP*
Haemorrhoids*	Haemorrhoids may be improved by increasing fibre in the diet and drinking plenty of water. If clinical symptoms remain troublesome, standard haemorrhoid creams can be considered.	PP*
Varicose veins*	Varicose veins will not cause harm to the woman or baby. Compression stockings can improve symptoms but will not prevent varicose veins.	Grade A*
Vaginal discharge*	An increase in vaginal discharge is common during pregnancy. If it is associated with itch, soreness, offensive smell or pain on passing urine, there maybe an infective cause and investigation should be considered.	PP*
Backache*	Exercising in water, massage therapy and group or individual back care classes might help to ease backache during pregnancy.	Grade A*
Pelvic pain*	There is little evidence on treatments for symphysis pubis dysfunction. Many medicines for relief of bone and joint pain may not be appropriate for use in pregnancy.	Future research required*
Carpal tunnel syndrome*	There is little evidence on treatments for carpal tunnel syndrome. Many medicines for relief of bone and joint pain may not be appropriate for use in pregnancy.	Future research required*

* Advice on these assessments or conditions is sourced from NICE (2008) *Antenatal Care. Routine Care for the Healthy Pregnant Woman*. National Collaborating Centre for Women's and Children's Health. Commissioned by the National Institute for Health and Clinical Excellence. London: RCOG Press.

** Antenatal prophylaxis for women who are RhD negative is discussed in NBA (2003) *Guidelines on the Prophylactic use of Rh D Immunoglobulin (anti-D) in Obstetrics*. Canberra: National Blood Authority.

7.1. Gestational age

Ultrasound examination in the first trimester allows accurate assessment of gestational age, and identifies and allows for appropriate care of women with multiple pregnancies.

7.1.1. Assessing gestational age

Methods used to assess gestational age include known date of ovulation, date of the last menstrual period (LMP) and diagnostic ultrasound. Diagnostic ultrasound is a sophisticated electronic technology, which uses pulses of high frequency sound to produce an image. This imaging enables measurement of the fetus and estimation of the gestational age.

Summary of the evidence

Accuracy and effectiveness

The NICE guidelines reviewed the diagnostic value and effectiveness of screening methods in determining gestational age. Studies identified included a Cochrane review, four RCTs and a number of observational studies. Findings were as follows.

› *Accuracy of screening tests* — Evidence suggests that ultrasound is a more accurate predictor of gestational age than LMP (Okonofua 1989; Rowlands & Roysten 1993; Alexander et al 1995; Crowther et al 1999; Taipale 2001; Savitz et al 2002; Olesen & Thomsen 2006). If only LMP is available the estimated date of birth should be calculated as the first day of the LMP plus 282 days (Nguyen 1999). The estimated date of birth based on LMP is subject to significant error and will be influenced by the woman's age, number of previous pregnancies, BMI and whether she smokes (Savitz et al 2002; Morin 2005).

› *Measurements used* — Crown–rump length (CRL) measurement should be used in the first trimester for estimating gestational age (Selbing 1983; Taipale 2001). CRL > 90 mm is unreliable in estimating gestational age in second trimester and head circumference (HC) measurement, which appears more reliable than the biparietal diameter (BPD) (Johnsen et al 2006), should be used instead when establishing an estimated date of birth in the second trimester.

These findings are largely supported by subsequent lower level studies as follows.

› A small comparative study (n=30)(Martins et al 2008) suggested that fetal head and trunk volume (HT) could be more accurate than CRL for estimating gestational age, possibly due to flexion of the fetal head affecting CRL measurement.

› An Australian prospective cohort study (n=396)(McLennan & Schluter 2008) found that CRL measurement predictions were superior to BPD measurement predictions.

› A retrospective comparative study (n=165,908)(Dietz et al 2007) found that ultrasound-based estimates of gestational age were more accurate than LMP based-estimates of gestational age.

› A prospective cohort study (Hoffman et al 2008) found that LMP classified more births as post term than ultrasound (4.0% vs. 0.7%), with a greater difference among young women, non-Hispanic Black and Hispanic women, women of non-optimal body weight and mothers of low birth weight babies.

› A retrospective study (n=40,730)(Koster et al 2008) showed that the estimation of gestational age from CRL was not consistent, with reported age for a single CRL differing by up to 10 days. This highlights the need to ensure that reference curves and standards are consistently applied.

› A prospective cross-sectional study (n=200) (Salpou et al 2008) concluded that significant ethnic differences between mothers were not reflected in fetal biometry at second trimester. The results support the recommendation that ultrasound in practical health care can be used to assess gestational age in various populations with little risk of error due to ethnic variation.

A recent Cochrane review (Whitworth et al 2010), which compared selective versus routine use of ultrasound in pregnancy, concluded that ultrasound improves the early detection of multiple pregnancies.

Timing of assessment

The systematic review conducted to inform the development of these Guidelines identified one prospective cohort study (n=8,313) (Verberg et al 2008) that investigated the best time to conduct gestational age assessment. The study found that the earlier the ultrasound assessment in pregnancy (preferably between 10 and 12 weeks), the more accurate the prediction of date of birth. The results indicate that after 24 weeks of pregnancy, a reliable LMP provides better estimates.

Recommendation	Grade B
2. Provide information and offer pregnant women who are unsure of their conception date an ultrasound scan between 8 weeks 0 days and 13 weeks 6 days to determine gestational age, detect multiple pregnancies and accurately time fetal anomaly screening. Use crown–rump length (CRL) measurement to determine gestational age. If the CRL is above 84 mm, estimate the gestational age using head circumference.	

Practice point
b. The timeframe for ultrasound assessment of gestational age overlaps with that for assessment of nuchal translucency thickness as part of screening for fetal chromosomal abnormalities (11 weeks to 13 weeks 6 days), which may enable some women to have both tests in a single scan. This should only occur if women have been provided with an explanation of both tests and have given their consent to them both.

Calculating the estimated date of birth

The ability to estimate the range of dates during which birth may occur is influenced by the regularity and length of a woman's menstrual cycle, whether the date of ovulation (rather than that of intercourse) is known and the timing of any ultrasound assessment. Selection of the better estimate of the date of birth is based on the following criteria (Altman & Chitty 1997; Campbell Westerway 2000; Callen 2008):

› if the LMP was certain and menstruation regular, compare the LMP estimate to the ultrasound estimate:

  – *ultrasound performed between 6 and 13 weeks pregnancy* — if the two dates differ by 5 days or less, use the LMP estimate; if the dates differ by more than 5 days, use the ultrasound estimate;

  – *ultrasound performed between 13 and 24 weeks pregnancy* — if the two dates differ by 10 days or less, use the LMP estimate; if the dates differ by more than 10 days, use the ultrasound estimate;

› if the ultrasound was performed between 6 and 24 weeks pregnancy and the LMP was not certain or menstruation irregular, use the ultrasound estimate;

› if the LMP was certain and menstruation regular and no ultrasound was performed between 6 and 24 weeks pregnancy (or none with a heartbeat), use the LMP estimate.

Practice point
c. The agreed due date should not be changed without advice from a health professional with considerable experience in antenatal care.

7.1.2. Other considerations in gestational age assessment

Safety

The NICE guidelines do not discuss the safety of ultrasound and the literature review conducted to inform these Guidelines identified only a single prospective observational study (n=52)(Sheiner et al 2007). The study found a negligible rise in temperature at the ultrasound beam's focal point. No studies were identified that assessed psychological harms to the mother, risk of overdiagnosis of placenta praevia or its contribution to anxiety.

Cost-effectiveness

An analysis of the cost implications of recommending routine ultrasound for gestational age assessment in the first trimester was undertaken to inform the development of these Guidelines (see Appendix E). The analysis aimed to balance the costs of additional scans undertaken against the savings resulting from:

› optimising the timing and performance of maternal serum screening and thereby reducing the number of diagnostic tests (chorionic villus sampling and amniocentesis) undertaken; and

› reducing rates of inductions (which in turn may reduce the rate of caesarean section).

The analysis was limited by a lack of data on privately funded ultrasounds and those carried out in hospitals and therefore could only identify implications for Medicare expenditure. Data limitations also meant that the analysis had to rely on a range of assumptions and on the literature, which is inconsistent in some areas. While some studies have found no significant difference in the rate of induction between women who have a first trimester scan and women who have both a first and second trimester scan (Crowther et al 1999; Ewigman et al 1990; Harrington et al 2005; Whitworth et al 2010), others have found decreased rates of induction associated with first trimester screening (Bennett et al 2004).

The analysis was therefore unable to conclusively determine whether the benefits of the recommendation would be likely to outweigh the costs. While a maximum number of additional scans (75,500) and associated costs ($A4.53 million) was estimated, the benefits vary considerably depending on whether a decrease in inductions is assumed — from $A230,000 if only improved power of maternal serum screening is included, to around $A17 million if a decrease in inductions is assumed, with an additional saving of around $A5 million if the link between induction and caesarean section is included.

Who should conduct the assessment?

A range of health professionals may be trained to carry out ultrasounds, including midwives, Aboriginal health workers and GPs. In addition to having appropriate training and accreditation, it is important that caseload is sufficient to maintain skills.

Minimum standards for health professionals conducting ultrasound assessments are disseminated by the Australian Society for Ultrasound in Medicine, the Australasian Sonographer Accreditation Registry, the Royal Australian and New Zealand College of Radiologists, and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists.

Practice point
d. Ultrasound assessment of gestational age should only be performed by a person who has had specific training.
e. Repeated ultrasound assessments should only be used when clinically indicated.

Additional considerations for Aboriginal and Torres Strait Islander women

Accurately assessing gestational age is particularly important among Aboriginal and Torres Strait Islander women as:

› many women live in rural and remote areas and move to a larger centre to give birth, requiring logistical arrangements to be made around the estimated date of birth (see below); and

› the higher rates of preterm birth and intrauterine growth restriction.

Issues of access in rural and remote areas

In remote regions, it may be difficult for women to access ultrasound examination early in pregnancy due to limited availability of adequate equipment, health professionals not offering ultrasound, a lack of accredited and trained professionals in some areas and the costs involved in travelling for the assessment (this is not consistently funded under State/Territory schemes to support travel and accommodation for women from rural and remote areas to access care and services). Health professionals should ensure that history taking is comprehensive and detailed, paying particular attention to ongoing assessment of fetal growth and wellbeing.

7.1.3. Practice summary — estimating or confirming gestational age

When — At first antenatal visit
Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker

› **Discuss the purpose of the ultrasound** — Explain that it is intended to assess the gestational age of the baby (when the conception date is not known) to enable other screenings that a woman elects to have to be conducted at the appropriate time.

› **If a woman chooses to have an ultrasound, arrange an appointment or referral** — Whether providing the ultrasound or arranging referral, ensure that the ultrasound takes place between 8 weeks 0 days and 13 weeks 6 days of pregnancy.

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7.2. Weight and body mass index

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

7.2.1. 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 World Health Organization classification of body mass index classification is given in Table 7.2.

Table 7.2. **International classification of adult underweight, overweight and obesity according to BMI**

Underweight–healthy range	BMI	Overweight–obese	BMI
Underweight	<18.50	Overweight	≥25.00
› Severe thinness	<16.00	› Pre-obese	25.00–29.99
› Moderate thinness	16.00–16.99	› Obese	≥30.00
› Mild thinness	17.00–18.49	– Class I	30.00–34.99
		– Class II	35.00–39.99
Healthy weight	18.50–24.99	– Class III	≥40.00

Source: Adapted from WHO 1995, WHO 2000 and WHO Expert Consultation 2004.

Prevalence of low or high BMI in Australia

› In 2007–08, 3.4% of women aged 25–34 were underweight, 26.5% were overweight and 18% were obese (AIHW 2010). In the 35–44 age group, 1.9% of women were underweight, 32.5% overweight and 22.8% obese (AIHW 2010). In 2004–05 age-adjusted rates of overweight/obesity were similar for Aboriginal and Torres Strait Islander and non-Indigenous adults. However, Aboriginal and Torres Strait Islander women were around one-and-a-half times more likely than non-Indigenous women to be overweight/obese (AIHW 2008).

› A retrospective analysis of women receiving antenatal care at an urban tertiary maternity hospital in Brisbane (n=14,230) found that 21% had a BMI ≤20, 45% had a BMI within the healthy range and 34% were classified as overweight, obese or morbidly obese (Callaway et al 2006).

> An RCT involving women attending antenatal care in Melbourne (n=236) found that 4.2% of women were underweight, 60.2% had a BMI within the healthy range, 16.1% were classified as overweight and 19.5% were classified as obese (Jeffries et al 2009).

> A Swedish cohort study (n=298,648)(Cedergren 2007) found a total prevalence of overweight and obesity of 33% among pregnant women, with 10.7% of women classified as obese.

Risks associated with a low or high pre-pregnancy BMI

> *Underweight* — a low pre-pregnancy BMI is associated with increased risk of preterm birth (Siega-Riz et al 1996; Panaretto et al 2006; Khashan & Kenny 2009) and small-for-gestational-age babies (Dawes & Grudzinskas 1991; Panaretto et al 2006). 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).

> *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 (Rassmussen 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 an inability to initiate breastfeeding (Viswanathan et al 2008), postpartum weight retention (Thornton et al 2009) and increased rate of caesarean birth (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 (Siega-Riz et al 1996; 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 birth (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, during, and after 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).

7.2.2.   Assessing BMI and weight gain

Summary of the evidence

Routinely measuring women's height and weight and calculating BMI at an early antenatal contact is recommended in the United Kingdom (NICE 2008; CMACE & RCOG 2010), the United States (IOM 2009) and Canada (AOM 2010; SOGC 2010). Additional advice on monitoring weight gain during pregnancy, in particular for women who are underweight, overweight or obese is also given in the Canadian and United States guidelines.

Measuring height and weight and calculating BMI

Recent evidence on the risks associated with low or high BMI during pregnancy (see Section 7.2.1) continues to support the routine measurement of women's weight and height and calculation of BMI at the first antenatal contact. This 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).

Recommendation	Grade B
3. Measure women's weight and height at the first antenatal visit and calculate their BMI.	

Monitoring 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 amount of weight gained during pregnancy varies and studies suggest that many women do not gain the amount recommended. In a large cohort study in the United States (n=94,696)(DeVader et al 2007), 17.8% of women gained less than the recommended amount of weight over the pregnancy, 39.4% gained the recommended amount and 42.8% gained more than recommended. Similar results were found in a Canadian cohort study (5,377)(Crane et al 2009), with 17.1% of women gaining less than the recommended amount, 30.6% gaining the recommended amount and 52.3% gaining more weight than recommended.

The US Institute of Medicine (IOM) provides guidance on weight gain in pregnancy based on pre-pregnancy BMI (see Table 7.3). 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).

Table 7.3: IOM recommendations for weight gain in pregnancy by pre-pregnancy BMI

<18.5	18.5 to 24.9	25.0 to 29.9	30.0 to 34.9	35.0 to 39.9	≥40
12.7–18.1kg	11.3–15.9kg	6.8–11.3kg	5–9kg	5–9kg	5–9kg

Practice point
f. Repeated weighing during pregnancy should be confined to circumstances that are likely to influence clinical management.

Supporting weight management

Two systematic reviews examining interventions to reduce excessive weight gain in pregnancy (Dodd et al 2010; Ronnberg et al 2010) found insufficient evidence to support specific interventions. A meta-analysis (Streuling et al 2010) however, found that interventions based on physical activity and dietary counselling, usually combined with supplementary weight monitoring, appear to be successful in reducing inappropriate weight gain in pregnancy. An RCT (n=236)(Jeffries et al 2009) found that self-monitoring of weight gain was effective in reducing excessive weight gain among women who were overweight but not obese before pregnancy, but not effective for women who were normal weight or obese before pregnancy. Protein/energy restriction of pregnant women who are overweight, or exhibit high weight gain, is unlikely to be beneficial and may harm the baby (Kramer & Kakuma 2003).

Dietary advice has been shown to be effective in increasing energy and protein intake in pregnant women but has no major benefit on the health of the mother or baby (Kramer & Kakuma 2003). Balanced energy/ protein supplementation improves fetal growth and may reduce the risk of fetal and neonatal death, however high-protein or balanced-protein supplementation alone is not beneficial and may be harmful to the fetus (Kramer & Kakuma 2003).

Recommendation	Grade B
4. Give women advice about appropriate weight gain during pregnancy in relation to their BMI.	

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, including monitoring fetal growth (HAPO 2010) 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 (Rassmussen 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 (Dawes & Grudzinskas 1991; 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
g.   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.

Considerations beyond the first trimester

›   Potential for sub-optimal visualisation on second trimester ultrasounds (20 to 22 weeks pregnancy may provide better results in women with BMI ≥30).

›   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.

7.2.3.   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.
›   **Estimate pre-pregnancy weight** — As many women do not attend for antenatal care until later in the first trimester, estimation of pre-pregnancy BMI may be based on self-reported weight.

7.2.4.   Resources

Health professionals

AOM (2010) *Ontario Midwives Clinical Practice Guideline No. 12 The Management of Women with a High or Low Body Mass Index.* Toronto: Association of Ontario Midwives.

CMACE & RCOG (2010) *CMACE & RCOG Joint Guideline. Management of Women with Obesity in Pregnancy.* London: Centre for Maternal and Child Enquiries & Royal College of Obstetricians and Gynaecologists.

IOM (2009) *Nutrition During Pregnancy*. National Academy of Sciences, Institute of Medicine, Food and Nutrition Board, Committee on Nutritional Status During Pregnancy and Lactation, Subcommittee on Dietary Intake and Nutrient Supplements During Pregnancy, Subcommittee on Nutritional Status and Weight Gain During Pregnancy. Washington DC: National Academy Press; 1990.

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SOGC (2010) Obesity in pregnancy. *J Obstet Gynaecol Can* 32(2): 165–73.

DoHA lifescripts:

Nutrition and weight gain
http://www.health.gov.au/internet/main/publishing.nsf/Content/DDEA0A1E90620C5BCA2577590006AC6E/$File/nutrition.pdf

Physical activity
http://www.health.gov.au/internet/main/publishing.nsf/Content/DDEA0A1E90620C5BCA2577590006AC6E/$File/physical.pdf

Women and families

DoHA (1998) *An Active Way to Better Health. National Physical Activity Guidelines for Adults.* Canberra: Australian Government Department of Health and Ageing.
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7.3. Blood pressure

Measuring blood pressure in the first trimester aims to identify women with chronic hypertension (high blood pressure), which may be related to existing kidney disease. Women with hypertension are at increased risk of pre-eclampsia and require additional monitoring for other relevant risk factors.

7.3.1. Background

Healthy pregnancy is characterised by a fall in blood pressure, detectable in the first trimester, usually reaching its lowest point in the second trimester and rising to pre-conception levels towards the end of the third trimester (Lowe et al 2008). Hypertensive disorders during pregnancy include (Lowe et al 2008):

› *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); and

› *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.

Prevalence of high blood pressure

› The AusDiab 2005 reported an incidence of hypertension of 0.6% per year for women aged 25–34 years and 1.2% for women aged 35–44 years (Barr et al 2006). In the 2004-05 National Aboriginal and Torres Strait Islander Health Survey, high blood pressure was the most commonly reported heart and circulatory condition, affecting 5% of adults aged 25–34 years (ABS 2006).

› Around 1–2% of women experience chronic hypertension during pregnancy (Murray et al 2002; Brown 2003) and 2–3% experience pre-eclampsia (Brown 2003). Superimposed pre-eclampsia in the second half of pregnancy occurs in about 20% of women with chronic hypertension (Lowe et al 2008).

Risks associated with high blood pressure during pregnancy

Women with chronic hypertension are at greater risk of pregnancy complications, such as placental abruption, superimposed pre-eclampsia, fetal loss, preterm labour, low birth weight, perinatal death (Jain 1997; Silbai 2002) and gestational diabetes (Hedderson & Ferrara 2008).

Risk factors for pre-eclampsia

Risk factors for pre-eclampsia include a personal or family history of pre-eclampsia, pre-existing diabetes or kidney disease, maternal hyperglycaemia (HAPO 2008), first or multiple pregnancy, raised BMI, age >40 years, more than 10 years since the last pregnancy, and raised blood pressure at the first antenatal visit (Duckitt & Harrington 2005).

7.3.2.   Measuring blood pressure

Summary of the evidence

Routine measurement of women's blood pressure at the first antenatal visit and throughout pregnancy is recommended in the United Kingdom (NICE 2008; 2010) and Canada (SOGC 2008). This advice reflects the importance of predicting the risk of pre-eclampsia to allow monitoring and preventive treatment. After 20 weeks, high blood pressure and/or proteinuria may indicate pre-eclampsia.

Studies investigating the accuracy of blood pressure measurement and other screening tests in predicting pre-eclampsia report conflicting results. Recent studies include:

› a systematic review (n=60,599)(Cnossen et al 2008), which found that, while mean arterial pressure is a better predictor of pre-eclampsia than systolic or diastolic blood pressure or an increase of blood pressure in the first or second trimester, its use is not supported as the sole diagnostic tool;

› prospective studies, which also suggest the use of a combination of factors — for example maternal history, uterine artery Doppler imaging, blood pressure at 11–13 weeks, body mass index — to predict pre-eclampsia (Onwudiwe et al 2008; Poon et al 2008; 2009; Nijdam et al 2010);

› retrospective cohort studies into screening tests, which found associations between pre-eclampsia and: maternal history of chronic hypertension, body mass index, and blood pressure; activated partial thromboplastin time (APTT), prothrombin time (PT), activated factor VIII, homocysteine, free protein S and vitamin B1; and relative plasma volume (Emonts et al 2008) and average mean arterial pressure in the first trimester (Miller et al 2007); and

› a systematic review of screening tests (n=211,369) (Conde-Agudelo et al 2004), which found that, in women at low risk of pre-eclampsia, tests of anticardiolipin antibodies, bilateral diastolic notches during Doppler ultrasonography and urinary kallikrein had limited use and other ultrasonography characteristics and the measurement of fetal and placental peptides had low predictive accuracy and that, in women at high risk, the use of Doppler ultrasonography had low predictive accuracy and the evidence on other tests was too limited for conclusions to be drawn.

Overall there was great heterogeneity between individual studies with regard to population, gestation, definitions of pre-eclampsia, method of performing tests, test thresholds, frequency of testing, intervals between the test and outcome, and reference standards.

Recommendation	Grade B
5. Measure blood pressure at a woman's first antenatal visit to identify existing high blood pressure.	

Measuring blood pressure

Blood pressure should be measured as outlined below (NICE 2008):

› using the woman's right arm (Lowe et al 2008), remove tight clothing and ensure arm is relaxed and supported at heart level;

› use cuff of appropriate size (eg use a large cuff if arm circumference is >33cm and a thigh cuff if it is >42cm);

› inflate cuff to 20–30 mmHg above palpated systolic blood pressure;

› lower column slowly, by 2 mmHg per second or per beat;

› read blood pressure to the nearest 2 mmHg; and

› measure diastolic blood pressure as disappearance of sounds (phase V; or IV if phase V is absent).

Women with a single diastolic blood pressure reading of 110 mmHg or more, or two consecutive readings of 90 mmHg or more at least 4 hours apart and/or significant proteinuria (1+) require increased monitoring and treatment should be considered. Women with a systolic blood pressure equal to or above 140 mmHg on two consecutive readings at least 4 hours apart require further assessment and treatment should be considered.

Automated blood pressure measuring devices

Although mercury sphygmomanometry remains the gold standard for measuring blood pressure, due to environmental and safety concerns its use is declining and automated devices are increasingly being used in the general hypertensive population (Brown et al 2011). Few studies have compared these devices with sphygmomanometry in pregnant women (Lowe et al 2008). While they may give similar mean blood pressure values to those obtained with sphygmomanometry, there is wide intra-individual error and their accuracy may be further compromised in pre-eclamptic women (Gupta et al 1997; Brown et al 1998).

The potential errors of automated devices may be offset by comparing blood pressure recordings by routine mercury sphygmomanometry (Brown et al 2011). Considerations with automated devices include:

› using only devices that have been validated for use in pregnancy by the British Hypertensive Society, the Association for the Advancement of Medical Instruments or other accepted and published criteria;

› maintaining some mercury sphygmomanometers for the purpose of allowing regular calibration of all devices; and

› when a pregnant woman uses an automated device for home blood pressure measurements, checking the device against mercury sphygmomanometry to ensure accuracy of readings.

White coat hypertension

White coat or "office" hypertension occurs in early pregnancy with the same frequency as it does in non-pregnant women (Brown et al 2005). A prospective study (n=241) (Brown et al 2005) found that 32% of women early in pregnancy who were given an initial diagnosis of essential hypertension had white coat hypertension. Half of these women retained this phenomenon throughout pregnancy and had good pregnancy outcomes, 40% developed (benign) gestational hypertension and also had good pregnancy outcomes and 8% developed proteinuric pre-eclampsia, which was significantly fewer than in women with confirmed essential hypertension (22%).

<u>Women with pre-existing hypertension</u>

Women presenting for antenatal care currently on medication for hypertension should have their medicines reviewed to ensure their safety in pregnancy.

Considerations beyond the first trimester

› Any woman presenting with new hypertension after 20 weeks pregnancy should be assessed for signs and symptoms of pre-eclampsia.

› The presence of hypertension and/or proteinuria should alert the healthcare professional to the need for increased surveillance (NICE 2008).

7.3.3.   Practice summary — measuring blood pressure

When — At first antenatal visit
Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker
› **Explain the risks associated with high blood pressure in pregnancy** — Discuss the importance of identifying high blood pressure early in pregnancy.
› **Offer lifestyle advice** — Highlight to women who experience raised blood pressure in pregnancy the benefits of not smoking, maintaining a healthy weight, regular physical activity and a healthy diet.
› **Arrange treatment or referral if required** — For women with chronic hypertension, further testing may be required to exclude white coat hypertension or kidney disease and treatment may be needed.

7.3.4.   Resources

British Hypertensive Society Automatic Digital Blood Pressure Devices for Clinical Use
http://www.bhsoc.org/bp_monitors/automatic_clinic.stm

Lowe SA, Brown MA, Dekker G et al (2008) Guidelines for the management of hypertensive disorders of pregnancy 2008. Society of Obstetric Medicine of Australia and New Zealand. *Aust NZ J Obstet Gynaecol* 49(3): 242–46.
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7.3.5.   References

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Murray N, Homer CS, Davis GK et al (2002) The clinical utility of routine urinalysis in pregnancy: a prospective study. *Med J Aust* 177: 477–80.

NICE (2008) *Antenatal Care. Routine Care for the Healthy Pregnant Woman*. National Collaborating Centre for Women's and Children's Health. Commissioned by the National Institute for Health and Clinical Excellence. London: RCOG Press.

NICE (2010) *Hypertension in Pregnancy: the Management of Hypertensive Disorders during Pregnancy*. National Collaborating Centre for Women's and Children's Health. Commissioned by the National Institute for Health and Clinical Excellence. London: RCOG Press.

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7.4. Proteinuria

Detection of proteinuria in the first trimester does not predict pre-eclampsia but may lead to identification and treatment of kidney disease or urinary tract infection.

7.4.1. Background

High amounts of protein in the urine (proteinuria) can be caused by a range of conditions. Proteinuria in the first trimester may suggest underlying kidney disease or the presence of urinary tract infection (see Section 8.5). After 20 weeks pregnancy, proteinuria is associated with pre-eclampsia.

Kidney disease in Australia

› The first phase of the AusDiab study found that 16% of participants had at least one indicator of kidney damage (Chadban et al 2003; Atkins et al 2004) and the subsequent phase found that every year 1% of adults developed reduced kidney function and 1% had evidence of kidney damage (Barr et al 2006). Kidney disease is more prevalent among Aboriginal and Torres Strait Islander peoples than in the non-Indigenous population, with the overall age-standardised rate being 10 times the non-Indigenous rate (AIHW 2008). Between 2001 and 2004–05, there was a significant increase in the proportion of Aboriginal and Torres Strait Islander people reporting kidney problems (from 1% to 2%) (Barr et al 2006).

Risks associated with proteinuria in pregnancy

› Maternal proteinuria has been strongly associated with preterm birth (Franceschini et al 2005).

› Chronic kidney disease in pregnancy has been associated with pre-eclampsia, preterm labour, small-for-gestational age babies and perinatal death (Bramham et al 2011).

7.4.2. Testing for proteinuria

Summary of the evidence

Testing for proteinuria in pregnancy in combination with blood pressure measurement at each antenatal visit is recommended in the United Kingdom (NICE 2008).

Accuracy of tests for detecting proteinuria

The 24-hour urine collection test is considered 'the gold standard' for testing for proteinuria in women during pregnancy, although it is often inconvenient for pregnant women to undertake a 24-hour urine collection. The test is frequently used as a reference point when evaluating the accuracy of other tests such as urine dipstick visual check, urine automated analyser, 2-hour and 12-hour tests, spot protein:creatinine ratio or microalbumin:creatinine ratio (Risberg et al 2004; Price et al 2005; Waugh et al 2005; Schubert et al 2006; Rizk et al 2007; Abebe et al 2008; Côté et al 2008a; Dwyer et al 2008; Kyle et al 2008; Gangaram et al 2009a; 2009b). One study has questioned the accuracy of the 24-hour urine test (Côté et al 2008b).

Studies evaluating other test types have found that:

› *dipstick testing* — is inaccurate in predicting significant proteinuria (Waugh et al 2004; Gangaram et al 2005) and has a high incidence of false positives (Davey & MacGillivray 1988; Phelan et al 2004);

› *2-hour and 12-hour collections* — correlate with 24-hour collections in quantifying proteinuria, with the 12-hour collection having higher sensitivity (89% versus 86%), specificity (93% versus 82%) and positive predictive value (84% versus 77%) and lower false positive (12% versus 18%) and false negative (11% versus 14%) rates than 2-hour collection (Abebe et al 2008); and

› *protein:creatinine ratio* — is a better screening test than automated dipstick urinalysis to detect significant proteinuria (Risberg et al 2004; Dwyer et al 2008), may be useful to rule out clinically significant proteinuria (Waugh et al 2004; Price et al 2005; Côté et al 2008a; Meads et al 2008; Gangaram et al 2009a) and has the advantage of results being available immediately (Kyle et al 2008).

<u>Automated analysis of dipsticks</u>

Due to considerable observer errors involved in dipstick urinalysis, an RCOG Study Group recommended that automated dipstick readers be employed (Shennan & Waugh 2003). This can significantly improve false positive and false negative rates. An initial result of 1+ or greater of protein should be confirmed by a 24-hour urinary protein measurement or a protein:creatinine ratio (Rodriguez-Thompson & Lieberman 2001).

Consensus-based recommendation
iii.   Routinely offer testing for proteinuria at the first antenatal visit, regardless of stage of pregnancy.

Recommendation	Grade B
6. For point-of-care testing, use an automated analyser if available, as visual inspection of a urinary dipstick is the least accurate method to detect true proteinuria.	

<u>Repeat testing in the first trimester</u>

Repeat testing for proteinuria in the first trimester is of little or no benefit in predicting pre-eclampsia and should be confined to women with other risk factors such as existing or newly diagnosed high blood pressure and new or pre-existing kidney disease (Beunis et al 2004; Alto 2005; Sirohiwal et al 2009).

Testing in rural and remote areas

Considerations in urine testing in rural and remote areas include (Bookallil et al 2005):

› the availability of appropriate storage facilities for dipstick tests and for urine collections for women with abnormal dipstick results (see below); and

› if a woman has an abnormal dipstick result, whether specimens can be provided to pathology services within the timeframe in which they can still be cultured (ideally within 24 hours).

7.4.3. Responding to test results

A finding of 300 mg/24 hours or more or a protein:creatinine ratio of 30 mg/mmol of creatinine is customarily regarded as significant (Ferrazzani et al 1990; Waugh et al 2003). However, a proteinuria threshold of 500 mg/24 hours has been suggested to be more predictive in relation to the likelihood of adverse outcome (Shennan & Waugh 2003).

› Women with abnormal dipstick urine test results (including the presence of leukocytes, nitrites or blood) should have a midstream urine sample sent for microscopic examination, culture and sensitivity testing. If the result is asymptomatic bacteriuria, this should be treated appropriately (Murray et al 2002).

› Women found to have true proteinuria and/or haematuria at their first antenatal visit may have underlying kidney disease, which should be investigated (Murray et al 2002).

7.4.4. Practice summary — testing for proteinuria

When — At first antenatal visit
Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker
› **Explain the risks associated with proteinuria in pregnancy** — Discuss the importance of identifying kidney disease or urinary tract infection early in pregnancy.
› **Arrange treatment or referral if required** — For women with proteinuria, further testing may be required to exclude urinary tract infection or kidney disease and monitoring for pre-eclampsia may be needed.

7.4.5. Resources

Lowe SA, Brown MA, Dekker G et al (2008) Guidelines for the management of hypertensive disorders of pregnancy 2008. Society of Obstetric Medicine of Australia and New Zealand. *Aust NZ J Obstet Gynaecol* 49(3): 242–46.

NICE (2010) *Hypertension in Pregnancy: the Management of Hypertensive Disorders during Pregnancy*. National Collaborating Centre for Women's and Children's Health. Commissioned by the National Institute for Health and Clinical Excellence. London: RCOG Press.

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7.5. Psychosocial factors affecting mental health[5]

A number of factors affect mental health during pregnancy. Asking a woman about relevant psychosocial factors early in pregnancy enables her to access support if she chooses.

7.5.1. Background

Some women may be more vulnerable to mental health problems during pregnancy due to a combination of biological, genetic, physiological or social factors (Fisher et al 2002; Boyce 2003). Psychosocial factors that have been identified as influencing mental health during pregnancy include the following.

› *Past mental health disorders* — These increase the likelihood of depression developing and bipolar disorder recurring during pregnancy (NICE 2007). Family history of psychosis in the postnatal period also increases a woman's risk of mental health disorder (NICE 2007). The risk associated with family history depends on the closeness of the relationship and the severity of the condition.

› *Past or current physical, sexual or psychological abuse* — Childhood sexual, emotional or physical abuse is associated with depression, anxiety and low self-esteem in the postnatal period (Buist 1998). Women exposed to abuse during pregnancy are also more likely to develop depression in the postnatal period (Bacchus et al 2003; Mezey et al 2005).

› *Drug and/or alcohol use* — There are clear associations between mental health issues and drug and alcohol abuse (eg drugs and alcohol may be used as a means of coping with mental health issues). There is frequently an association between physical and emotional abuse and drug and alcohol misuse (Oei et al 2009).

› *Recent life stressors* — High scores on 'current life events' scales are associated with depression in the perinatal period (Eberhard-Gran et al 2002; Dennis et al 2004) and may interact with vulnerability factors such as having low self-esteem or a negative outlook, or being a young mother at home with several children (O'Hara et al 1991). Important stressors include negative life events and stressful events associated with pregnancy (Eberhard-Gran et al 2002). Women who experience multiple pregnancies (Choi et al 2009), conceive through in vitro fertilisation (Gelbaya 2010; Volgsten et al 2010) or have polycystic ovarian syndrome (Mansson et al 2008; Deeks et al 2010) may be more likely to develop depression. Other events that may be considered as stressors include bereavement, illness, relationship problems, pregnancy loss, problems conceiving and moving house. Two or more stressful life events during the year prior to pregnancy have been associated with recurrent or sustained depressive symptoms in early pregnancy and the postnatal period (Rubertsson et al 2005).

› *Quality of a woman's attachment with her own mother* — Insecure attachment with a woman's own mother may contribute to depression in the perinatal period. A woman's own experience as a child and the mental image of parental relationships that she brings to her role as mother is likely to affect how she anticipates, responds to and interprets her own infant's attachment behaviour (NSW Dept Community Services 2006).

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5 The information in this section, including the consensus-based recommendation, is based on Sections 1.3 and 3.2 in *beyondblue* (2011) *Clinical Practice Guidelines on Depression and Related Disorders in the Perinatal Period*.
http://www.beyondblue.org.au/index.aspx?link_id=6.1246

› *Current practical and emotional support* — The availability of support (Milgrom et al 2008; Dennis et al 2009), in particular, practical and emotional support from her mother and partner (Dennis & Ross 2006; Milgrom et al 2008), appears to be a crucial factor in protecting a woman against mental health disorders during pregnancy.

Factors contributing to mental health problems in specific population groups

Aboriginal and Torres Strait Islander women

In general, Aboriginal and Torres Strait Islander people experience higher rates of social and emotional wellbeing problems and some mental health disorders than non-Indigenous Australians (Social Health Reference Group 2004). Factors such as lower life expectancy, child and family separations, incarceration and higher infant mortality rates contribute to the level of grief, loss, trauma and anger experienced by Aboriginal and Torres Strait Islander individuals, families and communities (ABS & AIHW 1999).

In addition to disrupted cultural well-being and the continuing inter-generational effects of trauma and loss, Aboriginal and Torres Strait Islander people experience high levels of recent life stressors. Respondents to the National Aboriginal and Torres Strait Islander Health Survey (2004–05) indicated that in the last year they, their family and/or friends had experienced the death of a family member or close friend (42%), serious illness or disability (28%) or alcohol-related problems (20%)(AIHW 2008).

In this context, it is clear that Aboriginal and Torres Strait Islander women are at higher risk of mental health problems, both generally and in the perinatal period, than women from the general population. High rates of maternal and infant morbidity and mortality, and high rates of Aboriginal and Torres Strait Islander infants taken into care within the first year of life, support the notion that rates of perinatal emotional distress and mental health disorder are high and the burden of care significant for Aboriginal and Torres Strait Islander communities (Swan & Raphael 1995; Perinatal Mental Health Consortium 2008). Additional emotional distress may be caused for Aboriginal and Torres Strait Islander women in remote areas if they cannot access regular antenatal care, or if they are from traditional communities and cultural birthing practices cannot be followed (Swan & Raphael 1995; Perinatal Mental Health Consortium 2008).

Women from culturally and linguistically diverse backgrounds

Women who were born in other countries and give birth in Australia may experience isolation due to a loss of usual female family and community support systems. There may also be a history of grief, loss and trauma in addition to migration (McCarthy & Barnett 1996).

Newly arrived humanitarian refugees are likely to have experienced multiple levels of trauma. Families who have been forced to flee from their country of origin may have been subject to many traumas and disrupted attachments, including the loss of one or both parents or other family members and/or separation from extended family. During times of upheaval and displacement, social structures break down and people have limited experience of the normal routines of culture and society. The challenges of the resettlement process can be overwhelming. These include adapting to a new country, learning a new language, the pressure to succeed, changes in family roles and concern for family members still overseas, and living in precarious circumstances. Newly arrived refugees may also experience posttraumatic stress disorders, grief and/or physical injury (State Perinatal Reference Group 2008).

For these women, the increased stress associated with the perinatal period can add to an already difficult and challenging situation (State Perinatal Reference Group 2008). An unfamiliar environment, language difficulties, absence of support and lack of opportunities related to birth rites may place new mothers and their infants at a higher risk of mental health problems (State Perinatal Reference Group 2008).

<u>Adolescent women</u>

Research on adolescent mothers shows increasing rates of depressive symptoms in the postnatal period, particularly for young women with more family conflict, fewer social supports, and low self-esteem (Reid & Meadows-Oliver 2007). Guidelines for management of depression in young people are included in Section 7.5.4.

7.5.2.   Assessing psychosocial risk factors

Summary of the evidence

While the use of psychosocial assessment tools in improving outcomes is not currently supported by evidence, enquiry related to certain psychosocial factors of a significant nature is endorsed by relevant clinical practice guidelines (SIGN 2002; British Columbia Perinatal Health Program 2003a; 2003b; WA Statewide Obstetric Unit 2006; NICE 2007; NSW Dept Health 2009; *beyondblue* 2011). These include:

› past history of mental health disorders;

› availability of practical and emotional support;

› current or past abuse/violence; and

› current life events (major stressors).

These domains of enquiry were also supported by the findings of a large Australian prospective study (Milgrom et al 2008).

Some clinical practice guidelines also endorse enquiry relating to current drug and alcohol use (British Columbia Perinatal Health Program 2003a; 2003b; NSW Dept Health 2009; *beyondblue* 2011) and a woman's attachment with her own mother (*beyondblue* 2011).

Consensus-based recommendation
iv. As early as practical in pregnancy, ask all women questions about psychosocial factors, including previous or current mental health disorders. If a woman affirms their presence, ask whether she would like help with any of these issues.

Asking women about psychosocial factors

Many of the psychosocial factors outlined above are already explored as part of routine care (eg women are asked about domestic violence) and additional questions can be included in the clinical interview. The aim is to identify psychosocial factors without detracting from the normal experiences of pregnancy and motherhood or highlighting the potential for depression and related disorders to occur in the perinatal period.

Before asking women about psychosocial factors, health professionals need to identify local options for referral if required. Women should be given an explanation of the purpose of the questions (eg identifying any need for psychosocial support) and asked for their permission.

Women need to feel safe during the assessment, so consideration should be given to the other people who may be present. While the presence of a woman's partner or other family members may be appropriate, sensitivity is required about whether it is appropriate to continue with psychosocial assessment while they are in the room (eg if domestic violence is suspected).

Table 7.4: Example questions to identify psychosocial factors

Past or current mental health problems
1. Have you ever had a period of 2 weeks or more when you felt particularly low or down?
2. Do you sometimes worry so much that it affects your day-to-day life?
3. Have you ever needed treatment for a mental health disorder such as depression, anxiety disorder, bipolar disorder or psychosis?
4. Has anyone in your immediate family (eg grandparents, parents, siblings) experienced severe mental health problems?

Previous or current abuse
5. When you were growing up, did you always feel cared for and protected?
6. If you currently have a partner, do you feel safe in this relationship?

Drugs and alcohol
7. Do you or others think that you (or your partner) may have a problem with drugs or alcohol?

Recent life stressors
8. Have you had any major stressors, changes or losses in the last 12 months (eg moving house, financial worries, relationship problems, loss of someone close to you, illness, pregnancy loss, problems conceiving)?

Practical and emotional support
9. When you were growing up, was your mother emotionally supportive of you?
10. If you found yourself struggling, what practical support would you have available? Who could help provide that?
11. If you found yourself struggling, what emotional support would you have available? Who could help provide that?

Acting on the assessment

Assessing psychosocial factors provides information about a woman's mental health and well-being and identifies women who may benefit from additional care. In the following situations, comprehensive mental health assessment *is advisable*:

› the woman has a past history of mental health disorder;

› the woman is experiencing abuse or has experienced abuse in the past;

› the woman or her partner has a problem with alcohol or drugs; or

› the woman requests further assessment.

Comprehensive mental health assessment is *required* if the woman has, or is suspected to have, a recurrence or new onset of severe mental health disorder (eg bipolar disorder), suicidal thoughts or evidence of harm to herself or infant, or if other children in her care may be at risk of harm.

Considerations beyond the first trimester

› Women should be asked about psychosocial factors again 6–12 weeks after the birth.

7.5.3. Practice summary — assessing psychosocial factors

When — At first antenatal visit
Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker

› **Provide information** — Explain that pregnancy can be challenging and that some life factors make it more likely that a woman will experience symptoms of depression or anxiety.

› **Seek informed consent** — Explain that asking about psychosocial factors is a routine part of care during pregnancy and ask the woman for her consent.

› **Offer support** — If a woman has two or more psychosocial factors or one or more significant factors (past history of a mental health disorder, past or present abuse, drug and/or alcohol problems) ask if she would like help with any issues.

7.5.4. Resources

beyondblue (2011) *Clinical Practice Guidelines Depression and Related Disorders — Anxiety, Bipolar Disorder and Puerperal Psychosis — in the Perinatal Period. A Guideline for Primary Care Health Professionals*. Melbourne: *beyondblue: the national depression initiative*. http://www.beyondblue.org.au/index.aspx?link_id=6.1246

beyondblue (2011) *Clinical Practice Guidelines: Depression in Adolescents and Young Adults.* Melbourne: *beyondblue: the national depression initiative*. http://www.beyondblue.org.au/index.aspx?link_id=6.1247

Online training — *beyondblue* provides online training in assessing and managing mental health disorders in the perinatal period. http://thinkgp.com.au/beyondblue.

7.5.5. References

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7.6.   Depression and anxiety[6]

Detecting symptoms of depression and anxiety during pregnancy relies on clinical judgement and experience. Use of the Edinburgh Postnatal Depression Scale (EPDS) complements this process. The aim is not to form a diagnosis, but to identify women who may benefit from further follow-up.

7.6.1.   Background

Depression and anxiety during pregnancy and the postnatal period affect the wellbeing of the woman, her infant and her partner and have an impact on relationships within the family, during a time that is critical to the future health and wellbeing of children (Beck 1998; Halligan et al 2007).

Parental mental health is a key determinant of healthy development in infants (Murray & Cooper 2003). Infant social, psychological, behavioural and cognitive development occurs in the context of a caregiving relationship (Winnicott 1960). When the mother is experiencing depression, the mother-infant relationship is more likely to experience difficulties and infants are at increased risk of developing insecure attachment and mental health problems (Murray & Cooper 1996; Misri & Kendrick 2008; Murray 2009; Tronick & Reck 2009). Maternal distress during pregnancy influences obstetric and birth outcomes (Priest & Barnett 2008) and can adversely affect the developing fetal brain and thus influence infant behaviour (Glover & O'Connor 2002). Maternal anxiety is associated with difficult infant temperament (Austin et al 2005), increased infant cortisol (Grant et al 2009) and behavioural difficulties in childhood (O'Connor et al 2002). Antenatal distress increases risk of attentional deficit/hyperactivity, anxiety, and language delay (Talge et al 2007), and of later mental health problems (O'Connor et al 2002).

Depression and anxiety in pregnancy

Recent studies suggest that:

› depressive symptoms are as common during pregnancy as they are in the postnatal period (Austin 2004; Milgrom et al 2008);

› depression identified postnatally begins during pregnancy in up to 40% of women (Austin 2004); and

› anxiety disorders may be as common as depression during pregnancy and early parenthood (Wenzel et al 2003; Austin & Priest 2005).

Depressive episodes can be a reaction to the pregnancy itself, to associated health issues or to other major life stressors. They can also be a continuation or relapse of a pre-pregnancy condition, especially among women who stop taking medication on confirmation of pregnancy (Henshaw 2004; Oates 2006).

Anxiety may occur in response to fears about aspects of the pregnancy (eg parenting role, miscarriage, congenital disorders), or as a continuation of a pre-pregnancy condition and/or with depression. Higher levels of anxiety in pregnancy increase the risk of depression postnatally (Austin et al 2007).

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6 The information in this section, including the recommendations, is based on Section 3.3 in *beyondblue* (2011) *Clinical Practice Guidelines on Depression and Related Disorders in the Perinatal Period*. http://www.beyondblue.org.au/index.aspx?link_id=6.1246

7.6.2.   Screening for depression and anxiety

Summary of the evidence

Depression

There is a large body of evidence to support the use of the EPDS to detect possible depression (but not other mental health disorders) during pregnancy (Murray & Cox 1990; Areias et al 1996; Adouard et al 2005; Adewuya et al 2006; Felice et al 2006; Su et al 2007; Rowel et al 2008).

Recommendation	Grade B
7. Use the Edinburgh Postnatal Depression Scale as a component of the assessment of all women for symptoms of depression in the antenatal period.	

Anxiety

Although the EPDS was specifically developed to detect of symptoms of depression, there is evidence to support its use in the detection of symptoms of anxiety, taking into consideration the woman's scores on questions 3, 4 and 5 and applying clinical judgement (Matthey 2008; Phillips et al 2009).

Consensus-based recommendation
v.   Be aware that women who score 13 or more on the Edinburgh Postnatal Depression Scale (EPDS) may be experiencing anxiety, either alone or with depression. Base decisions about further assessment on the woman's answers to questions 3, 4 and 5 of the EPDS and her response to enquiry about 'worrying'.

Administering the EPDS[7]

The EPDS is generally administered in the presence of a health professional or immediately before a consultation. While the EPDS is a self-report tool, it can also be administered verbally if a woman has difficulty completing the questionnaire (eg due to language or literacy, cultural issues, disability). The use of the EPDS may be inappropriate in some circumstances (eg some cultural situations) or may not be acceptable to the woman being assessed; women also have the right to decline assessment.

Before the EPDS is administered, the aims and nature of the assessment should be explained. This includes highlighting that a score that suggests a woman may benefit from follow-up care does not mean she will develop depression. If consent is given, explanation should also be provided on how to complete the questionnaire (select appropriate response for each question) and that the woman should select the responses that are closest to her feelings *over the previous 7 days*, not just on that day.

Cultural considerations

Scores used to identify possible depression in Aboriginal and Torres Strait Islander and culturally and linguistically diverse populations are generally lower than those used in the general population. For Aboriginal and Torres Strait Islander women, the score may be influenced by the woman's understanding of the language used, mistrust of mainstream services or fear of consequences of depression being

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7 The EPDS questionnaire is included in Appendix 4 of *beyondblue* (2011) and is also available on the *beyondblue* website http://www.beyondblue.org.au/index.aspx?link_id=103.885.

identified. Translations of the EPDS developed in consultation with women from Aboriginal communities have been found to identify a slightly higher number of women experiencing symptoms of depression (Hayes et al 2006; Campbell et al 2008).

Cultural practices (such as attending the consultation with a family member) and differences in emotional reserve and the perceived degree of stigma associated with depression may also influence the performance of the EPDS in women from culturally and linguistically diverse backgrounds.

See Section 7.6.4 for a source of validated translated versions of the EPDS.

Acting on EPDS scores

The first step following the EPDS is determining whether comprehensive mental health assessment is required and, if necessary, identifying a health professional with appropriate mental health expertise to carry out this assessment. While clinical judgement is central to decision-making about further support and/or referral, it is complemented by scores from the EPDS.

› For women with a score of 10, 11 or 12, the EPDS should be repeated within 2–4 weeks and support services reviewed and increased if needed.

› A score of 13 or 14 is suggested as a 'flag' for further follow-up and women with this score should be offered the EPDS at least twice more during the pregnancy.

› Women with a score of 15 or more require timely mental health assessment and management.

› Women with a positive score on questions 3, 4 and/or 5 may be experiencing symptoms of anxiety and consideration should be given to repeating the EPDS in 2–4 weeks.

Chapter 5 of the *beyondblue* Guidelines (2011) gives more detailed information on referral.

Risk of self harm

Regardless of the total EPDS score, women who have a positive score on question 10 may be at risk of harming themselves and/or children in their care and further assessment is necessary. Health professionals should develop a system to assess the risk of suicide and ensure immediate management as needed. If a woman has a positive score on question 10 of the EPDS on one occasion, it is recommended that the EPDS be repeated as often as clinically required, with a view to reassessing risk over time.

Practice point
h. If a woman scores 1, 2 or 3 on EPDS question 10, assess her current safety and the safety of other children in her care and, acting according to clinical judgement, seek advice and/or refer immediately for mental health assessment.

The National Suicide Prevention strategy website (see Section 7.6.4) provides comprehensive resources on suicide prevention strategies, risk and protective factors, the relationship between mental health and suicide and issues specific to certain groups such as residents of Aboriginal and Torres Strait Islander communities and rural and remote communities.

Considerations beyond the first trimester

› It is preferable for women to be offered the EPDS twice during pregnancy and as often as is clinically required.

› Women should be offered the EPDS at least once, preferably twice in the year after the birth, ideally 6–12 weeks after the birth.

7.6.3. Practice summary — screening for depression and anxiety

When — As early as practical in pregnancy
Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker

› **Seek informed consent** — Before asking a woman for her consent, explain that screening for depression and anxiety is a routine part of care during pregnancy and that a score that suggests that she may benefit from follow-up care does not mean she will develop depression.

› **Identify level of support needed** — Base decisions on follow-up on clinical judgement and the woman's preferences, taking into account that not all women with a score of 13 or more will benefit from follow-up, and that low or high scores may reflect other factors.

› **Consider safety** — If concerned about the woman's mental health and safety, contact mental health services (see also Chapter 4 of the beyondblue guidelines [2011]).

› **Assist women who decline further care** — If a woman chooses not to seek further care, provide her with information about consumer-led and community-led supports.

7.6.4. Resources

beyondblue (2011) *Clinical Practice Guidelines Depression and Related Disorders — Anxiety, Bipolar Disorder and Puerperal Psychosis — in the Perinatal Period. A Guideline for Primary Care Health Professionals*. Melbourne: *beyondblue: the national depression initiative*. http://www.beyondblue.org.au/index.aspx?link_id=6.1246

Online training — *beyondblue* provides online training in assessing and managing mental health disorders in the perinatal period. http://thinkgp.com.au/beyondblue.

National Suicide Prevention Strategy website — http://www.livingisforeveryone.com.au

WA Dept Health (2006) *Edinburgh Postnatal Depression Scale (EPDS): Translated Versions – Validated*. Perth: State Perinatal Mental Health Reference Group. http://www.dhi.gov.au/Multicultural-Mental-Health-Australia/Information-for-Health-Professionals/Information-for-CALD-Population/default.aspx

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7.7. Domestic 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.

7.7.1. Background

Domestic violence (also referred to as intimate partner violence or family violence) occurs when one person attempts to control and dominate another in an intimate or familial relationship. Numerous studies have demonstrated that domestic violence is primarily perpetrated against women and children. Domestic violence manifests in a variety of forms, including physical, psychological, economic, social and sexual abuse. Domestic violence is relatively common during pregnancy. The frequency and severity of violence initiated by male partners against women may be higher during pregnancy (Burch & Gallup 2004; Martin et al 2004) but the evidence is not consistent (Campbell et al 2004; Walsh 2008).

Domestic violence in Australia

While differing definitions of domestic violence are used in studies, the following points give an indication of its prevalence.

› In Australia in 2005, 5.8% of women had experienced domestic violence in the previous 12 months (ABS 2006).

› Estimates from general populations are that between 1 and 20% of women experience domestic violence during pregnancy or after the birth (Taft 2002).

› In 2005, among Australian women who had ever experienced violence by a previous partner, 36% reported that this occurred when they were pregnant and 17% experienced violence for the first time when they were pregnant (ABS 2006).

› In an Australian survey of 400 pregnant women, 20% had experienced violence during pregnancy (Walsh 2008).

› Based on information from the Supported Accommodation Assistance Program, women in rural and remote areas are more likely to experience domestic violence than those in metropolitan areas. In 2004–05, the rates of domestic violence-related support provided per 1,000 population were highest in very remote areas (16.7), followed by remote areas (12.8), outer regional areas (3.4), inner regional areas (2.6) and major cities (2.0) (DTRS 2006).

› Aboriginal and Torres Strait Islander people are much more likely than non-Indigenous people to experience domestic violence and to be hospitalised for injuries arising from assault (AHMAC 2006). In 2002, 23% of Aboriginal women aged over 15 years reported an experience of physical violence or threatened violence in the previous 12 months (ABS & AIHW 2005).

Risks associated with domestic violence in pregnancy

›   Violence poses serious health risks to pregnant women (including breast and genital injury, miscarriage, antepartum haemorrhage and infection, blunt or penetrating abdominal trauma and death) and babies (including fetal fractures, low birth weight, injury, suppressed immune system) (Walsh 2008).

›   Young women exposed to violence are more likely to have a miscarriage, stillbirth, premature birth or termination of pregnancy than other young women (Taft et al 2004).

›   Women exposed to violence during pregnancy are more likely to develop depression in the postnatal period (Bacchus et al 2003; Mezey et al 2005).

7.7.2.   Assessing for domestic violence

The NICE guidelines note that health professionals need to be alert to the signs and symptoms of violence and give women the opportunity to disclose in an environment in which they feel secure. Canadian guidelines recommend that queries about violence be included as part of antenatal care (Cherniak et al 2005). The American College of Obstetricians and Gynecologists recommends assessing all women for domestic violence at the first antenatal visit and at least once per trimester (ACOG 2006). Routine questioning of women about domestic violence has been progressively introduced in antenatal services in some jurisdictions (eg Spangar 2007) and many State and Territories have guidelines that recommend that health care professionals routinely ask all pregnant women about their experiences of abuse (eg VCCCVM 2006).

Summary of the evidence

Acceptability to women

Most women find it acceptable for health professionals to ask them about experiences of domestic violence (Keeling & Birch 2004; Renker & Tonkin 2006; Roelens 2010). Some women may not disclose to health professionals (Bacchus et al 2003) unless asked directly (Hegarty et al 2007; Roelens et al 2008). Screening or assessment tools may increase the identification of domestic violence (Moonesinghe et al 2004; Kataoka et al 2004; Webster & Holt 2004; Ameh et al 2008; O'Reilly et al 2010) as they provide a series of structured questions asked of all women. The presence of the woman's partner may be a barrier to disclosure of domestic violence (Taft 2002), so women should be seen alone at least once during pregnancy, particularly during the first antenatal visit (Stenson et al 2005; Salmon et al 2006).

Recommendation	Grade B
8. At the first antenatal visit, 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.	

Consensus-based recommendation
vi.   Ask about domestic violence when alone with the woman, tailoring the approach to her individual situation and your own skills and experience (eg use open-ended questions about her perception of safety at home or use an assessment tool).

<u>Acceptability to health professionals</u>

While routine enquiry about domestic violence is largely acceptable to health professionals (Morgan 2003; Protheroe et al 2004; Barnett 2005; Lazenbatt et al 2005; Stenson et al 2005; Hindin 2006; Salmon et al 2006; Lazenbatt et al 2009; Lazenbatt 2010), many are not comfortable with making such enquiry (Baird 2005; Gunn et al 2006; Herzig et al 2006; Edin et al 2010) feeling that they lack relevant knowledge and training to respond effectively if domestic violence is identified (Denham 2003; Lazenbatt 2010). Language and cultural barriers and fear of distressing the woman may also reduce levels of enquiry (Jeanjot et al 2008). Personal experiences of domestic violence may also affect health professionals' ability to enquire about domestic violence (Morgan 2003).

Training and support in discussing and responding to domestic violence provides health professionals with the knowledge and skills they need to respond effectively (Bacchus et al 2003; Denham 2003; Mezey et al 2003; Morgan 2003; Protheroe et al 2004; Baird 2005; Barnett 2005; Torres-Vitolas et al 2010).

Consensus-based recommendation
vii. Be aware that training programs improve the confidence and competency of health professionals in identifying and caring for women experiencing domestic violence.

<u>Interventions</u>

Brief psycho-behavioural interventions may improve domestic violence and pregnancy outcomes (Kiely et al 2010). Counselling sessions and advocacy programs for women experiencing domestic violence are effective in reducing domestic violence (Kataoka et al 2004).

Discussing and responding to domestic violence

Discussion of domestic 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. It is important for health professionals to enquire about domestic violence in a sensitive manner and provide a response that takes into account the complexity of women's needs (Bacchus et al 2003).

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

Table 7.5:   Key considerations in discussing and responding to domestic violence

› Use direct or indirect questions or an assessment tool, depending on clinical experience and the perceived level of trust in the relationship

› Explain that the woman's responses will be kept confidential

› Actively listen to what the woman tells you

› Do not blame or judge the woman or her partner

› Inform the woman that she is not alone, there are other women experiencing domestic violence

› Affirm that the woman has made an important step by discussing her experiences

› Reinforce that domestic violence is against the law and that the woman has a choice not to live with the violence

› Reinforce that the woman should not self-blame

› Affirm to the woman that the decision to discuss domestic 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 (eg women's refuge, safe house, family or friends, hospital)

› Encourage the woman to access specialist support services (eg woman'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 domestic violence may require further discussion and possible reporting in relation to child protection issues[8]

› 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[8]

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

Health professionals with limited experience in responding to domestic violence can enhance their practice by:

› seeking training and support (eg clinical supervision) where available (see Section 7.7.4);

› planning a response to disclosure of violence, including considerations of safety, confidentiality, sensitivity and informed support; and

› being familiar with specialised counselling services, emergency housing agencies and legal support services in the local area.

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8   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.

Considerations in Aboriginal and Torres Strait Islander communities

Domestic violence has a significant impact in some Aboriginal and Torres Strait Islander communities. Historical circumstances, the loss of land and traditional culture, the disempowerment of traditional elders, breakdown of Aboriginal law and community kinship systems, entrenched poverty and racism are factors underlying the use of violence in Aboriginal and Torres Strait Islander communities (Mulroney 2003). Intergenerational effects of institutionalisation, oppression and child removal policies, have also resulted in ongoing trauma, loss and unresolved grief and contributed to a range of health and wellbeing problems and issues, including violence (NACCHO 2006).

Aboriginal and Torres Strait Islander women may choose not to disclose domestic violence. Factors that may influence a woman's decision to disclose include:

› mistrust of police, the law and other state institutions (Heenan 2004);

› the implications of reporting (eg fear of the woman's partner being imprisoned in the context of the disproportionate rates of Aboriginal men in prison and high rates of Aboriginal deaths in custody) (Heenan 2004);

› the cultural competence of the health professional involved; and

› kinship systems (eg in intrafamilial violence there may be a need to cut ties with the family following disclosure) (Cox 2008).

These factors also influence responses to disclosure of domestic 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.

Practice point
i.   Responses to assisting Aboriginal and Torres Strait Islander women who are experiencing domestic violence need to be appropriate to the woman and her community. Health professionals should be aware of family and community structures and support.

Approaches to addressing factors underlying domestic violence in Aboriginal and Torres Strait Islander communities are beyond the scope of these Guidelines. Some relevant resources are identified in Section 7.7.4.

Considerations in rural and remote areas

Assisting women experiencing domestic 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; and

› difficulties when the health professional has a relationship with the woman (eg through family, kinship or friendship), particularly if mandatory reporting is required.

> **Practice point**
>
> j.   Health professionals should be aware of resources for domestic violence services in their community that can be called for urgent assistance. This may include local safe houses or the Strong Women Workers in their community.

Considerations beyond the first trimester

Multiple assessments for domestic violence during pregnancy increase reporting (O'Reilly et al 2010).

7.7.3.   Practice summary — assessing for domestic violence

When — At the first antenatal visit
Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker

› **Discuss assessment for domestic violence** — Explain that enquiry about domestic 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 domestic violence in privacy (eg without her partner present).

› **Take a holistic approach** — If a woman affirms that she is experiencing domestic 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 domestic 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 domestic violence with women and assisting them if they are experiencing domestic 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.

7.7.4. Resources

Training

DiVeRT - Domestic Violence Response Training. Free face-to-face or online training for health professionals through Lifeline.
http://www.lifeline.org.au/About-Lifeline/Learning---Development/DiVeRT---Domestic-Violence-Response-Training/DiVeRT---Domestic-Violence-Response-Training-for-Health-Professionals

Responding Appropriately to Domestic Violence Online Generic Resource Package. The University Department of Rural Health, Tasmania. http://www.ruralhealth.utas.edu.au/padv-package/index.html

Guidance

Family Violence Risk Assessment and Risk Management. Identifying Family Violence. Maternal and Child Nurses' Training Handbook. An initiative of the Victorian Government Family Violence Reform program developed by Domestic Violence Resource Centre (Victoria) Swinburne University of Technology.
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Assessment tools

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7.8. Nausea and vomiting

Nausea and vomiting are common in pregnancy, particularly in the first trimester, with the severity varying greatly among pregnant women. A range of non-pharmacological and pharmacological interventions can be used to assist in managing nausea and vomiting in pregnancy. Women may find these interventions useful, although the evidence for their effectiveness remains inconclusive.

7.8.1. Background

Nausea and vomiting in pregnancy ranges from mild discomfort to significant morbidity (King & Murphy 2009). Symptoms generally start around 4–9 weeks of pregnancy (Gadsby et al 1993). Nausea and vomiting due to other conditions (eg gastrointestinal, metabolic, neurologic or genitourinary) should always be excluded, particularly in women who report nausea or vomiting for the first time after 10 weeks (Koch & Frissora 2003).

The most severe form of nausea and vomiting in pregnancy is Hyperemesis gravidarum, which is intractable vomiting in early pregnancy, leading to dehydration and ketonuria severe enough to justify hospital admission and intravenous fluid therapy (Bottomley & Bourne 2009).

The cause of nausea and vomiting in pregnancy is not known but is probably multifactorial (Ebrahimi et al 2010). The rise in human chorionic gonadotrophin during pregnancy has been implicated; however, data about its association with nausea and vomiting are conflicting (Weigel & Weigel 1989).

Nausea and vomiting in pregnancy

› *Prevalence* — Nausea is the most common gastrointestinal symptom of pregnancy, occurring in 80–85% of all pregnancies during the first trimester, with vomiting an associated complaint in approximately 52% of women (Whitehead et al 1992; Gadsby et al 1993). Retching (or dry heaving, without expulsion of the stomach's contents) has been described as a distinct symptom that is increasingly measured separately to vomiting and nausea (Matthews et al 2010).

› *Timing* — Most women report nausea and vomiting within 8 weeks of their LMP (94%), with over one-third (34%) reporting symptoms within 4 weeks of their LMP (Whitehead et al 1992; Gadsby et al 1993). Most women (87–91%) report cessation of symptoms by 16–20 weeks of pregnancy. Although nausea and vomiting is commonly referred to as 'morning sickness', only 11–18% of women report having nausea and vomiting confined to the mornings (Whitehead et al 1992; Gadsby et al 1993).

› *Hyperemesis gravidarum* — This condition is much less common, affecting 0.3–1.5% of women (Bottomley & Bourne 2009). Symptoms typically start between 5 and 10 weeks pregnancy and resolve by 20 weeks. However, up to 10% of women will continue to vomit throughout the pregnancy. The hospital admission rate for the condition falls from 8 weeks onwards (Bottomley & Bourne 2009).

Impact of nausea and vomiting in pregnancy

Although distressing and debilitating for some women, nausea and vomiting do not appear to have a negative impact on pregnancy outcomes. A systematic review of observational studies found a reduced risk of miscarriage associated with nausea and vomiting (odds ratio [OR] 0.36; 95% confidence interval

[CI] 0.32–0.42) and conflicting data regarding reduced risk for perinatal mortality (Weigel & Weigel 1989). No studies have reported an association between nausea and vomiting in pregnancy and teratogenicity (Klebanoff & Mills 1986).

However, despite reassurance that nausea and vomiting do not have harmful effects on pregnancy outcomes, these symptoms can have a severe impact on a pregnant woman's quality of life. Two observational studies have reported on the detrimental impact that nausea and vomiting may have on women's day-to-day activities, including interfering with household activities, affecting relationships, greater use of healthcare resources and time off work (Smith et al 2000; Attard et al 2002).

7.8.2.   Managing nausea and vomiting in pregnancy

Interventions for nausea and vomiting that do not require prescription include ginger, acupressure, acupuncture and vitamin B6. Prescribed treatments include antihistamines and phenothiazines.

Summary of the evidence

The systematic review conducted to inform these Guidelines identified additional evidence that was consistent with the NICE guidelines. The highest quality study, a Cochrane review (Matthews et al 2010) examined 27 trials of interventions including **acustimulation, acupuncture, ginger, vitamin B6 and several antiemetic medicines**. Systematic review of studies in this area is complicated by the heterogeneity of studies and limited information on outcomes (Matthews et al 2010).

The available evidence suggests the following.

› *Ginger* — While small RCTs have found reduced severity of nausea and vomiting with ginger products (syrup or capsules) (Murphy 1998; Vutyavanich et al 2001; Keating & Chez 2002), there is limited and inconsistent evidence of their effectiveness, although there is evidence that their use may be helpful to women (Matthews et al 2010). Dosages of up to 250 mg four times a day appear to be safe (Vutyavanich et al 2001).

› *Acupressure, acustimulation and acupuncture* — While some evidence from systematic reviews of RCTs (Murphy 1998; Vickers 1996) supports the use of P6 acupressure and it appears to be safe in pregnancy (Smith et al 2000), the evidence on the effectiveness of P6 acupressure, auricular acupressure and acustimulation of the P6 point is inconsistent and limited and there appears to be no significant benefit of acupuncture (P6 or traditional) (Matthews et al 2010).

› *Pyridoxine (vitamin B6)* — There is limited evidence to support the use of pyridoxine (Matthews et al 2010) and concerns about possible toxicity at high doses.

› *Antihistamines* — A meta-analysis of 12 RCTs that compared antihistamines ± pyridoxine with placebo or no treatment found a significant reduction in nausea in the treated group (OR 0.17; 95% CI 0.13–0.21)(Jewell & Young 2001). A systematic review of three RCTs (n=389) found that phenothiazines reduced nausea or vomiting when compared with placebo (relative risk [RR] 0.31; 95% CI 0.24–0.42) (Mazzotta & Magee 2000), although different phenothiazines were grouped and one of the trials recruited women after the first trimester. The bulk of the evidence demonstrates no association between birth defects and phenothiazines (n=2,948; RR 1.03; 95% CI 0.88–1.22)(Mazzotta & Magee 2000; Attard et al 2002).

› Other pharmacological treatments — Antiemetic medicines are more likely to have a place in treatment of severe symptoms and the intractable nausea and vomiting of Hyperemesis gravidarum than in the relief of mild or moderate nausea and vomiting (Matthews et al 2010).

It is currently not possible to identify with certainty interventions for nausea and vomiting in early pregnancy that are both safe and effective (Matthews et al 2010). As nausea and vomiting mostly resolves within 16 to 20 weeks with no harm to the pregnancy, prescribed treatment in the first trimester is usually not indicated unless the symptoms are severe and debilitating (BMA 2003).

> **Practice point**
>
> k.   Women who experience nausea and vomiting in pregnancy can be advised that, while it may be distressing, it usually resolves spontaneously by 16 to 20 weeks pregnancy and is not generally associated with a poor pregnancy outcome.

Discontinuing iron

Iron supplementation may be an aggravating factor in nausea and vomiting. The systematic review conducted for these Guidelines identified a prospective cohort study (Gill et al 2009) in which 63 of 97 (p =0.001) women with severe nausea qualitatively reported an improvement in symptoms after discontinuing iron-containing antenatal multivitamins. If multivitamins are discontinued, consideration should be given to ensuring folate and iodine intake remain sufficient.

> **Practice point**
>
> l.   Discontinuing iron-containing multivitamins for the period that women have symptoms of nausea and vomiting may improve symptoms.

Oral health

Nausea and vomiting have the potential to affect oral health and women should be given advice on how to minimise these effects (see Section 10.5).

7.8.3. Practice summary — managing nausea and vomiting

When — At the first contact with all women and at subsequent contacts for women who report nausea and vomiting
Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker; dietitian; pharmacist

› **Inform women that nausea and vomiting is not associated with adverse effects** — Explain that nausea and vomiting is common in pregnancy, is not necessarily confined to the morning and is likely to lessen by week 16.

› **Provide lifestyle/diet advice** — Acknowledge that nausea and vomiting affects quality of life, and suggest tips on managing nausea and vomiting, including drinking plenty of fluids, eating little and often during the day, getting plenty of rest and avoiding fatty or spicy food. Avoiding iron-containing multivitamins while nausea and vomiting are present may also help.

› **Discuss non-pharmacological and pharmacological treatments** — If the woman asks about treatments for nausea and vomiting, suggests interventions that may help and are thought to be safe, beginning with non-pharmacological approaches (e.g. travel sickness bands). The saftey and effectiveness of antiemetics should be discussed with women with more severe symptoms who choose to consider medication.

7.8.4. Resources

Health professionals

Arsenault M-Y, Lane CA (2002) *The Management of Nausea and Vomiting of Pregnancy. Clinical Practice Guideline no.120.* Society of Obstetricians and Gynaecologists of Canada. *J Obstet Gynaecol Can* 24(10): 817–23.

Women

RACGP Family Doctor Home Advisor
http://www.racgp.org.au/familyhealth/Nausea_and_vomiting_in_pregnancy_women

SOGC Women's Health Information — http://www.sogc.org/health/pregnancy-nausea_e.asp

7.8.5. References

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Keating A & Chez RA (2002) Ginger syrup as an antiemetic in early pregnancy. *Alt Ther Health Med* 8: 89–91.

King TL & Murphy PA (2009) Evidence-based approaches to managing nausea and vomiting in early pregnancy. *J Midwif Womens Health* 54(6): 430–44.

Klebanoff MA & Mills JL (1986) Is vomiting during pregnancy teratogenic? *Brit Med J* 292: 724–26.

Koch KL & Frissora CL (2003) Nausea and vomiting during pregnancy. *Gastroenterol Clin North Am.* 32: 201–34.

Matthews A, Dowswell T, Haas DM et al (2010) Interventions for nausea and vomiting in early pregnancy. *Cochrane Database of Systematic Reviews* 2010, Issue 9. Art. No.: CD007575. DOI: 10.1002/14651858.CD007575.pub2.

Mazzotta P & Magee LA (2000) A risk–benefit assessment of pharmacological and nonpharmacological treatments for nausea and vomiting of pregnancy. *Drugs* 59: 781–800.

Murphy PA (1998) Alternative therapies for nausea and vomiting of pregnancy. *Obstet Gynecol* 91: 149–55.

Smith C, Crowther C, Beilby J et al (2000) The impact of nausea and vomiting on women: a burden of early pregnancy. *Aust NZ J Obstet Gynaecol* 40: 397–401.

Vickers AJ (1996) Can acupuncture have specific effects on health? A systematic review of acupuncture antiemesis trials. *J Royal Soc Med* 89: 303–11.

Vutyavanich T, Kraisarin T, Ruangsri R (2001) Ginger for nausea and vomiting in pregnancy: randomized, double-masked, placebo controlled trial. *Obstet Gynecol* 97: 577–82.

Weigel RM & Weigel MM (1989) Nausea and vomiting of early pregnancy and pregnancy outcome. A meta-analytical review. *Brit J Obstet Gynaecol* 96: 1312–18.

Whitehead SA, Andrews PL, Chamberlain GV (1992) Characterisation of nausea and vomiting in early pregnancy: a survey of 1000 women. *J Obstet Gynaecol* 12: 364–69.

7.9. Constipation

Constipation is a common gastrointestinal symptom in pregnancy, particularly in the first trimester. Guidance about increasing dietary fibre and appropriate use of laxatives may assist women to treat constipation and reduce the risk of further episodes.

7.9.1. Background

Constipation is the delay in the passage of food residue, associated with painful defecation and abdominal discomfort. Rising levels of progesterone in pregnancy can cause a reduction in gastric motility and increased gastric transit time. Poor dietary fibre intake can contribute to constipation during pregnancy, as at any time of life. Iron supplementation, common during pregnancy, is also associated with constipation (Bradley et al 2007). In Aboriginal and Torres Strait Islander communities with a high prevalence of anaemia, iron supplementation is common.

Constipation is generally defined by Rome II criteria — the presence of at least two of the following symptoms for at least one in four defecations: straining, lumpy or hard stools, sensation of incomplete evacuation, sensation of anorectal obstruction, manual manoeuvres to facilitate defecation, and fewer than three defecations per week.

Prevalence of constipation in pregnancy

Constipation is a commonly reported condition during pregnancy that appears to decrease as the pregnancy progresses.

› A case series study (Meyer et al 1994) found that 39% of pregnant women reported symptoms of constipation at 14 weeks, 30% at 28 weeks and 20% at 36 weeks; this study may have resulted in overestimates, as routine iron supplementation was recommended for all pregnant women in the United Kingdom at the time the study was conducted.

› Later studies have found that constipation affects up to 25% of women during pregnancy:

  – a prospective case series study (Bradley et al 2007) found prevalence rates of 24% (95% CI 16–33%), 26% (95% CI 17–38%), 16% (95% CI 8–26%) in the first, second, and third trimesters, respectively. In multivariable longitudinal analysis, iron supplements (OR 3.5; 95% CI 1.04–12.10) and past constipation treatment (OR 3.58; 95% CI 1.50–8.57) were associated with constipation during pregnancy; and

  – a correlational study (Ponce et al 2008) found prevalence rates of 29.6%, 19% and 21.8% in the first, second and third trimesters respectively. This study also reported laxative use among pregnant women as 11% (95% CI 7–16), 15% (95% CI 10–21) and 13.5% (95% CI 8–19) in the first, second and third trimesters.

7.9.2.   Guidance on managing constipation

The first-line treatment for constipation is increasing dietary fibre and fluid intake. Dietary fibre intake can be improved by eating more wholegrain foods, fruit and vegetables, or through wheat or bran fibre supplementation. Where fibre supplementation does not alleviate symptoms, laxatives (stimulant, bulk-forming or osmotic) may be helpful in the short-term, although they can cause adverse side effects such as abdominal pain and diarrhoea.

Summary of the evidence

Findings are consistent across the NICE guidelines and the systematic review conducted to inform these Guidelines.

› *Increasing fluid intake* — while there are no RCTs or cohort studies in this area, there is some evidence to suggest that dietary factors such as water intake may play a role in preventing, or alleviating, bowel habit perturbations during and after pregnancy (Derbyshire et al 2006). In spite of the lack of high-level evidence, increased fluid intake should be recommended as one of the first measures to relieve constipation in pregnancy. Increasing fluid intake is not expensive, is readily available and has several other beneficial effects during pregnancy (Vasquez 2008).

› *Dietary fibre supplementation* — Evidence from a Cochrane review (Jewell & Young 2009) based on two RCTs (n = 215) supports the effectiveness of fibre supplementation in safely treating constipation in pregnancy. Fibre supplements were found to increase the frequency of defecation (OR: 0.18; 95% CI 0.05–0.67), lead to softer stools and appear to have no adverse effects.

› *Laxatives* — The same Cochrane review (Jewell & Young 2009) found that when discomfort was not alleviated by fibre supplementation, stimulant laxatives were more effective than bulk-forming laxatives (Peto OR 0.30; 95% CI 0.14–0.61), although stimulants were associated with significantly more abdominal pain and diarrhoea. Preliminary evidence indicates that osmotic laxatives (eg polyethylene glycol or PEG) are effective and well tolerated during pregnancy (Neri et al 2004) but currently there is insufficient evidence about potential effects on the fetus (Vasquez 2008).

Recommendation	Grade C
9. Offer women who are experiencing constipation information about increasing dietary fibre intake and taking bran or wheat fibre supplementation.	

Recommendation	Grade C
10. Advise women who choose to take laxatives that preparations that stimulate the bowel are more effective than those that add bulk but may cause more adverse effects such as diarrhoea and abdominal pain.	

7.9.3.   Practice summary — managing constipation

When — At the first contact with all women and at subsequent contacts for women who report symptoms of constipation
Who — Midwife; maternal and child health nurse; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; , multicultural health worker; practice nurse; allied health professional; pharmacist

› **Advise about fluid intake** — Drinking more fluids has a range of benefits and may assist in easing constipation. Water is a good source of fluids as it hydrates without adding additional energy to the diet. Other drinks such as milks and fruit juices add variety and nutrients. Intake of fluids containing added sugars should be moderated.

› **Talk about dietary fibre** — Advise all women to eat a wide variety of nutritious foods, including plenty of vegetables, fruit, wholegrain cereals and breads, nuts, seeds and legumes. Bran or wheat fibre supplementation is safe and effective during pregnancy and may relieve symptoms. Fibre supplements should be introduced slowly and plenty of water consumed while they are being taken.

› **Discuss laxative use** — Laxatives can be used to relieve symptoms but should not be used long-term. Bulk-forming laxatives may cause fewer side effects than stimulant laxatives.

7.9.4.   Resources

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7.9.5.   References

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Meyer LC, Peacock JL, Bland JM et al (1994) Symptoms and health problems in pregnancy: their association with social factors, smoking, alcohol, caffeine and attitude to pregnancy. *Paediatr Perinatal Epidemiol* 8: 145–55.

Neri I, Blasi I, Castro P et al (2004) Polyethylene glycol electrolyte solution (Isocolan) for constipation during pregnancy: an observational open-label study. *J Midwifery Womens Health* 49(4): 355–58.

Ponce J, Martinez B, Fernandez A et al (2008) Constipation during pregnancy: a longitudinal survey based on self-reported symptoms and the Rome II criteria. *Eur J Gastroenterol Hepatol* 20(1): 56–61.

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8. Maternal health screening

This section discusses the evidence for offering women tests during the first trimester.[9] Discussion is included about tests for human immunodeficiency virus (HIV), chlamydia, syphilis, rubella, hepatitis B, hepatitis C, asymptomatic bacteriuria, bacterial vaginosis and vitamin D deficiency. Recommendations are based on evidence about the diagnostic accuracy of available tests, the effectiveness of interventions to prevent mother-to-child transmission of infection or other effects on the unborn baby, and the availability of treatments to improve the health and wellbeing of the mother. For some conditions, testing is recommended for all women. For others, testing is only recommended for women who may be at higher risk.

For notifiable infections (HIV, hepatitis B, hepatitis C, rubella, syphilis, chlamydia), diagnoses are reported to the National Notifiable Diseases Surveillance System (NNDSS) and analysis of trends in jurisdictions and groups at risk is possible (although data quality varies for the different conditions and reporting of Indigenous status is incomplete in some States and for some conditions). Evidence on the prevalence and incidence of other conditions is generally from observational studies and may not be representative of the Australian population or groups within the population. While incidence or prevalence data are not always available, each chapter includes a brief discussion that aims to give health professionals an understanding of the likelihood that women in their community will be affected.

Considerations before testing

Before tests are carried out, it is essential that:

› women are informed that it is their choice to have tests;

› women are able to give informed consent — verbal discussion should cover the harms and benefits of testing and associated treatments and be supported by appropriate resources (eg written materials, audio or video);

› women have opportunities to ask questions about tests and treatments;

› women are reassured that test results remain confidential;

› discussions about consent are documented by the health professional involved;

› women who decline testing are offered the opportunity to discuss any concerns they may have without being coerced to reconsider the test; and

› there are processes for follow-up of women with a positive test result and their babies.

Considerations after a positive test result

› *Referral for specialist care* — For some conditions, such as HIV and hepatitis C, specialist involvement will be required.

› *Psychosocial support* — Receiving a diagnosis of a condition that may affect pregnancy and/or the health of the unborn baby can be distressing, particularly if there are no interventions that can change outcomes. Women should be given information about available supports and assisted to access these.

› *Sexually transmitted infections* — Partner testing and contact tracing are additional considerations.

› *Blood-borne infections* — Specific supports are likely to be required for women identified as using intravenous drugs.

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9 Systematic literature reviews were not conducted for all tests offered as part of antenatal care. Table 6.1 (page 37) outlines tests that should be offered at the first antenatal visit based on the systematic reviews, guidance from NICE (2008) and relevant Australian guidelines.

Testing in rural and remote areas

It is acknowledged that in Australia access to tests may vary (eg due to distance from pathology services), storing tests and samples appropriately may be challenging (eg due to high temperatures or humidity) and there may be difficulties in recalling women to receive test results. In these situations, resources should be focussed on responding to identified local needs (eg ensuring that tests are available to identify conditions that are highly prevalent).

Table 8.1:   Summary of advice on offering certain tests in the first trimester[10]

Screening offered to all woman

Condition	Test(s)	Follow-up*
HIV	EIA and Western blot Blood-based rapid tests	Antiretroviral treatment in pregnancy reduces risk of transmission Specialist care and psychosocial support for the woman are required
Hepatitis B	Blood test for HbsAg	Vaccination of newborn reduces risk of infection Specialist care and psychosocial support for the woman are required
Rubella	Blood test for rubella antibody	Vaccination after birth protects future pregnancies Inadvertent vaccination in early pregnancy is highly unlikely to harm the baby
Syphilis	Treponemal EIA tests Onsite tests	Treatment benefits mother and prevents congenital syphilis Psychosocial support, partner testing and contact tracing required
Asymptomatic bacteriuria	Midstream urine culture	Treatment reduces risk of pyelonephritis

10 Screening tests are offered in the context of engagement and consultation with women.
     When conducting screening tests, health professionals must use standard precautions for infection prevention and control.

Screening offered to woman at higher risk

Condition	Offer test to:	Test(s)	Follow-up*
Hepatitis C	Women with a history of: • Intravenous drug use • Tattoos or body piercing • Needle sharing • Incarceration • Receipt of blood products or invasive procedures overseas or before 1990 in Australia	Blood test for hepatitis antibody RNA test if antibodies detected	No interventions available to prevent transmission Specialist care and psychosocial support for the woman are required
Chlamydia	Women younger than 25 yrs All pregnant women in areas of high prevalence	First pass urine Antigen detection test Nucleic acid amplification test	Treatment may reduce the risk of preterm birth, premature rupture of the membranes and low birth weight Psychosocial support, partner testing and contact tracing required
Asymptomatic bacterial vaginosis	Women with a previous preterm birth	High vaginal swab Amsel's criteria Nugent's criteria	Early treatment (<20wks) may reduce risk of premature rupture of the membranes and low birth weight
Vitamin D deficiency	Women considered to be at risk	Blood test for serum 25-OHD	Supplementation may be beneficial for women at high risk of deficiency

Notes: * Considerations for follow-up and support of women with a positive test result are included on page 99.
EIA=enzyme immunoassay; HbsAg=hepatitis B surface antigen; 25-OHD=25-hydroxyvitamin D; RNA=ribonucleic acid

8.1. HIV

Screening for HIV in pregnancy enables measures to be taken to reduce the risk of mother-to-child transmission and for the woman to be offered treatment and psychosocial support.

8.1.1. Background

Human immunodeficiency virus (HIV) is a blood-borne infection that is initially asymptomatic but involves gradual compromise of immune function, eventually leading to acquired immunodeficiency syndrome (AIDS). The time between HIV infection and development of AIDS ranges from a few months to as long as 17 years in untreated patients (PHLS 1998). Undiagnosed HIV infection during pregnancy has serious implications for the health of both the woman and her child. Early HIV diagnosis can reduce the risk of mother-to-child transmission and the rate of disease progression in the mother (NICE 2008).

HIV in Australia

› *Rates of diagnosis of HIV* — Over the period 2006–2009, new HIV diagnoses in Australia remained relatively stable at around 1,000 a year (NCHECR 2010a). The rate of HIV diagnosis was considerably higher in men (86.7%) (NCHECR 2010a). The population rate of diagnosis was similar for Aboriginal and Torres Strait Islander and non-Indigenous populations, with a rate of 4 and 5 per 100,000, respectively (NCHECR 2010b). However, among Aboriginal and Torres Strait Islander peoples a higher proportion of infections was attributed to injecting drug use (20% vs 3% for non-Indigenous) and a higher proportion of infections was among women (25.5% vs 7.3% for non-Indigenous) (NCHECR 2010b).

› *Geographical distribution* — Trends in new diagnoses differ across jurisdictions, with rates in NSW, WA, Tasmania and the ACT remaining relatively stable and increases in Queensland, SA, NT and Victoria (NCHECR 2010a). In 2009, the rate of HIV diagnosis was highest among people resident in major cities in both the Aboriginal and Torres Strait Islander population and the non-Indigenous population (NCHECR 2010b). The rate of HIV diagnosis in the Aboriginal and Torres Strait Islander population was 10 per 100,000 in major cities compared to 1 per 100,000 in very remote areas.

› *Country of origin* — Rates of HIV diagnosis among people from other regions of birth have increased, with at least a doubling of rates among people born in sub-Saharan Africa, Asia, South/Central America and the Caribbean, and Oceania (other than Australia) (NCHECR 2010a).

› *Risk factors* — Recognised risk factors include having a history of intravenous drug taking or sexual partners who have injected drugs or have HIV, and/or residence in a country where HIV is endemic (Brocklehurst 2000).

› *Perinatal exposure* — In Australia, identified perinatal HIV exposure has risen from 2.3 per 100,000 live births in 1982–86 (McDonald et al 2009) to 12.3 per 100,000 live births in 2008–09 (NCHECR 2010a).

Risks associated with HIV infection in pregnancy

Globally, the vast majority of children with AIDS acquire infection as a result of mother-to-child transmission during pregnancy, during birth or through breastfeeding (Volmink et al 2007). Maternal viral load is a strong independent determinant of transmission risk (Khouri et al 1995; Mofenson 1995; John & Kreiss 1996; Warszawski et al 2008).

In developed countries the rate of mother-to-child transmission is 14–25% (Branson et al 2006). In Australia, the mother-to-child transmission rate among children whose mothers were diagnosed antenatally has declined significantly, from 25% in 1987–1990 to 5% in 2003–2006 (McDonald et al 2009). The rate declined from 8% in 1987–1998 to 1% in 1999–2006 among children whose mother used at least two interventions. Mother-to-child transmission remained high among children born to women diagnosed postnatally (50%) and women diagnosed antenatally who used no interventions.

8.1.2.   Screening for HIV infection in pregnancy

Summary of the evidence

Universal screening for HIV in pregnancy is recommended in the United Kingdom (de Ruiter et al 2008; NICE 2008; RCOG 2010), the United States (Branson et al 2006) and Canada (SOGC 2006; CPS 2008). The Australian Department of Health and Ageing also recommends that all women be routinely offered HIV screening in the first trimester (DoHA 2006). These policies are based on the availability of accurate diagnostic tests and effectiveness of antiretroviral treatment in preventing mother-to-child transmission. They also reflect the fact that screening based on risk factors would miss a substantial proportion of women with HIV (Chou et al 2005).

Diagnostic accuracy of tests

Tests for HIV diagnosis in pregnant women include:

› standard tests — the enzyme immunoassay and Western blot protocol is highly (>99%) sensitive and specific (Samson & King 1998; Butlerys et al 2004; Chou et al 2005; Chappel et al 2009); and

› rapid HIV tests,[11] which have similar accuracy (Butlerys et al 2004; Chou et al 2005) and provide results within hours without requiring a return visit (Tepper et al 2009), with blood-based tests having greater sensitivity than tests using oral fluids (Pai et al 2007).

The sensitivities and specificities of various commercial HIV screening assays can be found at the Therapeutic Goods Administration website: www.tga.gov.au

Interventions to prevent mother-to-child transmission

Cochrane reviews into the effectiveness of interventions in preventing mother-to-child transmission have found that:

› short courses of certain antiretroviral medicines are effective and are not associated with any safety concerns in the short term (Volmink et al 2007);

› caesarean section before labour and before ruptured membranes is effective among women with HIV not taking antiretrovirals or taking only zidovudine (Read & Newell 2005);

› vitamin A supplementation is not effective in preventing transmission (Wiysonge et al 2011);

› there is no evidence of an effect of vaginal disinfection (Wiysonge et al 2005);

› complete avoidance of breastfeeding is effective in preventing mother-to-child transmission of HIV (Horvath et al 2009); and

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11 The use of these tests is not widespread in Australia and remains controversial.

› if breastfeeding is initiated, the combination of exclusive breastfeeding during the first few months of life and extended antiretroviral prophylaxis to the infant is effective (Horvath et al 2009).

Prospective cohort studies and meta-analyses have not found a significant association between antiretroviral treatments and intrauterine growth restriction (n=8,192) (Briand et al 2009), congenital abnormalities (n=8,576)(Townsend et al 2009), or preterm birth (n=20,426)(Kourtis et al 2007).

Recommended interventions appear to be acceptable to pregnant women and are associated with mother-to-child transmission rates of 1% to 2% (Chou et al 2005). In Australia between 1982 and 2005, uptake of interventions to reduce mother-to-child transmission of HIV was high (Giles et al 2008).

Recommendation	Grade B
11. Routinely offer and recommend HIV testing at the first antenatal visit as effective interventions are available to reduce the risk of mother-to-child transmission.	

Practice point
m. A system of clear referral paths ensures that pregnant women who are diagnosed with an HIV infection are managed and treated by the appropriate specialist teams.

Pre-test and post-test discussions

Pre- and post-test discussions are an integral part of HIV testing.

Considerations before testing

Providing information and support associated with testing aims to minimise the personal and social impact of HIV infection (DoHA 2006). The Australian Department of Health and Ageing HIV testing guidelines recommend that (DoHA 2006):

› antenatal testing only be performed with the informed consent of the woman;

› all women contemplating pregnancy or seeking antenatal care be made aware of the benefits of diagnosis of HIV infection and management, and prevention strategies available for both the mother and the baby;

› women receive materials (in written and other formats) outlining the tests that will be offered antenatally and explaining the testing procedure;

› women with limited literacy or for whom English is a second language receive appropriate educational resources (eg using media such as video, audio, multimedia or in languages other than English); and

› women with a first language other than English be offered access to accredited interpreting services.

Women most at risk of HIV may decline screening (Boxhall 2004; Plitt 2007) or may not access screening and available interventions (Ferguson et al 2008; Struik 2008). Women who decline testing should be given opportunities to discuss any concerns.

Considerations after testing

› Women who accept testing may experience anxiety while waiting for the initial test result or while waiting for results of repeat testing.

› Unexpected detection of HIV can result in distress, which is exacerbated in the context of pregnancy. Health professionals delivering the test result should use their best judgement when deciding the most appropriate way to deliver the test result (DoHA 2006).

Screening in rural and remote areas

Rapid tests improve the availability of HIV testing in situations where there is limited access to pathology services and returning for results may be difficult (DoHA 2006). However, the use of these tests should be limited to situations where (DoHA 2006):

› testing is conducted in, or backed up by, a clinical setting;

› testing is conducted under the auspice of a National Association of Testing Authorities/Royal College of Pathologists of Australia medical testing accredited laboratory;

› reliable Therapeutic Goods Administration approved rapid tests are available;

› high quality information on the tests and their use is available and provided;

› the health professional performing the test is suitably trained in conducting and interpreting the test and has the skills to provide pre and post-test information/discussion (if conducted outside an accredited laboratory); and

› quality assurance programs are available to ensure ongoing competency of healthcare professionals performing the tests.

Considerations beyond the first trimester

› Rapid HIV testing[12] of women who are late in antenatal booking or who present in labour with undocumented HIV status.

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12 The use of these tests is not widespread in Australia and remains controversial.

8.1.3.   Practice summary — HIV screening

When — Early in antenatal care
Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker

› **Discuss HIV screening** — Explain that it is important to find out whether a woman has HIV because of the risk of transmission to the baby. Testing also gives the woman the opportunity to receive appropriate treatments.

› **Document and follow-up** — Note the results of HIV screening in the woman's record and have a follow-up system in place so women who have HIV have access to counselling to discuss the test results and available interventions to prevent transmission during pregnancy.

› **Take a holistic approach** — If a woman is found to have HIV, specialist advice on management is required. Other considerations include psychosocial support, contact tracing, partner testing, testing for other sexually transmitted infections and continuing follow-up.

8.1.4.   Resources

DoHA (2006) National HIV Testing Policy 2006. Canberra: Australian Government Department of Health and Ageing. http://www.health.gov.au/internet/main/publishing.nsf/Content/096241E4779437F5CA257841001EF1C9/$File/hiv-testing-policy-2006.pdf

RCOG (2010) Green Top Guideline no 39 Management of HIV in Pregnancy. London: Royal College of Obstetricians and Gynaecologists. http://www.rcpch.ac.uk/sites/default/files/asset_library/Research/Clinical%20Effectiveness/Supported%20Guidelines/Full%20guidelineX.pdf

8.1.5.   References

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8.2. Hepatitis B

Screening in pregnancy allows arrangements to be made for vaccinating the newborn if the mother is found to have hepatitis B.

8.2.1. Background

Hepatitis B virus is a global acute and chronic communicable disease that causes major hepatic disease (Beasley & Hwang 1984). The virus has an incubation period of 6 weeks to 6 months and is excreted in various body fluids including blood, saliva, vaginal fluid and breast milk. These fluids may be highly infectious. Adults who have hepatitis B may have no symptoms. After infection, some people do not clear the virus; they become carriers and may infect other people.

Hepatitis B in Australia

› *Rates of diagnosis of hepatitis B* — Of 238 diagnoses of newly acquired hepatitis B in 2009, 6% were among Aboriginal and Torres Strait Islander people, 83% among non-Indigenous people and Indigenous status was not recorded for 11% (NCHECR 2010). The population rates of diagnosis for the non-Indigenous and Aboriginal and Torres Strait Islander populations were 1 and 3 per 100,000, respectively (NCHECR 2010).

› *Geographical distribution* — In 2005–09, the rate of diagnosis of newly acquired hepatitis B infection remained low in all States and Territories. In NSW, Victoria, Queensland and WA, newly acquired hepatitis B infection was diagnosed among Aboriginal and Torres Strait Islander people at between one and seven times the rate in the non-Indigenous population; the rate of diagnosis was highest in outer regional areas (4 per 100,000) compared to remote areas (1 per 100,000)(NCHECR 2010).

› *Country of origin* — The prevalence of hepatitis B carriage varies between and within countries (NHMRC 2009). Carrier rates vary from 0.1–0.2% among Caucasians in the United States, northern Europe and Australia, 1–5% in the Mediterranean countries, parts of eastern Europe, China, Africa, Central and South America, and greater than 10% in many sub-Saharan African, south-east Asian and Pacific island populations (Mast et al 2004; Wood et al 2005; Clements et al 2006). First-generation immigrants usually retain the carrier rate of their country of origin, but subsequent generations show a declining carrier rate irrespective of vaccination (Mast et al 2004).

› *Risk factors* — Routes of transmission of hepatitis B virus include sharing injecting equipment (such as occurs in injecting drug use), needle-stick injury and sexual contact (NHMRC 2009). Based on reported cases, hepatitis B transmission in Australia in 2009 continued to occur predominantly among people with a recent history of injecting drug use (NCHECR 2010).

› *Hepatitis B in pregnancy* — A retrospective cohort study (n=14,857) found around 2% of women to HbsAg positive (Guirgis et al 2009). A prevalence study in the NT found 3.7% of Aboriginal and Torres Strait Islander women and 0.98% of non-Indigenous women to be HbsAg positive (Schultz et al 2008).

Risks associated with hepatitis B in pregnancy

Mother-to-child transmission occurs frequently either in the uterus, through placental leakage, or through exposure to blood or blood-contaminated fluids at or around the time of birth (Lee et al 2006). Perinatal transmission is believed to account for 35–50% of hepatitis B carriers (Yao 1996).

The risk of perinatal transmission is associated with the hepatitis B envelope antigen (HbeAg) status of the mother. If a woman is both hepatitis surface antigen (HbsAg) and HbeAg positive, 70–90% of her children will develop hepatitis B (Stevens et al 1975; Akhter et al 1992). If the mother is HbsAg positive but HbeAg negative, the risk is reduced (Okada et al 1976; Beasley et al 1977; Beasley et al 1983; Nayak et al 1987; Aggarwal & Ranjan 2004). In a cohort study of HbsAg-positive, hepatitis B DNA-positive women in Sydney (n=313) (Wiseman et al 2009), transmission rates were 3% among hepatitis B DNA-positive women overall, 7% among HbeAg-positive mothers and 9% among women with very high hepatitis B DNA levels.

It has been estimated that people who are chronic carriers of HbsAg are 22 times more likely to die from hepatocellular carcinoma or cirrhosis than noncarriers (95% CI 11.5–43.2) (Beasley & Hwang 1984).

8.2.2. Screening for hepatitis B infection in pregnancy

Summary of the evidence

Screening of all pregnant women for hepatitis B is recommended in the United Kingdom (NICE 2008) and the United States (Mast et al 2005; Lin & Vickery 2009; USPSTF 2009). The *Australian Immunisation Handbook*, while making recommendations on vaccination rather than screening, notes that routine antenatal screening for hepatitis B (ATAGI 2009):

› is essential for preventing babies from becoming carriers of hepatitis B; and

› enables appropriate follow-up and management of the woman, identification of the immune status of other household members, and protection of those who are susceptible.

Screening of all women is supported by the findings of observational studies into selective screening:

› screening using risk factors to identify 'high-risk' women for HbsAg would miss about half of all pregnant women with HbsAg infection (Summers et al 1987);

› of women offered examination for hepatitis B at 18 weeks pregnancy (n=4,098), one third of women at risk of hepatitis B were not identified by selective screening (Jensen et al 2003); and

› universal screening resulted in an estimated detection of 50 additional pregnant women carrying hepatitis B each year who would not have been detected through selective screening (Cowan et al 2006).

A recent systematic review (Lin & Vickery 2009) found no new evidence on the benefits or harms of testing for hepatitis B infection in pregnant women.

Recommendation	Grade A
12. Routinely offer and recommend hepatitis B virus testing at the first antenatal visit as effective postnatal intervention can reduce the risk of mother-to-child transmission.	

Testing method

Testing of blood samples is the accepted standard for antenatal detection of hepatitis B virus (NICE 2008) and consists of stages (Balmer et al 2000) – testing for HbsAg and confirmatory testing with a new sample upon a positive result.

Considerations beyond the first trimester

› Mother-to-child transmission of the hepatitis B virus is approximately 95% preventable by administering vaccine and hepatitis B immunoglobulin to the baby at birth (Beasley et al 1983; Nair et al 1984; Wong et al 1984; Lo et al 1985; Xu et al 1985; Sehgal et al et al 1992; Zhu 1997; Lee et al 2006).

› While a meta-analysis (n=5,900) found that multiple hepatitis B immunisation injections in women with a high degree of infectiousness in late pregnancy reduced rates of intrauterine transmission (Shi et al 2010), all studies included were carried out in China and the findings may not be applicable in the Australian context.

› For women with high viral loads (>log 7 IU/ml), discussion with a hepatologist and maternal antiviral treatment in the third trimester are considerations.

8.2.3. Practice summary — hepatitis B screening

When — Early in antenatal care
Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker

› **Discuss hepatitis B screening** — Explain that it is important to find out whether a woman has or is carrying hepatitis B because of the risk to the baby.

› **Document and follow-up** — Note the results of hepatitis B screening in the woman's record and have a follow-up system in place so that the babies of women who are found to have hepatitis B are vaccinated on the day of birth.

› **Take a holistic approach** — If a woman is found to have or be a carrier of hepatitis B, other considerations include counselling, contact tracing, partner testing, testing for other sexually transmitted infections and continuing follow-up. Consider screening other children, depending on circumstances.

8.2.4. Resources

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8.3. Hepatitis C

As there is currently no way of preventing mother-to-baby transmission of hepatitis C or treating the virus during pregnancy, the benefits of screening are doubtful.

8.3.1. Background

Hepatitis C is a blood-borne virus that is one of the major causes of liver cirrhosis, hepatocellular carcinoma and liver failure (Pembrey et al 2000). Perinatal transmission is the main source of hepatitis C in Australian children, with babies with hepatitis C mostly born to mothers who used intravenous drugs, had invasive procedures overseas or have tattoos (Ridley et al 2009). Currently, there are no specific interventions known to decrease perinatal transmission (CPS 2008; McIntyre et al 2010).

Hepatitis C in Australia

› *Rates of diagnosis of hepatitis C* — Of 11,486 diagnoses of newly acquired hepatitis C in 2009, 5% were among Aboriginal and Torres Strait Islander people, 32% among non-Indigenous people and Indigenous status was not recorded for 63% (NCHECR 2010a). Diagnoses among Aboriginal and Torres Strait Islander people comprised almost 5% of all diagnoses where Indigenous status was reported. Among women, rates of diagnosis were highest in the 20–29 year age group, with Aboriginal and Torres Strait Islander women diagnosed at four times the rate of non-Indigenous women (NCHECR 2010a). From 2005 to 2009, the rate of newly diagnosed hepatitis C in the Aboriginal and Torres Strait Islander population increased (from 120 to 131 per 100,000), while the rate in the non-Indigenous population decreased (from 46 to 44 per 100,000 (NCHECR 2010a).

› *Prevalence in pregnancy* — Prevalence among pregnant women without risk factors is the same as that among the general population (DoHA 2007).

› *Geographical distribution* — In 2005–2009, rates of diagnosis of newly acquired hepatitis C remained relatively stable in SA, WA and Victoria, decreased in NSW, the NT and Queensland and increased in ACT and Tasmania (NCHECR 2010b). While the rate among Aboriginal and Torres Strait Islander people in the NT was lower than in the non-Indigenous population, it is increasing (NCHECR 2010a). In SA, WA and NT, rates of diagnosis among Aboriginal and Torres Strait Islander people decreased in major cities, remained stable or decreased in outer regional, remote and very remote communities but almost doubled in inner regional areas (NCHECR 2010a).

› *Incarceration* — Imprisonment has been shown to be an independent risk factor for hepatitis C transmission. Hepatitis C prevalence for all prisoners is estimated at 30–40% and higher for women (DoHA 2007). Aboriginal and Torres Strait Islander peoples are 12 times more likely to be incarcerated than non-Indigenous Australians (ABS 2005).

› *Country of origin* — Regions of high hepatitis C prevalence (>1.0%) include south-east Asia, the Middle East, southern and eastern Europe, and parts of South America and Africa (Pawlotsky et al 1995; Frank et al 2000; RACGP 2003; Caruana et al 2005).

› *Routes of transmission of hepatitis C virus* — These include sharing injecting equipment (such as occurs in injecting drug use), tattooing and piercing, needle-stick injury and blood transfusion (in Australia, if transfusion occurred before 1990) (RACGP 2003). Based on reported diagnoses, hepatitis C transmission in

Australia predominantly occurs among people with a history of injecting drug use (NCHECR 2010a).

Risks associated with hepatitis C in pregnancy

Around 4–6% of babies born to women who are positive for both hepatitis C antibody and hepatitis C RNA during pregnancy will acquire hepatitis C (Conte et al 2000; Di Domenico et al 2006; Hardikar et al 2006; McMenamin et al 2008). Although there is consistent evidence that the risk of mother-to-child transmission of hepatitis C increases with increasing maternal viral load (Okamoto et al 2000; Tajiri et al 2001; Pembrey et al 2003), no threshold level for transmission has been identified. The risk of transmission is increased if the mother also has HIV (Pembrey et al 2003; Hardikar et al 2006).

An association between maternal hepatitis C positive status and increased risk of low birth weight, neonatal intensive care unit admissions and assisted ventilation has been suggested by a cohort study (Pergam et al 2008).

Babies who acquire hepatitis C in *utero* or at birth do not develop clinically apparent liver problems in early childhood, but most develop chronic hepatitis C and are likely to be at risk of longer term problems related to chronic liver disease, including hepatic fibrosis, cirrhosis, and hepatocellular carcinoma (Tovo et al 2000; Resti et al 2003; Rerksuppaphol et al 2004; Liu et al 2009).

8.3.2. Screening for hepatitis C infection in pregnancy

Summary of the evidence

There is limited evidence on screening of pregnant women for hepatitis C and routine testing is advised against in the United Kingdom (NICE 2008), the United States (ACOG 2007) and Canada (CPS 2008). The Australian Department of Health and Ageing advises that routine screening of pregnant women is not a clinically justifiable or cost effective approach (DoHA 2007). Lack of effective treatment options and potential psychological harm of false positive screening results have been cited as reasons not to screen routinely (Pembrey et al 2003; 2005).

Some bodies recommend selective testing for hepatitis C in pregnant woman with identifiable risk factors (ACOG 2007; DoHA 2007; Hepatitis Australia 2007; CPS 2008). However, population-based cohort studies suggest that screening based on risk factors may not identify all women with hepatitis C (Hutchinson et al 2004; Lui et al 2009), particularly if risk factors are not present or women conceal them (Prasad et al 2007). These studies acknowledge that screening of all women is not appropriate while an effective intervention to prevent transmission remains unavailable.

Recommendation	Grade C
13. Do not routinely offer pregnant women hepatitis C testing	

> **Practice point**
>
> n. Hepatitis C testing may be offered to women with identifiable risk factors:
>   › intravenous drug use or needle sharing;
>   › tattooing or body piercing;
>   › incarceration;
>   › receipt of blood products or invasive procedures overseas or before 1990 in Australia; or
>   › country of origin has a high prevalence of hepatitis C.

Planned invasive procedures

Screening 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**
>
> o. Women who are having an invasive procedure (eg chorionic villus sampling, amniocentesis) should be offered screening for hepatitis C before the procedure.

Testing process

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

8.3.3. Practice summary — hepatitis C screening

When — In the antenatal period
Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker

› **Discuss hepatitis C screening with women with identified risk factors** — Explain the association between relevant risk factors and hepatitis C infection and that, as there are no treatments to prevent transmission, follow-up of mother and baby are needed if the mother is found to have hepatitis C.

› **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.

8.3.4. Resources

Ministerial Council on Drug Strategy (2006) *National Clinical Guidelines for the Management of Drug Use During Pregnancy, Birth and the Early Development Years of the Newborn.* Sydney: NSW Health. http://www.health.nsw.gov.au/pubs/2006/pdf/ncg_druguse.pdf

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Websites

Hepatitis C Council of NSW — http://www.hep.org.au/index.php?article=content/home

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Northern Territory AIDS and Hepatitis C Council — http://www.ntahc.org.au/

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8.4. Rubella

Rubella screening in pregnancy does not attempt to identify current affected pregnancies. Instead, it aims to identify women who are non-immune, so that they can be vaccinated after the birth and future pregnancies are protected against rubella infection and its consequences.

8.4.1. Background

Rubella (German measles) is usually a mild self-limiting disease with few complications. However, if contracted during the first trimester, it can affect the pregnancy and lead to congenital rubella syndrome at birth. Preventing congenital infection relies on maintaining high levels of immunity to rubella in the general population. There is no treatment to prevent or reduce mother-to-child transmission of rubella once infection has been detected in pregnancy. Rubella vaccination is contraindicated in pregnancy.

Rubella infection and immunity in Australia

› *Diagnoses of rubella* — In 2008, there were 37 diagnoses of rubella (0.2 per 100,000 population) (NNDSS 2009). The majority were adults, with 83% of the women being of childbearing age (17–47 years).

› *Geographical distribution* — Rates of diagnosis of rubella were low and fairly consistent across jurisdictions in 2008, ranging from no reported diagnoses in the ACT, NT and Tasmania to 0.1 per 100,000 population in Queensland, Victoria and NSW and 0.2 per 100,000 population in SA and WA (NNDSS 2009).

› *Congenital rubella syndrome* — Only two cases of congenital rubella syndrome in babies of Australian-born mothers (Forrest et al 2003; Gidding et al 2003) have been notified since 2000.

› *Risk factors* — In Australia, populations at risk of non-immunity to rubella have been identified as including:

  – women born overseas who may not have received rubella vaccines in their countries of birth (Francis et al 2003; Sathanandan et al 2005) and are twice as likely to be non-immune than Australian-born women, with a higher likelihood of non-immunity among women born in Asia (Sathanandan et al 2005);

  – Aboriginal and Torres Strait Islander women from rural and remote communities, with fewer than 75% of women tested antenatally having adequate levels of immunity (compared with more than 90% of women living in an urban area) (Hunt & Lumley 2004); and

  – women 35 years of age or older, who were found to be twice as likely to be non-immune as younger women, possibly due to declining immunity over time (Sathanandan et al 2005).

Risks associated with rubella infection in pregnancy

Maternal rubella infection can result in spontaneous miscarriage, fetal infection, stillbirth, or fetal growth restriction (Reef et al 2000). Congenital infection is most likely if the maternal infection occurs in the first 16 weeks of pregnancy, with congenital rubella syndrome occurring in all fetuses infected before the 11th week and in 35% of those infected at 13–16 weeks (Miller et al 1982). If infection occurs after 16 weeks of pregnancy, the risk of fetal damage is negligible.

Features of congenital rubella syndrome include cardiac defects, deafness, ocular defects, thrombocytopenic purpura, haemolytic anaemia, enlarged liver and spleen, and inflammation of the meninges and brain (Sanchez et al 2010). Pneumonitis, diabetes, thyroid dysfunction and progressive panencephalitis are other late expressions of the syndrome (Weil et al 1975; Cooper et al 1995).

8.4.2.   Screening for rubella non-immunity

Summary of the evidence

The NICE guidelines reviewed the evidence on rubella screening in pregnancy and found:

› high sensitivity and specificity of tests for immunity (Grangeot-Keros & Enders 1997);

› high rates of congenital infection among babies born to women with symptoms of rubella in the first 12–16 weeks of pregnancy (Miller et al 1982; Grillner et al 1983); and

› no association between congenital infections and inadvertent rubella vaccination in pregnancy (CDC 2001).

The lack of association between inadvertent vaccination in pregnancy and congenital rubella syndrome has been substantiated in subsequent prospective cohort studies (Bar-Oz et al 2004; Hamkar et al 2006; Badilla et al 2007), with no cases reported.

Recommendation	Grade B
14. Routinely offer and recommend testing for rubella immunity at the first antenatal visit to identify women at risk of contracting rubella and enable postnatal vaccination to protect future pregnancies.	

Recommendation	Grade A
15. Inform women who have been vaccinated against rubella before they were aware of the pregnancy that the baby is highly unlikely to have been affected by the vaccine.	

Practice point
p. Women identified as non-immune to rubella antenatally should be advised to avoid contact with people experiencing possible symptoms of rubella.

8.4.3.   Practice summary — rubella screening

When — Early in antenatal care
Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker

› **Discuss rubella non-immunity** — Explain that it is important to find out whether a woman is immune to rubella because of the effects that infection can have on the pregnancy and the baby.

› **Document and follow-up** — Note the results of rubella screening in the woman's record. Have a follow-up system in place so that non-immune women are offered vaccination after the birth. Some women may not develop immunity even after repeated vaccination.

› **Take a holistic approach** — If a woman is found to be non-immune to rubella, offer advice on symptoms and transmission of rubella so that she can avoid contact as far as possible. Advise vaccination of family members who may also be non-immune.

› **Report inadvertent vaccination** — Report inadvertent vaccination with MMR (or MMRV) to the jurisdictional immunisation unit to enable follow-up and collection of data on adverse events following immunisation with this vaccine during pregnancy.

8.4.4.   Resources

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8.5. Chlamydia

Chlamydia is a common sexually transmitted infection that can cause long-term complications and, in pregnancy, may cause adverse maternal and neonatal outcomes. Antenatal care provides opportunities for testing women from population groups with a high prevalence of the infection.

8.5.1. Background

Chlamydia is caused by the bacterium *Chlamydia trachomatis*. Genital chlamydial infection remains asymptomatic in at least 70% of women and the majority of infections probably clear spontaneously without morbidity (Geisler et al 2008; Rogers et al 2008). Complications that may arise for women include chronic pelvic pain, pelvic inflammatory disease, infertility and ectopic pregnancy.

Prevalence of chlamydia

› *Rates of diagnosis of chlamydia* — Chlamydia is the most common bacterial sexually transmitted infection in developed countries and the most frequently reported notifiable diagnosis in Australia, with over 62,000 diagnoses in 2009 (AIHW 2010). The rate of diagnosis of chlamydia continues to rise in both the non-Indigenous and Aboriginal and Torres Strait Islander populations, with increases between 2005 and 2009 of 59% and 10%, respectively (NCHECR 2010).

› *Geographical distribution* — Diagnoses of chlamydia in 2009 (NNDSS 2010) varied considerably by State/Territory, ranging from 210.5 per 100,000 population in NSW to 940.6 per 100,000 in the NT. Rates of diagnosis also vary considerably at the regional level (eg rates of diagnoses of between 740.9 and 2121.1 per 100,000 population have been reported in some areas of the Queensland, WA and the NT [NCHECR 2010]). The rate of diagnosis of chlamydia among the Aboriginal and Torres Strait Islander population resident in major cities in SA, Victoria and WA in 2009 was 3.5 times that among non-Indigenous people. Among Aboriginal and Torres Strait Islander people resident in remote and very remote areas in the NT, SA, Tasmania, Victoria and WA, the rate of diagnosis of chlamydia was at least 7 times that among non-Indigenous people (NCHECR 2010).

› *Risk factors* — Chlamydia is highly prevalent among younger people, with around 80% of all diagnoses being in young people (NCHECR 2010). Recent change in sexual partner is also a risk factor for chlamydia infection.

Data on diagnoses of chlamydia are incomplete and may provide a distorted view of population rates in Australia. Differences in rates of diagnosis between areas and populations may reflect a range of factors, including variations in approaches to offering testing, access to services, and recording of Indigenous status.

Risks associated with chlamydia in pregnancy

Chlamydia infection during pregnancy has been associated with adverse outcomes including higher rates of preterm birth (OR 1.6; 90% CI 1.01–2.5) and intrauterine growth restriction (OR 2.5; 90% CI 1.32–4.18) (John Hopkins Study Team 1989). Left untreated, it has also been associated with increased low birth weight and infant mortality (Ryan et al 1990).

Babies born to mothers who have cultured positive to *C. trachomatis*, may subsequently also culture positive (approximately 25%) and have been reported to have higher rates of neonatal conjunctivitis, lower respiratory tract infections and pneumonia (Schachter et al 1986; Preece et al 1989).

However, the NICE guidelines note that the causal link between chlamydia infection and adverse outcomes of pregnancy has not been established and the evidence remains difficult to evaluate in relation to neonatal morbidities (NICE 2008).

8.5.2. Chlamydia screening in pregnancy

Summary of the evidence

The NICE guidelines reviewed the evidence on diagnostic accuracy and effectiveness of screening methods in identifying genital chlamydia and found no good evidence to support routine antenatal screening.

Diagnostic accuracy

The evidence on diagnostic accuracy was limited to prospective cohort studies. The accuracy of antigen detection tests using endocervical specimens (Stamm et al 1984; Baselski et al 1987; Smith et al 1987) and of nucleic acid amplification tests using first-void urine and endocervical specimens (Thejls et al 1994; Andrews et al 1997; Garland et al 2000; Macmillan et al 2003; Renton 2006) was supported. While nucleic acid hybridisation test (DNA probe test) may be accurate the evidence is limited and of moderate quality (Yang et al 1991; Hosein et al 1992). Based on limited evidence, Gram staining (Asbill et al 2000) and Pap smear (Spence et al 1986) had insufficient accuracy to detect chlamydia.

Effectiveness of screening

Review of the effectiveness of screening in reducing adverse outcomes for the pregnancy and the neonate found limited evidence (one RCT [Martin et al 1997] and five cohort studies [Macmillan et al 1985; Black-Payne et al 1990; Cohen et al 1990; Ryan et al 1990; Rivlin et al 1997]) to indicate that treating chlamydia infection during pregnancy is effective in reducing the incidence of premature rupture of the membranes, preterm birth and low birth weight babies. There was no significant evidence to show that treating chlamydia infection during pregnancy leads to decreased incidence of adverse neonatal outcomes (conjunctivitis, pneumonia).

The literature review conducted to inform these Guidelines found no additional systematic reviews or RCTs to support or refute the findings presented in the NICE guidelines. However, there is additional information from systematic reviews and prevalence studies from 2008–2010 to suggest a specific population-based screening program (eg for those at highest risk). This evidence is discussed below.

Groups at higher risk

The *Second National Sexually Transmitted Infections Strategy 2010–13* (DoHA 2010) identifies young people as a priority population for chlamydia screening, noting that in 2008, slightly more than 25% of all chlamydia infections were in the 15 to 19–year–old age group and nearly a further 65% were in 20 to 29–year–olds (NCHECR 2009).

Antenatal care provides an opportunity to discuss chlamydia testing with young women. Other considerations before testing is offered include whether the pregnancy is unplanned, the number of recent male sexual partners and antibiotic use in the previous 3 months (Chen et al 2009).

In the United Kingdom and the United States, chlamydia screening is recommended for pregnant women younger than 25 years (NICE 2008) and younger than 24 years (USPSTF 2007), respectively. Screening of young women in Australia is supported by:

› the known high prevalence of chlamydia in young people in Australia (Vajdic et al 2005; NCHECR 2009) and modelling that predicts a rapid reduction in prevalence through screening of people aged 25 years or younger (Regan et al 2008);

› estimates of the prevalence of chlamydia during pregnancy in young Australian women, which range from 3.2% (95% CI 1.8–5.9) among women aged 16–24 (n=403) (Chen et al 2009) to 13.7% among women aged 20 years or younger (n=212) (Cheney & Wray 2008); and

› qualitative research conducted as part of a prospective, cross-sectional study of pregnant women aged 16–25 years, which found a high level of acceptability of screening (Bilardi et al 2010).

Recommendation	Grade C
16. Do not routinely offer chlamydia testing to all women as part of antenatal care. Routinely offer chlamydia testing at the first antenatal visit to pregnant women younger than 25 years.	

While data are lacking to support routine screening, the prevalence of chlamydia is regionally variable and, in some areas, high prevalence may occur with that of other sexually transmitted infections, such as gonorrhoea. While screening of young women should take place in all areas, it is also important for health professionals to be aware of the rates of sexually transmitted infection in their community and develop local protocols accordingly.

Practice point
q. Testing for chlamydia and other sexually transmitted infections regardless of age should be considered for women who live in areas where their prevalence is high. An understanding of local prevalence will inform planning for population screening when this is indicated.

Type and timing of test

As discussed above, antigen detection (eg nucleic acid amplification tests) are accurate in diagnosing chlamydia. Study of the acceptability of these tests to young women found a preference for non-invasive methods. Both urine and vulval swab methods were highly sensitive, acceptable, and not affected by pregnancy status (Macmillan et al 2003). However, women may be unable to produce urine on demand and unrefrigerated transport time has been reported to influence sensitivity of testing. There is also preliminary evidence that urine has the lowest organism load when compared to endocervical, self-collected vaginal, and urethral specimens.

8.5.3. Practice summary — chlamydia screening

When — At the first contact with women younger than 25 and women in high prevalence areas
Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker

› **Discuss chlamydia** — Explain the association between chlamydia and preterm birth and low birth weight, that tests for the infection are available and that it is easily treated with antibiotics.

› **Take a holistic approach** — If a woman tests positive for chlamydia, other considerations include counselling, contact tracing, partner testing, testing for other sexually transmitted infections and follow-up.

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

8.5.4. Resources

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8.6. Syphilis

Screening for syphilis in pregnancy aims to detect infection in order to treat mothers and prevent transmission to babies.

8.6.1. Background

Syphilis is a sexually acquired infection caused by *Treponema pallidum*. In pregnancy, it can result in spontaneous miscarriage or stillbirth or cause congenital syphilis infection. Syphilis in pregnancy can be safely treated with antibiotics, which can prevent these complications (Walker 2001).

Syphilis in Australia

› *Rates of diagnosis of syphilis* — There were 1,292 diagnoses of infectious syphilis in 2009, with 10% among Aboriginal and Torres Strait Islander people, 86% among non-Indigenous people and a further 4% for which Indigenous status was not reported (NCHECR 2010). In the period 2005–09, the rate of diagnosis trebled among non-Indigenous Australians (from 2 to 6 per 100,000 population) and decreased from 31 to 25 per 100,000 Aboriginal and Torres Strait Islander population. Aboriginal and Torres Strait Islander women aged 29–40 years were diagnosed at 28 times the rate of non-Indigenous women in the same age group.

› *Geographical distribution* — In the non-Indigenous population, the majority of diagnoses occur in urban and regional areas (NCHECR 2010). In the Aboriginal and Torres Strait Islander population the rate of diagnosis increases exponentially as remoteness of residence increases — in 2009, the rate of diagnosis per 100,000 population was 10 in major cities, 32 in regional and 133 in remote areas (NCHECR 2010).

› *Congenital syphilis* — Australia is considered to be a country of low prevalence for congenital syphilis. From 2000 to 2009 there was a total of 116 cases of congenital syphilis, which is a rate of 0.1 per 100,000 or less per year (NNDSS website). Three cases of congenital syphilis were diagnosed in 2009 (NNDSS 2010).

› *Risk factors* — Ratios of male to female diagnoses indicate that transmission occurs predominantly through male homosexual contact in the non-Indigenous population and through heterosexual contact among Aboriginal and Torres Strait Islander people (NCHECR 2010). In 2009, 27% and 50% of diagnoses of infectious syphilis in the non-Indigenous and Aboriginal and Torres Strait Islander populations respectively occurred among people aged less than 30 years of age (NCHECR 2010). In a cohort of urban Aboriginal and Torres Strait Islander women, predictors for sexually transmitted infection were young age, harmful/hazardous alcohol use and unwanted pregnancy (Panaretto et al 2006).

Risks associated with syphilis in pregnancy

Maternal syphilis infection results in congenital infection in at least two-thirds of cases (Zenker & Rolfs 1990; Chakraborty & Luck 2008; Woods 2009). Congenital infection can occur at any stage of maternal disease, including during incubation (Doroshenko et al 2006), as early as 9–10 weeks of pregnancy and at any subsequent time during pregnancy (Woods 2005).

Congenital syphilis is a serious condition that, if not fatal at a young age, can cause permanent impairment, debilitation and disfigurement (Chakraborty & Luck 2008; Richens & Mabey 2008). Pancreatitis and inflammation of the gastrointestinal tract are common (Woods 2005).

8.6.2. Syphilis screening

Summary of the evidence

Effectiveness of universal screening

Universal syphilis screening programs have been shown to significantly increase the detection of pregnant women who have syphilis compared with selective screening of women considered to be a high-risk (Cameron et al 1997; Duthie et al 1990; Villar & Bergsjo 1997; Hurtig et al 1998). Based on convincing observational evidence, universal screening of pregnant women is recommended by the United States Preventive Services Task Force (USPST 2009; Wolff et al 2009), the World Health Organization (WHO 2004), the International Union against Sexually Transmitted Infections (IUSTI)(French et al 2009) and the United Kingdom national guidelines on the management of syphilis (Kingston et al 2008) as it decreases the proportion of babies with clinical symptoms of syphilis infection.

Universal screening for syphilis has been shown to be cost-effective (Garland & Kelly 1989; Abyad 1995; Cameron et al 1997; Connor et al 2000; Walker 2001) even in areas of low prevalence.

Recommendation	Grade B
17. Routinely offer and recommend syphilis testing at the first antenatal visit as treating syphilis benefits both mother and baby.	

Type of test

There are two main classifications of serological tests for syphilis (NICE 2008):

› non-treponemal tests, which detect non-specific treponemal antibodies and include the Venereal Diseases Research Laboratory (VDRL) and rapid plasma reagin (RPR) tests; and

› treponemal tests, which detect specific treponemal antibodies and include EIAs, T. pallidum haemagglutination assay (TPHA) and the fluorescent treponemal antibody-absorbed test (FTA-abs).

The NICE guidelines reviewed the evidence on syphilis screening in pregnancy and found:

› treponemal IgG EIA tests have high sensitivity (98%) and specificity (99%) at all stages of syphilis (except early primary syphilis), are useful for detecting syphilis antibodies in patients who are infected with HIV, and are comparable to the VDRL and TPHA combination in terms of sensitivity and specificity (Young et al 1989; 1992);

› non-treponemal tests may result in false negatives, particularly in very early or late syphilis, in patients with reinfection or those who are HIV positive, and have poor positive predictive value when used alone in low prevalence populations; and

› neither type of test will detect syphilis in its incubation stage (PHLS 1998).

The initial test is usually a test for antibodies of treponema (eg enzyme immunoassay), which identifies women with current untreated or incompletely treated infection or previous history of treated syphilis. If the test is positive, a non-treponemal test will be performed by the laboratory to confirm diagnosis and enable a quantitative value of disease activity to guide treatment.

Testing in rural and remote areas

On-site syphilis screening tests are being developed to allow results to be given and overcome the barrier to treating pregnant women who have to return to the clinic for tests results and treatments. The tests evaluated appear to have adequate sensitivity and specificity to be useful in remote areas or where equipment and lab equipment is not available (Mabey et al 2006; Marongoni et al 2005) and, in one study, reduced delays in treatment (Myer et al 2003).

Follow-up for women who test positive to syphilis

Not all women who test positive will have syphilis, as these serological tests cannot distinguish between different treponematoses (eg syphilis, yaws, pinta and bejel). Therefore, positive results should be interpreted with caution. Following confirmation of a reactive specimen, a second specimen should be tested to verify the results and ensure correct identification of the woman.

Practice point
r. Because syphilis is a rare condition in most parts of Australia and a positive result does not necessarily mean that a woman has syphilis, expert advice regarding the care of women who test positive and their partners should be sought. Assessment/testing for other sexually transmitted infections in women with positive serology is advisable.

8.6.3. Practice summary — syphilis screening

When — Early in antenatal care
Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker

› **Discuss the reasons for syphilis screening —** Explain that it is important to find out whether a woman has syphilis because of the effects that infection can have on the pregnancy and the baby.

› **Document and follow-up —** Note the results of syphilis screening in the woman's record, including whether the syphilis is newly diagnosed or was previously treated. Have a follow-up system in place so that infected women receive timely treatment or referral.

› **Take a holistic approach —** If a woman is found to be infected with syphilis, other considerations include counselling, contact tracing, partner testing, testing for other sexually transmitted infections and follow-up.

8.6.4. Resources

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8.7. Asymptomatic bacteriuria

Screening for asymptomatic bacteriuria in pregnancy allows treatment to be offered to reduce the risk of progression to pyelonephritis.

8.7.1. Background

Asymptomatic bacteriuria is the persistent bacterial colonisation of the urinary tract (usually by *Escherichia coli*) without symptoms. It is common in pregnancy.

Asymptomatic bacteriuria in Australia

› *Incidence* — Incidence of asymptomatic bacteriuria during pregnancy has been reported to be 2–10% in the United States (Andrews & Gilstrap 1992; Sweet 1977) and 2–5% in the United Kingdom (Little 1966; Campbell-Brown et al 1987; Foley et al 1987). In Australia, available estimates suggest that asymptomatic bacteriuria during pregnancy may be more common among Aboriginal and Torres Strait Islander women (Hunt 2004; Bookallil et al 2005; Panaretto et al 2006).

› *Risk factors* — The prevalence of infection is most closely related to socioeconomic status and is similar in pregnant and non-pregnant women (Turck et al 1962; Whalley 1967). Other factors associated with an increased risk of bacteriuria include a history of recurrent urinary tract infections, diabetes and anatomical abnormalities of the urinary tract (Golan et al 1989).

Risks associated with asymptomatic bacteriuria in pregnancy

While asymptomatic bacteriuria in non-pregnant women is usually benign, in pregnancy it increases the likelihood of kidney involvement (pyelonephritis), with an incidence of around 30% in affected women (Whalley 1967).

An association between untreated asymptomatic bacteriuria and low birth weight and preterm birth has also been suggested (LeBlanc & McGanity 1964; Kincaid-Smith & Bullen 1965; Little 1966; Savage et al 1967). However, while a reduction in preterm birth and low birth weight is consistent with understanding of the role of infection in pregnancy complications (Smaill 2007; Smaill & Vasquez 2007), other factors may be involved (eg other asymptomatic genitourinary infections) (Campbell-Brown et al 1987; Maclean 2001) or links with socioeconomic status (Romero et al 1989). There may only be an association between asymptomatic bacteriuria and preterm birth if the infection progresses to pyelonephritis (Meis et al 1995).

8.7.2. Screening for asymptomatic bacteriuria

Summary of the evidence

Universal screening for asymptomatic bacteriuria in pregnancy is recommended in the United Kingdom (NICE 2008), the United States (USPSTF 2004; Nicolle et al 2005), Canada (Nicolle 1994) and Scotland (SIGN 2006), based on the effectiveness of available treatments and the reduced risk of pyelonephritis.

Benefits of screening

Screening for asymptomatic bacteriuria has been shown to reduce the number of women per 1,000 who experience pyelonephritis from 23.2 with no screening, to 16.2 with dipstick testing and 11.2 with urine culture (Rouse et al 1995). Both tests were found to be cost beneficial compared to no screening.

Effectiveness of interventions to treat asymptomatic bacteriuria

A Cochrane review found that antibiotic treatment compared with placebo or no treatment is effective in clearing asymptomatic bacteriuria (RR 0.25; 95% CI 0.14–0.48). The incidence of pyelonephritis was reduced by 75% (RR 0.23; 95% CI 0.13–0.41) (Smaill & Vasquez 2007).

Recommendation	Grade A
18. Routinely offer and recommend testing for asymptomatic bacteriuria early in pregnancy as treatment is effective and reduces the risk of pyelonephritis.	

Testing method

Midstream urine culture is considered the standard for diagnosis of asymptomatic bacteriuria in pregnancy (NICE 2008).

Dipstick urinalysis of nitrites may be useful for excluding asymptomatic bacteriuria but is not accurate for diagnosis (Deville et al 2004). A meta-analysis (Deville et al 2004) and a small number of RCTs (Teppa & Roberts 2005; Karabulut 2007; Eigbefoh et al 2008; Mignini et al 2009) have shown high specificity (89–100%) but low sensitivity (33–98%), with a mid range around 50%. Lower level studies have had similar results.

Recommendation	Grade A
19. Use urine culture testing wherever possible, as it is the most accurate means of detecting asymptomatic bacteriuria.	

Timing of the test

There is no consensus in the literature about the optimal timing and screening frequency for asymptomatic bacteriuria. However, in a prospective study (n=3,254), a single urine specimen obtained between 12 and 16 weeks gestation identified 80% of women who ultimately had asymptomatic bacteriuria (Stenqvist et al 1989).

Testing in rural and remote areas

Due to difficulties in transporting specimens to laboratories, dipstick tests are commonly used in remote areas to 'rule out' asymptomatic bacteriuria, with samples from women testing positive then sent for culture to confirm infection. While urine culture is the preferred method of testing, this process has been found to be cost effective (Rouse et al 1995). However, factors specific to conditions in rural and remote Australia (eg high humidity and ambient temperatures) may contribute to under diagnosis and overtreatment. Considerations in testing for asymptomatic bacteriuria in these areas include (Bookallil et al 2005):

› whether specimens can be provided to pathology services within the timeframe in which they can still be cultured (ideally within 24 hours);

› the availability of appropriate storage facilities for dipstick tests;

› the consequences of treating all women with a positive dipstick result given the high rate of false positives and the risk of increased resistance to antibiotics associated with over-prescribing; and

› and recall systems for women with a positive result on culture.

> **Practice point**
>
> s. Where access to pathology services is limited, dipstick tests may be used to exclude infection, with positive results confirmed by urine culture. Appropriate storage of dipsticks is essential to the accuracy of these tests.

Considerations beyond the first trimester

Although most guidelines recommend a single urine culture at the first antenatal visit, two prospective studies have concluded that urine should be cultured in each trimester of pregnancy to improve the detection rate of asymptomatic bacteriuria (McIsaac et al 2005; Tugrul et al 2005). There has been no prospective evaluation of repeated testing during pregnancy (Schnarr & Smaill 2008).

8.7.3.   Practice summary — screening for asymptomatic bacteriuria

When — Early in antenatal care
Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker

› **Discuss screening for asymptomatic bacteriuria —** Explain that identifying urinary tract infection enables women to be treated with antibiotics and avoids the risk of complications.

› **Document and follow-up —** Note the results of screening in the woman's record and have a follow-up system in place so that appropriate treatment is provided if a woman is found to have bacteriuria.

8.7.4.   Resources

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8.8. Asymptomatic bacterial vaginosis

As identifying and treating asymptomatic bacterial vaginosis does not appear to change the risk of preterm birth or other pregnancy complications, routine screening in pregnancy is not appropriate.

8.8.1. Background

Bacterial vaginosis results from the relative deficiency of normal Lactobacillus species in the vagina and relative overgrowth of anaerobic bacteria. This reduces the normal acidity of the vagina. Bacterial vaginosis is asymptomatic for 50% of women in pregnancy (Joesoef & Schmid 2002) but may result in a vaginal discharge that can be grey in colour with a characteristic 'fishy' odour (McDonald et al 2007).

Asymptomatic bacterial vaginosis in pregnancy

› Several large prospective, longitudinal studies have found the prevalence of bacterial vaginosis to be in the range 9–23% (Hillier et al 1992; 1995; Meis et al 1995; Goldenberg et al 1996; 1998; Pastore et al 1999). A study in remote central Australia (n=205) (Smith et al 2005) found a prevalence of 26–36% among women attending clinics for a women's health assessment (for either a symptomatic episode or routine check but not for antenatal care).

› *Risk factors* — Bacterial vaginosis in pregnancy is more common among women of low socioeconomic status and women who had low birth weight babies in previous pregnancies (Hillier et al 1995; French et al 2006).

Risks associated with asymptomatic bacterial vaginosis in pregnancy

Bacterial vaginosis has been associated with an increased risk of preterm birth (McGregor et al 1990; Kurki et al 1992; Hay et al 1994; Hillier et al 1995), with a review of case–control and cohort studies finding that women with bacterial vaginosis were 1.85 times more likely (95% CI 1.62–2.11) to give birth preterm than women without (Flynn et al 1999). The higher risk of preterm birth remains in women diagnosed with bacterial vaginosis early in pregnancy, even if the bacterial vaginosis spontaneously resolves later in pregnancy (Gratacos et al 1998).

8.8.2. Screening for asymptomatic bacterial vaginosis

Summary of the evidence

Routine screening for asymptomatic bacterial vaginosis in pregnancy is not recommended in the United Kingdom (NICE 2008), the United States (USPSTF 2008) or Canada (SOGC 2008). The systematic review supporting the United States statement (Nygren et al 2008) found that:

› no studies directly addressed the adverse effects of screening pregnant women who are asymptomatic for bacterial vaginosis;

› there is no clear benefit for the general population from screening and treating asymptomatic bacterial vaginosis during pregnancy; and

› although a subgroup of high-risk women may benefit from screening and treatment for bacterial vaginosis in pregnancy, a sizeable group would receive either no benefit or may experience harm.

Diagnosis of bacterial vaginosis

Bacterial vaginosis is generally diagnosed by either:

› Amsel's criteria (thin white-grey homogenous discharge, pH greater than 4.5, release of 'fishy odour' on adding alkali, clue cells present on direct microscopy) (Amsel et al 1983); or

› Nugent's criteria (Gram-stained vaginal smear to identify proportions of bacterial morphotypes with a score of greater than six indicating bacterial vaginosis) (Nugent et al 1991), which has both high sensitivity and specificity (Nelson et al 2003; Taylor-Robinson et al 2003; Hogan et al 2007; Nelson et al 2007), does not seem to vary with the vaginal site of collection (Culhane et al 2005) and has greater sensitivity than standard antenatal clinical diagnosis or a commercial test (Hogan et al 2007).

Other forms of testing, including the pH/whiff test or QuickVue Advanced pH and Amines test, have not been found to be reliable in detecting asymptomatic bacterial vaginosis in pregnancy (Charonis & Larsson 2006; Nelson et al 2007).

Effect of treatments on risks associated with bacterial vaginosis

While antibiotics are effective in eradicating bacterial vaginosis (McDonald et al 2007), treatment does not change the risk of preterm birth, low birth weight or premature rupture of the membranes in women at low risk of preterm birth. The Cochrane review (McDonald et al 2007) found:

› no statistically significant decrease in the risk of preterm birth at less than 37 weeks gestation for any treatment versus no treatment or placebo (n=5,888; OR 0.91; 95% CI 0.78–1.06);

› no evidence of an effect on birth before 34 weeks (n=851; OR 1.22; 95% CI 0.67–2.19) or birth before 32 weeks (n=3,565; OR 1.14; 95% CI 0.76–1.70);

› no difference in the incidence of low birth weight (n=4,107; OR 0.95; 95% CI 0.77–1.17);

› no decrease in the risk of preterm rupture of membranes (n=2,579; OR 0.88; 95% CI 0.61–1.28); and

› a possible reduction in risk of preterm birth if treatment is given before 20 weeks pregnancy (n=2,387; OR 0.72; 95% CI 0.55–0.95).

In women with a previous preterm birth, treatment did not affect the risk of subsequent preterm birth (n=622; OR 0.83; 95% CI 0.59–1.17). However, two small studies showed a decrease in the risk of preterm rupture of the membranes (OR 0.14; 95% CI 0.05–0.38) and low birth weight (OR 0.31; 95% CI 0.13–0.75) (n=114).

Although there is no evidence that screening and treating all women with bacterial vaginosis in the antenatal period will have a major impact on the rate of preterm birth, there is emerging evidence that early treatment may be more effective (McDonald et al 2007).

Recommendation	Grade B
20. Do not routinely offer pregnant women testing for bacterial vaginosis.	

Practice point
t. Early treatment (before 20 weeks pregnancy) of proven bacterial vaginosis may be beneficial for women with a previous preterm birth.

8.8.3.   Practice summary — testing for bacterial vaginosis

When — In the antenatal period
Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker

› **Document and follow-up —** If a woman is tested for bacterial vaginosis, note the results in her record. Have a system in place so that women who test positive are given information about treatments.

8.8.4.   Resources

BASHH (2006) *National Guideline for the Management of Bacterial Vaginosis*. Clinical Effectiveness Group, British Association for Sexual Health and HIV. www.bashh.org/documents/62/62.pdf

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8.9. Vitamin D deficiency

There is limited evidence to support screening of all women for vitamin D deficiency in pregnancy and it is not possible to reliably identify women who are vitamin D deficient. However, some women and their babies may benefit from supplementation.

8.9.1. 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. In the skin, provitamin D_3 is activated by ultraviolet B light to form cholecalciferol (vitamin D_3), which is converted in the liver to 25-hydroxyvitamin D (25-OHD). Vitamin D deficiency is defined as serum 25O-HD of ≤ 25 nmol/L and insufficiency as 26–50 nmol/L (ANZBMS 2005; Munns et al 2006).

Vitamin D deficiency in Australia

Estimates of the prevalence of vitamin D deficiency in Australia vary but may be higher than previously thought (Nowson & Margerison 2002). Observational studies have reported vitamin D deficiency in a range of populations, with the following findings:

› 7.2% of women aged 20–90 in Geelong had serum 25O-HD lower than 28 nmol/L (n=861) (Pasco et al 2001);

› among women attending for antenatal care in Sydney (n=971)(Bowyer et al 2009), (n=308) (Clifton Bligh et al 2008) and rural Victoria (n=330) (Teale & Cunningham 2010), 15%, 11% and 5.2%, respectively had serum 25O-HD lower than 25 nmol/L, however studies did not report on women's exposure to sunlight or covering of skin; and

› among high-risk groups, 80% of women with dark skin or covered skin (veiled) attending for antenatal care in Melbourne (n=82) had serum 25O-HD lower than 22.5 nmol/L (Grover & Morley 2001) and 81% of mothers of infants with rickets (n=55) had serum 25O-HD lower than 25 nmol/L (Nozza & Rodda 2001).

Risks associated with vitamin D deficiency in pregnancy

Maternal vitamin D deficiency in pregnancy is associated with (Bowyer et al 2009):

› low serum calcium in the newborn, with or without convulsions (Watney et al 1971; Roberts et al 1973; Rosen et al 1974; Robinson et al 2006);

› rickets (Ford et al 1973; Moncrieff & Fadahunsi 1974; Nozza & Rodda 2001; Robinson et al 2006); and

› defective tooth enamel (Purvis et al 1973; Stimmler et al 1973).

Effects on fetal growth have also been associated with maternal vitamin D deficiency (Marya et al 1981; Brunvand et al 1996; Nozza & Rodda 2001; Morley et al 2006). Population-based studies have found:

› lower birth weights and a higher risk of being small for gestational age (Leffelaar et al 2010);

› lower newborn bone mineral accrual to be lower in the vitamin D deficient groups, although bone mineral density differences were not statistically significant (Viljakainen et al 2010); and

> › greater femoral metaphyseal cross-sectional area and a higher femoral splaying index at 19 and 34 weeks pregnancy, suggesting that maternal vitamin D deficiency can influence fetal femoral development as early as 19 weeks pregnancy (Mahon et al 2010).

Low maternal vitamin D concentrations may also affect the function of other tissues, leading to a greater risk of multiple sclerosis, cancer, insulin-dependent diabetes mellitus, and schizophrenia later in life (McGrath 2001) and may influence early-life respiratory health (Devereux et al 2007; Litonjua 2009).

8.9.2.   Vitamin D deficiency in pregnancy

Summary of the evidence

Screening for vitamin D deficiency is not considered a cost-effective option (NZ MOH 2008) and is recommended against in the United States (ACOG 2011). However, many health organisations recommend vitamin D supplementation during pregnancy (IOM 1997; CPS 2007; NZ MOH 2008; RCOG 2009; UK Dept Health 2009; Weggemans et al 2009).

Further research is needed concerning screening for vitamin D deficiency, including identifying predictive factors for vitamin D insufficiency and deficiency in Australia and determining the cost-effectiveness of routine screening of all women in pregnancy. Research is also needed into the effectiveness and safety of vitamin D supplementation.

Groups at higher risk of vitamin D deficiency

Traditionally, women thought to be at high risk of vitamin D deficiency are dark-skinned inhabitants of high latitude or low sunshine climates (Holvik et al 2005; van der Meer et al 2006). Small studies of pregnant Asian women in England and Norway and black women from the United States have shown vitamin D insufficiency rates of more than 50% (Brooke et al 1980; Alfaham et al 1995; Brunvand et al 1996; Bodnar et al 2007a; Lee et al 2007). A study from the United Kingdom found 18% of white women were vitamin D deficient (<27 nmol/l) late in pregnancy (Gale et al 2008). Studies in the Netherlands (Djikstra et al 2007) and Lebanon (Nabulsi et al 2008) found that women who covered their skin during pregnancy were more likely to have babies deficient in vitamin D. High pre-pregnancy body mass index (BMI) has also been associated with low levels of vitamin D (Bodnar et al 2007b). Seasonal influences have been noted (Basile et al 2007; O'Riordan et al 2008).

A recent population-based study in south-eastern Sydney (Bowyer et al 2009) identified the following factors as being associated with vitamin D deficiency in mothers:

› maternal birthplace outside Australia (OR 2.2; 95% CI 1.4–3.5; p=0.001);

› dark skin (phototype V or VI)[13] (OR 2.7; 95% CI 1.6–4.5; p<0.001);

› wearing a veil (OR 21.7; 95% CI 11.7–40.3; p<0.001); and

› younger maternal age (mean age 27.8 versus 29.9 for insufficiency and 30.3 for sufficiency) (OR 0.93; 95% CI 0.89–0.97; p<0.001).

The study noted significant seasonal variation in maternal serum 25-OHD, which has also been found in studies in northern (Teale & Cunningham 2010) and southern Victoria (Pasco et al 2001) and among Aboriginal people in southern SA (Vanlint et al 2011). Comparison of cross-sectional data from three regions (south-eastern Queensland, southern Victoria and Tasmania) found season to be more important than latitude

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13 Defined using the Fitzpatrick phototypes in response to the question 'If your skin was untanned, for example, after winter and you exposed it to the sun for 30–45 min what would happen?' — V Brown: rarely burns, tans profusely (dark brown); VI Dark brown or black: never burns, deeply tans (black).

but behavioural factors were also important (eg the study found deficiency in months when sun exposure protection would be recommended based on the ultraviolet index)(van der Mei et al 2007).

Effectiveness of vitamin D supplementation

Vitamin D supplementation improves maternal vitamin D status during pregnancy (Yu et al 2009), which in turn directly influences the fetal and newborn supply of vitamin D (Brooke et al 1980). The NICE guidelines found no evidence that routine vitamin D supplementation for healthy women improves pregnancy outcomes but found that supplementation may be beneficial in groups of women at risk of deficiency:

› antenatal vitamin D supplementation improved the vitamin D status of African, African-Caribbean, far and middle Eastern, South Asian and Caucasian women, with no adverse effects reported (Brooke et al 1980; Cockburn et al 1980; Brooke et al 1981; Maxwell et al 1981; Greer et al 1981; 1982; Delvin et al 1986; Mallet et al 1986; Datta et al 2002);

› infants of South Asian mothers who received an antenatal vitamin D supplement achieved a higher body weight during the first year after birth than infants of mothers who received no antenatal vitamin D supplement (Brooke et al 1980; 1981; Maxwell et al 1981); and

› the effect of vitamin D supplements on infant bone mineral content was uncertain, with two studies having conflicting results (Congdon et al 1983; Greer & Marshall 1989).

More recent studies of the effects of maternal vitamin D supplementation have found:

› no reduction in risk of gestational hypertension or pre-eclampsia in a population-based study (Oken et al 2007);

› no significant effect of combined vitamin D and calcium supplementation on preventing pre-eclampsia in a small controlled trial (Chung et al 2009);

› no difference in birth weight in controlled trials (Brook et al 1980; Mallet et al 1986); and

› insufficient evidence of an association between 25-OHD levels and change in bone density in pregnancy (Cranney et al 2007).

There is no conclusive evidence on the benefits of maternal vitamin D supplementation on pregnancy outcomes. However, supplementation in women identified as deficient may be beneficial for long-term maternal health.

Consensus-based recommendation
viii. Offer vitamin D screening to women with limited exposure to sunlight (eg because they are predominantly indoors or usually protected from the sun when outdoors), or who have dark skin or a pre-pregnancy BMI of >30, as they may be at increased risk of vitamin D deficiency and benefit from supplementation for their long-term health. Base decisions about whether to offer screening on these factors, season and climate.

8.9.3.   Practice summary — testing for vitamin D deficiency

When — In the antenatal period
Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker

› **Document and follow-up —** If a woman is tested for vitamin D deficiency, 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.

8.9.4.   Resources

Australian And New Zealand Bone And Mineral Society, Osteoporosis Australia, The Australasian College Of Dermatologists, The Cancer Council Australia (2007) *Risks and Benefits of Sun Exposure Position Statement.* http://www.cancer.org.au//File/PolicyPublications/PSRisksBenefitsSunExposure03May07.pdf

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8.9.5.   References

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9.   Screening for fetal chromosomal abnormalities

The availability of screening tests enables women to choose to identify whether or not they are at risk of having a baby with a chromosomal abnormality. The level of decision-making needed requires sensitive engagement with women, partners and family members.

9.1.   Background

In recent years an increasing number of non-invasive biochemical screening tests and ultrasound techniques have been developed that can significantly increase the identification of pregnancies at risk of chromosomal abnormalities 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 positive screening test leads to the offer of a diagnostic test (chorionic villous sampling, amniocentesis, or ultrasound). 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 screening test depends on the gestation of pregnancy. Any screening test must include extensive pre- and post-test information and counselling, with consideration also being given to the woman's preferences, availability of testing facilities, costs to the woman and, for ultrasound, operator expertise. All women should be made aware of the options for antenatal screening, with both verbal and written explanations being given which contain best current evidence.

Screening in the first trimester for trisomy 21 and trisomy 13/18 must be done between 11 weeks and 13 weeks 6 days pregnancy (when the fetus has a crown-rump length of 45–84mm). Tests to assess risk are:

› maternal serum testing of pregnancy-associated placental protein-A (PAPP-A) and free beta-human chorionic gonadotrophin (ß-hCG); combined with

› ultrasound measurement of fetal nuchal translucency thickness.

The results of these tests are combined with the background risks of maternal age and gestation of pregnancy, maternal weight, ethnic background and smoking status to provide a risk value.

Later in pregnancy (14 to 20 weeks), the triple test (maternal serum testing of α-fetoprotein [AFP], free ßhCG [or total hCG] and unconjugated estriol) or the quadruple test (which also includes inhibin A) is used to assess the risk of fetal chromosomal abnormality.

Chromosomal abnormalities in Australia

The National Perinatal Statistics Unit reported on congenital anomalies in Australia in 2002–03 (Abeywardana & Sullivan 2008). Trisomy 21 was the most commonly reported chromosomal condition at birth (11.1 per 10,000 births), but there was a high proportion (60%) of fetal deaths and terminations. When terminations were included, the estimated rate was 26.3 per 10,000 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.

Analysis of the WA birth defects register between 1980 and 1996 (Leonard et al 2000) found the prevalence of Down syndrome to be similar among Aboriginal and Torres Strait Islander women and non-Indigenous women of the same age.

9.2.   Discussing screening with women

At the first antenatal visit or as early as possible in pregnancy, the availability of screening for chromosomal abnormalities should be discussed and women given relevant written information or other appropriate materials (eg video, DVD) (see Section 9.5). Providing information is particularly important, due to the complexity of the screening 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 screening is increased have not observed a corresponding increase in anxiety (Green et al 2004).

In discussing screening tests, it is important to explain:

› that it is the woman's decision whether any testing takes place;

› the chromosomal abnormalities for which screening is available;

› the screening pathway, the decisions that need to be made at each point and their consequences (see Figure 9.1);

› the importance of timing the tests against an accurate assessment of gestational age;

› that a screening test alone indicates a risk but does not give a diagnosis of any abnormalities;

› the sensitivity and specificity of the test and a full explanation of the risk score obtained following testing (eg high risk/low risk, 1 in 300);

› the options for women who receive a high-risk result, including information about chorionic villus sampling and amniocentesis (see Section 9.3.2);

› a high risk screen in a fetus with normal chromosomes may indicate the presence of other fetal anomalies (diaphragmatic hernia, cardiac anomaly);

› factors that increase the risk of fetal chromosomal abnormalities (advanced maternal age, family history of chromosomal abnormalities);

› where and how tests can be accessed if the woman chooses to have them;

› situations in which first-trimester screening may be difficult or impossible (eg high BMI, fetal positioning, multiple pregnancy);

› situations in which the testing may be modified to exclude serum testing (multiple pregnancy);

› the availability of evaluated decision aids (eg the Ottawa Decision Framework) (Arimori 2006; Nagle et al 2006; 2008)(see Section 9.5); and

› the costs involved for the woman and the timeframe for receiving results.

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

Consensus-based recommendation

ix. At the first antenatal visit, give all women information about the purpose and implications of testing for chromosomal abnormalities to enable them to make informed choices about whether or not to have the tests.

Practice point

u. Information about testing for chromosomal abnormalities should be provided in a way that is appropriate and accessible to the individual woman, with particular regard given to language and literacy.

Figure 9.1: Pathway of screening for and diagnosis of chromosomal abnormalities in the first trimester

Women offered screening for chromosomal abnormalities Purpose: Identify women who may be at risk of having a baby with a chromosomal abnormality Offer counselling from informed professional eg ultrasound specialist/obstetrician/midwife/GP/geneticist	→ Woman chooses not to have test
↓	
Woman chooses to have screening test	
↓	
Screening test: nuchal translucency ultrasound + blood test	→ Low risk
↓	
Increased risk (1 in 300 or greater)	
↓	
Woman is offered referral to a genetic counsellor	
↓	
Women with a high-risk screening result offered diagnostic test Purpose: To enable the woman to have further testing to make an informed decision about the pregnancy	→ Woman chooses not have diagnostic test
↓	
Woman chooses to have diagnostic test	
↓	
Diagnostic test: chorionic villus sampling at >11 wks amniocentesis at >15 wks	→ Negative result
↓	
Positive result	
↓	
Woman is offered counselling and preparations are made for additional care required during and after the pregnancy or for termination*	

Normal antenatal care (vertical, right column)

* The circumstances in which termination of pregnancy is permissable vary between States/Territories. Health professionals should be aware of relevant legislation in their State/Territory.

9.3. Screening tests in the first trimester

9.3.1. Effectiveness of tests

Offering the genetic screening test 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 (HGSA & RANZCOG 2007).

Summary of the evidence

The combined test identifies factors that are known to be associated with fetal chromosomal abnormalities and that are independent of each other.

The risk of an adverse outcome (which includes chromosomal and other abnormalities and fetal and postnatal death) increases with nuchal translucency thickness from approximately 5% for a measurement between 2.0–3.0 mm (the 95th percentile) and 3.4 mm to 30% for a measurement of 3.5–4.4 mm, 50% for a measurement of 4.5–5.4 mm and 80% for a measurement of >5.5 mm (Souka et al 1998; 2001).

Combining nuchal translucency assessment with testing of maternal serum increases the predictive value (Alexioy et al 2009). There is strong evidence on the sensitivity of the combined test. For example:

› a good-quality cohort study (n=75,821) (Nicolaides et al 2005) showed the test to have a detection rate of 92.6% at a false positive rate of 5.2% for the detection of trisomy 21 and a slightly lower detection rate for trisomy 18 or 13 and other chromosomal abnormalities;

› another study (n=5,084) (Stenhouse et al 2004) observed a detection rate for trisomy 21 of 93% at a false-positive rate of 5.9% and a detection rate of 96% and overall false-positive rate of 6.3% for all chromosomal abnormalities; and

› a multicentre study (n=8,514) (Wapner et al 2003) found a detection rate of 85.2% for trisomy 21 at a false positive rate of 9.4% and 78.7% at a false-positive rate of 5% and a detection rate for trisomy 18 of 90.9% at a 2% false positive rate.

For comparison, the detection rates achieved by maternal age alone and second trimester maternal serum testing are 30% and 65%, respectively (Nicolaides 2004).

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 risk assessment algorithms. The inclusion of age in risk calculation, either alone or in combination with serum test results, increases detection of chromosomal abnormalities (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). Other relevant factors include maternal weight and height, whether the woman has insulin-dependent diabetes and whether there is a previous history of chromosomal abnormalities (NSW Health 2007).

Offering the combined ultrasound and biochemistry tests reduces the number of women offered diagnostic testing (Saltvedt et al 2005; Marsk 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 negative screening 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).

Recommendation	Grade B
21. 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 and ultrasound assessment takes place between 11 weeks 0 days and 13 weeks 6 days.	

9.3.2. Supporting women who receive a high-risk result

Referral of women with high-risk results

Following a high-risk result, women should be offered urgent referral to a health professional (eg a genetic counsellor) to discuss their options (see below). In the event that the woman has a diagnostic test and positive result, follow-up with an appropriate health professional should occur at the earliest opportunity. Appropriate heath professionals include experienced midwives, obstetricians, genetic counsellors and clinical geneticists.

Practice point
v. For women with a risk of 1 in 300 or greater, referral to a genetic counsellor should be considered.

Discussing diagnostic testing with women

The suitability of diagnostic tests is determined by the gestation of pregnancy. The tests are invasive and increase the risk of miscarriage by approximately 1% over and above the background risk of miscarriage from natural causes (NSW Health 2007). 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 abnormalities that may be diagnosed;

› the available tests, the gestation of pregnancy 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 abnormalities that are not identified by the test;

› the timeframe for receiving results and making further decisions if necessary;

› options to consider if a chromosomal abnormality is identified (eg continuation of the pregnancy or termination where this is permitted under jurisdictional legislation) and the need for additional care if the pregnancy continues (eg 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 (eg anxiety among women receiving false positives may remain [Green et al 2004]); and

> › costs involved and how they are to be met.

Timing of diagnostic tests

There is good quality evidence from a Cochrane review (Alfirevic et al 2003) and a 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 abnormalities before 14 weeks pregnancy (Philip et al 2004).

Some women may not have the option of chorionic villus sampling (eg 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	Grade B
22. If a woman chooses to have a diagnostic test for chromosomal abnormalities, base the choice of test on the gestation of pregnancy and the woman's preferences. Chorionic villus sampling is safer before 14 weeks pregnancy. Amniocentesis is safe after 15 weeks.	

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 an abnormal result may be unable to absorb any 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 abnormality is detected may require referral to genetic counselling services, other professional services or support networks (see Section 9.5).

If a woman has a normal diagnostic test result, she should be advised of her residual risk as the diagnostic tests have a sensitivity of less than 100%.

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

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

9.4. Other considerations in screening for fetal chromosomal abnormalities

Availability and uptake of screening

The range of screening tests available, screening policies and uptake of screening by women vary regionally (O'Leary et al 2006). Overall, approximately 50% of pregnant women participated in nuchal translucency screening in 2007–08 (Nisbet et al 2010). Studies in Victoria and Queensland have shown higher uptake of screening 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 screening 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 towards screening (Dormandy et al 2005).

No data have been reported on the uptake of Down syndrome screening among Aboriginal and Torres Strait Islander women. However, a study at Royal Darwin Hospital in 1999 suggested that screening or diagnostic tests were rarely offered to Aboriginal women, including those in older age groups (Hunt 2004). A recent study into screening for chromosomal abnormalities among Aboriginal and Torres Strait Islander women (MSHR 2010) has highlighted the importance of providing information about screening and identified a number of challenges involved in offering screening, 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 has to be done and when, and organisational logistics (eg patient travel, where to send blood, referral procedures).

Practice point
x. There is inadequate access to screening for chromosomal abnormalities in rural and remote areas. Every effort should be made to support women in these areas to access screening.

Education

Health professionals caring for pregnant women should undertake continuing education regarding options available for screening for chromosomal abnormalities (see Section 9.5) and be aware of current screening tests available and the settings in which they can be implemented (HGSA & RANZCOG 2007).

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 either through the Fetal Medicine Foundation UK or through the Nuchal Translucency – Ultrasound, Education and Monitoring Project (NT-UEMP) administered through the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (see Section 9.5).

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.

9.5. Practice summary — screening for chromosomal abnormalities

When — In the antenatal period
Who —Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker; genetic counsellor

› **Discuss the process of screening for chromosomal abnormalities** — Explain the purpose of screening, 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 screening, make arrangements for the tests to be carried out before 13 weeks and 6 days pregnancy.

› **Offer women with a high-risk screening result referral to a genetic counsellor** — This may assist women in considering options and making decisions about diagnostic testing. If a diagnostic test is carried out and the result is positive, referral for counselling should occur at the earliest opportunity.

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

9.6. 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.

Biotechnology Australia (2007) Genetics in Family Medicine The Australian Handbook for GPs. Commonwealth of Australia. http://www.nhmrc.gov.au/your_health/egenetics/practitioners/gems.htm

HGSA & RANZCOG (2007) Prenatal Screening Tests for Trisomy 21 (Down Syndrome), Trisomy 18 (Edwards Syndrome) and Neural Tube Defects. College Statement C-Obs 4. Human Genetic Society of Australasia and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists.

MSHR (2010) Resources developed as a result of Screening for Fetal Anomalies: Views of Indigenous People and their Health Care Providers project — http://www.menzies.edu.au/childhealthresources.

NSW Health (2007) PD2007_067 Prenatal Testing/Screening for Down Syndrome and other Chromosomal Abnormalities. Sydney: NSW Health www.health.nsw.gov.au/policies/pd/2007/PD2007_067.html

Nuchal Translucency Online Learning Program — http://www.nuchaltrans.edu.au/

Resources for women and their families

Association for Genetic Support of Australasia — http://www.agsa-geneticsupport.org.au/index.php

Centre for Genetics Education's Prenatal Testing – Overview http://www.genetics.edu.au/pdf/factsheets/fs17.pdf

Decision Aid for Prenatal Testing for Fetal Abnormalities –Your Choice: Screening & Diagnostic tests in Pregnancy|| Murdoch Children's Institute http://www.mcri.edu.au

Ottawa Personal Decision Aid http://decisionaid.ohri.ca/decguide.html

Prenatal Testing – Special tests for your baby during pregnancy http://www.genetics.com.au/pdf/pubs/prenatal.pdf

9.7.   References

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10. Lifestyle considerations

Many lifestyle factors contribute to the health and wellbeing of a woman and her baby during pregnancy. This chapter discusses the health risks and benefits associated with specific social and lifestyle factors. Other lifestyle factors (eg nutrition, physical activity, illicit drug use) will be considered in detail in Module II of the Guidelines. The table below summarises current advice, drawing from the NICE guidelines as well as recommendations included in these Guidelines.

Table 10.1: Summary of advice for women about lifestyle considerations in the first trimester

Lifestyle factors		Evidence
Tobacco smoking	Smoking and passive smoking can have negative effects on the pregnancy and the baby.	Grade B
Food-acquired infections*#	Women can reduce the risk of listeriosis by drinking only pasteurised or UHT milk, not eating ripened soft cheese, not eating paté of any sort and not eating uncooked or undercooked ready-prepared meals.	Grade D*
Alcohol	Not drinking is the safest option for women who are pregnant.	CBR
Physical activity*	Beginning or continuing a moderate course of exercise during pregnancy is not associated with negative effects on the pregnancy or baby.	Grade A*
	Certain activities — eg contact sports, high-impact sports and vigorous racquet sports that may involve the risk of abdominal trauma, falls or excessive joint stress, and scuba diving — should be avoided.	Grade D*
Cannabis*	The direct effects of cannabis on the baby are uncertain but may be harmful. As cannabis use is associated with smoking, using cannabis should be avoided during pregnancy.	Grade C*
Medicines		**Evidence**
Medicines	Use of medicines should be limited to circumstances where the benefit outweighs the risk.	CBR
Herbal medicines	Herbal medicines should be avoided in the first trimester.	PP
General advice		
Travel*	Correct use of three-point seatbelts during pregnancy is to have the belt 'above and below the bump, not over it'.	Grade B*
	Wearing correctly fitted compression stockings may reduce the risk of venous thrombosis during longhaul air travel.	Grade B*
	Women who are pregnant and planning to travel should discuss considerations such as flying and vaccinations with their midwife or doctor	PP*

General advice		
Oral health	Good oral health protects a woman's health and treatment can be safely provided during pregnancy.	Grade B
Sexual intercourse*	Sexual intercourse in pregnancy is not known to be associated with any adverse outcomes.	Grade B*
Preventive health interventions		**Evidence**
Folic acid	Folic acid taken preconception and in the first trimester reduces the risk of a baby having neural tube defects and a supplement of 500mg a day is recommended.	Grade A
Other vitamins	Supplements of vitamins A, C and E are not of benefit during pregnancy and may cause harm.	Grade B
Iron	Iron supplementation is only recommended when a deficiency is identified as it does not benefit the health of the woman or baby. Not only does unnecessary iron supplementation offer no benefit, it may be harmful.	Grade B
Iodine	Iodine requirements increase during pregnancy and a supplement of 150 micrograms a day is recommended.	CBR
Immunisation**	It is recommended that influenza vaccine be offered in advance to women planning a pregnancy, and to pregnant women who will be in the second or third trimester during the influenza season, including those in the first trimester at the time of vaccination.	Not graded**

* Advice from NICE (2008) *Antenatal Care. Routine Care for the Healthy Pregnant Woman.* London: RCOG Press.

** Advice from ATAGI (2009) *Australian Immunisation Handbook.* 9th edition. Australian Technical Advisory Group on Immunisation. Canberra: Department of Health and Ageing.

\# See also www.foodauthority.nsw.gov.au/_Documents/consumer_pdf/pregnancy-brochure.pdf.

10.1. Tobacco smoking

Health professionals have an important role in advising women of the risks associated with smoking in pregnancy, assessing smoking status on first contact with a woman and supporting efforts to stop or reduce smoking at subsequent contacts.

The effects of tobacco smoking on an individual's health are well documented. Tobacco smoking in pregnancy is a risk factor for complications, and is associated with low birth weight, preterm birth, small-for-gestational-age babies and perinatal death (Laws et al 2006). While the prevalence of smoking in pregnancy has declined in high-income countries over the last decade, this decline has not been consistent across all sectors of society.

Women who continue to smoke in pregnancy generally have a low income, have a high number of previous births, are without a partner, have low levels of social support, receive publicly funded maternity care, have limited education and are more likely to feel criticised by society (Graham 1977; Frost et al 1994; Graham 1996; Tappin et al 1996; US DHHS 2004; Ebert & Fahy 2007). Globally, there is a significantly higher prevalence of smoking in pregnancy in several Indigenous and ethnic minority groups, including Aboriginal and Torres Strait Islander women, which is in accord with their social and material dispossession (Wiemann et al 1994; Kaplan et al 1997; Chan et al 2001; Hunt 2003; US DHHS 2004).

10.1.1. Background

Smoking during pregnancy among Australian women

› *General population* — A considerable number of Australian women (around 16% in 2008) smoke during pregnancy (Laws et al 2010). The rate varies between jurisdictions (eg almost 13% in NSW and the ACT compared to around 28% in NT and Tasmania).

› *Adolescent women* — A high proportion of adolescent women (39%) smoked during pregnancy in 2008 (Laws et al 2010).

› *Aboriginal and Torres Strait Islander women* — Around half of Aboriginal and Torres Strait women (50.9%) smoked during pregnancy in 2008 (Laws et al 2010). Aboriginal and Torres Strait Islander women are considerably more likely to become pregnant before the age of 20 (21% versus 4% in the general population in 2009)(AIHW 2011) and these young women are more likely to smoke during pregnancy than non-Indigenous adolescents (Lewis et al 2009).

› *Women with serious mental health disorders* — Prevalence of smoking during pregnancy is higher among women with serious mental disorders than among women in general (eg 51% vs 24% for women with schizophrenia [Nilsson et al 2002]). A considerable proportion of adverse pregnancy outcomes among women with serious mental health disorders is attributable to smoking (Hauck et al 2008; King-Hele et al 2009; Matevosyan 2011).

Risks associated with smoking during pregnancy

High-level evidence identified in the NICE guidelines indicates a significant association between smoking in pregnancy and adverse outcomes. These include:

› *birth defects* including cleft lip and palate (Wyszynski et al 1997);

› *effects on the pregnancy* including perinatal mortality (DiFranza & Lew 1995), placental abruption (Ananth et al 1999; Castles et al 1999), preterm premature rupture of membranes (Castles et al 1999), ectopic pregnancy (Castles et al 1999), placenta praevia (Castles et al 1999), preterm birth (Shah & Bracken 2000), and miscarriage (DiFranza & Lew 1995);

› *effects on the baby,* in particular reduced birth weight (with babies born to smokers being a consistent 175–200 g smaller than those born to similar non-smokers) (Lumley 1987), small-for-gestational-age baby (Clausson et al 1998), stillbirth (Raymond et al 1994), fetal and infant mortality (Kleinman et al 1988) and sudden infant death syndrome (DiFranza & Lew 1995); and

› although studies into *long-term effects r*eport conflicting results (Faden & Graubard 2000; MacArthur et al 2001; von Kries et al 2002), there is evidence of an association between low birth weight and coronary heart disease, type 2 diabetes and adiposity in adulthood (Gluckman et al 2008).

Passive smoking (exposure to second-hand or environmental tobacco smoke) during pregnancy may also be associated with increased risk of low birth weight or preterm birth (Khader et al 2010).

10.1.2. Assessing smoking status

While many women who smoke quit spontaneously before their first antenatal visit, a significant proportion will relapse during or after pregnancy (Panjari et al 1997). Other women may not be aware of the risks associated with smoking in pregnancy or find it difficult to quit. It is important that women are asked early in pregnancy about their smoking status and whether others in the household smoke.

Women may feel guilty or stigmatised if they smoke during pregnancy, and as a result may deny or underreport their smoking (Walsh et al 1996; Windsor et al 1998; Gilligan et al 2009 a). Questions about smoking should be phrased in a non-judgmental way, or collected using a written questionnaire rather than verbally, for example using a multiple-choice question as outlined below.

'Which of the following statements best describes your cigarette smoking?

› I smoke daily now, about the same as before finding out I was pregnant

› I smoke daily now, but I've cut down since I found out I has pregnant

› I smoke every once in a while

› I quit smoking since finding out I was pregnant

› I wasn't smoking around the time I found out I was pregnant and I don't currently smoke.'

Specific resources to assist with assessing smoking status are available (see Section 10.3.6).

Recommendation	Grade A

23. At the first antenatal visit:

› assess the woman's smoking status and exposure to passive smoking;

› give the woman and her partner information about the risks to the unborn baby associated with maternal and passive smoking; and

› if the woman smokes, emphasise the benefits of quitting as early as possible in the pregnancy and discuss any concerns she or her family may have about stopping smoking.

10.1.3. Interventions to assist women to stop smoking

Pregnancy is a time when women who smoke may be more receptive to quitting (McDermott et al 2004) and there are many opportunities for supporting women to quit at this time. This section summarises the available evidence on smoking cessation interventions in pregnancy. Discussion of ways to support people to quit smoking is included in specific smoking cessation guidelines (see Section 10.1.6).

Summary of the evidence

There is high-level evidence, based on systematic reviews and RCTs, that smoking cessation interventions reduce smoking rates in pregnant women. A Cochrane review (Lumley et al 2009), which is the largest study on this topic to date, found that interventions:

› improved smoking cessation rates by 6% (RR 0.94; 95% CI 0.93–0.96); and

› reduced rates of low birth weight (RR 0.83; 95% CI 0.73–0.95) and preterm birth (RR 0.86; 95% CI 0.74–0.98) and there was a 53.91g increase in mean birth weight (95% CI 10.44–95.38g).

Of the interventions studied, cognitive behavioural interventions (including educational strategies and motivational interviewing; see Glossary) (RR 0.95; 95% CI 0.93–0.97) were similar in effect to interventions in general. Incentives (eg vouchers) increased the effectiveness of interventions (RR 0.76; 95% CI 0.71–0.81), while using the 'stages of change' theory (RR 0.99; 95% CI 0.97–1.00) or providing feedback to the mother (eg fetal health status) (RR 0.92; 95% CI 0.84–1.02) did not. While nicotine replacement therapy (NRT) was as effective as cognitive behaviour therapy (CBT) (RR 0.95; 95% CI 0.92–0.98), there is no clear evidence on its safety during pregnancy.

Other recent studies are consistent with the Cochrane review. Additional findings include that:

› telephone-based support combined with face-to-face sessions is beneficial (Dennis & Kingston 2008);

› providing information (eg at ultrasound appointments) has a significant effect (Stotts et al 2009); and

› smoking cessation may be influenced by concern about weight gain (Berg et al 2008).

Cost-effectiveness of interventions

An economic analysis conducted to inform the development of these Guidelines (see Appendix E) found that smoking cessation interventions for both pregnant women and the wider population may be cost-effective from both a health system and societal perspective.

CBT and NRT have the same effect on life-years saved but the cost to the health system for NRT is lower. However, NRT is not an appropriate option for women who smoke less than 10 or 15 cigarettes a day (Hotham et al 2006) and CBT is likely to be more successful in these women. Also, a woman's out-of-pocket costs are higher for NRT. If the health system were to cover the total costs of treatment, CBT would be the

more cost-effective option.

Recommendation	Grade A
24. Offer women who smoke referral for smoking cessation interventions such as cognitive behavioural therapy.	

Supporting smoking cessation

Antenatal care is an opportunity to provide women with information about interventions that have been identified as effective (see above), are available locally or through the phone or internet, and are suitable to the individual woman's age, education level, intellectual capacity, language and/or cultural factors and motivation. Providing written or other form of information can reinforce this advice.

Practice point
y. At each antenatal visit, offer women who smoke personalised advice on how to stop smoking and provide information about available services to support quitting, including details on when, where and how to access them.

Pharmacological therapy

While the safety or otherwise of single-agent NRT in pregnancy has not been established (Lumley et al 2009), a large cohort study (Lassen et al 2010) found no serious effect on birth weight unless more than one type of NRT product was used.

NRT appears to be effective in reducing smoking among pregnant women with nicotine dependence (Smith et al 2006; Oncken et al 2008). Prescribing NRT or other pharmacological therapy requires consideration of the risks from the treatment versus the benefits of the woman not smoking. If NRT is prescribed, women should be advised that smoking while using NRT leads to high nicotine levels.

Recommendation	Grade B
25. If, after options have been explored, a woman expresses a clear wish to use nicotine replacement therapy, discuss the risks and benefits with her.	

Practice point
z. If nicotine replacement therapy is used during pregnancy, intermittent–use formulations (gum, lozenge, inhaler and tablet) are preferred to continuous-use formulations (nicotine patches).

Reducing smoking if quitting is not possible

Women who are unable to quit during pregnancy often reduce the number of cigarettes that they smoke. This can reduce nicotine concentrations and offer some measure of protection for the fetus, with a 50% reduction being associated with a 92g increase in birth weight (Li et al 1993; Windsor et al 1999). However, the greatest health benefits for the woman and baby are from quitting completely.

Monitoring and relapse prevention

Even where women are motivated to quit smoking in pregnancy, they may relapse either later in the pregnancy or after the birth. Health professionals should reinforce quitting behaviours and continue to monitor all women who have recently quit about their willingness to stay smoke free. Partner smoking is highly correlated to relapse so it may be beneficial to extend the offer of smoking cessation support strategies to the woman's partner.

At each visit, congratulate the woman for having quit, review and reinforce the reasons for quitting, and encourage the non-smoker image. Discuss some high-risk times for relapse, such as late pregnancy, post-partum and after breastfeeding has stopped. Remind the woman about useful resources and sources of support (RACGP 2007). Continue to advise women who are trying to reduce their exposure to passive smoking.

Practice point
aa. Smoking status should be monitored and smoking cessation advice, encouragement and support offered throughout pregnancy.

10.1.4. Considerations among specific population groups

As discussed in Section 10.1.1, the prevalence of smoking among Aboriginal and Torres Strait Islander women is high, with around half of women smoking in pregnancy. The recommendations given in the preceding sections apply to all women in the antenatal period. This section outlines additional considerations and approaches that may assist in supporting Aboriginal and Torres Strait Islander women and adolescent women to quit smoking. Having an understanding of community attitudes to smoking and language used when referring to tobacco products will support both assessment and intervention.

Aboriginal and Torres Strait Islander women

A range of factors has contributed to the relatively high proportion of Aboriginal and Torres Strait Islander women who smoke and continue to smoke in pregnancy. These include:

› the 'normalisation' of tobacco use within many Aboriginal and Torres Strait Islander communities in which smoking continues to play a key role in social interaction and relationship building (Harvey et al 2002; Briggs et al 2003; Power et al 2009);

› continuing socioeconomic disadvantage (Power et al 2009); and

› the potential for children and non-smoking adults to be exposed to tobacco smoke in larger households (Cunningham 1994; Briggs et al 2003; ABS 2006).

At the individual level, knowledge and attitudes influence smoking behaviour. Qualitative research into the context surrounding smoking among Aboriginal and Torres Strait Islander women has identified some factors that may affect motivation or ability to quit (Heath et al 2006; Wood et al 2008; Gilligan et al 2009b):

› smoking provides an opportunity for 'time out' from social pressures and for 'sharing with others';

› smoking is perceived as reducing stress, easing social interaction, relieving boredom and controlling weight;

› smoking may be seen as a less immediate problem relative to other issues; and

› high levels of smoking by the woman's partner or among family and friends make it harder to quit.

In some areas, women may use chewing tobacco (with or without pituri[14]) and enquiry about this may also be useful.

Practice points

bb. Health care professionals involved in the care of Aboriginal and Torres Strait Islander women should be aware of the high prevalence of smoking in some communities, and take account of this social norm when discussing smoking and supporting women to quit.

cc. Culturally appropriate smoking cessation services should be offered.

Effective smoking cessation interventions

A recent review of evidence regarding smoking cessation and prevention programs for Aboriginal and Torres Strait Islander Australians (Power et al 2009) identified that:

› strategies at the individual level such as culturally appropriate counselling and/or NRT are likely to be effective for Aboriginal and Torres Strait Islander people who are motivated to quit;

› brief interventions may be effective (Harvey et al 2002);

› group-based programs need to be tailored to individual needs;

› health workers who are able to quit smoking themselves will be in a stronger position to be a role model for others; and

› a range of health promotion resources are available and may be used to support other interventions.

National action to reduce smoking in Aboriginal and Torres Strait Islander communities

The Australian Government is funding a national network of regional tobacco coordinators and tobacco action workers to work with Aboriginal and Torres Strait Islander communities to reduce the number of people smoking. This workforce will implement a range of community-based smoking prevention, awareness raising and cessation support activities tailored to local communities.

Practice point

dd. In discussing smoking and supporting Aboriginal and Torres Strait Islander women to quit smoking, health professionals should draw on the expertise of anti-tobacco workers where available.

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14 The collective name for wild tobacco plants in Central Australia.

Adolescent women

Smoking is one of a range of risk-taking behaviours engaged in by adolescents. Adolescents who are pregnant and smoke may be at risk of other behaviours that compromise their health and that of the unborn baby (eg drinking alcohol)(Mohsin & Bauman 2005).

Very few studies have investigated the effectiveness of interventions designed to help young people stop smoking and none are specific to pregnancy in this age group. It is likely that interventions aimed at young people need to be different from those developed for adults, given differences in lifestyle and attitudes to smoking and quitting (NZ MOH 2007).

Smoking cessation programs that combine a variety of approaches show promise, including taking into account the young person's preparation for quitting, supporting behavioural change and enhancing motivation (Grimshaw & Stanton 2010). Nicotine replacement has not yet been shown to be successful with adolescents (Grimshaw & Stanton 2010).

10.1.5. Practice summary — assessing smoking status and supporting women to quit

Assessing smoking status
When — At the first contact with all women and at subsequent contacts for women who report smoking or have recently quit
Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker

› **Discuss risks to the pregnancy** — Explain that smoking during pregnancy makes it more likely that the baby will be born prematurely and that there are other serious risks to the pregnancy that can be life-threatening to mother or baby.

› **Discuss risks to the unborn baby** — Discuss the increased risk of the baby having a low birth weight. Explain that this does not just mean that the baby will be small, it is known to contribute to the development of coronary heart disease, type 2 diabetes and obesity in adulthood.

› **Take a non-judgemental approach** — Women may feel uncomfortable telling a health professional that they smoke. They may also underreport the amount that they smoke or answer in a way that does not really quantify their level of smoking (eg "half a pack a day", "socially"). The important message to get across is that if they smoke, stopping smoking is the safest option.

› **Seek information about passive smoking** — Women who are exposed to smoke from others smoking around them may be more likely to have low birth weight or premature babies. Explain that smoke-free environments give people of all ages the best chance to be healthy.

Supporting women to stop or reduce smoking
When — At subsequent antenatal contacts with women who smoke or have recently quit

› **Be aware of local smoking cessation programs** — Provide women with advice on locally available supports for smoking cessation. Depending on location this may include community support groups, Quitline or State/Territory quit services.

› **Inform decision-making** — Help each woman to select smoking cessation options that are suitable to her needs. For example, NRT would be inappropriate for a woman who does not appear to be nicotine-dependent or only smokes when she is with friends.

› **Continue monitoring** — While many women are able to stop smoking when they are pregnant, many relapse either during the pregnancy or after the birth. It is helpful to continue enquiring about a woman's smoking or passive smoking and to offer advice about quitting or reducing the family's exposure to smoke.

10.1.6.   Resources

Smoking cessation guidelines

Bittoun R & Femia G (2010) Smoking cessation in pregnancy. *Obstet Med* 3: 90–93.
http://obmed.rsmjournals.com/cgi/content/abstract/3/3/90

Flenady V, New K, MacPhail J (2005) *Smoking Cessation in Pregnancy*. Clinical Practice Guideline
Working Party on Smoking Cessation in Pregnancy. Brisbane: Centre for Clinical Studies, Mater Health Services.
http://www.stillbirthalliance.org.au/doc/Guideline_for_Smoking_Cessation_in_Pregnancy.pdf

NZ MOH (2007) *Guidelines for Smoking Cessation*. Wellington: Ministry of Health.
http://www.moh.govt.nz/moh.nsf/indexmh/nz-smoking-cessation-guidelines

RACGP (2007) *Smoking Cessation Guidelines for Australian General Practice*. Melbourne: Royal Australian College of General Practitioners. http://www.racgp.org.au/smoking/9a

Psychological services

The *beyondblue* website (www.beyondblue.org.au) includes a directory of medical and allied health professionals in mental health, including psychologists, clinical psychologists, social workers and mental health nurses.

Government funding to receive treatment from psychiatrists, psychologists, appropriately trained GPs, social workers, occupational therapists and nurses can be accessed through initiatives including Access to Allied Psychological Services (ATAPS), Better Access to Mental Health Care (Medicare items), Better Outcomes in Mental Health Care and the Mental Health Nurse Incentive Program.

Resources for Aboriginal and Torres Strait Islander women

smokecheck NSW — www.smokecheck.com.au

smokecheck Queensland — http://www.health.qld.gov.au/atod/prevention/smokecheck.asp

smokecheck NT — www.healthinfonet.ecu.au/key-resources/programs-projects/

A range of materials on smoking cessation can be found at:

›   www.ceitc.org.au (Centre for Indigenous Tobacco Control)

›   HealthInfoNet: http://www.healthinfonet.ecu.edu.au/

›   National action to reduce Indigenous smoking rate http://www.health.gov.au/internet/ctg/publishing.nsf/Content/national-action-to-reduce-indigenous-smoking-rate

Resources that are culturally appropriate to the area should be selected, taking into consideration local language and literacy.

Australian quit services

National quitline

131 848

New South Wales

Tobacco and Health Branch, NSW Health
ph 02 9391 9111
fax 02 9424 5995
tobacco@doh.health.nsw.gov.au
http://www.health.nsw.gov.au

Victoria

QUIT Victoria
ph 03 9663 7777
fax 03 9635 5510
http://www.quit.org.au

Queensland

Queensland Cancer Fund
ph 07 3258 2200
fax 07 3257 1306
qldcf@qldcancer.com.au
http://www.qldcancer.com.au

Western Australia

Tobacco Control Branch,
Department of Health
ph 08 9242 9633
fax 08 9382 0770
http://www.quitwa.com/

South Australia

QUIT South Australia
ph 08 8291 4141
fax 08 8291 4194
http://www.quitsa.org.au

Tasmania

QUIT Tasmania
ph 03 6228 2921
fax 03 6228 4149
http://www.quittas.org.au

Australian Capital Territory

ph 02 6257 9999
fax 02 6257 5055
http://www.actcancer.org

Northern Territory

Tobacco Action Project, Department
of Health and Community Services
ph 08 8999 2661
fax 08 8999 2420

10.1.7. References

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10.2. Alcohol[15]

Alcohol consumption increases the risk of injury in the short-term and chronic disease in the longer term. Drinking in pregnancy can have significant effects on fetal development.

10.2.1. Background

Alcohol consumption among pregnant women in Australia

›   Most Australian women consume alcohol once a month or more, with 18% of women aged 18–23 years having five or more drinks on one occasion, once a week or more (Young & Powers 2005).

›   Rates of drinking during pregnancy are high, with recent Australian surveys reporting rates of 47% in a national survey (Wallace et al 2007) and 59% in a West Australian study (Colvin et al 2007).

›   Drinking levels in the period before pregnancy are also high. In the West Australian survey, 14% of respondents reported drinking five or more standard drinks on a typical occasion during this period (Colvin et al 2007). As many pregnancies are unplanned (47% in the West Australian survey), many fetuses may inadvertently be exposed to alcohol before pregnancy is confirmed.

›   Studies into drinking among Aboriginal women in some areas have found that between 19% and 44% of Aboriginal women drink alcohol in pregnancy (Zubrick et al 2005; Zubrick 2006; Hayes 2001) and between 10% and 19% drink at harmful levels (Zubrick et al 2006; Hayes 2001).

Risks associated with alcohol consumption in pregnancy

›   High-level and/or frequent intake of alcohol in pregnancy increases the risk of miscarriage, stillbirth and premature birth (O'Leary 2004).

›   Alcohol crosses the placenta and nearly equal concentrations in the mother and fetus can be attained. Exposure of the fetus to alcohol may result in a spectrum of adverse effects, referred to collectively as fetal alcohol spectrum disorders (FASD). Of these, fetal alcohol syndrome (FAS) has been described in children exposed to high levels of alcohol *in utero* as a result of either chronic or intermittent maternal alcohol use (Lemoine et al 1968; Jones et al 1973; Hoyme et al 2005; Astley & Clarren 2000). These children have characteristic facial abnormalities (and often a range of other birth defects), impaired growth and abnormal function or structure of the central nervous system. The diagnosis may not be evident at birth. However, not all children exposed to alcohol during pregnancy are adversely affected, or affected to the same degree. Expression of FAS appears to depend on other factors including (O'Leary 2004): the timing of alcohol intake in relation to the stage of fetal development; the pattern and quantity of alcohol consumption (dose and frequency); and socio-behavioural risk factors (maternal age/duration of drinking, lower socioeconomic status, race, genetic differences, polydrug use).

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15 The information in this section, including the consensus-based recommendation, is based on Guideline 4 in NHMRC (2009) Australian Guidelines to Reduce Health Risks from Drinking Alcohol. Canberra: National Health and Medical Research Council. Literature on prevalence of alcohol consumption and associated risks during pregnancy published subsequent to the NHMRC guidelines has not been reviewed. http://www.nhmrc.gov.au/guidelines/publications/ds10

› A number of alcohol-related birth defects (ARBD) and alcohol-related neurodevelopmental disorders (ARND) have also been described following exposure to alcohol during pregnancy and can be included, with FAS, under the umbrella term of FASD (Hoyme et al 2005; Astley & Clarren 2000). Although children with ARND do not have birth defects, they have significant developmental, behavioural and cognitive problems similar to children with FAS.

› People with FASD experience lifelong problems, including learning difficulties and disrupted education, increased rates of mental illness, drug and alcohol problems and trouble with the law (Streissguth et al 2004).

› The effects of alcohol exposure on fetal development occur throughout pregnancy (including before the pregnancy is confirmed), with the developing fetus being most vulnerable to structural damage during the first three to six weeks of gestation (O'Leary 2004). Effects also vary depending on the dose of alcohol and the pattern of consumption. The most serious of the adverse pregnancy outcomes occur when pregnant women consume high levels of alcohol frequently.

10.2.2. Discussing alcohol consumption in pregnancy

While there is convincing evidence linking chronic or intermittent high level alcohol intake with harms, including adverse pregnancy outcomes and FASD, there remains uncertainty about the potential for harm to the fetus if a woman drinks low levels of alcohol during pregnancy. It is important that all women of child-bearing age are aware, before they consider pregnancy, of both this uncertainty and the potential risks of harm, so they can make informed decisions about drinking in pregnancy. Health professionals should highlight that:

› the risk is higher with high alcohol intake, including episodic intoxication;

› the risk appears to be low with low alcohol intake; and

› it is impossible to determine how other maternal and fetal factors will alter risk in the individual.

The high rates of drinking in Australian women, including pregnant women, and the high rates of unplanned pregnancy suggest that, regardless of policy, many fetuses will be inadvertently exposed to alcohol. Assessment of women who have consumed alcohol before knowing that they were pregnant should include appraisal of how much alcohol was consumed and at what stage in the pregnancy. Efforts should be made not to induce unnecessary anxiety for isolated episodes of drinking. Women who drank alcohol before they knew they were pregnant or during pregnancy should be reassured that the risk to the fetus is likely to be low if they had drunk at low risk levels. Women who remain concerned should seek specialist medical advice. Health professionals who are uncertain how to advise pregnant women seeking information concerning the potential for alcohol-related harm should seek expert advice from specialist medical services.

Consensus-based recommendation
xi. Advise women who are pregnant or planning a pregnancy that not drinking is the safest option as maternal alcohol consumption may adversely affect the developing fetus.

Section 7.5.2 includes an example question that may assist in asking women about their alcohol consumption.

10.2.3.   Practice summary — advising women about alcohol

When — At the first antenatal visit
Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker

› **Discuss alcohol consumption during pregnancy** — Explain that not drinking is the safest option and the risk of harm to the fetus is highest when there is high, frequent maternal alcohol intake. However the level of risk to the individual fetus is influenced by maternal and fetal characteristics and is hard to predict.

› **Assist women who consumed alcohol before knowing they were pregnant** — Advise these women that risk of harm to the fetus is likely to be low if a woman has consumed only small amounts of alcohol before she knew she was pregnant or during pregnancy.

› **Take a holistic approach** — If there are concerns about the effects of a woman's alcohol consumption on the pregnancy, specialist medical advice should be sought. Women who find it difficult to decrease their alcohol intake will require support and treatment and should be offered referral to Drug and Alcohol services.

10.2.4.   Resources

Assessment tools

T-ACE and TWEAK are validated and reliable tools that have been developed for use with pregnant women. However, they may not be useful with lower levels of drinking that may still be risky in pregnancy. AUDIT is a validated tool, but is not designed specifically for use during pregnancy.

AUDIT

Thomas F. Babor John C. Higgins-Biddle John B. Saunders Maristela G. Monteiro Babor TF, Higgins-Biddle JC, Saunder JB et al (2001)The Alcohol Use Disorders Identification Test Guidelines for Use in Primary Care Second Edition. Geneva: World Health Organization. http://whqlibdoc.who.int/hq/2001/WHO_MSD_MSB_01.6a.pdf

TWEAK

T	**Tolerance:** How many drinks can you hold?
W	Have close friends or relatives **Worried** or complained about your drinking in the past year?
E	**Eye Opener:** Do you sometimes take a drink in the morning when you get up?
A	**Amnesia:** Has a friend or family member ever told you about things you said or did while you were drinking that you could not remember?
K (C)	Do you sometimes feel the need to **Cut down** on your drinking?

Scores are calculated as follows: A positive response to question T on Tolerance (ie consumption of more than five drinks) or question W on Worry yields 2 points each; an affirmative reply to question E, A, or K scores 1 point each. A total score of 2 or more points on the TWEAK indicates a positive outcome for pregnancy risk drinking.

<u>T-ACE</u>

T	**Tolerance:** How many drinks does it take to make you feel high?
A	Have people **Annoyed** you by criticising your drinking?
C	Have you ever felt you ought to **Cut down** on your drinking?
E	**Eye opener:** Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover?

Scores are calculated as follows: a reply of More than two drinks to question T is considered a positive response and scores 2 points, and an affirmative answer to question A, C, or E scores 1 point, respectively. A total score of 2 or more points on the T-ACE indicates a positive outcome for pregnancy risk drinking.

Treatment guidelines

DoHA (2007) *Alcohol Treatment Guidelines for Indigenous Australians.* Canberra: Commonwealth of Australia. http://www.health.gov.au/internet/alcohol/publishing.nsf/Content/AGI02

DoHA (2009) *Guidelines for the Treatment of Alcohol Problems*. Canberra: Commonwealth of Australia. http://www.health.gov.au/internet/alcohol/publishing.nsf/Content/treat-guide

DoHA (2009) *Quick Reference Guide for the Treatment of Alcohol Problems*. Canberra: Commonwealth of Australia. http://www.health.gov.au/internet/alcohol/publishing.nsf/Content/treat-quick

Ministerial Council on Drug Strategy (2006) *National Clinical Guidelines for the Management of Drug Use During Pregnancy, Birth and the Early Development Years of the Newborn.* Sydney: NSW Health. http://www.health.nsw.gov.au/pubs/2006/pdf/ncg_druguse.pdf

NHMRC (2009) *Australian Guidelines to Reduce Health Risks from Drinking Alcohol.* Canberra: National Health and Medical Research Council. http://www.nhmrc.gov.au/guidelines/publications/ds10

10.2.5.   References

Astley SJ & Clarren SK (2000) Diagnosing the full spectrum of fetal alcohol-exposed individuals: introducing the 4-digit diagnostic code. *Alcohol* 35(4): 400–10.

Colvin L, Payne J, Parsons D et al (2007) Alcohol consumption during pregnancy in nonindigenous West Australian women. *Alcohol Clin Exp Res* 31(2): 276–84.

Hayes L (2001) *An Evaluation of a District Rural Health Service Data Collection on Social Health Risk Factors during Pregnancy.* Unpublished Masters Thesis, Australian National University, Canberra.

Hoyme HE, May PA, Kalberg WO et al (2005) A practical clinical approach to diagnosis of fetal alcohol spectrum disorders: clarification of the 1996 Institute of Medicine criteria. *Pediatrics* 115: 39–47.

Jones KL, Smith DW, Ulleland CN et al (1973) Pattern of malformation in offspring of chronic alcoholic mothers. *Lancet* 1: 1267–71.

Lemoine P, Harousseau H, Borteyru JP et al (1968) Les enfants des parents alcooliques: anomolies observees a propos de 127 cas. [The children of alcoholic parents: anomalies observed in 127 cases.] *Quest Medical* 25: 476–82.

O'Leary CM (2004) Fetal alcohol syndrome: diagnosis, epidemiology, and developmental outcomes. *J Paediatr Child Health* 40: 2–7.

Streissguth AP, Bookstein FL, Barr HM et al (2004) Risk factors for adverse life outcomes in fetal alcohol syndrome and fetal alcohol effects. *J Dev & Behavioral Pediatrics* 25: 228–38.

Wallace C, Burns L, Gilmour S et al (2007) Substance use, psychological distress and violence among pregnant and breastfeeding Australian women. *Aust NZ J Public Health* 31: 51–56.

Young A & Powers J (2005) *Australian Women and Alcohol Consumption 1996–2003.* Australian Longitudinal Study on Women's Health (ALSWH) report to the Australian Government Department of Health and Ageing. Commonwealth of Australia.

Zubrick SR, Silburn SR, Lawrence D et al (2005) *The Western Australian Aboriginal Child Health Survey: The Social and Emotional Wellbeing of Aboriginal Children and Young People.* Curtin University of Technology and Telethon Institute for Child Health Research, Perth.

Zubrick SR, Silburn SR, De Maio J et al (2006) *The Western Australian Aboriginal Child Health Survey: Improving the Educational Experiences of Aboriginal Children and Young People.* Curtin University of Technology and Telethon Institute for Child Health Research, Perth.

10.3. Medicines

10.3.1. Prescription medicines

Prescribing medicines during pregnancy involves balancing the likely benefit to the pregnant woman against the potential harm to the fetus. Only a small number of medicines have proven safety in pregnancy and a number of medicines that were initially thought to be safe in pregnancy were later withdrawn. General principles include prescribing only well-known and tested medicines at the smallest possible doses and only when the benefit to the woman outweighs the risk to the fetus.

The Therapeutic Goods Administration has categorised medicines that are commonly used in Australia, taking into account the known harmful effects on the developing baby, including the potential to cause birth defects, unwanted pharmacological effects around the time of birth and future health problems (see Table 10.3).

Table 10.3:   Therapeutic Goods Administration categorisation of medicines

Category	
A	Medicines which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the fetus having been observed.
B1	Medicines which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals have not shown evidence of an increased occurrence of fetal damage.
B2	Medicines which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of fetal damage.
B3	Medicines which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals have shown evidence of an increased occurrence of fetal damage, the significance of which is considered uncertain in humans.
C	Medicines which, owing to their pharmacological effects, have caused or may be suspected of causing, harmful effects on the human fetus or neonate without causing malformations. These effects may be reversible. Accompanying texts should be consulted for further details.
D	Medicines which have caused, are suspected to have caused or may be expected to cause, an increased incidence of human fetal malformations or irreversible damage. These medicines may also have adverse pharmacological effects. Accompanying texts should be consulted for further details.
X	Medicines which have such a high risk of causing permanent damage to the fetus that they should not be used in pregnancy or when there is a possibility of pregnancy.

10.3.2.   Over-the-counter medicines

As few medicines have been established as safe to take during pregnancy, a general principle of use is that as few should be used as possible. However, over-the-counter medicines may be useful for relieving symptoms of pregnancy such as nausea and vomiting (see Section 7.8), heartburn, constipation (see Section 7.9) and haemorrhoids.

Consensus-based recommendation
xii. Advise women that use of prescription and over-the-counter medicines should be limited to circumstances where the benefit outweighs the risk as few medicines have been established as safe to use in pregnancy. xiii. Therapeutic Goods Administration Category A medicines have been established to be safe in pregnancy.

Practice point
ee. Health professionals should seek advice from a tertiary referral centre for women who have been exposed to Category D or X medicines during pregnancy.

10.3.3.   Herbal medicines

The use of complementary therapies (including herbal medicines) is increasingly common in Australia (AMA 2002). Women may choose to use them to support wellbeing, because they are perceived to be 'safe' alternatives to pharmacological treatments or because they are part of traditional practices in pregnancy. However, there is a lack of evidence on the safety of complementary medicines during pregnancy and some are known to be harmful in the first trimester.

There is little evidence from randomised trials to support the benefits or safety of herbal medicines (preparations derived from plants) and, even if active ingredients have been studied in trials, supplements may contain other ingredients with unknown effects. Studies have identified harms associated with some European (Cuzzolin et al 2010) and Chinese (Chuang et al 2006) herbal medicines.

Practice point
ff.   Few herbal preparations have been established as being safe and effective during pregnancy. Herbal medicines should be avoided in the first trimester.

10.3.4. Providing advice on medicines

Health professionals can support women in safe use of medicines by being well informed themselves and by providing advice on relevant information services. Current information on specific medicines in pregnancy is available from:

› Therapeutic Goods Administration medicines in pregnancy database — http://www.tga.gov.au/hp/medicines-pregnancy.htm, which can be searched by name or classification level;

› medicines in pregnancy information services in each State/Territory, which provide advice to health professionals and consumers on supplements, over-the-counter and prescription medicines (see Section 10.3.6); and

› the National Prescribing Service website — http://www.nps.org.au/, which publishes resources for health professionals and consumers, with an emphasis on quality use of medicines.

10.3.5. Practice summary — advising women about use of medicines in pregnancy

When — At antenatal visits
Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker; pharmacist
› **Discuss use of medicines with women** — Explain that while many medicines are not safe in pregnancy, they may be needed in some situations (eg to treat high blood pressure, epilepsy, depression) or relieve some symptoms of pregnancy. Advise women to tell the pharmacist that they are pregnant if they are purchasing over-the-counter medicines.
› **Discuss risks and benefits** — If prescribing medicines, explain any risks to the fetus and the benefits of the treatment to the mother so that women can make an informed decision about the treatment.

10.3.6. Resources

Medicines in pregnancy information services for health professionals

Australian Capital Territory

ACT Drug Information Service
The Canberra Hospital
Garran ACT 2605
Phone: 02 6244 3333
Fax: 02 6244 3334

New South Wales

Mothersafe
Medications in Pregnancy and Lactation Service
Royal Hospital for Women
Randwick NSW 2031
Phone: 02 9382 6539 or 1800 647 848

Victoria

Royal Women's Hospital
Medicines Information Centre
Cnr Grattan St and Flemington Rd
Parkville VIC 3052
Phone: 03 8345 3190
Fax: 03 8345 3195

Monash Medical Centre
Obstetric Drug Information
246 Clayton Road
Clayton VIC 3168
Phone: 03 9594 2361
Fax: 03 9594 2595

GPO Box 1061L
Hobart TAS 7001
Phone: 03 6238 8737
Fax: 03 6222 8029 or 03 6231 2905

Northern Territory

Northern Territory Drug Information Centre
Royal Darwin Hospital
PO Box 41326
Casuarina NT 0811
Phone: 08 8922 8424
Fax: 08 8922 8499

South Australia

Drugs in Pregnancy and Lactation Information Service
Women's and Children's Hospital
72 King William Road
North Adelaide SA 5006
Phone: 08 8161 7222
Fax: 08 8161 6049

Western Australia

Obstetric Drug Information Service
King Edward Memorial Hospital for Women
374 Bagot Road
Subiaco WA 6008
Phone: 08 9340 2723
Fax: 08 9340 2713

Queensland

Royal Women's Hospital
Obstetric Drug Information Service
Brisbane QLD
Phone: 07 3253 7300
Fax: 07 3253 3544

Queensland Drug Information Centre
Royal Brisbane Hospital
E Floor, Block 7
Herston Road
Herston QLD 4029
Phone: 07 3253 7098 or 07 3253 7599
Fax: 07 3253 1393

Tasmania

Drug Information Centre
Pharmacy Department
Royal Hobart Hospital

Websites

Information about specific medicines regarding safety during pregnancy is available from:

› Medsafe (NZ): http://www.medsafe.govt.nz/

› MICROMEDIX: http://www.ciap.health.nsw.gov.au/home.html

› Mothersafe (NSW): http://www.sesiahs.health.nsw.gov.au/Mothersafe/

› National Prescribing Service: http://www.nps.org.au/

› Therapeutic Goods Administration Prescribing Medicines in Pregnancy Database:
http://www.tga.gov.au/hp/medicines-pregnancy.htm

10.3.7. References

AMA (2002) *Complementary Medicine.* Australian Medical Association Position Statement.

Chuang CH, Doyle P, Wang JD et al (2006) Herbal medicines used during the first trimester and major congenital malformations: an analysis of data from a pregnancy cohort study. *Drug Saf* 29(6): 537–48.

Cuzzolin L, Francini-Pesenti F, Verlato G et al (2010) Use of herbal products among 392 Italian pregnant women: focus on pregnancy outcome. *Pharmacoepidemiol Drug Saf* 19(11): 1151–58.

10.4. Nutritional supplements

While there is evidence to support routine supplementation with folic acid and iodine in pregnancy, other vitamin and mineral supplements are not of benefit unless there is an identified deficiency. The evidence on complementary therapies in pregnancy is limited.

10.4.1. Folic acid

Folic acid supplementation prevents first and second time occurrence of neural tube defects (De-Regil et al 2010). In Australia, the rates of abnormalities such as encephalocele, anencephaly and spina bifida have fallen with promotion of folic acid supplements and voluntary fortification (Bower et al 2009). However, no such falls have been seen for Aboriginal babies (Bower et al 2009) and the prevalence of neural tube defects among Aboriginal and Torres Strait Islander babies is almost double that in the non-Indigenous population (Bower et al 2004). Levels of knowledge about folic acid supplementation appear to be lower among Aboriginal and Torres Strait Islander women (55% vs 67.5% of the mostly non-Indigenous women surveyed), particularly among adolescent women (38%) (Bower et al 2004). Restricted food choices and higher costs in rural and remote areas may also contribute to lower levels of folate intake and higher prevalence of neural tube defects (Bower et al 2004).

Women taking medicines that are folate antagonists (eg carbamazepine, lamotrigine) should be encouraged to take high-dose folate supplements preconception and during the first trimester (beyondblue 2011).

Recommendation	Grade A
26. Inform women that dietary supplementation with folic acid, from 12 weeks before conception and throughout the first 12 weeks of pregnancy, reduces the risk of having a baby with a neural tube defect and recommend a dose of 500 micrograms per day.	

Practice point
gg. Specific attention needs to be given to promoting folic acid supplementation to Aboriginal and Torres Strait Islander women of childbearing age and providing information to individual women at the first antenatal visit.

10.4.2. Other vitamins

Studies into the effects of supplementation during pregnancy of vitamin C (Rumbold & Crowther 2005), combined vitamins C and E (Xu et al 2010) and vitamin A (Kirkwood et al 2010; van den Broek et al 2010) have found no benefit. However, supplementation has been associated with:

› preterm birth (vitamin C) (Rumbold & Crowther 2005);

› perinatal death and preterm rupture of the membranes (vitamins C and E) (Xu et al 2010); and

› congenital malformation (vitamin A)(Oakley & Erickson 1995; Rothman et al 1995; Dolk et al 1999).

› There is insufficient evidence about the effects of other combinations of vitamins on pregnancy outcomes (Rumbold et al 2011).

Recommendation	Grade B
27. Advise women that taking vitamins A, C or E supplements is not of benefit in pregnancy and may cause harm.	

10.4.3. Iodine[16]

Increased thyroid activity during pregnancy increases iodine requirements. If iodine intake is inadequate before pregnancy, maternal stores may run low and be inadequate to support the unborn baby in later stages of pregnancy (Smyth 2006). Iodine deficiency is of particular concern during pregnancy because abnormal function of the mother's thyroid has a negative impact on the nervous system of the unborn baby, and increases the risk of infant mortality (Zimmerman 2009). Adverse effects on early brain and nervous system development are generally irreversible and can have serious implications for mental capacity in later life (WHO 2005–09).

There are limited studies specific to the iodine status of pregnant women in Australia, but those available prior to fortification suggest it was inadequate (APHDPC 2007). With the introduction of mandatory iodine fortification of bread, most of the Australian population will get enough iodine (Food Standards Australia New Zealand 2008) and women of child-bearing age should enter pregnancy with adequate iodine intake. However, the extra iodine available through fortified bread is not enough to meet the additional needs of pregnancy and during breastfeeding (Burgess et al 2007).

Consensus-based recommendation
xiv Advise women who are pregnant to take an iodine supplement of 150 micrograms each day. Women with pre-existing thyroid conditions should seek advice from their medical practitioner before taking a supplement.

10.4.4. Iron supplementation

There is a lack of evidence that, in otherwise healthy women, the benefits of treatments for mild iron-deficiency anaemia in pregnancy will outweigh the adverse effects associated with them (Reveiz et al 2007). There is a potential dose response relationship between dose of iron and reported adverse events (Reveiz et al 2007).

Women can be advised to consume iron-rich foods and that vitamin C (eg in fruit juice) aids absorption while tea and, to a lesser degree, coffee reduce the amount of iron available for absorption (NHMRC 2005).

Recommendation	Grade B
28. Do not routinely offer iron supplementation to women during pregnancy.	

16 This section, including the consensus-based recommendation, is based on NHMRC (2010) NHMRC Public Statement: Iodine Supplementation for Pregnant and Breastfeeding Women. Canberra: National Health and Medical Research Council.

10.4.5.   Practice summary — advising women about nutritional supplements

When — At antenatal visits
Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker; pharmacist

› **Discuss use of nutritional supplements with women** — Explain that some supplements (folic acid, iodine) are recommended for all women during pregnancy, while others (vitamins A, C and E and iron) are not of benefit and may be harmful and that iron should only be supplemented if a deficiency is identified.

10.4.6.   Resources

NHMRC (2010) *NHMRC Public Statement: Iodine Supplementation for Pregnant and Breastfeeding Women*. Canberra: National Health and Medical Research Council. http://www.nhmrc.gov.au/guidelines/publications/new45

FSANZ (undated) *Thinking About Having a Baby? Important Things You Need to Know About What You Eat and Drink*. Food Standards Australia and New Zealand. http://www.foodstandards.gov.au/_srcfiles/FSANZ%20Pregnancy_WEB.pdf

National Health and Medical Research Council (2013) *Australian Dietry Guidelines*. Canberra*: National Health and Medical Research Council*.

NHMRC (2005) *Nutrient Reference Values for Australia and New Zealand*. Canberra: National Health and Medical Research Council. http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/n35.pdf

10.4.7.   References

APHDPC (2007) *The Prevalence and Severity of Iodine Deficiency in Australia*. Australian Population Health Development Principal Committee. Report Commissioned by the Australian Health Ministers' Advisory Committee.

beyondblue (2011) *Clinical Practice Guidelines for Depression and Related Disorders — Anxiety, Bipolar Disorder and Puerperal Psychosis — in the Perinatal Period. A Guideline for Primary Care Health Professionals*. Melbourne: *beyondblue: the national depression initiative.*

Bower C, D'Antoine H, Stanley FJ (2009) Neural tube defects in Australia: Trends in encephaloceles and other neural tube defects before and after promotion of folic acid supplementation and voluntary food fortification. *Birth Defects Res A Clin Mol Teratol* 85(4): 269–73.

Bower C, Eades S, Payne J et al (2004) Trends in neural tube defects in Western Australia in Indigenous and non-Indigenous populations. *Paediatr Perinatal Epidemiol* 18(4): 277–80.

Burgess JR, Seal JA, Stilwell GM et al (2007) A case for universal salt iodisation to correct iodine deficiency in pregnancy: another salutary lesson from Tasmania. *Med J Aust* 186: 574–76.

De-Regil LM, Fernández-Gaxiola AC, Dowswell T et al (2010) Effects and safety of periconceptional folate supplementation for preventing birth defects. *Cochrane Database of Systematic Reviews* DOI: 10.1002/14651858. CD007950.pub2.

Dolk HM, Nau H, Hummler H et al (1999) Dietary vitamin A and teratogenic risk: European Teratology Society discussion paper. *Eur J Obstet Gynecol Reprod Biol* 83: 31–6.

Food Standards Australia New Zealand (2008) *Approval Report Proposal P1003 – Mandatory Iodine Fortification for Australia*. Commonwealth of Australia. Available online at http://www.foodstandards.gov.au.

Kirkwood BR, Hurt L, Amenga-Etego S et al (2010) Effect of vitamin A supplementation in women of reproductive age on maternal survival in Ghana (ObaapaVitA): a cluster-randomised, placebo-controlled trial. *Lancet* 375(9726): 1640–49.

NHMRC (2005) *Nutrient Reference Values for Australia and New Zealand.* Canberra: National Health and Medical Research Council. http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/n35.pdf

Oakley GP Jr & Erickson JD (1995) Vitamin A and birth defects. Continuing caution is needed. *New Engl J Med* 333: 1414–15.

Reveiz L, Gyte GM, Cuervo LG (2007) Treatments for iron-deficiency anaemia in pregnancy. *Cochrane Database of Systematic Reviews* DOI: 10.1002/14651858.CD003094.pub2.

Rothman KJ, Moore LL, Singer MR et al (1995) Teratogenicity of high vitamin A intake. *New Engl J Med* 333: 1369–73.

Rumbold A & Crowther CA (2005) Vitamin C supplementation in pregnancy. *Cochrane Database of Systematic Reviews* DOI: 10.1002/14651858.CD004072.pub2.

Rumbold A, Middleton P, Pan N et al (2011) Vitamin supplementation for preventing miscarriage. *Cochrane Database of Systematic Reviews* DOI: 10.1002/14651858.CD004073.pub3.

Smyth PP (2006) Dietary iodine intakes in pregnancy. *Irish Med J* 99(4): 103.

van den Broek N, Dou L, Othman M et al (2010) Vitamin A supplementation during pregnancy for maternal and newborn outcomes. *Cochrane Database of Systematic Reviews* DOI: 10.1002/14651858.CD008666.pub2.

WHO (2005–09) *Micronutrient Deficiencies.* World health Organization Regional Office for the Western Pacific. http://www.wpro.who.int/.

Xu H, Perez-Cuevas R, Xiong X et al (2010) An international trial of antioxidants in the prevention of preeclampsia (INTAPP). *Am J Obstet Gynecol* 239.e231–39.e210.

Zimmermann MB (2009) Iodine deficiency in pregnancy and the effects of maternal iodine supplementation on the offspring: a review. *Am J Clin Nutr* 89: 668S–72S.

10.5.   Oral health

Treatment of periodontal disease improves a woman's wellbeing and is safe in pregnancy.

10.5.1.   Background

Oral health refers to the health of tissues in the mouth, including mucous membrane, connective tissue, muscles, bone, teeth and periodontal structures or gums (gingiva). Pregnancy itself does not have a negative effect on oral health, but may increase the risk of dental problems (eg frequent vomiting may raise acidity in the mouth and contribute to caries). As well, high levels of hormones increase blood flow to the gums and may cause inflammation and bleeding (gingivitis) (Taanni et al 2003). In the absence of local plaque build up, healthy gums will not show changes during pregnancy but the risk of peridontitis (inflammation and destruction of supporting tissues around the teeth [ADA 1999]) is increased.

Measures to prevent caries and periodontal disease include regular brushing and flossing and regular dental checkups, with teeth cleaning and treatment as required.

Oral health in Australia

Access to dental services in Australia varies, with limited services available in rural and remote areas and women in all areas potentially affected by the costs of dental services, which are not covered under Medicare. Data from the Australian Institute of Health and Welfare show that:

›   dental care in Australia is largely provided in the private sector, with public dental patients generally being health care card holders and socioeconomically disadvantaged (AIHW 2010);

›   adults living outside major cities are more likely to have poorer dental health, such as more tooth loss and untreated decay and less likely to have visited the dentist in the previous 12 months than those in major cities (AIHW 2009); and

›   Aboriginal and Torres Strait Islander adults seeking dental care in Australia in 2004–06 had a greater average number of decayed and missing teeth and a lower average number of filled teeth than non-Indigenous adults across most age groups (AIHW 2008).

Prevalence of periodontal disease in pregnancy

A multicentre randomised trial (n=3,563) found a prevalence of periodontal disease of 50% during pregnancy (Macones et al 2010). The incidence of periodontal disease has been associated with lower levels of education and socioeconomic status (Machuca et al 1990; Gaffield et al 2001; Taanni et al 2003).

Risks associated with periodontal disease in pregnancy

Associations between periodontal disease and preterm birth (Jeffcoat et al 2003; Lopez et al 2005; Offenbacher et al 2006; Polyzos et al 2009) and low birth weight (Lopez et al 2005; Sadatmansouri et al 2006; Tarannum & Faizuddin 2007) have been suggested. However, a recent cohort study (n=876) found no association between periodontal disease and adverse pregnancy outcomes (Srinivas et al 2009) and a meta-analysis of observational studies (Khadar & Ta'ani 2005) found that treating periodontal disease did not decrease the rate of preterm birth. Controlled trials into treating periodontitis during pregnancy have also found:

› improved periodontal disease and safety of treatment but no significant change in rates of preterm birth, low birth weight or fetal growth restriction (n=812) (Michalowicz et al 2006; Novak et al 2008; Michalowicz et al 2009);

› no significant reduction in the risk of preterm birth (n=824) (Offenbacher et al 2009; Macones et al 2010), although treatment may protect against low birth weight (n=339) (Cruz et al 2010);

› no significant differences between women receiving treatment during or after pregnancy in terms of preterm birth (9.3% versus 9.7%), birth weight (3,450 versus 3,410g) or pre-eclampisa (4.1% versus 3.4%) (n=1,082) (Newnham et al 2009); and

› a reduction in the incidence of caries among children whose mothers received oral health advice during pregnancy (1.7% versus 9.6% in the control group) (n=649) (Plutzer & Spencer 2008).

10.5.2. Providing advice on oral health

Good oral health and control of oral disease protects a woman's health and quality of life and has the potential to reduce transmission of pathogenic bacteria from mothers to their children (CDAF 2010). Dental treatment can be safely provided at any time during pregnancy (ADA 1999) if the dentist is informed of the pregnancy.

An Australian survey of women who had recently given birth (n=388) (Thomas et al 2008) found that most were knowledgeable about oral and dental health but only a small percentage knew about periodontal disease. Lack of knowledge about oral and dental health was strongly linked to lower educational achievement and lower socioeconomic background. Over half of respondents had not attended a dentist in the previous 12 months, and only 30% attended during their most recent pregnancy.

Nausea and vomiting

Nausea and vomiting have the potential to affect oral health:

› frequent snacks and soft drinks/carbonated drinks and cravings for particular foods (often sweet) can increase risk of tooth decay;

› excessive vomiting brings teeth into contact with strong stomach acid; and

› repeated reflux and vomiting can damage tooth enamel and increase the risk of decay.

Measures to reduce the impact of nausea and vomiting on oral health include (Morgan et al 2008; CDAF 2010; Rogers 2011):

› waiting for at least an hour before brushing teeth after vomiting or rinsing the mouth with a solution of bicarbonate of soda;

› using fluoridated mouthwash and toothpaste;

› eating small amounts of nutritious yet non-cariogenic foods (snacks rich in protein) throughout the day; and

› chewing sugar-free gum (especially gums containing xylitol or casein phosphopeptide – amorphous calcium phosphate [CPP-ACP]) after meals or high sugar or acidic drinks.

Recommendation	Grade B
29. At the first antenatal visit, advise women to have oral health checks and treatment, if required, as good oral health protects a woman's health and treatment can be safely provided during pregnancy.	

10.5.3. Practice summary — advising women about oral health

When — At antenatal visits
Who — Midwife; GP; obstetrician; Aboriginal and Torres Strait Islander health worker; multicultural health worker; pharmacist

› **Discuss oral health with women** — Explain that pregnancy does not causes dental problems but may make them more likely. Advise women to have their oral health checked and to tell the dentist that they are pregnant.

› **Provide advice on oral health to women experiencing nausea and vomiting** — Explain that vomiting exposes teeth to acid and give tips on how to reduce the impact (see above).

10.5.4. Resources

CDAF (2010) Oral health during pregnancy and early childhood: evidence-based guidelines for health professionals. California Dental Association Foundation, American College of Obstetricians and Gynecologists. *J Calif Dent Assoc* 38(6): 391–403, 405–40.

NACOH (2004) *Healthy Mouths Healthy Lives: Australia's National Oral Health Plan 2004-2013.* Adelaide: National Advisory Committee on Oral Health, Australian Health Ministers' Advisory Council.

10.5.5. References

ADA (1999) American Dental Association: International workshop for classification of periodontal disease and conditions. *Ann Periodontol* 4: 1–112.

AIHW (2008) *The Health and Welfare of Australia's Aboriginal and Torres Strait Islander Peoples*. ABS Cat No 4704.0, AIHW Cat No IHW 21. Commonwealth of Australia.

AIHW (2009) *Geographic Variation in Oral health and Use of Dental Services in the Australian Population 2004–06.* Cat. no. DEN 188. Canberra: AIHW.

AIHW (2010) *Australia's Health 2010.* Australia's health series no. 12. Cat. no. AUS 122. Canberra: Australian Institute of Health and Welfare.

CDAF (2010) Oral health during pregnancy and early childhood: evidence-based guidelines for health professionals. California Dental Association Foundation, American College of Obstetricians and Gynecologists. *J Calif Dent Assoc* 38(6): 391–403, 405–40.

Cruz SS, Costa Mda C, Gomes-Filho IS et al (2010) Periodontal therapy for pregnant women and cases of low birthweight: an intervention study. *Pediatr Int* 52(1): 57–64.

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PART C —
AREAS FOR FURTHER RESEARCH

The systematic reviews undertaken to develop these Guidelines identified a number of areas where evidence to support recommendations on antenatal care in the first trimester is limited or lacking. High quality evidence on which to base recommendations about care to meet the specific needs of Aboriginal and Torres Strait Islander women is also limited. This list is not intended to be exhaustive. These areas are listed here with the expectation of encouraging research to further inform practice.

Gestational age assessment

The systematic reviews undertaken to develop these Guidelines did not identify any studies that assessed the use of early ultrasound to estimate gestational age in relation to psychological harms to the mother, risk of over-diagnosis of placenta praevia or its contribution to anxiety. In addition, issues of access need to be studied to ensure that there is equity, especially for women in rural and remote settings and those from marginalised or vulnerable groups.

There is a lack of economic evaluations of the cost effectiveness of ultrasound dating screening. In addition, future research needs to identify reliable indicators to measure how the proposed recommendation might affect rates of first trimester ultrasound screening, number of additional scans and induction of labour in terms of cost, benefit and unintended consequences.

Weight gain in pregnancy

More research is needed on appropriate weight gain or weight loss in pregnancy, particularly for women who start pregnancy at a higher BMI, the effectiveness of routine weighing in improving outcomes, including the impact on women, and interventions that are effective in treating overweight and underweight in pregnancy. More research in this area will guide future practice.

Nausea and vomiting in early pregnancy

While most instances of nausea and vomiting in pregnancy resolve without treatment, many women find nausea and vomiting affect their quality of life. It is currently not possible to identify with certainty interventions for nausea and vomiting in early pregnancy that are both safe and effective. There is also limited research on complementary and alternative medicines that may assist women with these conditions in early pregnancy.

Preterm birth

More research is needed to better understand the high rates of preterm birth experienced by Aboriginal and Torres Strait Islander women, and to identify effective prevention strategies including during the antenatal period.

Hepatitis C

Routine screening of women for hepatitis C remains controversial, particularly as there are no known interventions to reduce the rate of mother-to-child transmission. More research needs to be undertaken into the prevalence of hepatitis C in pregnant women in Australia and the implications of routine screening; in particular, women's views about screening and the way they will use information about having hepatitis C when there are no preventive transmission interventions.

Chlamydia

There is a need for further research about the prevalence and incidence of Chlamydia infection during pregnancy for different population groups of women, and the acceptability and effectiveness of different approaches to population based screening for chlamydia and other sexually transmitted infections during pregnancy, including for Aboriginal and Torres Strait Islander women.

Asymptomatic bacterial vaginosis

The diagnosis and possible treatment of asymptomatic bacterial vaginosis has been somewhat controversial in the development of these Guidelines. Diagnosis of asymptomatic bacterial vaginosis and its early treatment (before 20 weeks pregnancy) may be beneficial for women with a previous preterm birth. More research needs to identify whether this is the case in Australia and whether there are other benefits or risks associated with screening for this condition.

Vitamin D

As there is limited evidence to support screening of all women for vitamin D deficiency in pregnancy, research in this area is important. Future research needs to identify the predictive factors for vitamin D insufficiency and deficiency in Australia, particularly among Aboriginal and Torres Strait Islander women and quantified for the degree of sunlight exposure including latitude of residence. Research is also needed to identify the potential benefits and risks of supplementation for women who have vitamin D insufficiency compared with those who have a vitamin D deficiency, especially longer term implications for women and their infants. Cost-effectiveness studies of screening and supplementation are also needed.

Women's experiences of maternal health screening in early pregnancy

These Guidelines recommend a considerable amount of screening in early pregnancy. Some of these tests are commonplace in Australia today while others will provide new challenges to women and health professionals. There is limited research about the benefits, risks and unexpected consequences of screening in pregnancy. Qualitative research is also needed to explore the implications of screening for women, especially those for women in rural and remote settings, Aboriginal and Torres Strait Islander women and women from marginalised or vulnerable groups. The best ways in which to provide evidence-based information in a non-judgmental way and to seek informed consent are poorly researched. Understanding of effective ways of providing evidence-based information and effectively enabling input into decision making about care during pregnancy for Aboriginal and Torres Strait Islander women is also limited.

These areas are fundamental to many of the recommendations in these Guidelines and more research into this important area is needed.

Non-prescription and alternative medicines

There is a paucity of high-level evidence about the effects of various non-prescription medicines and other therapies including herbal preparations on the developing fetus and on pregnancy outcome. As their use is widespread there is a need for research into these effects.

Smoking cessation

The cost-effectiveness analysis identified that future health expenditure savings from pregnant women ceasing smoking could be included as benefits. However, there is considerable debate about whether smoking interventions, and preventive measures more generally, reduce long-term health expenditure. The analysis could not estimate future health expenditure savings from pregnant women quitting smoking. This is an important area for future research. Cost-effectiveness analyses are limited in maternity care and this area would benefit from future targeted research to help guide policy and practice.

One of the beneficial interventions identified in these Guidelines is CBT to assist women to quit smoking. However, it is not known how many CBT sessions would be required for a successful quit.

New areas for research

Areas that were not covered in these Guidelines but where research may improve outcomes for women and babies include:

› optimal methods for providing information to women to promote health in pregnancy;

› effective models of antenatal care;

› approaches to contraception, pregnancy planning and preconception care;

› the validity and acceptability of psychosocial assessment tools for use in specific populations;

› alcohol use in pregnancy, specifically fetal alcohol syndrome; and

› screening for thyroid disease in the first trimester.

APPENDICES

A. Membership of advisory committees

This appendix lists the membership of the Expert Advisory Committee and the multidisciplinary working groups convened for the development of the Guidelines. Secretariat support for these committees was provided by the Australian Government Department of Health and Ageing. Details of the project officers, systematic literature reviewers, methodological consultants and technical writers are also included.

Name	Discipline and affiliation/s
Expert Advisory Committee (EAC) Executive	
Professor Jeremy Oats Co-Chair	Chair Victorian Consultative Council on Obstetric and Paediatric Mortality and Morbidity Medical Co-Director, Integrated Maternity Services, Northern Territory Women's Hospitals Australasia
Professor Caroline Homer Co-Chair	Professor of Midwifery Centre for Midwifery, Child and Family Health, Faculty of Nursing, Midwifery and Health University of Technology, Sydney
Dr Anne Sved Williams Co-Chair Screening and Monitoring Working Group	Director, Perinatal and Infant Mental Health, Children Youth and Women's Health Service, South Australia Australasian and New Zealand College of Psychiatrists
Professor Sue McDonald Co-Chair Clinical Working Group Chair Implementation Working Group	Professor of Midwifery and Women's Health La Trobe University, Victoria
Mr Bruce Teakle[17] Co-Chair Social and Lifestyle Group (until end December 2009)	Consumer representative National committee member of Maternity Coalition
Ann Catchlove[17] Co-Chair Social and Lifestyle Group Member of Implementation Working Group	Consumer representative President, Victorian Branch of The Maternity Coalition (from January 2010)

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17 Consumer representatives were identified through advertisements placed in Consumer Health Forum Publications for consumers with an interest in national guidelines.

Name	Discipline and affiliation/s
Professor Warwick Giles Co-Chair Clinical Working Group	Senior Staff Specialist, Maternal Fetal Medicine; Conjoint Professor Northern Clinical School University of Sydney Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Dr Henry Murray Co-Chair Screening and Monitoring Group	Fetomaternal Specialist, Acting Director of Obstetrics, John Hunter Hospital, Newcastle, NSW
Associate Professor Ruth Stewart Co-Chair Social and Lifestyle Group Member of Implementation Working Group	Director of Parallel Rural Community Curriculum, Faculty of Health, Medicine, Nursing and Behavioral Science School of Medicine, Deakin University Australasian College of Rural and Remote Medicine
Dr Jenny Hunt Co-Chair Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care	Public Health Medical Officer Aboriginal Health and Medical Research Council
Dr Marilyn Clarke Co-Chair Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care	Obstetrician and gynaecologist
EAC Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care	
Dr Jenny Hunt Co-Chair Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care	Public Health Medical Officer Aboriginal Health and Medical Research Council
Dr Marilyn Clarke Co-Chair Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care	Obstetrician and gynaecologist
Associate Professor Katie Panaretto	Population Health Medical Officer, Centre for Indigenous Health, University of Queensland, Queensland Aboriginal and Islander Health Council
Prof Sue Kildea	Chair of Midwifery, Australian Catholic University and Mater Mother's Hospital Australian College of Midwives
Ms Francine Eades	Senior Research Officer, Kulunga Research Network
Ms Mary Buckskin (until January 2011)	Chief Executive Officer, Aboriginal Health Council of South Australia

Name	Discipline and affiliation/s
Ms Sue Hendy	Director of Women's, Children's & Youth Health, Western Sydney and Nepean Blue Mountains Local Health Networks
Ms Gwen Wallenburg	Community Midwife, Thursday Island
Ms Leshay Maidment	Branch Manager, Congress Alulkura, and Acting Deputy Chief Executive Officer, Central Australian Aboriginal Congress
Ms Stephanie Bell (until April 2011)	Chief Executive Officer, Central Australian Aboriginal Congress
Ms Simone Andy	Koori Maternity Strategy, Victorian Aboriginal Community Health Organisation
Ms Nicole Randriamahefa (until January 2011)	Tasmanian Aboriginal Centre National Aboriginal Community Controllled Health Organisiation
EAC Clinical Working Group	
Prof Warwick Giles Co-Chair Working Group	Senior Staff Specialist, Maternal Fetal Medicine; Conjoint Professor Northern Clinical School University of Sydney Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Professor Sue McDonald Co-Chair Working Group	Professor of Midwifery and Women's Health La Trobe University, Victoria
Dr Andrew Bisits Member of Implementation Working Group	Lead Clinician, Birthing Services, Royal Hospital for Women, Sydney
Dr John Overton	Obstetrician, Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Associate Professor Jenny Gamble	Associate Professor of Midwifery, Deputy Head of School (Logan campus) Griffith University, Qld Australian College of Midwives
Ms Chris Cornwell	Service Manager, Women's and Children's Hospital Adelaide, SA
Dr Elizabeth Boyd	General Practitioner, Royal Australian College of General Practitioners
Ms Nellie Vagana[18]	Consumer representative
Ms Terri Barrett	Midwifery Director, Statewide Obstetric Support Unit, King Edward Memorial Hospital, Department of Health WA

18 Consumer representatives were identified through advertisements placed in Consumer Health Forum Publications for consumers with an interest in national guidelines.

Name	Discipline and affiliation/s
EAC Screening and Monitoring Group	
Dr Anne Sved Williams Co-Chair Working Group	Director, Perinatal and Infant Mental Health, Children Youth and Women's Health Service, South Australia Australasian and New Zealand College of Psychiatrists
Dr Henry Murray Co-Chair Working Group	Fetomaternal Specialist, Nepean Clinical School University of Sydney Australian and New Zealand College of Obstetricians and Gynaecologists
Associate Professor Jenny Fenwick	Associate Professor of Midwifery, University of Technology, Sydney, NSW Australian College of Midwives
Professor Jane Fisher	Key Centre for Women's Health in Society, University of Melbourne
Associate Professor Elizabeth Sullivan	Director, AIHW National Perinatal Statistics Unit
Professor Michael Permezel	Head of Department, University of Melbourne, Mercy Hospital for Women Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Ms Tanya Farrell	Director, Maternity Services, Royal Women's and Children's Hospital, Melbourne, Victoria
Dr Sandra Eades	Senior Research Fellow, Baker IDI Heart and Diabetes Institute, Melbourne
Ms Kay Hyde	Director, Professional Governance Nurses and Midwives Board of WA
Prof Marie-Paule Austin	Consultant Psychiatrist, St John of God Chair of Perinatal and Women's Mental Health School of Psychiatry, University of NSW
Dr Helen Roxborough	General Practitioner
EAC Social and Lifestyle Group	
Ann Catchlove[19] Co-Chair Working Group	Consumer representative from January 2010
Mr Bruce Teakle[19] Co-Chair Working Group	Consumer representative from January 2009 to December 2009
Louise Hartley[19]	Consumer representative August 2008 to December 2008

19 Consumer representatives were identified through advertisements placed in Consumer Health Forum Publications for consumers with an interest in national guidelines.

Name	Discipline and affiliation/s
Associate Professor Ruth Stewart Co-Chair Working Group	Director of Clinical Studies, Integrated Model of Medical Education in Rural Settings (formerly Parallel Rural Community Curriculum), Faculty of Health, Medicine, Nursing and Behavioral Science School of Medicine, Deakin University Australasian College of Rural and Remote Medicine
Professor Maralyn Foureur	Professor of Midwifery, University of Technology, Sydney Australian College of Midwives
Mr Scott Wilson	State Director, Aboriginal & Drug Council (SA) Inc National Indigenous Drug and Alcohol Committee
Ms Robyn Collins	Chief Executive Officer, Nurses and Midwives Board of WA
Dr Ted Weaver	Obstetrician and gynaecologist, Past President, Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Professor Anne Buist	National Program Director, *beyondblue*
Ms Susan Stratigos	Policy Advisor, Rural Doctors Association of Australia, National Rural Women's Coalition
Ms Debra Oag	Policy Officer, Smokefree Pregnancy Project (until July 2010)
Ms Noelle Mason	Group President, Country Women's Association
Project Officers / Systematic Literature Reviewers	
Dr Stuart Barrow	Project Officer until 2010
Ms Glenda McDonald	Project Officer until 2010
Ms Wendy Cutchie	Midwifery Project Officer from 2010
Ms Vanessa Watkins	Midwifery Project Officer from June 2010
Dr Andrea Gordon	Pharmacologist, Research Fellow, Sansom Institute for Medical Research University of South Australia (contracted to project from November 2010)
Dr Antonina Mikocka-Walus	Research Fellow, School of Nursing & Midwifery, University of South Australia (contracted to project from November 2010)
Dr Rasika Jayasekara	Registered Nurse, Lecturer, School of Nursing & Midwifery, University of South Australia (contracted to project from November 2010)
Dr Lois McKellar	Lecturer, Nursing & Midwifery, University of South Australia (contracted to project from November 2010)
Ms Penny Williamson	Research Assistant (contracted to project from November 2010)
Ms Dianne Gall	Research Assistant (contracted to project from November 2010)

Name	Discipline and affiliation/s
Methodological Consultants	
Professor Sally Green	Co-Director of the Australasian Cochrane Centre and Professorial Fellow School of Public Health & Preventative Medicine, Monash University
Dr Tari Turner	Senior Research Fellow Australian Cochrane Centre, Monash University
Technical Writers	
Ms Jenny Ramson	Technical writer, Ampersand Health Science Writing
Ms Elizabeth Hall	Technical writer, Ampersand Health Science Writing

B. Terms of reference

Expert Advisory Committee

The Expert Advisory Committee will convene to:

1. provide advice, expertise and direction on the appropriateness of the Guidelines to promote optimal care for pregnant women across Australia;

2. supervise the parties that are commissioned to:

   a. consult with a number of advisory groups to draft and review evidence-based guidelines as well as national and international literature on antenatal care with specific attention to the health needs of Aboriginal and Torres Strait Islander pregnant women, their families and other vulnerable groups;

   b. consult widely to develop evidenced-based guidelines that will function as a useful resource for clinicians and pregnant women and their families in a variety of Australian healthcare contexts;

   c. undertake analysis of harms and benefits in the Australian context and determine the costs/benefits and cost effectiveness of proposed interventions in accordance with available literature; and

   d. produce a dissemination plan for the implementation and determine a process for ongoing monitoring of clinical uptake of the Guidelines; and

3. ensure the Guidelines are developed as set out in National Health and Medical Research Council (NHMRC) protocols and are approved by the NHMRC.

Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care

The Working Group will:

1. provide advice, expertise and direction on the appropriateness of the Guidelines to promote optimal care for Aboriginal and Torres Strait Islander pregnant women across Australia;

2. review draft evidence-based Guidelines and provide advice to ensure relevance and applicability of the Guidelines to the cultural and health needs of Aboriginal and Torres Strait Islander pregnant women;

3. identify additional questions and appropriate sources of evidence;

4. identify appropriate sources of evidence relevant to guideline topics, additional to those identified in formal literature searches (this may include grey literature and other unpublished sources);

5. provide advice and draft practice points, where relevant;

6. provide advice to the technical writer regarding appropriate terminology and language used throughout the guideline document;

7. in consultation with the technical writer contribute to the drafting of a separate guidance around cultural and other issues relevant to antenatal care for Aboriginal and Torres Strait Islander women;

8. provide advice regarding the implementation of the Guidelines in settings where Aboriginal and Torres Strait Islander women receive pregnancy care;

9. identify areas and topics for future guideline documents; and

10. provide ideas for making guidelines as practical as possible.

C. Process report

Background

The development of national evidence-based antenatal care guidelines was one of four projects to improve child health and wellbeing approved in July 2005 by the Australian Health Ministers' Conference (AHMC) and the Community and Disability Services Ministers' Conference (CDSMC).

During 2006, a National Working Group engaged Women's Hospitals Australasia (WHA) to develop a report on existing antenatal care guidelines and how they might be adapted to Australian circumstances. This work was developed in consultation with key stakeholder groups across Australia. The report was endorsed by AHMC and CDSMC in July 2006. Ministers recognised, however, the need for further work to develop a guideline document that would be suitable for distribution and one that followed the key principles and processes outlined in the document *NHMRC Standards and Procedures for Externally Developed Guidelines (2007)*.

At this time the value of high quality antenatal care guidelines was recognised by the Council of Australian Governments (COAG) as an important part of the work undertaken by the COAG Human Capital Reform Agenda and the AHMC Maternity Collaboration project. More recently, antenatal care, and the importance of providing nurturing environments for children, underpins key elements of the productivity focus and work program of COAG, including the National Early Childhood Development Strategy. In addition, antenatal care for Aboriginal and Torres Strait Islander women and their families is a key element of the 'Closing the gap in Indigenous life expectancy' policy platform, being progressed through COAG, via the Indigenous Early Childhood Development National Partnership.

Governance

This project is co-sponsored by the Child Health and Wellbeing Subcommittee (CHWS), a subcommittee of the Australian Population Health Development Principal Committee (APHDPC) and the Maternity Services Inter-Jurisdictional Committee (MSIJC), a subcommittee of the Health Policy Priorities Principal Committee of the Australian Health Ministers' Advisory Council (AHMAC).

Objectives

The key objectives of the Guidelines, as approved by the APHDPC in February 2008 were to:

› undertake a systematic review of national and international literature on antenatal care and antenatal care guidelines to systematically identify and synthesise the best available scientific evidence on antenatal care;

› appraise and collate evidence on antenatal care and apply it to the Australian context;

› consider economic factors in aspects of care, for example cost effectiveness of proposed interventions, and identify future research trends;

› ensure appropriate stakeholder consultation throughout process;

› draft a set of antenatal care guidelines which are approved by the NHMRC; and

› make recommendations for the implementation and ongoing maintenance of the Guidelines.

Consultative principles

The following principles underpinned the project's consultative approach:

› each stage of the project was developed and completed at the direction of the EAC;

› the methodology for each stage of the project was developed in consultation with the NHMRC Guidelines Assessment Register (GAR) consultant until 30 June 2010. Further advice was sought from NHMRC where required;

› extensive consultation (via email, secure website portal, teleconferences and face-to-face meetings) with key academics and professionals in the field and Aboriginal health workers and health professionals involved in antenatal care informed each element of the Guidelines and the development of consensus-based recommendation (where evidence was weak or lacking) and practice points (for aspects of care beyond the scope of the systematic literature review); and

› implications for implementation, including resource implications, cultural diversity, equity and access to services, informed the Guideline's recommendations to ensure that these can be achieved in a range of care contexts across Australia.

Cultural considerations — antenatal care for Aboriginal and Torres Strait Islander women

With a view to improved health outcomes for Aboriginal and Torres Strait Islander women and babies, a key objective was to ensure that the Guidelines are relevant, appropriate and applicable to Aboriginal and Torres Strait Islander women. To achieve this objective the EAC implemented the following strategies:

› establishment of an Aboriginal and Torres Strait Islander Women's Antenatal Care Working Group to provide advice and guidance to the EAC throughout the guideline development process;

› inclusion of discussion about cultural safety for Aboriginal and Torres Strait Islander women;

› inclusion of specific input/advice relevant to identified characteristics or risk factors for pregnant Aboriginal and Torres Strait Islander women;

› review of the wording and expression of all recommendations to ensure they are inclusive of the needs and experiences of Aboriginal and Torres Strait Islander women;

› identification of any available sources of evidence to inform recommendations for Aboriginal and Torres Strait Islander women, with specific reference to the AHMAC Cultural Respect Framework;

› formulation of specific recommendations for Aboriginal and Torres Strait Islander women where this is possible from available reviews of evidence;

› articulation of current gaps in evidence that would inform the development of a full range of recommendations required specifically for Aboriginal and Torres Strait Islander women;

› consultation on the draft Guidelines with relevant Aboriginal and Torres Strait Islander stakeholders; and

› articulation of implementation issues relevant to Aboriginal and Torres Strait Islander women and those providing antenatal care.

Overview of methodology

The methods and tools used in the development of the Guidelines built on the National Working Group report, completed by the WHA in 2006, used the ADAPTE *Manual for Guideline Development Version 1.0* (2007) to identify a reference guideline and thereafter followed the key principles and processes outlined in the document *NHMRC Standards and Procedures for Externally Developed Guidelines* (2007). The key steps in the guideline development process are outlined in Table C1.

Table C1:   Key steps in the guideline development process

1. Initial detailed scope of the Guidelines identified including topics to be included and research questions

2. Systematic search undertaken for existing antenatal care guidelines in the national and international arena

3. Retrieved guidelines screened to select guidelines for further appraisal

4. AGREE appraisals of selected guidelines completed

5. Guideline(s) to use as a reference determined

6. Reference guideline(s) currency assessed

7. Topics and research questions prioritised to finalise scope and cross referenced with questions and recommendations from reference guideline

8. Reference guideline(s) content (recommendations matrices) assessed

9. Systematic literature search and review undertaken to:
    – answer research questions not covered in the reference guideline; and
    – update evidence tables (where new evidence exists).

10. Evidence tables prepared using reference guideline evidence and updated evidence (if relevant) following the key principles and processes outlined in the document *NHMRC Standards and Procedures for Externally Developed Guidelines* (2007).

11. Topics and questions that require economic evaluation identified and work contracted.

12. EAC provided with evidence tables (comprising reference guideline evidence and recommendations and updated evidence) and Evidence Statement/ Matrix (adapted from NHMRC *Levels of Evidence and Grades for Recommendations for Developers of Guidelines* [2009]).

13. Evidence tables and evidence statement reviewed by EAC and advice provided on clinical impact and implementation issues, including applicability to the Australian context.

14. Where evidence was sufficient to support recommendations, recommendations formulated and graded by EAC.

15. Where evidence was weak or lacking, consensus-based recommendations formulated by EAC.

16. Where advice was needed but the area was beyond the scope of the literature review, practice points developed by EAC.

17. Draft Guidelines, a document that respects the needs of the end users and provides a detailed transparent explanation of the process and with implementation issues considered, prepared.

18. Draft Guidelines reviewed by EAC.

19. Draft Guidelines reviewed by Working Group for Aboriginal and Torres Strait Islander Care Women's Antenatal Care and additional practice points developed.

20. Public consultation (advertisement, available on Health and NHMRC website, mail-out, email alert to relevant stakeholder organisations) conducted for a period of 30 days.

21. Guidelines updated and summary document outlining response to each submission developed.

22. Draft Guidelines approved by EAC and provided to CHWS and MSIJC for clearance.

23. Submitted to the NHMRC for independent methodological and peer review and consideration for approval.

Managing conflict of interest

A robust and transparent system was used to manage conflict of interest throughout the development of the draft Guidelines. All members were asked to complete declaration of interest forms before acceptance onto the EAC, and requested to advise the Chairs of the EAC of any competing interests if these arose during the development of the Guidelines. A review of potential conflicts of interest was undertaken at every committee meeting.

The only conflicts of interest identified involved members being authors of studies included in the evidence base for a recommendation. When this was the case, this was noted and the member did not participate in grading of the evidence.

Process

The development of the draft Guidelines has followed the key principles and processes outlined in the document *NHMRC Standards and Procedures for Externally Developed Guidelines* (http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/nh56.pdf).

The ADAPTE framework was used to identify and appraise relevant international and national guidelines. Following appraisal of identified guidelines using the Appraisal of Guidelines Research and Evaluation (AGREE) instrument, the NICE (2008) *Antenatal Care. Routine Care for the Healthy Pregnant Woman* were selected as a reference guideline. Following review of the evidence (see Appendix D), the grading of evidence and recommendations followed the NHMRC *Levels of Evidence and Grades for Recommendations for Developers of Guidelines* (NHMRC 2009). Consensus by the EAC on the grading of the systematic literature review evidence was achieved for all items and recorded in detailed summary sheets used to form the basis of the EAC's decisions about which recommendations were appropriate to develop, and the subsequent grading of these recommendations.

Consensus-based recommendations were developed where insufficient evidence was identified to support a recommendation.

Practice points (PPs) were developed to cover areas that were beyond the scope of the systematic literature reviews but where practical advice is needed.

The process of the systematic literature reviews is discussed in more detail in Appendix D.

Public consultation

The draft Guidelines were released for a 30-day public consultation, as required in the *NHMRC Act,* 1992 (as amended), on 28 May 2011. Submissions were received from health departments, non-government organisations, health services and individuals, with a total of 55 submissions. Key issues and how these were addressed are outlined below.

› A number of submissions raised the need for guidance to be included within the Guidelines rather than readers being referred to other guidelines. Summaries of the perinatal mental health, alcohol and iodine guidelines have therefore been included. Other topics suggested — nutrition, breastfeeding and physical activity — are being reviewed for inclusion in Module II of the Guidelines.

› Some submissions suggested that more emphasis be given to the environment of the developing baby, including differing experiences of pregnancy, partner/family involvement in antenatal care and education and child protections issues. This has been included where relevant.

› There was considerable support for coverage of issues relevant to women from culturally and linguistically diverse backgrounds throughout the document. The existing discussion of improving the experience of antenatal care for these women has been expanded based on information provided in submissions and additional resources included. The development of Module II of the Guidelines will be informed by a working group representing women from culturally and linguistically diverse backgrounds.

› A number of submissions suggested inclusions for the content of the first antenatal visit and for the suggested schedule of visits. Discussion of the first antenatal visit has been expanded. As evidence concerning antenatal care beyond the first trimester was not reviewed and many topics included are being reviewed to inform Module II of the Guidelines, it was agreed to remove the schedule.

› While there was some support for a recommendation to weigh women at all antenatal visits, a number of submissions raised the point that while there is evidence for poorer outcomes associated with low or high weight gain, there is no evidence for the effectiveness of screening in improving outcomes. The recommendation has been replaced with the NICE recommendation to repeat weighing when clinical management is likely to be influenced. Submissions also requested guidance on weight gain. The IOM advice, which is already in use in some jurisdictions, is specified.

› Some submissions queried the criteria in the recommendation on repeat testing for proteinuria. It was agreed that the recommendation be removed as the literature in this area had not been reviewed. This will be included in the review to inform Module II of the Guidelines.

› Some submissions suggested that hepatitis C should be a routine screen and others noted the incongruity in recommending against screening but offering screening before an invasive procedure when it is hard to predict whether procedures will be required during labour. It was agreed that the evidence only supports selective screening due to the lack of effective treatment options. The point on screening before invasive procedures (specifically chorionic villus sampling and amniocentesis) has been retained due to the potential risk to the fetus.

› Responses to selective screening for vitamin D deficiency were mixed; one submission suggested universal screening, some suggested reducing the current criteria and others expanding them. It was agreed that the included recommendation was supported by the evidence. A number of submissions questioned the recommendation on vitamin D supplementation, either due to the costs involved or the dose recommended. Due to the lack of evidence on outcomes, harms and benefits, it was agreed to remove the recommendation.

› Some submissions questioned the evidence base and accuracy of the section on chromosomal abnormalities. The evidence for this section has been reviewed and the section rewritten based on the advice provided.

Implementation

The following multidisciplinary team will contribute to the design and execution of strategies aiming to increase the uptake of the Guidelines through liaison with their professional groups and promotion of the recommendations:

› Assoc Prof Ruth Stewart (EAC, Director Parallel Rural Community Curriculum, School of Medicine Deakin University, Australian College of Rural & Remote Medicine Representative);

› Prof Susan McDonald (EAC, Professor of Midwifery La Trobe University/ Mercy Hospital for Women);

› Dr Andrew Bisits (EAC, Lead Clinician, Birthing Services, Royal Hospital for Women, Sydney);

› Ms Ann Catchlove (EAC, consumer representative);

› Ms Debra Reid, Senior Adviser, Office of Aboriginal and Torres Strait Islander Health;

› Assoc Prof Danielle Mazza, Department of General Practice, Monash University;

› Prof Sally Green, methodological consultant, Co-Director Australasian Cochrane Centre, Monash University; and

› Ms Sue Hendy (EAC, Director of Women's, Children's and Youth Health, Nepean Blue Mountains and Western Sydney Local Health Networks).

Professor Jeremy Oats (Chair Victorian Consultative Council on Obstetric and Paediatric Mortality and Morbidity, Medical Co-Director Integrated Maternity Services, Northern Territory) and Professor Caroline Homer (Professor of Midwifery, Child and Family Health University of Technology, Sydney) will act as *ex officio* members. Members of the Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care will contribute to the implementation plan for the Guidelines, because of the need to specifically consider and develop strategies for implementation in the full range of specific settings and contexts where Aboriginal and Torres Strait Islander women receive care.

The EAC includes a number of members in positions of influence within various organisations and government departments. Similarly, the Maternity Services Inter-jurisdictional Committee and Child Health and Wellbeing Subcommittee members are well-placed to affect change in clinical and regulatory environments.

Key messages for dissemination and implementation

Central to the dissemination and implementation plan is the identification of key messages resulting from the Guidelines, which will be prioritised for communication and implementation. High priority will be given to recommendations that have:

› strong evidence underpinning the recommendation;

› an identified gap or need for a change to current practice;

› an identified burden of care including the number of women and babies likely to be affected by implementation of the recommendation; or

› cost implications

Key priorities for the Australian context will be based on identified gaps in current practice and where wide variations in clinical practice currently exist.

<u>Dissemination formats</u>

The Guidelines will be accompanied by a range of dissemination products published in varying formats to meet the needs of different target audiences. These are likely to include:

› summaries (in a range of languages) for women and their families;

› summaries for health professionals; and

› a guide for health care workers in Aboriginal and Torres Strait Islander communities.

The Guidelines will be published on the DoHA website.

<u>Implementation strategies: facilitating uptake of the disseminated Guidelines</u>

A range of strategies, harnessing the multidisciplinary team of opinion leaders involved in the development of the Guidelines, will be employed, informed in some cases by an assessment of the likely barriers to uptake of the prioritised recommendations. Potential implementation strategies include:

› education through meetings, conferences and presentations;

› outreach education; and

› opinion leaders — EAC endorsement.

Key messages from the Guidelines may also be implemented through a number of existing initiatives. (eg Pregnancy life scripts).

<u>Monitoring uptake of the Guidelines</u>

The extent to which the Guidelines have influenced practice and policy will be monitored in a number of ways. Selected indicators are reported on annually by all States and Territories, through the National Policy Response to the Children's Headline Indicators.

› The *Headline Indicators for Children's Health, Development and Wellbeing* of the AHMC, the CDSMC and the Australian Education, Early Childhood Development and Youth Affairs Senior Officials Committee provides measurements suitable for defining the current situation. Indicators related to antenatal care are: smoking in pregnancy; low birth weight; and infant mortality (noting that this indicator measures the number of deaths of live-born infants less than one year of age).

› The Australian Institute of Health and Welfare also publishes a number of indicators in this area (eg infant mortality rate).

› The COAG "Closing the Gap" initiative provides indicators relevant to antenatal care for Aboriginal and Torres Strait Islander people.

The indicators and methods for monitoring are under development.

D. Summary of the systematic literature reviews

The NICE 2008 guidelines *Antenatal Care. Routine Care for the Healthy Pregnant Woman* were used as the reference guidelines for this project based on their quality as assessed using the AGREE instrument. The review methodology employed by NICE is outlined in Section 1.6 of the NICE guidelines (see also http://guidance.nice.org.uk/CG/WaveR/57). For these Guidelines, separate systematic literature reviews were conducted for each clinical chapter in Part B. For most clinical areas relevant research questions had been considered in the NICE guidelines. The studies identified by NICE were included in the evidence tables and regraded according to the NHMRC *Levels of Evidence and Grades for Recommendations for Developers of Guidelines* (2009). Searches were then conducted to bring the literature review up to date. To ensure the most up-to-date evidence was reviewed, for some topics repeat reviews were conducted in 2010–2011. This appendix provides a brief summary of this process.

Process of the reviews

Research questions

For each clinical topic, research questions were developed by the EAC based on the relevant research questions used in the NICE guidelines. The groups contracted to undertake reviews of the evidence related to these questions used a systematic method of literature searching and selection.

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.

As the search strategies were very specific to each clinical area reviewed, studies on all groups were included rather than aiming to identify studies on particular groups. This process identified evidence on socioeconomic disparities where these exist (for example number of antenatal visits, adolescent mothers, asymptomatic bacteriuria, access to screening for chromosomal abnormalities and oral health)

Appraisal of the evidence

Abstracts of studies within the review period and in English were reviewed. Exclusion criteria included:

› already included in NICE guidelines;

› not specific to target population (eg specific to non-pregnant women or high-risk women only);

› not specific to first trimester;

› does not answer research question;

› does not meet criteria for grading (eg no outcomes reported or high risk of bias); and

› narrative review or opinion paper (editorial, letter, comment).

Evidence included in the reviews was graded as per NHMRC designations (see Table D1).

Table D1:   Designations of levels of evidence according to type of research question

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

Source: *NHMRC Levels of Evidence and Grades of Recommendations for Developers of Guidelines* (NHMRC 2009).

Grading of the evidence

Grading of the body of evidence involved:

› review of the evidence base, including the number of studies, level of evidence and quality of studies (eg risk of bias), and consistency across studies;

› examination of the effect size, the relevance of the evidence base to the research question and whether the risks and benefits had been considered in terms of clinical impact; and

› judgement by members of the EAC of the generalisability of the body of evidence to the target population for the Guidelines and the applicability of the body of evidence to the Australian healthcare context, taking into account feasibility issues (workforce, geographical distance, cost) and existing health care systems.

The Evidence Statement Form/Matrix (adapted from *NHMRC Levels of Evidence and Grades for Recommendations for Developers of Guidelines* [2009]) was used for each research question addressed. The form was used as the basis of discussion regarding the key components, which were rated according to the matrix shown in Table D2. Conflicts of interest (eg where an EAC member was author of evidence under consideration) were declared at the commencement of discussion of each topic.

Table D2: Components of body of evidence considered when grading each recommendation

Evidence base	A	One or more level I studies with a low risk of bias or several level II studies with low risk of bias
	B	One or two level II studies with a low risk of bias or systematic review/several level III studies with a low risk of bias
	C	One or two level III studies with a low risk of bias or level I or II studies with a moderate risk of bias
	D	Level IV studies or level I to III studies/systematic review with a high risk of bias
Consistency	A	All studies consistent
	B	Most studies consistent and inconsistency can be explained
	C	Some inconsistency, reflecting genuine uncertainty around question
	D	Evidence in inconsistent
	NA	Not Applicable – one study only
Clinical Impact	A	Very large
	B	Moderate
	C	Slight
	D	Restricted
	UD	Unable to be determined
Generalisability	A	Evidence directly generalisable to target population
	B	Evidence directly generalisable to target population with some caveats
	C	Evidence not directly generalisable to target population but could be sensibly applied
	D	Evidence not directly generalisable to target population and hard to judge whether it is sensible to apply
Applicability	A	Evidence directly applicable to Australian healthcare context
	B	Evidence applicable to Australian healthcare context with few caveats
	C	Evidence probably applicable to Australian healthcare context with some caveats
	D	Evidence not applicable to Australian healthcare context

Source: *NHMRC Levels of Evidence and Grades of Recommendations for Developers of Guidelines (*NHMRC 2009).

Formulating and grading of recommendations

The systematic reviewers provided grades for the evidence base and consistency of the evidence. EAC members then applied grades for the clinical impact, generalisability and applicability of the evidence. The overall grade of the evidence was then determined, based on a summation of the rating for each individual component of the body of evidence. Where NICE recommendations were used, these were adapted to the Australian context and language used in the Guidelines. If there was no NICE recommendation or recent evidence required a change to the recommendation, these were formulated by EAC members. Initial wording of recommendations was agreed by a quorum of the EAC and recommendations were then circulated to all members and further discussed at a teleconference. All recommendations were then discussed with the Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care.

Any notes relevant to developing the recommendation, including barriers to implementing the recommendations and support required for successful uptake of the Guidelines, were recorded.

Consensus-based recommendations

Consensus-based recommendations were formulated when a systematic review of the evidence was conducted but no good quality evidence identified. Initial wording of consensus-based recommendations was agreed by a quorum of the EAC and recommendations were then circulated to all members and further discussed at a teleconference. All recommendations were then discussed with the Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care.

Practice points

Practice points (PPs) were developed to cover areas that were beyond the scope of the systematic reviews but where it was determined by the EAC that practical advice is needed. The formulation of PPs involved a process of:

› identifying areas where advice was required or PPs were needed as adjuncts/corollaries of recommendations and/or other PPs; and

› discussion of a PP by members of the EAC and the Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care until consensus on the wording was reached.

Limitations of the review methodology

This review used a structured approach to reviewing the literature. However, all types of study are subject to bias, with systematic reviews being subject to the same biases seen in the original studies they include, as well as to biases specifically related to the systematic review process. Reporting biases are a particular problem related to systematic reviews and include publication bias, time-lag bias, multiple publication bias, language bias and outcome reporting bias (see Glossary).

Some of these biases are potentially present in these reviews. Only data published in peer-reviewed journals were included. Unpublished material was not included as such material typically has insufficient information upon which to base quality assessment, and it has not been subject to the peer-review process. In addition, the search was limited to English-language publications only, so language bias is also a potential problem. Outcome reporting bias and inclusion criteria bias are unlikely as the methodology used in the review and the scope of the review was defined in advance.

The studies were initially selected by examining the abstracts of these articles. Therefore, it is possible that some studies were inappropriately excluded prior to examination of the full text article. However, where detail was lacking, ambiguous papers were retrieved as full text to minimise this possibility.

Summary of systematic literature reviews

The following tables provide a summary of the NICE recommendation (where relevant), the research questions, search strategy and findings of each review, recommendations and their supporting references, and consensus-based recommendations where these were developed.

Antenatal visits

Antenatal visits

NICE recommendations

A schedule of antenatal appointments should be determined by the function of the appointments. For a woman who is nulliparous with an uncomplicated pregnancy, a schedule of ten appointments should be adequate. For a woman who is parous with an uncomplicated pregnancy, a schedule of seven appointments should be adequate. [B]

Early in pregnancy, all women should receive appropriate written information about the likely number, timing and content of antenatal appointments associated with different options of care and be given an opportunity to discuss this schedule with their midwife or doctor. [D]

Each antenatal appointment should be structured and have focused content. Longer appointments are needed early in pregnancy to allow comprehensive assessment and discussion. Wherever possible, appointments should incorporate routine tests and investigations to minimise inconvenience to women. [D]

Research questions

1. What is the most effective frequency of antenatal visits? (Informed Recommendation 1)

    –   In low risk pregnant women is a schedule of 7–10 visits as effective as the traditional schedule of 14 visits in achieving positive perinatal outcomes?

    –   In low risk pregnant women is a schedule of 7–10 visits as effective as the traditional schedule of 14 visits in terms of women's satisfaction with care?

    –   What is the optimal number/timing of visits for low risk primigravida and low risk multigravida?

2. When is the optimum time for a pregnant woman to have her first visit? (Limited evidence identified)

3. In low risk women is a reduced schedule of visits (7–10) more cost effective than the traditional schedule of 14 visits? (No studies identified)

4. What information should be provided to women about the schedule of visits? (No studies identified)

    –   What is the impact of a woman's expectations about the schedule of visits on her satisfaction with care? (No studies identified)

5. What is the impact of a reduced number of visits on shared care models particularly in relation to rapport building? (No studies identified)

6. What are the additional considerations for Aboriginal and Torres Strait Islander Australian women? (Informed narrative)

Search Strategy

Databases searched: Medline; Embase; Psychinfo; Cochrane Database of Systematic Reviews; Australasian Medical Index.

Date of searches: February 2009; November 2010

Limits: English language

Publication dates for searches: January 2003 – February 2009
                                                     January 2008 – November 2010

Antenatal visits

Review findings

1. 1 level I and 3 level IV studies identified. The Cochrane review suggests that where the number of visits is already low, these should not be further reduced.

2. 1 level IV study found that initiating antenatal care in the first trimester had no significant effect on birth weight

3. No studies identified

4. No studies identified

5. No studies identified

6. 1 level IV study and 2 qualitative reviews informed narrative around antenatal visits for Aboriginal and Torres Strait Islander women

New evidence is limited and does not suggest a change to the NICE recommendations. However, the evidence base is strengthened by the recent Cochrane review.

EAC recommendation

1. Determine the schedule of antenatal visits based on the individual woman's needs. For a woman's first pregnancy without complications, a schedule of ten visits should be adequate. For subsequent uncomplicated pregnancies, a schedule of seven visits should be adequate.

Evidence supporting recommendation (see Section 6.5)

Carroli et al 2001; Clemet et al 1996; Dowswell et al 2010; Hildingsson et al 2002; Villar & Khan-Neelofur 2003

Grading of evidence — Recommendation 1

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
A	B	A	A	B	**B**

Consensus-based recommendations

i. At the first contact with a woman during pregnancy, make arrangements for the first antenatal visit, which requires a long appointment and should occur within the first 10 weeks.

ii. Early in pregnancy, provide women with information in an appropriate format about the likely number, timing and content of antenatal visits associated with different options of care and the opportunity to discuss this schedule.

Clinical assessments

Gestational age assessment

NICE recommendations

Pregnant women should be offered an early ultrasound scan between 10 weeks 0 days and 13 weeks 6 days to determine gestational age and to detect multiple pregnancies. This will ensure consistency of gestational age assessment and reduce the incidence of induction of labour for prolonged pregnancy. [not graded]

Crown–rump length measurement should be used to determine gestational age. If the crown–rump length is above 84 mm, the gestational age should be estimated using head circumference. [not graded]

Research questions

1. What is the most accurate method to arrive at an agreed due date (eg last menstrual period [LMP], crown-rump length [CRL], biparietal diameter [BPD])? (Informed Recommendation 2)
2. Which women should be offered a dating scan? (Informed Recommendation 2)
3. When is the best time to conduct a dating scan? (Informed Recommendation 2)
4. What is the cost effectiveness of offering women a dating scan? (Cost analysis undertaken)
5. Is it feasible to offer all women a dating scan? (Cost analysis undertaken)
6. What are the other potential benefits of a first trimester scan? (No new evidence found)
7. Who should conduct a dating scan? (No studies identified)
8. What are the potential harms caused by a dating scan? (Limited evidence identified)
9. What are the issues of access to dating scans for rural and remote woman? (No studies identified)
10. What are the issues for some women if unable to get accurate measurements abdominally especially if male sonographer? (No studies identified)
11. Are dating scans done by occasional operator accurate? (No studies identified)
12. What are the risks of induction if dates not accurate? (Beyond scope)
13. Are there risks that placenta praevia is over-diagnosed in early ultrasound scans, and if so, does this contribute to elevated anxiety? (No studies identified)
14. What are the additional considerations for Indigenous Australian women? (Informed narrative)
15. What are the cost implications of a dating scan in remote areas? (Informed narrative)

Search Strategy

Databases searched: Medline; Embase; Psychinfo; Cochrane Database of systematic Reviews; Australasian Medical Index.

Date of searches: March 2009; November 2010

Limits: English language

Publication dates for searches: January 2007 onwards (January 2000 onwards in Australian databases)
January 2008–12 November 2010

Clinical assessments

Review findings

1. 5 level III-2 studies and 1 level IV study

2. No direct evidence to change NICE recommendation

3. 1 level I study and 1 level III-2 study that support 'early' ultrasound

4. See Appendix E

5. See Appendix E

6. No new studies identified. Potential benefits include decreased anxiety and decreased induction of labour.

7. No studies identified. Reference made to relevant professional bodies in Australia.

8. No evidence found on harms except for one study which examined potential harm to the fetus caused by exposure to acoustic energy.

9. No studies identified. Narrative informed by Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care.

10. No evidence found

11. No evidence found

12. Beyond scope

13. No evidence found

14. Narrative informed by Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care

15. Narrative informed by Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care

The review identified a systematic review and a number of lower level studies that support the NICE recommendation. Economic analysis was undertaken to assess the cost implications of recommending routine ultrasound in the first trimester (see Appendix E).

EAC recommendation

2. Provide information and offer pregnant women an ultrasound between 8 weeks 0 days and 13 weeks 6 days to determine gestational age, detect multiple pregnancies and accurately time fetal anomaly screening.

   Use crown–rump length measurement to determine gestational age. If the crown–rump length is above 84 mm, estimate the gestational age using head circumference.

Evidence supporting recommendation (see Section 7.1.4)

Alexander et al 1995; Crowther et al 1999; Dietz et al 2007; Hoffman et al 2008; Johnsen et al 2006; Koster et al 2008; Martins et al 2008; McLennan & Schluter 2008; Morin 2005; Nguyen 1999; Okonofua 1989; Olesen & Thomsen 2006; Rowlands & Roysten 1993; Salpou et al 2008; Savitz et al 2002; Selbing 1983; Taipale 2001; Verberg et al 2008; Whitworth et al 2010

Grading of evidence — Recommendation 2

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
B	B	A	B	A	**B**

Clinical assessments

Weight and body mass index

NICE recommendations

Maternal weight and height should be measured at the first antenatal appointment, and the woman's BMI calculated (weight [kg]/height[m]2). [B]

Repeated weighing during pregnancy should be confined to circumstances where clinical management is likely to be influenced. [C]

Research questions

1. How and when should maternal weight, height and BMI be measured in the general maternity population? (Informed Recommendation 3)

2. What information should be provided to women regarding healthy weight in pregnancy? (Informed Recommendation 4)

3. What dietary advice should be provided to pregnant women (see review on nutritional supplements)

4. What specific risk assessments are required for pregnant women above and below their most healthy weight? (Informed narrative)

5. What are the additional needs of Aboriginal or Torres Strait Islander women? (Informed narrative)

Search Strategy

Databases searched: Medline; Embase; Informit; Cochrane Database of systematic Reviews; Australasian Medical Index.

Date of search: November 2010

Limits: English language

Publication dates for search: January 2003 – November 2010

Review findings

1. There is evidence from 5 level III-2 studies to support the NICE (2003) recommendation to record height, weight and BMI at the antenatal booking visit and this is advised in other clinical practice guidelines.

2. New evidence regarding the risks associated with a high or low pre-pregnancy BMI has emerged since the NICE (2003) recommendation, including 1 level I, 4 level II, and 7 level III-2 studies. The evidence is also consistent regarding the risk of excessive gestational weight gain for women of normal to high pre-pregnancy BMI, and the risk of poor weight gain for women who have a pre-pregnancy BMI in the underweight category. Recommendations for gestational weight gain are less clear.

3. 2 level I and 4 level II studies were identified that supported the provision of verbal and written information.

4. There is evidence from 7 level III-2 studies and 1 level IV study to support assessment of the associated risks of high pre-pregnancy BMI and enhanced surveillance for small-for-gestational age babies for women with a pre-pregnancy BMI in the underweight category. This informed the narrative.

5. 1 level III-2 and I level IV study informed the narrative on risks associated with low pre-pregnancy BMI.

Clinical assessments

EAC recommendations

3. Measure women's weight and height at the first antenatal visit and calculate their BMI.

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

Evidence supporting recommendations (see Section 7.2.5)

Recommendation 3 — Bodnar et al 2009; Callaway et al 2006; Chu et al 2007a; Chu et al 2007b; Dawes & Grudzinskas 1991; HAPO 2010; Khashan & Kenny 2009; McDonald et al 2010; Oddy et al 2009; Panaretto et al 2006; Rassmussen et al 2008; Siega-Riz et al 1996; Stothard et al 2009; Thornton et al 2009; Viswanathan et al 2008

Recommendation 4 — Dodd et al 2010; Jeffries et al 2009; Ronnberg et al 2010; Streuling et al 2010

Grading of evidence — Recommendation 3

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
B	B	B	B	B	**B**

Grading of evidence —Recommendation 14

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
A	B	B	B	B	**B**

Clinical assessments

Blood pressure

NICE recommendations

At the booking appointment, the following risk factors for pre-eclampsia should be determined:

› age 40 years or older

› nulliparity

› pregnancy interval of more than 10 years

› family history of pre-eclampsia

› previous history of pre-eclampsia

› body mass index 30 kg/m² or above

› pre-existing vascular disease such as hypertension

› pre-existing renal disease

› multiple pregnancy.

Blood pressure measurement and urinalysis for protein should be carried out at each antenatal visit to screen for pre-eclampsia. More frequent blood pressure measurements should be considered for pregnant women who have any of the above risk factors.

The presence of significant hypertension and/or proteinuria should alert the healthcare professional to the need for increased surveillance.

Hypertension in which there is a single diastolic blood pressure of 110 mmHg or two consecutive readings of 90 mmHg at least 4 hours apart and/or significant proteinuria (1+) should prompt increased surveillance.

If the systolic blood pressure is above 160 mmHg on two consecutive readings at least 4 hours apart, treatment should be considered.

Research questions

1.   When should blood pressure be monitored in the first trimester of pregnancy? (Informed Recommendation 5)

2.   How is blood pressure monitored in pregnancy? (Beyond scope)

3.   What is the diagnostic test accuracy of measuring diastolic and systolic blood pressure, and mean arterial pressure in pregnancy and the significance of an increase of 15mmHg from baseline? (Informed narrative)

4.   What would be the benefits or harms of intervention strategies? (Specific to pre-eclampsia)

5.   What pre-existing medical conditions affect blood pressure in the first trimester of pregnancy? (Informed narrative)

6.   What is the psychological impact of hypertension screening? (Informed narrative)

7.   What are the additional needs of Aboriginal and Torres Straight Islander women? (No evidence identified)

Search Strategy

Databases searched: Medline; Embase; Cochrane Database of systematic Reviews.

Date of searches: December 2010; March 2011

Limits: English language

Publication dates for searches: January 2003 – December 2010
                                          December 2010 – March 2011

Clinical assessments

Review findings

1&2. There is minimal low level evidence on how or when to take blood pressures in the first trimester and none to refute the NICE 2003 recommendations.

3. The 2 level IV studies identified informed the narrative but did not alter the NICE recommendations.

4. The 2 level II, 6 level III-2, 4 level III-3 and 1 level IV studies identified reported conflicting results on the accuracy of blood pressure measurement in predicting pre-eclampsia. However, the presence of risk factors and/or blood pressure recordings raised above the norm during the first trimester are inextricably linked with later pregnancy pre-eclampsia (as well as pre-existing conditions, see 5 below) and should not be overlooked.

5. 1 level II and 3 level IV studies informed the narrative but did not alter the NICE recommendations.

6. 1 level II studies and 1 level IV study informed the narrative but did not alter the NICE recommendations.

7. No evidence identified.

There is insufficient new evidence to justify changing the NICE recommendations.

EAC recommendation

5. Measure blood pressure at a woman's first antenatal visit to identify existing high blood pressure.

Evidence supporting recommendations (see Section 7.3.5)

Brown et al 2005; Cnossen et al 2008; Conde-Agudelo et al 2004; Emonts et al 2008; Miller et al 2007; Nijdam et al 2010; Onwudiwe et al 2008; Poon et al 2008; 2009

Grading of evidence — Recommendation 5

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
B	B	B	B	A	**B**

Clinical assessments
Proteinuria

NICE recommendations

NICE did not cover proteinuria as a separate topic in 2003 or the 2008 update. All NICE references have been extracted from chapters on hypertensive disorders of pregnancy and/or pre-eclampsia.

Whenever blood pressure is measured in pregnancy, a urine sample should be tested at the same time for proteinuria. Research is needed to determine the optimal frequency and timing of blood pressure measurement and on the role of screening for proteinuria.

Use an automated reagent-strip reading device or a spot urinary protein:creatinine ratio for estimating proteinuria in a secondary care setting.

Research questions

1. What is the diagnostic test accuracy for proteinuria testing in the first trimester? (Informed Recommendation 6)

2. What would be the benefits or harms of testing for proteinuria in the first trimester? (No studies identified)

3. How is testing for proteinuria in the first trimester predictive of later pregnancy complications? (Informed narrative)

Search Strategy

Databases searched: Medline; Embase; Psychinfo; Cochrane Database of Systematic Reviews, Australasian Medical Index.

Date of search: December 2010

Limits: English language

Publication dates for search: January 2003 – December 2010

Review findings

1. The 1 level I study, 9 level III-2 studies, 3 level III-3 and 4 level IV studies identified found urine collection tests, protein:creatine ratio and automated dipstick analysis to be more accurate that visual inspection of urinary dipsticks.

2. No studies identified.

3. Two level II studies, 1 level III-2 study, 1 level III-3 study and 3 level IV studies suggest that proteinuria in the first trimester does not predict pre-eclampsia and subsequent testing should be confined to those with other risk factors such as existing or newly diagnosed hypertension, new or pre-existing kidney disease.

Clinical assessments

EAC recommendation

6. For point-of-care testing, use an automated analyser if available, as visual inspection of a urinary dipstick is the least accurate method to detect true proteinuria.

Evidence supporting recommendations (see Section 7.4.6)

Abebe et al 2008; Cote et al 2008a; 2008b; Davey & MacGillivray 1988; Dwyer et al 2008; Gangaram et al 2005; Gangaram et al 2009a; 2009b; Kyle et al 2008; Meads et al 2008; Phelan et al 2004; Price et al 2005; Risberg et al 2004; Rizk et al 2007; Rodriguez-Thompson & Lieberman 2001; Schubert et al 2006; Shennan & Waugh 2003; Waugh et al 2004; 2005

Grading of evidence — Recommendation 6

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
B	B	C	A	A	**B**

Consensus-based recommendations

iii. Routinely offer testing for proteinuria at the first antenatal visit, regardless of stage of pregnancy.

Clinical assessments

Psychosocial factors affecting mental health

Consensus-based recommendations

Consensus-based recommendation iv is based on *beyondblue* (2011) *Clinical Practice Guidelines on Depression and Related Disorders in the Perinatal Period* Good Practice Point 7. The systematic literature review included a research question on the assessment of psychosocial factors but identified insufficient evidence to support a recommendation.

iv. As early as practical in pregnancy, ask all women questions about psychosocial factors. If a woman affirms the presence of psychosocial factors, ask whether she would like help with any of these issues.

Depression and anxiety

Recommendation

Recommendation 7 is based on *beyondblue* (2011) *Clinical Practice Guidelines on Depression and Related Disorders in the Perinatal Period* Recommendation 2, which was informed by the systematic literature review and graded in accordance with *NHMRC Levels of Evidence and Grades for Recommendations for Developers of Guidelines* (NHMRC 2009).

7. Use the Edinburgh Postnatal Depression Scale as a component of the assessment of all women for symptoms of depression in the antenatal period.

Consensus-based recommendations

Consensus-based recommendation v is based on *beyondblue* (2011) *Clinical Practice Guidelines on Depression and Related Disorders in the Perinatal Period Good* Practice Point 9. The systematic literature review included a clinical question on using tools to detect anxiety but identified insufficient evidence to support a recommendation..

v. Be aware that women who score 13 or more on the Edinburgh Postnatal Depression Scale (EPDS) may be experiencing anxiety, either alone or with depression. Base decisions about further assessment on the woman's answers to questions 3, 4 and 5 of the EPDS and her response to enquiry about 'worrying'.

Clinical assessments
Domestic violence

NICE recommendations

None

Research questions

1. What do health professionals need to do to identify women at risk from domestic violence? (Informed Recommendation 8)

2. Is routine enquiry about domestic violence acceptable to women? (Informed Consensus-based recommendation vi)

3. Is routine enquiry about domestic violence acceptable to clinicians? (Informed Consensus-based recommendation vii)

4. What interventions in a health care setting are effective for assisting women affected by domestic violence? (Informed narrative)

5. What do health professionals need to do to identify Aboriginal and Torres Strait Islander women experiencing domestic violence? (No studies identified)

6. Is routine enquiry about domestic violence acceptable to Aboriginal and Torres Strait Islander women? (No studies identified)

7. Is routine enquiry about domestic violence acceptable to clinicians caring for Aboriginal and Torres Strait Islander women? (No studies identified)

8. What interventions in a health care setting are effective for assisting Aboriginal and Torres Strait Islander women affected by domestic violence? (Informed narrative)

Search Strategy

Databases searched: Medline + Pub Med, EMBASE, CINAHL, NHS Evidence, SIGLE, JBI, COCHRANE, PsycINFO, LILACS, CONTROLLED TRIALS, NDLTD, Informit

Date of search: February 2011

Limits: English language

Publication dates for search: January 2003 – February 2011

Review findings

1. 1 level I, 1 level II and 5 level III-2 studies supported enquiry about domestic violence.

2. 6 level III-2 and 1 qualitative study suggested that enquiry is acceptable to women.

3. 1 level II, 15 level III-2, 2 level IV and 6 qualitative studies highlighted barriers to health professionals enquiring about domestic violence and informed development of the narrative.

4. 2 level II studies included in narrative.

5. No studies identified. Advice provided by Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care.

6. No studies identified. Advice provided by Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care.

7. No studies identified. Advice provided by Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care.

8. 1 qualitative study identified. Advice provided by Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care.

Clinical assessments

EAC recommendation

8. At the first antenatal visit, 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.

Evidence supporting recommendations (see Section 7.7.5)

Ameh et al 2008; Bacchus et al 2003; Hegarty et al 2007; Kataoka et al 2004; Keeling & Birch 2004; Mezey et al 2005; Moonesinghe et al 2004; O'Reilly et al 2010; Renker & Tonkin 2006; Roelens 2010; Roelens et al 2008; Salmon et al 2006; Stenson et al 2005; Taft 2002; Taft et al 2004; Walsh 2008; Webster & Holt 2004

Grading of evidence — Recommendation 8

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
B	A	B	B	A	**B**

Consensus-based recommendations

vi. Ask about domestic violence when alone with the woman, tailoring the approach to her individual situation and your own skills and experience (eg use open-ended questions about her perception of safety at home or use an assessment tool).

vii. Be aware that training programs improve the confidence and competency of health professionals in identifying and caring for women experiencing domestic violence.

Clinical assessments

Nausea and vomiting

NICE recommendation

Women should be informed that most cases of nausea and vomiting in pregnancy will resolve spontaneously within 16 to 20 weeks and that nausea and vomiting are not usually associated with a poor pregnancy outcome. If a woman requests or would like to consider treatment, the following interventions appear to be effective in reducing symptoms:

› non-pharmacological: ginger, P6 (wrist) acupressure

› pharmacological: antihistamines.

Information about all forms of self-help and nonpharmacological treatments should be made available for pregnant women who have nausea and vomiting. [PP]

Research question

Are there effective interventions to treat nausea and vomiting in pregnancy and what are the perinatal outcomes associated with these interventions? (Informed narrative)

Search Strategy

Databases searched: Medline; Embase; Google Scholar

Date of searches: November 2009; November 2010

Limits: English language

Publication dates for searches: January 2003 – August 2009
                                 January 2008 – November 2010

Review findings

While there is a growing body of evidence in support of the use of various interventions for symptoms of nausea and vomiting, as yet there remain insufficient data to recommend any particular treatment. The recent Cochrane strengthens the evidence base but found insufficient evidence to recommend specific interventions or alter the NICE practice point.

Clinical assessments

Constipation

NICE recommendation

Women who present with constipation in pregnancy should be offered information regarding diet modification, such as bran or wheat fibre supplementation. [A]

Research questions

1. What is the prevalence of constipation in pregnant women? (Informed narrative)
2. What interventions help relieve constipation and are safe in pregnancy? (Informed Recommendations 9 and 10)

Search Strategy

Databases searched: Medline; Embase; Psychinfo; Cochrane Database of Systematic Reviews, Australasian Medical Index.

Date of searches: March 2009; November 2010

Limits: English language

Publication dates for searches: January 2003 – March 2009
                                  January 2008 – November 2010

Review findings

1. 4 level IV studies informed the narrative.
2. The 1 level I study (a Cochrane review) identified was consistent with the NICE recommendation. This review, 1 level III-3 study and 1 level IV study also supported a recommendation on laxatives.

EAC recommendations

9. Offer women who present with constipation in pregnancy information about increasing dietary fibre intake and taking bran or wheat fibre supplementation.
10. Advise women who choose to take laxatives that preparations that stimulate the bowel are more effective than those that add bulk but may cause more adverse effects such as diarrhoea and abdominal pain.

Evidence supporting recommendations (see Section 7.9.5)

Recommendation 9 — Jewell & Young 2010

Recommendation 10 — Jewell & Young 2010; Neri et al 2004; Vasquez 2008

Grading of evidence — Recommendation 9

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
C	NA	B	B	A	**C**

Grading of evidence — Recommendation 10

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
C	C	B	B	A	**C**

Maternal health screening

HIV

NICE recommendation

Pregnant women should be offered screening for HIV infection early in antenatal care because appropriate antenatal interventions can reduce mother-to-child transmission of HIV infection. [A]

A system of clear referral paths should be established in each unit or department so that pregnant women who are diagnosed with an HIV infection are managed and treated by the appropriate specialist teams. [D]

Research questions

1.   What is the prevalence of HIV infection in pregnant women in Australia? (Informed narrative)
2.   What is the prevalence of congenitally acquired HIV infection in Australia? (Informed narrative)
3.   What is the diagnostic accuracy of screening tests for HIV infection? (Informed Recommendation 11)
4.   What benefits would result from screening for HIV in pregnancy? (Informed Recommendation 11)
5.   What are the harms of not screening for HIV in pregnancy? (Informed Recommendation 11)
6.   What are the harms of screening for HIV in pregnancy? (Informed Recommendation 11)
7.   What are the additional needs of Aboriginal or Torres Strait Islander women? (Informed narrative)

Search Strategy

Databases searched: Medline; Embase; Australasian Medical Index; ATSIhealth; Google Scholar; Cochrane Database

Date of search: November 2010

Limits: English language

Publication dates for search: January 2003 – November 2010

Review findings

1.   2 level III-2 studies and 1 level IV study used as basis of narrative on Australian prevalence.
2.   1 level III-2 study used as basis for narrative on prevalence of congenital HIV.
3.   3 level III-2 studies support the accuracy of diagnostic tests.
4.   1 level I study, 1 level III-2 study, 1 level IV study and 5 clinical practice guidelines support routine testing of all women in pregnancy due to the availability of effective interventions to prevent mother-to-child transmission.
5.   1 level III-2 study and 1 level IV study identify lack of treatment as a harm arising from not screening.
6.   3 level III-2 studies, 2 level IV studies and 1 clinical practice guideline found no significant harms from antiretroviral therapy during pregnancy.
7.   1 level III-2, 4 level IV and 1 clinical practice guideline informed the narrative. Advice on screening in rural and remote areas also provided by Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care.

Current available evidence supports the 2003 NICE recommendations for HIV screening in first trimester of pregnancy.

Maternal health screening

EAC recommendation

11. Routinely offer and recommend HIV testing at the first antenatal visit as effective interventions are available to reduce the risk of mother-to-child transmission.

Evidence supporting recommendations (see Section 8.1.5)

Briand et al 2009; Butlerys et al 2004; Chappel et al 2009; Chou et al 2005; Giles et al 2008; Horvath et al 2009; Kourtis et al 2007; Pai et al 2007; Read & Newell 2005; Samson & King 1998; Tepper et al 2009; Townsend et al 2009; Volmink et al 2007; Wiysonge et al 2005; 2011

Grading of evidence — Recommendation 11

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
B	B	B	B	B	**B**

Maternal health screening

Hepatitis B

NICE recommendation

Serological screening for hepatitis B virus should be offered to pregnant women so that effective postnatal intervention can be offered to infected women to decrease the risk of mother-to-child transmission. [A]

Research questions

1. What are the interventions to reduce mother-to-child transmission of hepatitis B virus? (Informed Recommendation 12)

2. What are the additional considerations for Aboriginal and Torres Strait Islander women? (Informed narrative)

Search Strategy

Databases searched: Medline; Embase; Australasian Medical Index; ATSIhealth; Google Scholar; Cochrane Database

Date of search: November 2010

Limits: English language

Publication dates for search: January 2003 – November 2010

Review findings

1. The 2 level I studies and 3 level IV studies identified support the NICE recommendation. This recommendation is also in accord with United States clinical practice guidelines and the *Australian Immunisation Handbook.*

2. 1 level IV study was identified. No additional considerations were identified by the Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care.

EAC recommendation

12. Routinely offer and recommend hepatitis B virus testing at the first antenatal visit as effective postnatal intervention can reduce the risk of mother-to-child transmission.

Evidence supporting recommendation (see Section 8.2.5)

Cowan et al 2006; Jensen et al 2003; Lin & Vickery 2009; Summers et al 1987

Grading of evidence — Recommendation 12

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
A	A	A	A	A	**A**

Maternal health screening

Hepatitis C

NICE recommendation

Pregnant women should not be offered routine screening for hepatitis C virus because there is insufficient evidence on its effectiveness and cost effectiveness. [C]

Research questions

1. What is the diagnostic value and clinical effectiveness of screening for hepatitis C? (Informed Recommendation 13)

2. What are the additional considerations for Aboriginal and Torres Strait Islander women? (No studies identified)

Search Strategy

Databases searched: Medline; Embase; Australasian Medical Index; ATSIhealth; Google Scholar; Cochrane Database

Date of search: November 2010

Limits: English language

Publication dates for search: January 2003 – November 2010

Review findings

1. 3 level III-2, 1 level III-3 and 5 level IV studies were identified in this review.

2. No evidence identified. Advice given by Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care.

The evidence does not suggest a change to the NICE recommendation, which is consistent with DoHA recommendations for hepatitis screening and the advice of Hepatitis Australia.

EAC recommendation

13. Do not routinely offer pregnant women hepatitis C testing.

Evidence supporting recommendation (see Section 8.3.5)

Hutchinson et al 2004; Lui et al 2009; Pembrey et al 2003; 2005; Prasad et al 2007

Grading of evidence — Recommendation 13

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
C	B	C	C	B	**C**

Maternal health screening

Rubella

NICE recommendation

Rubella susceptibility screening should be offered early in antenatal care to identify women at risk of contracting rubella infection and to enable vaccination in the postnatal period for the protection of future pregnancies. [B]

Research questions

1. What is the prevalence of rubella susceptibility in pregnant women? (Informed narrative)

2. Does screening pregnant women for rubella immunity lead to improved maternal and perinatal outcomes? (Informed Recommendations 14 and 15)

3. What are the additional considerations for Aboriginal and Torres Strait Islander women? (Informed narrative)

Search Strategy

Databases searched: Medline; Embase; Australasian Medical Index; ATSIhealth; Google Scholar; Cochrane Database

Date of search: November 2010

Limits: English language

Publication dates for search: January 2003 – November 2010

Review findings

1. 1 level IV study informed discussion of prevalence of non-immunity.

2. Recent evidence on screening (3 level II studies) focused on the risk of the risk of congenital rubella syndrome (CRS) for women inadvertently vaccinated during pregnancy or just prior to conception and found this to be very low.

3. 1 level IV study informed discussion of non-immunity among Aboriginal and Torres Strait Islander women.

There was insufficient new evidence to change the NICE recommendation.

EAC recommendations

14. Routinely offer women testing for rubella immunity at the first antenatal visit to identify women at risk of contracting rubella and enable postnatal vaccination to protect future pregnancies.

15. Inform women who have been vaccinated against rubella before they were aware of the pregnancy that the baby is highly unlikely to have been affected by the vaccine.

Evidence supporting recommendations (see Section 8.4.5)

Recommendation 14 — Grageot-Keros & Enders 1997; Grillner et al 1983; Miller et al 1982

Recommendation 15 — Badilla et al 2007; Bar-Oz et al 2004; Hamkar et al 2006

Grading of evidence — Recommendation 14

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
B	A	B	A	A	**B**

Grading of evidence — Recommendation 15

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
A	A	B	A	A	**A**

Maternal health screening

<u>Chlamydia</u>

NICE recommendation

Pregnant women should not be offered routine screening for asymptomatic chlamydia because there is insufficient evidence on its effectiveness and cost effectiveness. However, this policy is likely to change with the implementation of the national opportunistic chlamydia screening programme. [C]

Research questions

1. What is the diagnostic value and effectiveness of the following screening methods in identifying genital chlamydia: age, urine testing, endocervical swabs, serum antibody testing, history? (Informed Recommendation 16)

2. What are the additional needs of Aboriginal and Torres Strait Islander women? (Informed narrative)

Search Strategy

Databases searched: Medline; Embase; Australasian Medical Index; ATSIhealth; Google Scholar; Cochrane Database

Date of search: November 2010

Limits: English language

Publication dates for search: January 2003 – November 2010

Review findings

1. 1 level II study, 1 level III-1 study and 3 level IV studies investigated the diagnostic accuracy of tests and an additional 1 level I, 2 level III-2 studies and 8 level IV studies provided information on prevalence.

2. 1 level I and 4 level IV studies informed discussion of Aboriginal and Torres Strait Islander women in the narrative. Additional advice was also sought from the Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care.

No high quality evidence suggested a change to the NICE recommendation. Additional information from systematic reviews, modelling and prevalence studies suggest screening of specific populations.

EAC recommendation

16. Do not routinely offer chlamydia testing to all women as part of antenatal care.

Routinely offer chlamydia testing at the first antenatal visit to pregnant women younger than 25 years.

Evidence supporting recommendation (see Section 8.1.5)

Bilardi et al 2010; Black-Payne et al 1990; Chen et al 2009; Cheney & Wray 2008; Cohen et al 1990; Macmillan et al 1985; Martin et al 1997; Regan et al 2008; Rivlin et al 1997; Ryan et al 1990

Grading of evidence — Recommendation 16

Evidence base C	Consistency C	Clinical impact C	Generalisablity B	Applicability C	Recommendation **C**

Maternal health screening

Syphilis

NICE recommendation

Screening for syphilis should be offered to all pregnant women at an early stage in antenatal care because treatment of syphilis is beneficial to the mother and fetus. [B]

Research questions

1. What is the prevalence of syphilis in pregnant women in Australia? (Informed narrative)
2. What are the diagnostic tests available for detection of syphilis infection and how do they compare in terms of specificity, sensitivity, and cost-effectiveness? (Informed narrative)
3. What are the available interventions for managing women who are infected with syphilis? (Informed Recommendation 17)
4. What are the additional considerations for Aboriginal and Torres Strait Islander women? (Informed narrative)

Search Strategy

Databases searched: Medline; Embase; Australasian Medical Index; ATSIhealth; Google Scholar; Cochrane Database

Date of search: November 2010

Limits: English language

Publication dates for search: January 2003 – November 2010

Review findings

1. 1 level IV study informed discussion of prevalence in the narrative.
2. 2 level II and 3 level III-2 studies confirmed the diagnostic accuracy of tests for syphilis and informed the narrative.
3. 2 level I studies, 1 level II study, 2 level III-2 studies and 1 level III-3 study confirmed the effectiveness of treatment for syphilis.
4. 1 level IV study informed the narrative.

The new evidence did not warrant changing the NICE recommendation.

EAC recommendation

17. Routinely offer and recommend syphilis testing at the first antenatal visit as treating syphilis benefits both mother and baby.

Evidence supporting recommendation (see Section 8.6.5)

Abyad 1995; Cameron et al 1997; Connor et al 2000; Duthie et al 1990; Garland & Kelly 1989; Hurtig et al 1998; Villar & Bergsjo 1997; Walker 2001; Wolff et al 2009

Grading of evidence — Recommendation 17

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
B	B	B	B	B	**B**

Maternal health screening

Asymptomatic bacteriuria

NICE recommendation

Women should be offered routine screening for asymptomatic bacteriuria by midstream urine culture early in pregnancy. Identification and treatment of asymptomatic bacteriuria reduces the risk of pyelonephritis.
[no grading; area for further research]

Research questions

1. What is the diagnostic accuracy of screening tests for asymptomatic bacteriuria? (Informed Recommendation 18)
2. What benefits would result from screening for asymptomatic bacteriuria? (Informed Recommendation 18)
3. What are the harms of not screening for asymptomatic bacteriuria? (No studies identified)
4. What are the additional considerations for Aboriginal and Torres Strait Islander women? (Informed narrative)

Search Strategy

Databases searched: Medline, EMBASE, MIDIRS, CINAHL, BNI, SIGLE, JBI, CENTRAL, COCHRANE, PsycINFO, LILACS, DARE, CONTROLLED TRIALS, CONFERENCE PROCEEDINGS, NDLTD, APAIS – ATSIhealth, Health Collection, Health Source, Nursing Academic Edition, AHRQ, ISI Web of Knowledge, TRIP, MD Consult, HTA, NHS EED, Scopus, Google Scholar, Academic OneFile, MEDNAR, ANZCTR

Date of search: December 2010

Limits: Female/women, human

Publication dates for search: January 2003 – December 2010

Review findings

1. 1 level I study, 3 level II studies, 3 level III-2 studies and 5 level IV studies supported the accuracy of urine culture.
2. The NICE recommendation is supported by a Cochrane review and an analysis of cost-effectivness and cost-benefit of screening. No additional specific studies were identified which indicated benefits from screening. 1 level III-2 study found that urine cultures are of little clinical importance for predicting preterm labour.
3. No studies identified.
4. 1 level IV study identified challenges with screening for Aboriginal women in remote communities. The Working Group for Aboriginal and Torres Strait Islander Women's Antenatal care also provided advice on testing in rural and remote areas.

The evidence supports the NICE recommendation.

Maternal health screening

EAC recommendations

18. Routinely offer and recommend testing for asymptomatic bacteriuria early in pregnancy as treatment is effective and reduces the risk of pyelonephritis.

19. Use urine culture testing wherever possible as it is the most accurate means of detecting asymptomatic bacteriuria.

Evidence supporting recommendations (see Section 8.7.5)

Recommendation 18 — Rouse et al 1995; Smaill & Vasquez 2007

Recommendation 19 — Bookallil et al 2005; Deville et al 2004; Eigbefoh et al 2008; Karabulut 2007; Mignini et al 2009; Teppa & Roberts 2005

Grading of evidence — Recommendation 18

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
A	A	C	A	A	**A**

Grading of evidence — Recommendation 19

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
A	A	C	A	A	**A**

Maternal health screening

NICE recommendation

Pregnant women should not be offered routine screening for bacterial vaginosis because the evidence suggests that the identification and treatment of asymptomatic bacterial vaginosis does not lower the risk for preterm birth and other adverse reproductive outcomes. [A]

Research questions

1. What is the diagnostic accuracy of screening tests for asymptomatic bacterial vaginosis? (Informed narrative)

2. What benefits would result from screening for asymptomatic bacterial vaginosis? (Informed Recommendation 20)

3. What are the harms of not screening for asymptomatic bacterial vaginosis? (Informed Recommendation 20)

4. What are the additional considerations for Aboriginal and Torres Strait Islander women? (No studies identified)

Search Strategy

Databases searched: Medline, EMBASE, MIDIRS, CINAHL, BNI, SIGLE, JBI, CENTRAL, COCHRANE, PsycINFO, LILACS, DARE, CONTROLLED TRIALS, CONFERENCE PROCEEDINGS, NDLTD, APAIS – ATSIhealth, Health Collection, Health Source, Nursing Academic Edition, AHRQ, ISI Web of Knowledge, TRIP, MD Consult, HTA, NHS EED, Scopus, Google Scholar, Academic OneFile, MEDNAR, ANZCTR

Date of search: December 2010

Limits: English language

Publication dates for search: January 2003 – December 2010

Review findings

1. 9 level III-2 studies discussed tests for asymptomatic bacterial vaginosis and suggested that Gram stains were effective.

2. 1 level I, 1 level III-1, I level III-2 and I level III-3 study suggested that the general population seems to lack any clear clinical benefit from screening and treatment for asymptomatic bacterial vaginosis during pregnancy.

3. 1 level I study suggested that, although a subgroup of high-risk women may benefit from screening and treatment for bacterial vaginosis in pregnancy, a sizeable group would receive either no benefit or may experience harm.

4. No relevant studies identified.

The recent evidence supports the NICE recommendation.

EAC recommendation

20. Do not routinely offer pregnant women testing for bacterial vaginosis.

Evidence supporting recommendation (see Section 8.8.5)

McDonald et al 2007; Nygren et al 2008

Grading of evidence — Recommendation 20

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
B	B	B	B	B	**B**

Maternal health screening

Vitamin D

NICE recommendation

All women should be informed at the booking appointment about the importance for their own and their baby's health of maintaining adequate vitamin D stores during pregnancy and whilst breastfeeding. In order to achieve this, women may choose to take 10 micrograms of vitamin D per day, as found in the Healthy Start multivitamin supplement. Particular care should be taken to enquire as to whether women at greatest risk are following advice to take this daily supplement. These include:

› women of South Asian, African, Caribbean or Middle Eastern family origin

› women who have limited exposure to sunlight, such as women who are predominantly housebound, or usually remain covered when outdoors

› women who eat a diet particularly low in vitamin D, such as women who consume no oily fish, eggs, meat, vitamin D-fortified margarine or breakfast cereal

› women with a pre-pregnancy body mass index above 30 kg/m^2. [no grading; area for further research]

Research questions

1. Who should be screened for vitamin D deficiency? (Informed Consensus-based recommendation viii)

Search Strategy

Databases searched: Medline; Embase; Australasian Medical Index; ATSIhealth; Google Scholar; Cochrane Database

Date of search: November 2010

Limits: English language

Publication dates for search: January 2003 – November 2010

Review findings

1. Although 3 level I studies, 11 level II studies, 1 level III-2, 1 level III-3 and 5 level IV studies were identified, there is an absence of high quality evidence supporting a demonstrable reduction in morbidity or mortality from vitamin D supplementation. However, there is a growing international trend towards screening and/or recommending supplementation in pregnancy, due to the growing awareness of vitamin D deficiency and its sequelae.

Consensus-based recommendation

viii. Offer vitamin D screening to women with limited exposure to sunlight (eg because they are predominantly indoors or usually protected from the sun when outdoors), or who have dark skin or a pre-pregnancy BMI of >30, as they may be at increased risk of vitamin D deficiency and may benefit from supplementation for their long-term health. Base decisions about whether to offer screening on these factors, season and climate.

Maternal health screening

Chromosomal abnormalities

NICE recommendation

All pregnant women should be offered screening for Down's syndrome. Women should understand that it is their choice to embark on screening for Down's syndrome.

Screening for Down's syndrome should be performed by the end of the first trimester (13 weeks 6 days), but provision should be made to allow later screening (which could be as late as 20 weeks 0 days) for women booking later in pregnancy.

The 'combined test' (nuchal translucency, beta-human chorionic gonadotrophin, pregnancy-associated plasma protein-A) should be offered to screen for Down's syndrome between 11 weeks 0 days and 13 weeks 6 days. For women who book later in pregnancy the most clinically and cost-effective serum screening test (triple or quadruple test) should be offered between 15 weeks 0 days and 20 weeks 0 days.

When it is not possible to measure nuchal translucency, owing to fetal position or raised body mass index, women should be offered serum screening (triple or quadruple test) between 15 weeks 0 days and 20 weeks 0 days.

Information about screening for Down's syndrome should be given to pregnant women at the first contact with a healthcare professional. This will provide the opportunity for further discussion before embarking on screening. (Refer to Section 3.3 for more information about giving antenatal information). Specific information should include:

› the screening pathway for both screen-positive and screen-negative results

› the decisions that need to be made at each point along the pathway and their consequences

› the fact that screening does not provide a definitive diagnosis and a full explanation of the risk score obtained following testing

› information about chorionic villus sampling and amniocentesis

› balanced and accurate information about Down's syndrome.

If a woman receives a screen-positive result for Down's syndrome, she should have rapid access to appropriate counselling by trained staff.

Research questions

1. Which tests should be used to screen for chromosomal abnormalities? (Informed Recommendations 21 and 22)

2. What is the impact of maternal age on chromosomal screening and choice of test? (Inconsistent evidence)

3. Which tests are available/should be used in rural/remote locations? (Informed narrative)

4. Who should be offered prenatal testing? (Informed narrative)

5. What is the psychological impact of prenatal screening? (Informed Consensus-based recommendation ix)

6. What is the psychological impact of not offering prenatal screening? (No studies identified)

7. What counselling is required before and after screening? What constitutes informed consent? (Informed Consensus-based recommendations ix and x)

8. What additional information do pregnant women require regarding the results of their chromosomal screening tests? (Informed narrative)

9. What are the additional considerations for Aboriginal and Torres Strait Islander women? (No studies identified)

Maternal health screening

Search Strategy

Databases searched: Medline; Embase; Australasian Medical Index; ATSIhealth; Google Scholar; Cochrane Database

Date of search: January 2011

Limits: English language

Publication dates for search: January 2003 – January 2011

Review findings

1. The findings from 4 level I studies, 4 level II studies and 12 level III-2 studies suggest that nuchal translucency thickness scans before 12 weeks are more accurate. Adding biochemical markers will either improve detection of chromosomal abnormalities or not change it. The addition of first trimester screening may lead to reduced rates of invasive testing and fewer losses of normal pregnancies. Detailed ultrasound examination at early gestational age may not be superior to nuchal scan in screening for fetal abnormalities. Second trimester amniocentesis is safer than early amniocentesis. Amniocentesis at 13 weeks carries an increased risk of talipes equinovarus compared with chorionic villus sampling.

2. The evidence from 2 Level II studies, 22 Level III-2 studies, 2 Level III-3 studies and 2 Level IV studies was inconsistent regarding maternal age in relation to screening for chromosomal abnormalities and choice of test.

3. 2 Level III-2 studies suggested that interventions should be targeted at rural areas as there is unequal access to screening in these areas.

4. 2 level III-2 and 3 Level III-3 studies suggested that combining first trimester screening with screening in the second trimester is most effective.

5. 2 level I and 2 level II studies supported the need for counselling following screening.

6. No studies identified.

7. 1 level I study informed the narrative on the use of decision aids.

8. 1 level I study supported the provision of information about screening.

9. No relevant studies identified. Advice on information provision provided by the Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care.

Maternal health screening

EAC recommendations

21. 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 and ultrasound assessment takes place between 11 weeks 0 days and 13 weeks 6 days.

22. If a woman chooses to have a diagnostic test for chromosomal abnormalities, base the choice of test on the gestation of pregnancy and the woman's preferences. Chorionic villus sampling is safer before 14 weeks pregnancy. Amniocentesis is safe after 15 weeks.

Evidence supporting recommendations (see Section 9.7)

McDonald et al 2007; Nygren et al 2008

Grading of evidence — Recommendation 21

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
B	B	A	A	B	**B**

Grading of evidence — Recommendation 22

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
B	B	A	A	B	**B**

Consensus-based recommendations

ix. At the first antenatal visit, give all women information about the purpose and implications of testing for chromosomal abnormalities to enable them to make informed choices about whether or not to have the tests.

x. Offer rapid access to appropriate counselling and ongoing support by trained health professionals to women who receive a diagnosis of fetal chromosomal abnormality.

Lifestyle considerations

Tobacco smoking

NICE recommendation

At the first contact with the woman, discuss her smoking status, provide information about the risks of smoking to the unborn child and the hazards of exposure to second-hand smoke. Address any concerns she and her partner or family may have about stopping smoking.

Pregnant women should be informed about the specific risks of smoking during pregnancy (such as the risk of having a baby with low birth weight and preterm birth). The benefits of quitting at any stage should be emphasised.

Offer personalised information, advice and support on how to stop smoking. Encourage pregnant women to use local NHS Stop Smoking Services and the NHS pregnancy smoking helpline, by providing details on when, where and how to access them. Consider visiting pregnant women at home if it is difficult for them to attend specialist services.*

Monitor smoking status and offer smoking cessation advice, encouragement and support throughout the pregnancy and beyond.*

Discuss the risks and benefits of nicotine replacement therapy (NRT) with pregnant women who smoke, particularly those who do not wish to accept the offer of help from the NHS Stop Smoking Service. If a woman expresses a clear wish to receive NRT, use professional judgement when deciding whether to offer a prescription.*

Advise women using nicotine patches to remove them before going to bed.*

This supersedes NICE technology appraisal guidance 39 on NRT and bupropion.*

Women who are unable to quit smoking during pregnancy should be encouraged to reduce smoking. [B]

* Recommendation from the NICE public health guidance on smoking cessation (www.nice.org.uk/PH010).

Research questions

1. What are the maternal and perinatal outcomes associated with smoking in pregnancy? (No new studies identified)

2. Do smoking cessation programs lead to reduction in smoking rates for pregnant women and what are the characteristics of smoking cessation programs that are most effective in reducing smoking among pregnant women? (Informed Recommendation 24)

3. Do smoking cessation programs decrease perinatal mortality and morbidity? (No new studies identified)

4. What interventions assist women to quit smoking? (Informed Recommendation 24)

5. Is nicotine replacement therapy safe for pregnant women? (Informed Recommendation 25)

6. What are additional considerations for Aboriginal and Torres Strait Islander women? (Informed narrative)

Search Strategy

Databases searched: Medline; Embase; Australasian Medical Index; ATSIhealth; Google Scholar; Cochrane Database

Date of searches: October 2009; November 2010

Limits: English language

Publication dates for searches: January 2003 – October 2009
January 2008 – November 2010

Lifestyle considerations

Review findings

1. 6 level I studies were identified in the NICE review that indicated a significant association between smoking in pregnancy and adverse outcomes. No additional evidence was identified.

2. 1 level I study from NICE. See response to question 4.

3. 1 level 1 study from NICE.

4. 5 level I studies, 8 level II studies, 1 level III-3 study and 3 level IV studies examined the effectiveness of smoking cessation interventions and informed the narrative (note that these Guidelines discuss assessment rather than intervention). Of these, 2 level IV studies and 2 observational studies informed the narrative on smoking cessation among Aboriginal and Torres Strait Islander women.

5. 2 level I studies and 1 level II study supported the need for caution in considering NRT during pregnancy.

6. See Question 4.

EAC recommendations

23. At the first antenatal visit:
    – assess the woman's smoking status and exposure to passive smoking;
    – give the woman and her partner information about the risks to the unborn baby associated with maternal smoking and passive smoking; and
    – if the woman smokes, emphasise the benefits of quitting as early as possible in the pregnancy and discuss any concerns she or her family may have about stopping smoking.

24. Offer women who smoke referral for smoking cessation interventions such as cognitive behavioural therapy.

25. If, after other options have been explored, a woman expresses a clear wish to use nicotine replacement therapy, discuss the risks and benefits with her.

Evidence supporting recommendations (see Section 10.4.5)

Recommendation 23 — Based on evidence from NICE.

Recommendation 24 — Berg et al 2008; Dennis & Kingston 2008; Lumley et al 2009; Stotts et al 2009

Recommendation 25 — Lumley et al 2009; Oncken et al 2008; Smith et al 2006

Grading of evidence — Recommendation 23

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
A	B	A	B	B	**A**

Grading of evidence — Recommendation 24

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
A	B	A	B	B	**B**

Grading of evidence — Recommendation 25

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
A	B	A	B	B	**B**

Lifestyle considerations

Alcohol

Consensus-based recommendations

Consensus-based recommendation xi is based on Guideline 4 in NHMRC (2009) *Australian Guidelines to Reduce Health Risks from Drinking Alcohol.* Canberra: National Health and Medical Research Council. The recommendation is based on systematic review of the literature but was not graded. Literature on prevalence of alcohol consumption and associated risks during pregnancy published subsequent to the NHMRC guidelines has not been reviewed.

xi. Advise women who are pregnant or planning a pregnancy that not drinking is the safest option as maternal alcohol consumption may adversely affect the developing fetus or breastfeeding baby.

Medicines

Consensus-based recommendations

Consensus-based recommendations xii and xiii are based on advice from the Therapeutic Goods Administration.

xii. Advise women that use of prescription and over-the-counter medicines should be limited to circumstances where the benefit outweighs the risk as few medicines have been established as safe to use in pregnancy.

xiii. Therapeutic Goods Administration Category A medicines have been established to be safe in pregnancy.

Lifestyle considerations

Nutritional supplements

NICE recommendation

Pregnant women should be informed that vitamin A supplementation (intake above 700 micrograms) might be teratogenic and should therefore be avoided. Pregnant women should be informed that liver and liver products may also contain high levels of vitamin A, and therefore consumption of these products should also be avoided. [C]

Pregnant women (and those intending to become pregnant) should be informed that dietary supplementation with folic acid, before conception and up to 12 weeks of gestation, reduces the risk of having a baby with neural tube defects (anencephaly, spina bifida). The recommended dose is 400 micrograms/day. [A]

Research questions

1. What dietary advice should be provided to pregnant women? (Informed narrative in section on weight and BMI)
2. What are the risks of vitamin and mineral supplementation in pregnancy? (Informed Recommendations 26, 27 and 28)
3. What are the benefits of vitamin supplementation in pregnancy? (Informed narrative)
4. What are the risks of complementary medicines in pregnancy? (Informed narrative)
5. What are the benefits of complementary therapies in pregnancy? (Informed narrative)
6. What are the additional considerations for Aboriginal and Torres Strait Islander women? (Informed narrative)

Search Strategy

Databases searched: Medline; Embase; Australasian Medical Index; ATSIhealth; Google Scholar; Cochrane

Date of search: March 2011

Limits: English language

Publication dates for search: January 2003 – March 2011

Review findings

1. 2 level I and 4 level II studies incorporated into narrative in chapter on weight and BMI.
2. 1 level I study for iron; 1 Level I, 1 Level II for vitamin A; 1 Level I for vitamin C; 1 Level I for vitamin C+E supported the NICE recommendations on iron and vitamin A.
3. 6 level II studies supported the use of multinutrients in women experiencing malnutrition. 1 level I study supported the NICE recommendation on folic acid supplementation. Dosage changed in line with Australian advice.
4. 2 level III-2 and 1 qualitative study informed the narrative.
5. 3 Level I and 2 Level II studies on acupuncture were identified. Back pain was deferred until the next Module.
6. 3 level III-2 studies informed the narrative.

Lifestyle considerations

EAC recommendations

26. Inform women that dietary supplementation with folic acid, from 12 weeks before conception and throughout the first 12 weeks of pregnancy, reduces the risk of having a baby with a neural tube defect (for example, anencephaly or spina bifida) and recommend a dose of 500 micrograms per day.

27. Advise women that taking vitamins A, C or E supplements is not of benefit in pregnancy and may cause harm.

28. Do not routinely offer iron supplementation to women during pregnancy.

Evidence supporting recommendations (see Section 10.4.5)

Recommendation 26 — Bower et al 2004; 2009; De Regli et al 2010

Recommendation 27 — Kirkwood et al 2010; Rumbold & Crowther 2005; Rumbold et al 2011; van den Broek et al 2010; Xu et al 2010

Recommendation 28 — Reveiz et al 2007

Grading of evidence — Recommendation 26

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
A	A	C	A	A	**A**

Grading of evidence — Recommendation 27

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
A	NA	B	A	A	**B**

Grading of evidence — Recommendation 28

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
A	NA	B	A	A	**B**

Lifestyle considerations

Oral health

NICE recommendation

None

Research questions

1. Are there any dental procedures or treatments that are unsafe in pregnancy? (Informed narrative)
2. Does periodontal disease confer any risks to pregnancy or to the neonate? (Informed narrative)
3. Does dental caries confer any risks in pregnancy or to the neonate? (Informed narrative)
4. What is the optimal timing of screening for oral health? (No studies identified)
5. What information/education and advice should clinicians provide for women? (Informed Recommendation 29)
6. What are the additional considerations for Aboriginal and Torres Strait Islander women? (No studies identified)

Search Strategy

Databases searched: Medline; Embase; Australasian Medical Index; ATSIhealth; Google Scholar; Cochrane Database

Date of search: November 2010

Limits: English language

Publication dates for search: January 2003 – November 2010

Review findings

1. 1 level II, 1 level III-1, 2 level III-2 and 1 level IV were inconsistent on the safety of dental treatments in pregnancy.
2. 1 level I, 8 level II, 7 level III-2, 9 level III-3 and 14 level IV suggested that periodontal disease does not confer risks to pregnancy and informed the narrative.
3. 2 level III-2 and 2 level IV studies were inconclusive on the risks of caries in pregnancy.
4. No studies identified.
5. 1 level II and 5 level IV highlighted the importance of women receiving advice on oral health during pregnancy.
6. No studies identified.

EAC recommendation

29. At the first antenatal visit, advise women to have oral health checks and treatment, if required. Good oral health protects a woman's health and treatment can be safely provided during pregnancy.

Evidence supporting recommendation (see Section 10.5.5)

Cruz et al 2010; Khadar & Ta'ani 2005; Macones et al 2010; Michalowicz et al 2006; Michalowicz et al 2009; Newnham et al 2009; Novak et al 2008; Offenbacher et al 2009; Plutzer & Spencer 2008; Srinivas et al 2009; Thomas et al 2008

Grading of evidence — Recommendation 29

Evidence base	Consistency	Clinical impact	Generalisablity	Applicability	Recommendation
A	B	C	B	A	**B**

E. Economic analyses

This appendix provides a brief summary of the economic analyses carried out to inform the development of these Guidelines.

Gestational age assessment

Accurate assessment of gestational age through ultrasound measurement of CRL will impose a cost associated with ultrasound screening for chromosomal abnormalities in the first trimester.

Due to time, resource and data constraints, this analysis focussed on a relatively narrow set of costs and benefits, namely the financial cost of first trimester screening against cost-savings from a reduction in diagnostic testing and labour inductions at birth. The analysis is based on a whole-of-cohort model, and results will not be affected unless the age profile of pregnant woman in Australia significantly changes.

1 Potential costs and benefits of the proposed recommendation

Potential costs

A recommendation that pregnant women are offered an ultrasound scan in the first trimester is likely to increase the volume of scans — more health professionals may offer the scan and more women accept the offer.

Introducing the proposed recommendation would have a range of effects on health expenditure. In particular, it would be likely to:

› increase Medicare expenditure;

› increase public hospital expenditure where women receive ultrasounds as hospital outpatients; and

› potentially impose costs on individuals (eg where Medicare, or private health insurance, does not cover ultrasounds, and travel costs for women in rural and remote areas).

For reasons discussed later, this analysis focuses on the impact of introducing the recommendation on Medicare expenditure. This is also consistent with *How to Compare the Costs and Benefits: Evaluation of the Economic Evidence* (NHMRC 2001), which indicates that cost-benefit analyses should focus on health sector budget effects.

Potential benefits

Broadly, the proposed recommendation would, for the additional women receiving first trimester ultrasound scans, enable an accurate determination of gestational age in the first trimester. Potential benefits from this include:

› reducing the number of pregnancies that are incorrectly diagnosed as having gone beyond term, thereby reducing the number and the costs associated with unnecessary labour inductions;

– reducing the number of unnecessary labour inductions has in turn been found to reduce the risk of caesarean section (see Maslow & Sweeney 2000); and

› optimising the timing and performance of maternal serum screening usually undertaken later in pregnancy to detect chromosomal abnormalities (eg trisomy 21);

– improving the performance of maternal serum screening would potentially generate a cost saving by reducing the number of women referred for follow-up tests where no abnormality is present.

Ideal approach to cost-benefit analysis

Ideally, this cost-benefit analysis would:

› estimate the annual increase in first trimester ultrasound scans as a result of introducing the recommendation;

  – estimate the cost to Medicare of this annual increase; and

› compare this cost with estimated cost savings from:

  – the estimated annual reduction in labour inductions and the consequential estimated annual reduction in the number of caesarean sections; and

  – the estimated annual reduction in follow-up tests for chromosomal abnormalities.

However, the data limitations discussed in Section 2 require a modified approach to be undertaken, as set out in Section 4.

2 Data and related limitations

Potential costs

Data are available for Medicare-funded ultrasound scans. Relevant Medicare-funded ultrasound scans include:

› ultrasounds in the first 12 weeks of pregnancy (which are eligible for Medicare benefits under certain maternal or gestational conditions);

› nuchal translucency thickness scans between 11 and 13 weeks; and

› ultrasound scans between 17 and 22 weeks.

No data are available on pregnant women receiving ultrasounds as hospital outpatients or ultrasounds that are self-funded. Consequently, as noted above, the analysis is limited to the impact of introducing the proposed recommendation on Medicare expenditure.

Potential benefits

Reducing inductions

In 2008, labour was induced in 25% of pregnancies, a figure that remained broadly constant between 1999 and 2008 (Laws et al 2010). There are a number of reasons why health professionals decide to induce labour, including because the pregnancy is believed to have gone beyond term – typically beyond 41 or 42 weeks. Laws et al (2010) report on the reasons given for inducing labour. However, the proportion of inductions for post-term pregnancy was not published because of data problems.

In any case, as labour inductions predominately occur in hospital, it would only be possible to investigate correlations between Medicare-funded ultrasound scans and inductions incurring in hospitals by linking the relevant data sets. Investigating the potential for such a data linkage project is beyond the scope of the current study.

For these reasons, the current study was unable to use the available Australian data to estimate the likely reduction in the number of inductions from introducing the recommendation. Instead, the analysis relied on findings in the literature (see Section 3) to provide a broad indication of the potential reduction in inductions and caesarean sections from introducing the proposed recommendation.

Optimising maternal serum screening

Medicare data are available on the number of maternal serum screening, amniocentesis and chorionic villus sampling procedures undertaken and their associated cost. Between 2006 and 2009:

› around 550,000 women received a Medicare benefit for maternal serum screening; and

› of those, around 5.3 per cent received either an amniocentesis or chorionic villus sampling.

The Admitted Patient Data Collection held by the Department potentially could have provided data on amniocentesis and chorionic villus sampling received by admitted hospital patients. However, these data are not reported for privacy reasons.

3 Literature summary

A literature review of previous studies on this topic was undertaken. For the review, the Cochrane, Embase and Medline databases were searched for English-language articles published since 2006. Combinations of the following key words were used for the search — cost effectiveness, utility, benefit; economic; ultrasound; gestational age; pregnancy; antenatal; and prenatal. The search did not return any cost-benefit analyses of gestational age screening since 2006. The search was subsequently broadened to include literature from any year, as well as clinical studies. The terms crown to rump length (CRL), last menstrual period, inductions, induce, maternal serum screening, first trimester and screening were added to the above list of key words. Google, including Google Scholar, searches were conducted and the journals *British Journal of Obstetrics and Gynaecology* and *Obstetrics & Gynaecology* were searched directly. This identified:

› five studies on the clinical outcomes of first trimester ultrasound scans (Gardosi et al 1997; Crowther et al 1999; Maslow & Sweeny 2000; Bennett et al 2004; Whitworth et al 2010), including one comparative review (Whitworth et al 2010) and one study on the clinical outcomes of induction (Maslow & Sweeny 2000); and

› five economic studies relating to ultrasound screening (Roberts et al 1998; Benn et al 1999; MSAC 2002; Harris 2003; Ritchie et al 2005), including one Medical Services Advisory Committee evaluation (MSAC 2002).

Clinical studies

Whitworth et al (2010) conducted a comprehensive international review of studies assessing whether routine early pregnancy ultrasound scanning influences 33 antenatal, neonatal or postnatal outcomes. 'Early pregnancy' was defined as 'prior to 24 weeks'; that is, not just in the first trimester. The authors reported significant differences between women receiving routine and selective ultrasound screening in eight of the 33 outcomes, including:

› induction of labour for any reason and specifically for "post-term" pregnancy;

› detection of fetal abnormalities before 24 weeks gestation;

› detection of major anomaly before birth; and

› termination of pregnancy for fetal abnormality.

Assessing the implications of these results for the current study is complicated by the fact that women received scans at different points during the first 24 weeks of pregnancy in the studies reviewed by Whitworth et al (2010). For example, the general conclusion that early pregnancy ultrasound screening 'may result in fewer inductions for post-maturity' (Whitworth et al 2010) is not directly relevant to the current study as it covers scans undertaken in the first 24 weeks, not specifically the first trimester.

Whitworth et al (2010) reviewed two studies that analysed whether ultrasound screening in the first 14 weeks impacted upon the rate of induction for post-term pregnancy — Harrington et al (2006) and Ewigman et al (1990). Whitworth et al (2010) collated the results from these two studies and found no significant impact (RR: 0.99; CI: 0.67–1.46).

In the Harrington et al (2006) study, the intervention group received a first trimester scan in addition to a routine 20 week anomaly scan, while the control group received just the routine 20 week anomaly scan. The antenatal care strategy for the control group was not made clear in Ewigman et al (1990).

In an Australian study, Crowther et al (1999) found no significant difference in the rates of induction (for any reason). Similar to Harrington et al (2006), both the control and intervention groups received routine screening in the second trimester.

In a United States study, Bennett et al (2004) assigned pregnant women to either a first trimester scan group *or* a second trimester scan group. A significantly higher number of women in the second trimester group had their labour induced (12 women), compared with those in the first trimester group (5 women) (P=0.04; RR: 0.37; CI: 0.14–0.96).

Maslow and Sweeny (2000) conducted a historical review to analyse the risk of caesarean section associated with induction of labour. Of the 1,135 women reviewed, 263 (23.2%) elected to have their labour induced. Of these women, 11.0 per cent underwent caesarean section, compared with 4.2 per cent of those who did not have their labour induced (P < 0.001).

Benn et al (1999)[20] analysed the effect of ultrasound dating scans on improving the screening power of maternal serum screening. The authors found that ultrasound dating scans considerably increase the number of positive Down syndrome cases detected through maternal serum screening while reducing the number of false positive results.

Economic studies

The literature review did not reveal any Australian economic evaluations of ultrasound dating screening. Although there were some international economic studies, none were wholly relevant to this study.

Roberts et al (1998) compared different ultrasound strategies in pregnancy in the United Kingdom. The performance of each screening strategy was based on the detection rate of fetal anomalies, the false positive rate and the population prevalence of the anomaly. The results showed that first and second trimester screening together detected a higher number of fetal anomalies and missed a lower number of anomalies than second trimester screening alone. However, the cost per case detected was considerably higher for first and second trimester screening.

Ritchie et al (2005) performed an economic evaluation for a United Kingdom Health Technology Assessment on antenatal screening for identification of fetal abnormalities. The authors assessed the cost effectiveness of six screening strategies, including two involving a scan at the first antenatal visit and four involving NT scans. However, none of these strategies were compared against a strategy that did not involve a first trimester scan. The evaluation was not therefore able to inform the current analysis.

MSAC released its assessment of nuchal translucency thickness screening in the first trimester of pregnancy in 2002. While it did not specifically relate to ultrasound dating, a number of inputs and variables were taken from the assessment and applied to this study.

20 In addition to a clinical study, the authors performed an economic evaluation to estimate the cost effectiveness of ultrasound dating scans.

4 Cost benefit analysis

<u>Estimating the increase in ultrasound scans</u>

Preferably, data on, or studies of, changes in the patterns of first trimester screening where policies or guidelines similar to the proposed recommendation have been introduced would be used to estimate the increase in the number of ultrasound scans from introducing the recommendation. However, the study was not able to identify any relevant studies. Medicare data between 2006 and 2009 were also examined but did not reveal any changes in trends that might have assisted the analysis.

Ultimately, in the time available, the current study was unable to identify any reliable indicator of how the proposed recommendation might affect rates of first trimester ultrasound screening. Consequently, the study estimated the maximum number of additional scans that would be likely to result from introducing the recommendation.

Broadly, women may receive Medicare-funded ultrasound scans, scans not funded by Medicare or they may not receive a scan. This can be represented as follows:

$$mfs^{T1} + nmfs^{T1} + ns^{T1} = p^{T1}$$

$$mfs^{T2} + nmfs^{T2} + ns^{T2} = p^{T2} \approx b$$

> mfs: annual number of women receiving Medicare-funded ultrasound scans
>
> nmfs: annual number of women receiving non-Medicare-funded ultrasound scans
>
> ns: annual number of women not receiving scans
>
> p: annual number of pregnancies
>
> b: annual number of births
>
> T1: first trimester
>
> T2: 17–22 weeks

The maximum increase in first trimester scans is ns^{T1}; that is, the number of women who would not receive a scan without the recommendation. As discussed above, data are only available about Medicare-funded scans. Consequently, to estimate ns^{T1}, the following assumptions were made:

› the rate of miscarriage by the start of the 17–22 period – μ – is 15%; that is, 15% of first trimester pregnancies end in miscarriage:[21]

$$\mu * p^{T1} = p^{T2} \quad \text{where } \mu = 0.85$$

› pT2 is approximately equal to the number of births in the year;

› total annual births is 292,000;[22]

› all pregnant women have an ultrasound scan between 17 and 22 weeks;[23] that is:

$$ns^{T2} = 0$$

21 Advice from Expert Advisory Committee.
22 This is total births for 2008 (Laws et al 2010)
23 Between 2006 and 2009, around 916,000 women (or around 84 per cent of births) received one or more Medicare Benefits for a 17 to 22 week routine scan.

› the number of women who have Medicare-funded first trimester scans (including nuchal translucency thickness scans) is equal to the number of women who have Medicare-funded scans both in the first trimester and between 17 and 22 weeks; that is:

$$mfs^{T2,T1} = mfs^{T1}$$

where $mfs^{T2,T1}$ is the number of women who have Medicare-funded scans both in the first trimester and between 17 and 22 weeks

› the number of women who have non-Medicare-funded first trimester scans as a proportion of the number of women who have non-Medicare-funded scans between 17 and 22 weeks is equal to the number of women who have Medicare-funded scans in the first trimester and between 17 and 22 weeks as a proportion of women who have Medicare-funded scans between 17 and 22 weeks; that is:

$$nmfs^{T1}/ nmfs^{T2} \approx mfs^{T2,T1}/mfs^{T2}$$

Broadly, the assumption is that the proportion of first trimester to 17–22 week scans is the same in the Medicare and non-Medicare sectors.

Ultimately, under these assumptions, the maximum additional number of first trimester ultrasounds is estimated by the following equation:

$$ns^{T1} = b(1 - mfs^{T1,T2}/mfs^{T2})/ \mu$$

This produces an estimate of approximately 75,500 for the maximum number of additional scans annually arising from the introduction of the recommendation. This is likely to be more than the actual number of additional scans resulting from the introduction of the recommendation as not all women may elect or be able to have an additional scan in the first trimester due to personal choice or circumstances (noting that eligibility for Medicare benefits is restricted).

Estimating the cost of an increase in ultrasound scans

The total cost of 75,500 first trimester scans was estimated to be $A4,530,000. It has been assumed that the cost of a first trimester ultrasound scan is equal to the Medicare Benefit Schedule fee for an 'ultrasound scan prior to 12 weeks gestation where a specific condition is present – referred by a medical practitioner'. This fee is $A60.

The estimate of the maximum number of additional scans may include an unknown number of 12 to 16 week scans brought forward because of the introduction of the recommendation. Consequently, the total cost ($A4.53m) of the maximum additional first trimester scans may be offset by reductions in the number and cost of 12 to 16 week scans. As the level of this offset is unknown, it is not factored into the analysis at this point. However, the sensitivity of the analysis to this issue is tested below by assuming that all women who receive scans between 12 and 16 weeks bring forward their scan to the first 12 weeks and so offset the cost of their additional scan.

Change in post-term inductions

Estimating the decrease in inductions

As discussed in Section 2, it is not possible to estimate the impact of an increase in first trimester ultrasounds on the rate of post-term inductions from available data. Consequently, this study relies on key findings in the literature (see Section 3). In particular, Whitworth et al (2010) — relying on Harrington et al (2006) and Ewigman et al (1990) — and Crowther et al (1999) found no significant difference in the rate of induction between women who had a first trimester scan and women who had both a first and second trimester scan. These studies are particularly relevant to the current study, given that most women in Australia have a scan between 17 and 22 weeks. Consequently, this cost benefit analysis is effectively

assessing whether women having an additional first trimester scan would materially reduce the rate of induction. The two studies cited indicate that this is unlikely. It then follows that introducing the proposed recommendation would be unlikely to reduce caesarean sections. The sensitivity of these conclusions to underlying assumptions is tested in Section 5 below.

<u>Impact on the effectiveness of maternal serum screening</u>

Estimating the increase in screening power of maternal serum screening

Increasing the quality, or screening power, of maternal serum screening potentially reduces the number of women referred for amniocentesis or chorionic villus sampling and may thereby generate cost savings. The screening power of maternal serum screening can by measured by:

› the detection rate — that is, the proportion of cases where chromosomal abnormalities exist which are detected by maternal serum screening (higher detection rates are better); and

› the false positive rate — that is, the number of cases which incorrectly screen positive for chromosomal abnormalities as a proportion of cases where chromosomal abnormalities are not present (lower false positive rates are better).

The literature includes the following findings relevant to assessing the impact of introducing the recommendation on the screening power of maternal serum screening:

› Laws et al (2010) reported the mean age of Australian women who gave birth in 2008 as 29.9 years;

› according to Benn et al (1999), the maternal serum screening detection and false positive rates for women aged 30 are 61.9% and 5.9% respectively where gestational age is determined through ultrasound (CRL); and

› for a similar detection rate, Benn (1999) report the false positive rate of women who calculate gestational age through last menstrual period alone as 10.0%.

The current study therefore assumes that the maternal serum screening false positive rate of those women predicted to receive a first trimester scan as a result of the guideline would fall from 10.0% to 5.9%. The sensitivity of this result to the assumptions above is tested in Section 5.

Estimating the likely cost impact

The number of women potentially affected by an increase in the screening power of MSS from introducing the recommendation was estimated as follows.

› Of those women who received a Medicare benefit for a 17–22 week scan in 2009, around 50% also received maternal serum screening.

› Of that 50%, around 26% did not receive a Medicare benefit for a first trimester scan (or any other ultrasound) prior to receiving maternal serum screening.

› If these proportions are assumed to hold across the population of pregnant women as a whole, this equates to around 13% of pregnant women — that is, around 38,200 women — in the second trimester who receive maternal serum screening, but no first trimester scan.

In summary, for a maximum of 38,200 women, introducing the recommendation would lead to an increase in maternal serum screening power as measured by a fall in the false positive rate from 10% to 5.9%.

The maximum cost saving associated with the improvement in screening power was estimated by modelling the likely fall in the number of women referred for diagnostic tests where no abnormality is present, and multiplying this by the per unit cost of the relevant tests.

The modelling used a series of simulations where inputs, such as State/Territory of the mother's residence, the prevalence of chromosomal abnormalities (particularly Down syndrome), rate of spontaneous miscarriage, the false positive rates of maternal serum screening and the acceptance of screening and diagnostic tests, were assigned probabilities and randomly applied to a population of 38,200 pregnant women.

The relevant Medicare Benefits Schedule fees were used as proxies for the cost of the relevant tests.

The results of this modelling are given in Table E1.

Table E1:   Results of modelling of effect of ultrasound dating scan

Effect of ultrasound dating scan	Mean	95% confidence interval	
		Lower bound	Upper bound
Reduction in the number of false positive results for Down syndrome	1,560	1,483	1,637
Reduction in the number of amniocentesis/CVS tests where pregnancy is Trisomy 21 negative	1,327	1,225	1,430
Total cost saving of reduction in amniocentesis/ CVS tests	**$A233,372**	**$A214,915**	**$A251,828**

Overall cost-benefit

The analysis above indicates that:

›   the maximum additional cost arising from introducing the recommendation (from an increase in first trimester ultrasounds) is around $A4.5m; and

›   the maximum additional benefit arising from introducing the recommendation (from an improvement in the power of maternal serum screening) is around $A230,000.

Consequently, the costs of introducing the proposed recommendation appear likely to substantially outweigh the benefits.

5   Sensitivity analysis

Due to a lack of relevant, reliable and up-to-date data, a number of assumptions were made in the process of developing this analysis. Key assumptions include that:

›   findings from Whitworth et al (2010) and Crowther et al (1999) can be used to estimate the impact of ultrasound screening on the rate of induction; and

›   pregnant women do not bring forward scans obtained between 12 and 16 weeks to the first trimester as a result of the recommendation.

These assumptions might significantly influence the final conclusion of this study. In particular, as inductions are relatively costly (see below), if the assumption that first trimester ultrasound screening has no material impact on the level of inductions is significantly inaccurate, then the outcome of the cost-benefit analysis may change. To test the sensitivity of the cost-benefit analysis to these assumptions:

› data from a United States study — Bennett et al (2004), which found that ultrasound scans do reduce inductions — were used to estimate the impact of the maximum additional number of ultrasound scans from introducing the recommendation (adjusted for miscarriages) on the rate of induction;

– the potential for reduced inductions to reduce caesarean sections then arises. Data from Maslow and Sweeny (2000) were used to estimate the increased risk of caesarean section where pregnancies are induced; and

› it was assumed that all pregnant women who under current practice receive a scan between 12 and 16 weeks substitute this scan for a scan in the first 12 weeks as a result of the recommendation.

Utilising the risk ratio reported by Bennett et al 2004

Bennett et al (2004) report a risk ratio of 0.37 (95% CI 0.14–0.96). Data on the risk of caesarean section associated with the induction of labour were taken from Maslow and Sweeny (2000). The current study interprets the findings of the Maslow and Sweeny study to mean that every 100 inductions averted was estimated to avert 6.8 caesarean sections.

The average costs of an induction and caesarean section were estimated from admitted patient hospital data and the National Hospital Cost Data Collection and applied to the assumed fall in the number of inductions and caesarean sections.

The average cost of performing an induction of labour was estimated at $A860.48. For every caesarean section averted, an estimated $A3,851.39 was realised in cost savings.

Results are set out in Table E2.

Table E2:   Maximum cost savings if inductions are reduced by first trimester screening

Bennett et al 2004	Value	95% confidence interval	
		Lower bound	Upper bound
Risk ratio	0.37	0.14	0.96
Maximum number of inductions averted (64,200 first trimester scans)[24]	19,893	41,955	663
Cost saving (A$)	17,117,901	36,101,475	570,574
Maximum number of caesarean sections averted	1352	2,853	45
Cost saving (A$)	5,209,981	10.987,796	173659
Total maximum cost saving (A$)	**22,327,882**	**47,089,271**	**744,234**

Adopting the findings in Bennett et al (2004) therefore gives an entirely different outcome — that is, the benefits appear to substantially outweigh the costs of introducing the recommendation (around $A4.5 million). It is also noted that, even if the link between inductions and caesarean sections is dropped, the benefits would still substantially outweigh the costs.

This dilemma is discussed further in Section 6.

24 This is equal to maximum additional scans from introducing the recommendation (as calculated in Section 4) less scans received by women who subsequently miscarry (that is, it is 85% of maximum additional scans).

<u>Substitute 12 and 16 week scan with scans before 12 weeks</u>

In this study, if all women who received ultrasound screening between 12 and 16 weeks under current practice brought forward their scan to the first 12 weeks as a result of the introduction of the recommendation, a cost saving of $A2,007,125.65 would be realised — that is, the cost of the maximum increase in first trimester ultrasounds from introducing the proposed recommendation would be reduced from around $A4.5 million to around $A2.5 million. This reduction makes little difference to the outcome of this cost-benefit analysis.

6 Conclusion

Ultimately, this study has not been able to conclusively determine whether the benefits of introducing a recommendation that pregnant women have an ultrasound scan in the first trimester would be likely to outweigh the costs.

Initially, the study was unable to estimate the actual increase in first trimester ultrasound scans from introducing the recommendation, and so proceeded by using an estimate of the maximum additional number of scans (which was used to estimate both the dollar-value of the costs and the benefits of introducing the recommendation). This estimate itself relied on a range of assumptions that were needed because of data limitations.

Most importantly, data limitations meant that, at critical points, the study had to rely on findings in the literature. However, the literature — particularly on the impact of first trimester ultrasound scans on the rate of inductions — yielded starkly different findings. Whitworth et al (2010) suggested that a first trimester ultrasound had no significant impact on inductions, while Bennett et al (2004) suggested that first trimester ultrasounds would significant reduce the risk of induction. As inductions are relatively expensive, choosing one study over the other changed the outcome of the cost-benefit analysis.

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Smoking interventions

This analysis assesses whether recommending certain smoking cessation interventions to pregnant women who smoke, in addition to a minimum intervention, would be cost-effective compared to this minimum intervention.

The minimum intervention is the intervention likely to be received by pregnant women even if the recommendation is not implemented. Consistent with current Royal Australian College of General Practitioners guidelines (Zwar et al 2007), it is assumed to be the application of the 5As smoking cessation framework by general practitioners and referral to Quitline.

1 Cost-effectiveness

In order to measure the cost-effectiveness of these interventions, this paper calculates incremental cost-effectiveness ratios for the relevant smoking cessation interventions. The incremental cost-effectiveness ratio is calculated by dividing the relative cost of an intervention by the relative benefit of the intervention. That is,

$$ICER = (Cost_{intervention} - Cost_{comparator}) / (Health\ benefit_{intervention} - Health\ benefits_{comparator}).$$

The incremental cost-effectiveness ratio is calculated as the cost per life-year saved (based on an increase in life-expectancy for the mother due to a life-time quit and a reduction in perinatal deaths) and the cost of a woman successfully quitting smoking during pregnancy.

How to Compare the Costs and Benefits: Evaluation of the Economic Evidence (NHMRC 2001) recommends that when the incremental cost-effectiveness ratio is expressed as cost per life-year gained:

› health care options that fall below the threshold of $A30,000 per life-year gained are considered good value and are recommended;

› health care options that exceed a threshold of $A100,000 per life-year are not recommended without strong justification; and

› health care options that fall between $A30,000 and $A100,000 per life-year are given further consideration.

Where several interventions are considered, as is the case with the current study, and more than one is cost-effective (within the thresholds outlined above), the preferred intervention is the intervention offering the highest benefit (NHMRC 2001).

Costs

Consistent with *How to Compare the Costs and Benefits: Evaluation of the Economic Evidence* (NHMRC 2001), which indicates that economic evaluations should focus on health sector budget impacts, this analysis estimates costs to the health system payer (for example, Medicare and the Pharmaceutical Benefits Scheme [PBS]).

Benefits

Both mother and baby benefit from a pregnant woman ceasing smoking.

› Long-term smokers are at greater risk of developing diseases such as heart disease, stroke, lung diseases and various forms of cancer. However, as the period of abstinence increases, the risk of developing certain diseases approaches that of a non-smoker (Quit Victoria 2011).

› Smoking during pregnancy has been associated with, among other things, a higher rate of perinatal death (Laws et al 2006).

This analysis uses findings in the literature to estimate (discounted) life-years gained for mother and baby from each relevant smoking intervention.

Potentially, future health expenditure savings from pregnant women ceasing smoking could be included as benefits. However, there is considerable debate about whether smoking interventions, and preventive measures more generally, reduce long-term health expenditure.[25] Accordingly, this analysis does not attempt to estimate future health expenditure savings from pregnant women quitting smoking.

Pregnant women quitting smoking may also generate economic benefits — for example, increased productivity from reduced sick leave. These costs fall outside the scope of this analysis.

2 Excluded interventions

Motivational interviewing

Due to a lack of evidence that a combination of motivational interviewing and the minimum intervention is more effective than the minimum intervention alone, motivational interviewing is not further discussed in this paper. For instance:

› Ruger et al (2008) found that motivational interviewing was more costly and no more effective than usual care in promoting smoking cessation among pregnant women;

› only one of the seven studies reviewed by Lumley et al (2009) involving motivational interviewing interventions for pregnant women favoured the intervention over the control; and

› while Parker et al (2007) found that motivational interviewing provided over the phone could be cost-effective, the methodology employed in their evaluation may have produced biased estimates. Moreover, telephone-based motivational interviewing is already provided by the Quitline within the minimum intervention.

Bupropion SR

Two bupropion SR medicines, Zyban and Prexaton, are currently available on the PBS. The Therapeutic

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25 See for example, OECD 2010a, p20-1; OECD 2010b, p72. In addition, many of the studies reviewed by Woolacott et al (2002) (a key study outlined in section 3 of this analysis) did not include future health expenditure costs.

Goods Administration has rated bupropion as a class B2 medicine, indicating that while the use of bupropion does not appear to be associated with an increase in the frequency of harmful effects on the human fetus, it has only been taken by a limited number of pregnant women and women of childbearing age. Accordingly, the safety of using bupropion SR during pregnancy has not been sufficiently established and is therefore not discussed further in this analysis.

<u>Varenicline</u>

While varenicline tartrate is available on the PBS, the safety of using this medicine during pregnancy has not been established and it has not been rated by Therapeutic Goods Administration. Moreover, the manufacturer of Champix® (the only varenicline medicine available on the PBS) recommends against its use in pregnancy (Champix® Consumer Medicine Information). It is therefore not discussed further in this analysis.

3   Literature summary

Cochrane, Embase and Medline were searched for English-language articles published since 2006. The search terms *pregnancy* with *smoking cessation* were combined with *cost effectiveness*, *utility* or *benefit*. Manual searches were undertaken on the United Kingdom National Health Service Evidence website (www.evidence.nhs.uk). These searches resulted in one review of the relevant literature (Ruger & Emmons 2008) and three additional economic evaluations of smoking cessation interventions aimed specifically at pregnant women (Dornelas et al 2006; Parker et al 2007; Ruger et al 2008). The search also uncovered a number of articles relating to the effectiveness and costs of smoking cessation interventions for pregnant women, as well as the population more generally.

<u>Economic evaluations</u>

Ruger and Emmons (2008) assessed eight economic evaluations of smoking cessation and relapse prevention programs for pregnant women. The interventions included self-help programs, educational material and counselling. The authors found that the results from all studies 'indicated favourable outcomes for intervention methods aimed at reducing smoking during pregnancy and, subsequently, improving maternal and infant health outcomes'. Four of the studies also compared the costs of smoking cessation interventions with the potential cost-savings from reduced admissions to neonatal intensive care units and preventing neonatal complications and long-term disability. The cost-savings were found to be larger than the intervention costs for all four studies.

Dornelas et al (2006) conducted a randomised trial comparing usual care with a counselling intervention (which employed cognitive behavioural techniques) with telephone follow-up, in additional to usual care, among low-income pregnant women. The authors concluded that the intervention was a cost-effective way of yielding a non-smoker by the end of pregnancy.

A number of other studies have demonstrated the cost-effectiveness of smoking cessation interventions for the general population. For example, Cornuz et al (2006) estimated the cost-effectiveness of various forms of NRT (including patch, gum, spray and inhaler) and bupropion SR in addition to brief counselling by a GP, compared with counselling alone. The authors found that pharmacotherapies would be cost-effective potentially doubling the changes of achieving cessation, with bupropion followed by the NRT patch being the most favourable treatments.

Clinical literature

The Cochrane Collaboration published a review of 72 trials relating to the effectiveness of smoking cessation interventions during pregnancy (Lumley et al 2009). This review found, among other things:

› a significant reduction in smoking in late pregnancy attributable to the combined effect of various interventions with an absolute difference of six in 100 women (95% CI 4–7) who stopped smoking during pregnancy, compared with the control;

› a significant increase in smoking cessation from CBT, rewards and NRT, compared with the control; and

› a significant reduction in low birth weight and preterm births for women in the intervention group.

On the other hand, no significant difference was found for very low birth weight, stillbirths, neonatal deaths, neonatal intensive care admissions or total perinatal mortality. In addition, Lumley et al (2009) reviewed only a limited number of studies involving motivational interviewing interventions for pregnant women and only one that favoured the intervention over the control.

An Australian study examined the effectiveness of nicotine patches and counselling, versus counselling alone, for pregnant women who smoke more than 15 cigarettes per day (Hotham et al 2006). The study found that 35% of the treatment group recorded a 50% reduction in their cotinine level from the start of the study, compared with 25% for the control group. In addition, 15% of the treatment group reported that they had achieved cessation (confirmed by cotinine analysis) compared with none of the control group. The authors noted that 'nicotine metabolism is accelerated in pregnancy and higher than usual doses of NRT may be necessary to achieve nicotine levels that ease withdrawal and thus optimise efficacy'.

Woolacott et al (2002) performed a review of 157 studies relating to the clinical effectiveness and cost-effectiveness of bupropion SR and NRT as smoking cessation interventions for the general population. This study found that 'irrespective of the methods used or the assumptions involved, the results of existing economic evaluations consistently suggest that smoking cessation interventions are relatively cost-effective in terms of the cost per life-year saved'. The potential negative side-effects of NRT on an unborn child were not taken into account, as the studies reviewed by Woolacott et al were not aimed at pregnant women specifically.

Adams et al (2002) found that smoking during pregnancy increases the risk of admission to a neonatal intensive care unit by almost 20 per cent and increases the length of stay, compared to admitted babies with non-smoking mothers. The authors found that in 1995, 2.2% of neonatal costs across 13 states in the United States were attributable to smoking during pregnancy.

4 Methods

This section:

› estimates the cost-per-treatment of each intervention (costs are in Australian dollars and no discounting was applied, given that they would all occur within a nine-month period);

› estimates the likely quit-rate from each intervention; and

› estimates the consequential benefits to mother and baby from quitting (in avoided perinatal deaths and discounted life-years gained).

Cost-per-intervention

Minimum intervention: Advice, education and referral to the Quitline

The following assumptions were made in estimating the cost for the minimum intervention:

› the minimum intervention is provided to pregnant women over two Level B consultations[26] with their GP during which a range of standard antenatal care matters are addressed, with the minimum intervention taking up one-third of the consultation; and

› patients are bulk-billed.

Under these assumptions, the per patient cost (to Medicare) of the minimum intervention is $A23.27.

Cognitive behavioural therapy

It is unclear how many CBT sessions would be required for a successful quit — it is likely that the number of sessions would differ by patient.

This analysis initially assumes that CBT involves one session with a clinical psychologist, lasting between 30 and 50 minutes,[27] similar to the intervention studied by Dornelas et al (2006). Under this assumption, the cost (to Medicare) per patient for CBT, in addition to the cost of the minimum intervention, is $A81.60, with an additional $A14.40 borne by the patient.

NRT

It was assumed that the treatment protocol used by Hotham et al (2005) would be prescribed. This protocol was continuous (15 mg per 16 hours) patch use for up to 12 weeks, with an option to step down to lower strength patches over time. It was also assumed that pregnant women receive the prescription during the GP appointments included in the minimum intervention. Under these assumptions, the cost to the PBS per intervention for NRT was $A63.06 with an additional $A102.60 borne by the patient.

Quit rates

Minimum intervention and spontaneous quitting

The available data suggest that 16.6% of pregnant women smoked during pregnancy in 2007. Further, approximately 19% of women between 20 and 39 were smokers in 2007. This analysis assumes that the resulting 12.9% quit rate represents those women who spontaneously quit (that is, who quit without any assistance prior to their first appointment with their GP) and those who quit as a result of the minimum intervention.

To estimate the cost-effectiveness of the minimum intervention, it is necessary to estimate the spontaneous quit rate. Spontaneous quit rates of between 1% and 8% have been used in existing economic evaluations of smoking cessation interventions for the population in general, with a rate of 1% being used in most of the United Kingdom studies that were reviewed by Woolacott et al (2002). It was assumed, however, that the spontaneous quit rate for women who are pregnant would be higher than that for the total population. Accordingly, it was assumed that the spontaneous quit rate for Australian women who are pregnant was 4%.

Cognitive behaviour therapy

Lumley et al (2009) found an additional 5% quit rate from CBT (95% CI 3–7%), compared with the control. The control differed between studies, but was typically the provision of advice and education at a standard antenatal appointment. The Lumley finding was adopted in this analysis, implicitly assuming that the control in Lumley was equivalent to the minimum intervention.

26 January 2011 Medicare Benefits Schedule (MBS), item number 23. The MBS fee for this item is $34.90.
27 January 2011 MBS, item number 80000.

NRT

Lumley et al (2009) found an additional 5% quit rate from pharmacotherapies (95% CI 2–8%), after examining five studies that included the use of NRT compared with the control.

Caveats

Many of the studies that informed this analysis relied on self-reported smoking status, which may mean that quit rates are overstated (Lumley et al 2009).

The quit rates assumed above are the average quit rates across pregnant women who smoke differing numbers of cigarettes per day. It is conceivable, however, that quit rates may vary by the level of nicotine addiction.

In addition, as smoking rates across the general population fall, the marginal effectiveness of interventions aimed at assisting smoking cessation may decline (Woolacott et al 2002). That said, the quit rates assumed above are, for the most part, calculated based on studies conducted in the United States where the proportion of pregnant women that smoke (around 12% [Dornelas et al 2006]) is below that of Australia (around 16% [Laws & Sullivan 2009; Laws et al 2010]). Accordingly, the quit rates used here may underestimate the effect of these interventions on pregnant women in Australia.

Given these caveats, the sensitivity of the analysis in this analysis to the assumed quit rates is tested in Section 5.

Relapse rate

It was assumed that pregnant women will only realise benefits from quitting smoking if they remain a non-smoker for the rest of their lives. Relapse rates vary in the literature between 10% and 50%. For example, Cornuz et al (2006) used a 35% lifetime probability of relapse after one year of abstinence and varied this between 10% and 50% in their sensitivity analysis (see also Woolacott et al 2002; Etter & Stapleton 2006; Gordon et al 2007).

The conservative assumption was adopted that 50% of women who quit during pregnancy would relapse after birth (varied to 30% and 100% in the sensitivity analysis).

Health benefits for mother and baby

Mother

The median age of women who gave birth in 2007 was 30.0 years (Laws & Sullivan 2009). Doll et al (a 50year British study on the health impacts of smoking on male doctors cited in Woolacott et al [2002]) suggests that the number of life-years saved from quitting smoking could be as high as 7.1 for those who quit by the age of 35. Woolacott et al (2002) stated that, for all quitters of all ages, an average of 1 to 3 undiscounted life-years saved per long-term quitter seemed a reasonable assumption, based on their literature review.

Given the uncertainty about this issue, it was conservatively assumed that a life-time quit by a 30-year old pregnant woman would result in her gaining 5 life-years and living to an age of 84.6 years, this being the life-expectancy of all 30 year old women in 2009, including smokers and non-smokers (ABS 2010). This figure was varied in the sensitivity analysis between 2 and 7 years.

Discounting the additional 5 life-years by 5% per annum[28] gives 0.3377 additional life-years per successful lifetime quit (noting that the additional life-years come at the end of the woman's life).

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28 As per NHMRC (2001, page 54) recommendations.

Baby

Smoking during pregnancy has been associated with an increased risk of low birth weight, preterm birth, admission to a neonatal intensive care unit or special care nursery, perinatal death[29] and sudden infant death syndrome (SIDS) (Laws et al 2006). Data are available on the size of many of these increased risks. However, other data limitations mean that, in many cases, it is not possible to estimate the size of the benefits arising from eliminating the additional risk by quitting smoking.[30] Consequently, this analysis is limited to estimating the benefits arising from reducing perinatal deaths.

Laws et al (2006) reported that babies of mothers who smoked during pregnancy were 46% more likely to die during the perinatal period.[31] However, Lumley et al (2009) found no statistically significant difference between the rate of perinatal death for smoking mothers who received a cessation intervention and the control group. Lumley et al (2009) note, however, that women who had a perinatal death were often excluded from the outcome measurements of many of the studies they reviewed. Accordingly, it was concluded that the finding in Lumley et al (2009) does not rule out an increased risk of perinatal death from smoking.

Adopting the Laws et al finding, one successful quit during pregnancy would result in a reduction of 0.0044 perinatal deaths[32] — that is, for every 1,000 women that quit smoking during pregnancy, approximately four perinatal deaths would be avoided.

For each avoided perinatal death, it was assumed the baby would live to the average of the current life expectancy at birth for males of 79.3 years and females of 83.9 years (ABS 2010). After discounting, one avoided perinatal death was equivalent to 19.7089 life-years. One successful quit during pregnancy would therefore result in 0.0859 life-years saved.[33]

5 Results

This section:

› calculates the cost per successful quit during pregnancy and the cost per life-year saved, using the relative costs and outcomes from Section 4;

› draws conclusions about whether the proposed additional interventions are cost-effective compared to the minimum intervention alone; and

› assesses whether the minimum intervention is cost-effective compared with doing nothing.

Cost-effectiveness of the minimum and additional smoking interventions

CBT and NRT

Table E3 provides the cost per quit during pregnancy and the cost per life-year saved due to CBT and NRT, compared with the minimum intervention alone. In terms of cost per life-year saved, both interventions are potentially cost-effective methods of reducing the number of pregnant women who smoke, with a cost per life-year saved of well under $A30,000.

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29 Fetal or neonatal deaths of at least 400 grams birth weight or at least 20 weeks gestation.

30 For example, we do not have access to reliable weights to apply to life-years that would represent the health benefits associated with reduced low birth weight or preterm births. Reliable data on the risk of SIDS deaths due to smoking during pregnancy are lacking and it would be difficult to separate out the impact of second-hand smoke, from either parent, after birth. In addition, we have not included potential cost-savings due to reduced admissions to special care nurseries or neonatal intensive care units given a lack of suitable data and the uncertainty around competing factors (eg the longer median length of stay for babies of non-smoking mothers).

31 Laws et al notes, however, that this result has not been controlled for potential confounding factors, such as the age, educational level, socioeconomic status or medical conditions of the mother.

32 Or between 0.0035 and 0.0054 using the upper and lower bounds of the 95% CI of the risk ratio.

33 That is, 0.0044*19.7089.

Table E3: **Baseline estimates of the cost-effectiveness of additional smoking cessation interventions compared with the minimum intervention**

Intervention in addition to the minimum	Additional cost per quit attempt (A$)	Cost per additional quit during pregnancy due to the intervention (A$)	Cost per additional life-year saved due to the intervention (A$)
NRT	$63.06	$1,261	$4,951
CBT	$81.60	$1,632	$6,407

As discussed, this analysis was not able to account for all the potential health benefits of quitting smoking. However, the benefits of quitting smoking are well known and quitting smoking, or even cutting down, during pregnancy will always result in at least some small health benefit to the mother or the baby. Accordingly, with a cost per successful quit during pregnancy of less than $A2,000,[34] offering NRT or CBT to pregnant women who smoke, in addition to the minimum intervention, seems like a reasonable proposition.

How to Compare the Costs and Benefits: Evaluation of the Economic Evidence (NHMRC 2001) notes that when more than one health care option is deemed cost-effective, the preferred option is the one that is the preferred clinical practice which is generally that which offers the highest benefit. In this case, all three interventions are assumed to deliver the same quit and relapse rates and, therefore, deliver the same health benefit.

Given this, it is noted that the addition of NRT to the minimum intervention is less expensive than CBT per life-year saved, compared with the minimum intervention alone. That said, the addition of NRT may not always be the preferred clinical practice.

Minimum intervention

Based on the assumptions in Section 4, the cost per life-year saved of the minimum intervention, compared with doing nothing, is $A1,031. Given that this figure falls well below the threshold of $A30,000 indicated in *How to Compare the Costs and Benefits: Evaluation of the Economic Evidence* (NHMRC 2001) (see Section 1), the minimum intervention is very cost-effective.

Sensitivity analysis

Three types of sensitivity analysis were conducted:

› a one-way sensitivity analysis, under which key parameters were varied one at a time keeping all else equal to the baseline case;

› determination of the 'best' and 'worst-case' outcomes using sets of optimistic and pessimistic parameters from Table E3; and

› a comparison of the minimum quit-rates required for additional interventions to be cost-effective with findings in the literature.

One way sensitivity analysis

Table E4 provides the results of the one-way sensitivity analysis.

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34 The cost per life-year saved is greater than the cost per quit during pregnancy because of the small probably of a perinatal death for both smokers and non-smokers and because we assumed that only women who remain abstinent after birth will accrue health benefits due to quitting smoking.

Table E4: One-way sensitivity analysis cost per life-year saved per intervention in addition to the minimum, compared with the minimum intervention alone

		NRT (A$)		CBT (A$)	
Baseline case		**$4,951**		**$6,407**	
Quit rates during pregnancy	Lower bound	(0.02)	$12,378	(0.03)	$10,678
	Upper bound	(0.08)	$3,095	(0.07)	$4,576
Life-time relapse rate	100%	$14,686		$19,004	
	30%	$3,914		$5,064	
Perinatal deaths avoided per quit	0[1]	$7,470		$9,666	
	0.0035	$5,319		$6,883	
	0.0054	$4,583		$5,931	
Undiscounted life-years saved for the mother per lifetime quit	7	$3,761		$4,867	
	2	$8,506		$11,007	
Number of CBT sessions	4	na		$25,628	
	10	na		$64,070	
Direct patient out-of-pocket costs[2] are included in health system costs		$13,007		$7,538	
Discount rate applied to health benefits	1.50%	$944		$1,221	
	3.50%	$2,511		$3,250	

1   This extreme case relates particularly to pharmacotherapies – that is, it effectively assumes that the potential negative side-effects of pharmacotherapies on babies cancel out all the health benefits of smoking cessation.

2   That is, PBS co-payments and health professional fees above the relevant Medicare rebate.

Overall, this analysis indicates that NRT and CBT remain cost-effective even when key assumptions are significantly varied.

› The cost per life-year saved does not exceed $30,000 for NRT in any of the scenarios examined.

› The incremental cost-effectiveness ratios exceed $30,000 for CBT only when the number of sessions involved is greater than four. That said, even if 10 CBT sessions were required to produce a quit during pregnancy, the cost per life-year saved remains below $A100,000.

Best and worst case outcomes

Best and worst-case outcomes are shown in Table E5.

Table E5:   Best and worst case scenarios of cost per life-year saved per intervention in addition to the minimum, compared with the minimum intervention alone

	NRT	CBT
Best case scenario[1]	$A1,730	$A2,559
Worst case scenario[2]	$A46,191	$A39,848

1 The best case scenario assumed here is the upper bound for the 12-month quit rate, a relapse rate of 30 per cent, 0.0054 perinatal deaths avoided per successful quit and 7 undiscounted life-years saved for the mother per lifetime quit, using a discount rate of 5 per cent.

2 The worst case scenario assumed here is the lower bound for the 12-month quit rate, all women start smokingagain after giving birth and 0.0035 perinatal deaths avoided per successful quit, using a discount rate of 5 per cent.

Even in the worst-case outcome, the use of CBT or NRT with the minimum intervention, compared with the minimum intervention alone, may still be cost-effective. Importantly though, the worst-case scenario assumes that only a small percentage of pregnant women (3% for CBT and 2% for pharmacotherapies) quit as a result of the additional intervention, and that they all relapse — that is, it assumes the additional interventions are highly ineffective, a scenario that is inconsistent with clinical findings.

Minimum quit rate needed to make interventions cost-effective

The quit rate during pregnancy that would be required to result in an incremental costeffectiveness ratio of $A30,000 was calculated, assuming the parameters used in the main analysis above. These quit rates were compared with the findings in Lumley et al (2009). The results are set out in Table E6.

Table E6:   Minimum additional quitters per quit attempt required for each additional intervention to be considered cost-effective (compared with the minimum intervention alone)

Intervention	Additional cost to health system per quit attempt	Number of additional quitters required per 1000 quit attempts	Number of additional quitters per 1000 quit attempts due to the intervention found by Lumley et al (2009)
NRT	$A63.06	12	50 (CI 20–80)
CBT	$A81.60	16	50 (CI 30–70)

The minimum number of additional quitters required such that the interventions are considered to be cost-effective compare favourably with the findings of Lumley et al (2009) for CBT and NRT.

6 Discussion

CBT and NRT are likely to be cost-effective interventions for smoking cessation during pregnancy. Both were assumed to result in the same quit rate above that achieved by the minimum intervention alone. Accordingly, the preferred option is the least costly intervention, which for most scenarios considered is NRT. That said, cost-effectiveness should not be the only consideration in choosing the preferred intervention as NRT may not be a clinically appropriate option for women who, for example, only smoke a few cigarettes per day. Furthermore, if the direct costs to the patient are taken into account, CBT appears to be the most cost-effective intervention.

7 Limitations

The sensitivity of this study to the key assumptions upon which it relies was tested in Section 5. Specific limitations of the study have also been noted — for example, data limitations meant that a range of potential benefits to the baby from the mother quitting smoking were not able to be considered. More general limitations of the study include:

›   The study focuses on cost per life-year saved and does not take the quality of additional life-years into account.

›   The analysis does not take into account benefits to the pregnant woman and fetus when the pregnant woman reduces her smoking rather than quitting altogether. Hotham et al (2006) found that 35% of their intervention group achieved at least a 50% reduction in cotinine, but only 15% of the intervention group quit smoking.

›   The data do not take into account health benefits to the baby (and others) from a reduction in exposure to passive smoking as a result of the mother remaining abstinent after birth as a result of the smoking cessation intervention she received during pregnancy.

As a result of potentially significant benefits being excluded from this study, the incremental cost-effectiveness ratios may be over-estimates.

8 Conclusion

It is likely that offering CBT or NRT to pregnant women who smoke in addition to the minimum intervention would be cost-effective, compared with the minimum intervention alone.

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F.   Topics for review in Module II of the Guidelines

The initial consultation (2008) with the Expert Advisory Committee to develop the clinical questions for the National Antenatal Guidelines highlighted a number of topics to be addressed. A process of prioritisation decided which topics would be addressed in this first Module. The topics below are being considered for Module II.

Clinical assessments

Timing and content of antenatal visits

Abdominal palpation

Routine auscultation of the fetal heart

Fetal movement assessment

18–20 week ultrasound assessment

Pelvic girdle pain

Carpal tunnel syndrome

Heartburn

Haemorrhoids

Varicose veins

Screening

Anaemia including iron status

Haemoglobinopathies

Gestational diabetes

Cytomegalovirus

Toxoplasmosis

Trichomonas

Gonorrhoea

Group B streptococcus

Thyroid function

Cervical smear

Risk of pre-eclampsia

Risk of pre-term birth

Rheumatic heart disease

Lifestyle considerations

Breastfeeding and infant feeding decisions

Nutrition

Sexual activity

Immunisation

Travel including wearing of seat belts

Illicit drug use in pregnancy

Physical activity

Other aspects of antenatal care

Antenatal Education

External cephalic version

Post dates pregnancy

Acronyms and abbreviations

25-OHD	25-hydroxyvitamin D
ABS	Australian Bureau of Statistics
ACOG	American College of Obstetricians and Gynecologists
ADA	American Dental Association
AFP	α-fetoprotein
AGREE	Appraisal of Guidelines Research and Evaluation
AHMAC	Australian Health Ministers' Advisory Council
AHMC	Australian Health Ministers' Conference
AIDS	acquired immunodeficiency syndrome
AIHW	Australian Institute of Health and Welfare
AMA	Australian Medical Association
ANMC	Australian Nursing and Midwifery Council
ANZBMS	Australian and New Zealand Bone and Mineral Society
AOM	Association of Ontario Midwives
APHDPC	Australian Population Health Development Principal Committee
APTT	activated partial thromboplastin time
ARBD	alcohol-related birth defects
ARND	alcohol-related neurodevelopmental disorders
ATAGI	Australian Technical Advisory Group on Immunisation
ATAPS	Access to Allied Psychological Services
AusDiab	Australian Diabetes, Obesity and Lifestyle Study
AWHN	Australian Women's Health Network
β-hCG	beta-human chorionic gonadotrophin
BASHH	British Association for Sexual Health and HIV
BMA	British Medical Association
BMI	body mass index
BPD	biparietal diameter
CBR	consensus-based recommendation
CBT	cognitive behaviour therapy
CDAF	California Dental Association Foundation
CDC	Centers for Disease Control and Prevention (United States)
CDSMC	Community and Disability Services Ministers' Conference
CER	Centre for Epidemiology and Research
CHF	Consumers' Health Forum
CHWS	Child Health and Wellbeing Subcommittee

CI	confidence interval
CMACE	Centre for Maternal and Child Enquiries
COAG	Council of Australian Governments
CPS	Canadian Paediatric Society
CRL	crown–rump length
DNA	deoxyribonucleic acid
DoHA	Department of Health and Ageing
DTRS	Department of Transport and Regional Services
EAC	Expert Advisory Committee
EIA	enzyme immunoassay
EPDS	Edinburgh Postnatal Depression Scale
FAS	fetal alcohol syndrome
FASD	fetal alcohol spectrum disorders
FGM	female genital mutilation
FSANZ	Food Standards Australia and New Zealand
FTA-abs	fluorescent treponemal antibody-absorbed test
GAR	Guidelines Assessment Register
GP	general practitioner
HAPO	Hyperglycaemia and Adverse Pregnancy Outcome Study
HBeAg	hepatitis B envelope antigen
HBsAg	hepatitis B surface antigen
HC	head circumference
HGSA	Human Genetic Society of Australasia
HIV	human immunodeficiency virus
HT	head and trunk volume
IOM	Institute of Medicine (United States)
IUSTI	International Union against Sexually Transmitted Infections
LGR	ligase chain reaction
LMP	last menstrual period
MBS	Medicare Benefits Schedule
mmHg	millimetres of mercury
MSAC	Medical Services Advisory Committee
MSHR	Menzies School of Health Research
MSIJC	Maternity Services Inter-Jurisdictional Committee
NACCHO	National Aboriginal Community Controlled Health Organisation
NACOH	National Advisory Committee on Oral Health
NAHSWP	National Aboriginal Health Strategy Working Party

NATA	National Association of Testing Authorities
NCHECR	National Centre for HIV Epidemiology and Clinical Research
NHMRC	National Health and Medical Research Council
NICE	National Institute for Health and Clinical Excellence
NNDSS	National Notifiable Diseases Surveillance System
NRT	nicotine replacement therapy
NT-UEMP	Nuchal Translucency – Ultrasound, Education and Monitoring Project
NZ MOH	New Zealand Ministry of Health
OR	odds ratio
PAPP-A	pregnancy-associated placental protein-A
PBS	Pharmaceutical Benefits Scheme
PEG	polyethylene glycol
PHLS	Public Health Laboratory Service (United Kingdom)
PP	practice point
PT	prothrombin time
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 (United Kingdom)
RCT	randomised controlled trial
RNA	ribonucleic acid
RPR	rapid plasma reagin
RR	relative risk
SIDS	sudden infant death syndrome
SIGN	Scottish Intercollegiate Guidelines Network
SOGC	Society of Obstetricians and Gynaecologists of Canada
TPHA	Treponema pallidum haemagglutination assay
US DHHS	United States Department of Health and Human Services
USPFTS	United States Preventive Services Task Force
VCCCVM	Victorian Community Council on Crime and Violence Management
VDRL	Venereal Diseases Research Laboratory
WHA	Women's Hospitals Australasia
WHO	World Health Organization
WSDH	Washington State Department of Health

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.

Acupressure — Acupressure is a noninvasive variation of acupuncture that involves application of constant pressure to specific points or areas.

Acustimulation — Mild electrical stimulation to specific points or areas.

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

Antiretroviral treatment — the use of medicines to reduce growth of retroviruses, primarily HIV.

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

Citation bias — The citation or non-citation of research. Citing of trials in publications is not objective so retrieving studies using this method alone may result in biased results. Unsupported studies tend to be cited often which may also bias results.

Cleft lip and/or palate — variations of a congenital abnormality caused by non-fusion of embryonic facial lobes.

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.

Culturally and linguistically diverse background — Applies to women whose first language is one other than English, or whose family background involves migration from a non-English speaking country. It can refer to new arrivals to Australia as immigrants or refugees from non-English speaking countries as well as the children of migrant parents.

Ectopic pregnancy — a pregnancy in which implantation of the fertilised egg takes place outside the uterus, usually in a fallopian tube. Ectopic pregnancies usually result in miscarriage but can cause rupture of the fallopian tube and severe internal bleeding.

Edinburgh Postnatal Depression Scale (EPDS) — The EPDS was developed and validated as a screening tool for depression in the postnatal period. It has subsequently been validated for use in pregnant women and is therefore appropriate for use throughout the perinatal period.

Educational and motivational interviewing strategies — Education strategies given to all members of the intervention group. Counselling delivered by a number of means: through primary carer, medical professional, professional counsellor, targeted printed material etc.

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

First contact — The visit in which a woman attends to confirm pregnancy, seek antenatal care or make arrangements for the birth.

Herbal medicines — Preparations such as tablets, tinctures and infusions that are made from plant parts. These preparations are usually formulated based on traditional uses of Western or Chinese herbs.

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

Interventions based on stages of change (smoking cessation) — Similar to cognitive behavioural and education strategies, except that these interventions were grouped separately as they involve assessment of "readiness" to change and exposure to the intervention may be more selective.

Low birth weight — Birth weight of less than 2500g.

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

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.

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 fetus' neck – a marker of chromosomal abnormality, such as trisomy 21 (Down syndrome).

P6 (or Neiguan) point — an acupuncture point located on the anterior aspect of the forearm near the wrist.

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.

Pharmacotherapies (smoking cessation) — Studies cited in Lumley et al 2009 used nicotine replacement therapy, as patches, gum or lozenge. Other studies considered bupropion or other pharmacological agents.

Placenta praevia — An obstetric complication in which the placenta is attached to the uterine wall close to or covering the cervix.

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

Preterm birth — Birth at less that 37 weeks' gestation.

Psychosocial support (smoking cessation) — Includes discussion groups, provision of support materials (unless CBT-based), provision of telephone support etc.

Pyelonephritis — an ascending urinary tract infection that has reached the pyelum (pelvis) of the kidney.

Rewards and incentives (smoking cessation) — Intervention group provided rewards or incentives (payment; one study provided a lottery for participants), usually based on smoking status evaluated by biochemical markers.

Stillbirth — The birth of a baby that has died in the uterus after 20 weeks of pregnancy or reaching a weight of more than 400g if gestational age is unknown.

Sudden infant death syndrome — a syndrome marked by the sudden death of an infant that is unexpected by history and remains unexplained after a thorough forensic autopsy and a detailed death scene investigation.

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.

Woman-focused communication skills — These involve techniques and attitudes that indicate respect for the woman, a willingness to listen to her perspectives, values and current life circumstances around antenatal concerns, and not direct the woman into any particular course of action. Woman-centred communication skills can include giving appropriate information, but always includes communication that views the woman as a capable and responsible person, and creates a respectful, supportive and effective alliance between the woman and the health professional.

Methodological terms

ADAPTE framework — A systematic approach to aid in the adaptation of guidelines produced in one setting to be used in a different cultural and/or organisational context.

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.

Citation bias — The citation or non-citation of research. Citing of trials in publications is not objective so retrieving studies using this method alone may result in biased results. Unsupported studies tend to be cited often which may also bias results.

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

Language bias — The publication of research findings in a particular language. Significant results are more likely to be published in English so a search limited to English-language journals may result in an overestimation of effect.

Multiple publication bias — The multiple or singular publication of research findings. Studies with significant results tend to be published multiple times which increases the chance of duplication of the same data and may bias the results of a review.

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.

Outcome reporting bias — The selective reporting of some outcomes but not others. Outcomes with favourable findings may be reported more. For example, adverse events have been found to be reported more often in unpublished studies. This may result in more favourable results for published studies.

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 EAC or Working Group for Aboriginal and Torres Strait Islander Women's Antenatal Care determined there was a need for advice. These points are based on best practice clinical judgement.

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 and graded based on consideration of the evidence base, consistency of the evidence, clinical impact of the proposed recommendation and generalisability and applicability of the evidence.

Relative risk — The ratio of the risk (rate) of an outcome in an exposed group (eg 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.

Time-lag bias — The rapid or delayed publication of research findings. Studies with positive results tend to be published sooner than studies with negative findings and hence results may be overestimated until the negative studies 'catch up'.