The Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Excellence in Women's Health

Management of Hepatitis B in pregnancy

This statement has been developed and reviewed by the Women's Health Committee and approved by the RANZCOG Board and Council.

Principal Authors of this statement
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A list of Women's Health Committee Members can be found in Appendix A.

Disclaimer This information is intended to provide general advice to practitioners. This information should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any patient. This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The document has been prepared having regard to general circumstances.

First endorsed by RANZCOG: November 1990
Current: November 2019
Review due: November 2022

Objectives: To provide advice on the management of Hepatitis B in pregnancy and on the prevention of Hepatitis B.

Target audience: All health practitioners providing maternity care.

Outcomes: Reduced transmission of Hepatitis B from infected mothers to infants. Reduced incidence of Hepatitis B in the population through immunisation of infants.

Evidence: A literature search was undertaken to identify systematic reviews of randomised controlled trials relating to the management of Hepatitis B in pregnancy. Additional searches were undertaken for Australian, New Zealand and other international guidelines on this topic.

Values: The evidence was reviewed by the Women's Health Committee (RANZCOG), and applied to local factors relating to Australia and New Zealand.

Background: This statement was first developed by RANZCOG in November 1990 and was revised in Noevmber 2019.

Funding: This statement was developed by RANZCOG and there are no relevant financial disclosures.

1. Plain language summary

Pregnancy offers an opportunity for women to be offered screening for the highly-infectious condition of hepatitis B. To reduce the risk of transmitting the virus from mother to baby, women found to carry hepatitis B during pregnancy should be cared for by a multidisciplinary team with special expertise in infectious disease. Antiviral medication should be offered to women with a high level of virus in the blood to minimise the risk of transmission. Babies of women known to carry hepatitis B should be offered both passive and active immunisation at birth, and appropriate follow-up arranged for both mother and baby. Active immunisation should be offered for all newborns.

2. Summary of recommendations

Recommendation 1	Grade and reference
Screening and vaccination: • Universal screening for Hepatitis B is recommended for all pregnant women, regardless of previous testing or vaccination. (Grade A) • All HBsAg-positive women should have household contacts, other children and sexual partners screened. Those that are non-immune or not already infected should be vaccinated (Grade A). • All health care workers should be vaccinated and take standard precautions against exposure to blood and bodily fluids should be used (Grade A).	Evidence-based recommendation References 4,7,9

Recommendation 2	Grade and reference
Antenatal management: • HBsAg-positive women, particularly those with a high viral load, should be counselled about the potential risk of transmission with invasive procedures. NIPT may be an option for some women. In those requiring invasive procedures, amniocentesis is probably safer than CVS, and transplacental amniocentesis is best avoided, if possible (Grade B). • All HBsAg-positive women should be tested for HBeAg-anti-HBe, and HBV DNA level, to identify pregnancies at increased risk of post-exposure prophylaxis failure. Women should also have an assessment of liver function (Grade A). Women with a high viral load in the third trimester (>200,000IU/ml, equivalent to 6 log copies/ml) should be offered antiviral therapy during late pregnancy to reduce viral load prior to delivery, and the risk of mother-to child transmission of Hepatitis B (Grade B) • In women who are candidates for antiviral therapy, tenofovir is recommended as a suitable first-line agent. There is good evidence supporting the use of tenofovir to reduce perinatal transmission of Hepatitis B in pregnant women with a high viral load. (Grade B). If not already associated with a Chronic Hepatitis Clinical Service, pregnancy is an appropriate opportunity to refer to such a service, both to assist with immediate decision making regarding antiviral therapy in pregnancy if necessary, and to facilitate long-term follow-up of the patient +/- other affected family members.	Evidence-based recommendation References 9,10,13 1
Recommendation 3	**Grade and reference**
Intrapartum Care: Invasive procedures such as fetal scalp electrodes and fetal scalp blood sampling in labour should be avoided (Grade B). Hepatitis B infection should not alter mode of delivery and caesarean section should be reserved for usual obstetric indications (Grade B).	Evidence-based recommendation
Recommendation 4	**Grade and reference**
Postpartum: *In Australia:* • As part of the Australian childhood vaccination program, it is recommended that all newborn infants receive a monovalent paediatric formulation of hepatitis B vaccine at birth (within 24 hours). Following this birth dose, 3 doses of a hepatitis-B-containing combination vaccine are recommended for all children, at 2, 4 and 6 months of age. • If an infant has not received a birth dose within the 1st 7 days of life, a primary 3-dose course of a hepatitis B-containing combination vaccine should be given, at 2, 4 and 6 months of age; catch-up of the birth dose is not necessary. • In addition to routine vaccination, infants born to HBsAg-positive mothers should receive passive immunisation with HBIG	Consensus-based recommendation References 7

at birth (preferably within 12 hours and certainly within 48 hours). • Anti-HBs antibody and HBsAg levels should be measured in infants born to mothers with chronic hepatitis B infection 3 to 12 months after completing the primary vaccine course. Referral to a paediatrician with expertise in viral hepatitis is recommended if HBsAg positive.	
In New Zealand: • All infants are offered routine HBV vaccination at birth, 6 weeks, 3 months and 5 months as per the Immunisation schedule. • As in Australia, infants born to HBsAg-positive mothers should also receive passive immunisation with HBIG at birth (preferably within 12 hours). • It is recommended for infants for HBsAg-positive mothers to have serology testing at 9 months of age, and referral to a specialist if HbsAg positive.	8,19 20
<u>*Breastfeeding*</u> Provided appropriate immunoprophylaxis has been given at birth, breastfeeding by HBsAg-positive women has not been shown to increase rates of perinatal transmission. Breastfeeding is not contraindicated in women with HBV receiving tenofovir (Grade B)	2
<u>*Postpartum and long term follow up*</u> HBsAg-positive women receiving antiviral therapy in pregnancy should be monitored closely for several months post-partum for hepatitis flares. Lifelong follow up should be offered to HBsAg-positive women for monitoring of complications such as liver disease and hepatocellular carcinoma (Grade A).	

3. Introduction

In Australia, the estimated prevalence of chronic hepatitis B infection is 0.97 per cent with approximately 209,000 people living with hepatitis B infection in Australia in 2011.[1] The majority have come from areas of high prevalence, mainly from the Asia-Pacific region, but also from the Mediterranean, Eastern Europe, Africa and Latin America. Other high-risk groups include Indigenous Australians, Maori, Pacific Islanders, those travelling to endemic areas, people in correctional facilities, sex workers and injecting drug users. [2]

4. Definition

Chronic hepatitis B infection is defined as persistent detection of Hepatitis B surface antigen (HBsAg) for more than 6 months after initial exposure to the virus. The risk of chronic infection is higher with younger age of onset. 90 per cent of infants who become infected will develop chronic or lifelong infection, compared to a 5 per cent chronic infection rate if the virus is acquired in adulthood.[3] Perinatal transmission is thought to be the main cause of transmission in hepatitis B-endemic countries. This is a leading global health priority since chronic hepatitis B infection can lead to severe morbidity and mortality from cirrhosis of the liver, fibrosis and subsequent hepatocellular carcinoma in up to 40 per cent of affected people.[4] The 69th World Health Assembly (2016) passed the Global Health Sector Strategy on Viral Hepatitis,

which aims to eliminate HBV and HCV by 2030, through a combination of prevention targets (birth dose and 3-dose infant immunisation) and improved diagnosis and management of infected people.[4]

5. Evidence summary and basis for recommendations

5.1 How can Hepatitis B be prevented?

The hepatitis B virus is transmitted vertically as a perinatal event, and horizontally through blood products and sexual contact. It is preventable through vaccination.

Studies in Australia and the United States have shown that 30-65 per cent of chronically infected adults are unaware that they are infected until screened.[5] It is therefore critical that pregnant women are routinely screened so that effective treatment can be offered to the woman, and measures can be taken to prevent transmission to the infant.[6, 7]

Hepatitis B vaccination is recommended for infants and children in a **4-dose** schedule at birth, and 2, 4 and 6 months of age in Australia and at birth, 6 weeks and 5 months of age in New Zealand. [8] Hepatitis B vaccination is recommended for all other risk groups, usually in a 3-dose schedule (0, 1 and 6 months).[9]

If HBV vaccination is indicated in pregnancy, it is safe and effective.[10]

Household contacts, other children and sexual partners of HBsAg-positive women should be screened for HBsAg and HBsAb, and should be vaccinated if not immune or if not already infected.

All health care workers should be vaccinated, and standard precautions against exposure to blood or body fluids should be used.[11]

Recommendation 1	Grade and reference
Screening and vaccination: • Universal screening for Hepatitis B is recommended for all pregnant women, regardless of previous testing or vaccination. (Grade A). • All HBsAg-positive women should have household contacts, other children and sexual partners screened. Those that are non-immune or not already infected should be vaccinated (Grade A). • All health care workers should be vaccinated and take standard precautions against exposure to blood and bodily fluids should be used (Grade A).	Evidence-based recommendation References 5 9, 10

5.2 What are the antenatal management considerations?

5.2.1 What are the risks associated with invasive prenatal procedure?

The risk of HBV transmission to the fetus through invasive procedures such as amniocentesis and chorionic villous sampling is thought to be low, however it should be explained to women that there has been limited research on this.[10]

Women should be counselled carefully about the indications for invasive testing, and the possible risks involved.

The risk of fetal infection is likely to be higher among women with a high viral load. One study reported that the rate of perinatal transmission of Hepatitis B was 6.4% among women with chronic Hepatitis B who underwent amniocentesis, compared to 2.5% among those who did not. Importantly, when stratified by viral load, the risk of transmission was 50% in those with a viral load ≥ 7 log 10 copies/ mL, compared to 4.5% among those with the same viral load who did not undergo amniocentesis (OR 21.3).[12] The risk of fetal infection is likely to be higher with chorionic villus sampling than amniocentesis.

The risk of fetal infection is likely to be higher with blood contamination of amniotic fluid, which has been shown to be significantly higher with transplacental amniocentesis.[11]

Non-invasive prenatal testing may be useful for women found to be high probability on aneuploidy screen who have a blood borne virus at risk of perinatal transmission with invasive procedures.[6, 7]

5.2.2 What are the predictors of perinatal transmission?

The risk of perinatal transmission is highest during labour and birth, due to exposure to cervical secretions and maternal blood. In-utero transmission, while uncommon, can occur, for example, in situations such as threatened preterm labour, placental abruption, and invasive procedures (see above).[13]

The most important predictor of perinatal transmission is maternal HBV viral load.[14] In the absence of post exposure prophylaxis, HBeAg positive mothers have a 70-90 per cent risk of transmitting HBV compared with a 10-40 per cent risk in HBeAg-negative mothers.[13] HBV viral loads greater than 10^9 IU/ml have been correlated with an increased risk of intra-uterine transmission, and this is thought to play a large role in the

failure of immunoprophylaxis, with failure rates up to 10 per cent.[10, 13, 15, 16] It is therefore recommended that maternal HBeAg and HBV DNA levels are assessed in women known to be HBsAg positive in order to identify pregnancies at increased risk of post-exposure prophylaxis failure, and consider the potential role of antenatal treatment to reduce viral load prior to delivery (see below).[16] Liver function tests should also be performed in women who are HBsAg positive as an assessment of liver damage.

5.2.3 Should antiviral therapy be used to reduce the risk of perinatal hepatitis B transmission?

Pregnancies of women with high viral load are at greatest risk of post exposure prophylaxis failure, with studies confirming a linear association between vertical transmission and viral load. A recently published meta-analysis has confirmed that antenatal tenofovir significantly reduces maternal HBV DNA (WMD -2.33 $\log^{14}$ IU/mL, 95% CI: 1.01, 3.64; P < 0.0001). This study also demonstrated an attendant reduction in congenital Hepatitis B infection: tenofovir was associated with a significant lower rate of infant HBsAg positivity at the time of birth (RR = 0.28, 95% CI: 0.17, 0.48; P < 0.001), 6 months of age (RR =0.16, 95% CI: 0.05, 0.52; P = 0.002), and 12 months of age (RR = 0.22, 95% CI: 0.08, 0.62; P = 0.004). The pooled result showed that the infants in the tenofovir group had a significant lower rate of HBV DNA positivity compared with the control group (RR = 0.15, 95% CI: 0.07, 0.31; P < 0.001) and that the rate of immunoprophylaxis failure in infants was lower among mothers who received tenofovir (RR = 0.31, 95% CI: 0.13, 0.73; P = 0.008).[17] Tenofovir is effective, has extensive pregnancy safety data [15] (FDA Category B) and has a high barrier to antiviral resistance, which is important given that some women will require treatment for their chronic Hepatitis B in later life.[18]

Threshold for initiation of treatment

All HBsAg-positive women should be tested for HBeAg, anti-HBe, and HBV DNA level to identify those whose infants are at increased risk of post-exposure prophylaxis failure.

Women should also have an assessment of liver function. Women with a high viral load in the third trimester (>200,000IU/ml, which is equivalent to 6 log10 copies/ml) should be offered antiviral therapy during late pregnancy to reduce viral load prior to delivery, and the risk of mother-to child transmission of Hepatitis B.

Gestation at Initiation of treatment and duration of treatment

It is recommended that antiviral therapy be commenced in the third trimester, generally between 30-32 weeks. This may be modified by the initial viral load, and anticipated time to delivery. The median decline in Hep B DNA is -3 log 10, -3.8 log 10, -4.4 log 10 and -4.9 log 10 following 4, 8, 12 and 16 weeks of therapy, respectively. Tenofovir is generally continued for the first 6 weeks postpartum. The use of antivirals during pregnancy is associated with an increased risk of postpartum flare when treatment is withdrawn, and immunocompetence returns in the puerperium. HBsAg-positive women should be monitored closely for several months post-partum for hepatitis flares, which are usually self-limiting. Lifelong follow up should be offered to HBsAg-positive women for monitoring of complications such as liver disease and hepatocellular carcinoma.

Recommendation 2	Grade and reference
Antenatal management: • HBsAg-positive women, particularly those with a high viral load, should be counselled about the potential risk of transmission with invasive procedures. NIPT may be an option for some women. In those requiring invasive procedures, amniocentesis is probably safer than CVS, and transplacental amniocentesis is best avoided, if possible (Grade B). • All HBsAg-positive women should be tested for HBeAg anti-HBe, and HBV DNA level, to identify pregnancies at increased risk of post-exposure prophylaxis failure. Women should also have an assessment of liver function (Grade A). Women with a high viral load in the third trimester (>200,000IU/ml, equivalent to 6 log copies/ml) should be offered antiviral therapy during late pregnancy to reduce viral load prior to delivery, and the risk of mother-to child transmission of Hepatitis B (Grade B) • In women who are candidates for antiviral therapy, tenofovir is recommended as a suitable first-line agent. There is good evidence supporting the use of tenofovir to reduce perinatal transmission of Hepatitis B in pregnant women with a high viral load. (Grade B). If not already associated with a Chronic Hepatitis Clinical Service, pregnancy is an appropriate opportunity to refer to such a service, both to assist with immediate decision making regarding antiviral therapy in pregnancy if necessary, and to facilitate long-term follow-up of the patient +/- other affected family members.	Evidence- based recommendation References 10, 11, 14 1

5.3 What are the intrapartum management considerations?

5.3.1 Does the mode of delivery affect the perinatal transmission rate?

While it has been proposed that elective caesarean section may be a means to reduce mother to child transmission, mode of delivery has not been shown to affect perinatal transmission rates in most studies. [5, 18]

5.3.2 Should invasive procedures be undertaken?

Invasive procedures such as fetal scalp electrodes and fetal scalp blood sampling should be avoided as they may increase the risk of neonatal infection.

Recommendation 3	Grade and reference
Invasive procedures such as fetal scalp electrodes and fetal scalp blood sampling in labour should be avoided (Grade B). Hepatitis B infection should not alter mode of delivery and caesarean section should be reserved for usual obstetric indications (Grade B).	Consensus-based recommendation

5.4. What are the postpartum management considerations?

5.4.1 What are the recommended infant immunisations for the prevention of Hepatitis B in Australia and New Zealand?

Active and passive immunisation for the infant

Active immunisation requires repeated vaccinations over months in order to stimulate an effective antibody response. Immunoglobulin, on the other hand, is immediately effective and seems protective for several months, after which the effectiveness wanes.[19]

It is clear that immunoprophylaxis, when provided promptly to newborns of mothers with chronic Hepatitis B significantly reduces the incidence of perinatal HBV transmission. A recent meta-analysis of clinical trials showed that the relative risk of neonatal HBV infection in those who received HBV vaccine (plasma-derived or recombinant) was 0.28 (95 per cent confidence interval 0.2–0.4) compared with those who received placebo or no intervention. When HBIG (Hepatitis B Immunoglobulin) was given in addition to the vaccine, the occurrence of Hepatitis B was further reduced to 0.08 (95 per cent confidence interval 0.03 to 0.17). [19]

Infants born after 32 weeks or greater than 1000gms

It is recommended that in both Australia and New Zealand all newborn infants are immunized against hepatitis B. Both counties Immunisation handbooks recommend all newborn infants receive a birth dose of monovalent paediatric formulation hepatitis B vaccine. Following this birth dose, 3 doses of a hepatitis-B-containing combination vaccine (usually provided as DTPa-hepB-IPV-Hib).

The timing of the post-birth immunisations is slightly different in New Zealand and Australia.

In Australia: 2, 4 and 6 months of age.[9]

In New Zealand: 6 weeks, 3 months and 5 months [8]

If an infant has not received a birth dose within the 1st 7 days of life, a primary 3-dose course of a hepatitis B-containing combination vaccine should be given the usual schedule; catch-up of the birth dose is not necessary. Irrespective of whether a birth dose was given, the infant should not be given the final dose before 24 weeks of age. [9]

Preterm and low-birth weight infants

Preterm and low-birth weight infants do not respond as well to hepatitis B-containing vaccines as full-term infants.[9, 20, 217,23,24] Thus, for low-birth-weight infants (<2000 g) and/or infants born at <32 weeks gestation (irrespective of weight), it is recommended to give the vaccine in the usual 4-dose schedule as for full-term infants.

In Australia it is recommended that this is followed by either:

- measuring the anti-HBs antibody level at 7 months of age, and if the antibody titre is <10 mIU/mL, giving a booster at 12 months of age (due to a better immunogenic response at this age compared with a younger age); or

- giving a booster of a hepatitis B-containing vaccine at 12 months of age (without measuring the antibody titre).[9]

HBsAg-positive mothers

Infants born to HBsAg-positive mothers should be given HBIG and a dose of monovalent hepatitis B vaccine on the day of birth, concurrently but in separate thighs. The dose of HBIG is 100 IU, to be given by intramuscular injection. It is preferable to administer HBIG immediately after birth (preferably within 12 hours of birth and certainly within 48 hours) as its efficacy decreases markedly if given more than 48 hours after birth.[7] The dose of monovalent hepatitis B vaccine should be given to the infant preferably within 24 hours of birth, and definitely within 7 days. This regimen results in seroconversion rates of more than 90% in neonates, even with concurrent administration of HBIG. Vaccination should not be delayed beyond 7 days after birth, as vaccination alone has been shown to be reasonably effective in preventing infection, provided it is given early.[19] Three subsequent doses of a hepatitis B-containing vaccine should be given, (at 2, 4 and 6 months of age in Australia and 6 weeks, 2 and 5 months in NZ), so that the infant receives a total of 4 doses of hepatitis B-containing vaccines. Anti-HBs antibody and HBsAg levels should be measured in infants born to mothers with chronic hepatitis B infection 3 to 12 months after completing the primary vaccine course.

HBIG is prepared from plasma donated through routine blood bank collection, and stocks of HBIG are limited. Use should therefore be strictly reserved for those who are at high risk, such as babies born to hepatitis B carrier mothers.[9]

Infants at risk of perinatal HBV infection should be tested at 9-12 months of age for HBsAg and HBsAb, at least 3 months after completing primary vaccination course. The serology required is Hep B sAg (to determine whether immunoprophylaxis was successful at preventing MTCT) and antiHBS (to determine whether primary vaccination course was successful at inducing immunity). HBsAg positive children should be referred to a paediatrician experienced in viral hepatitis.

In New Zealand:

Babies of HBsAg-positive mothers are to be notified at birth using the form HE1446: Consent for hepatitis B vaccine and hepatitis B immunoglobulin and notification to the Medical Officer of Health, available from www.healthed.govt.nz or the local authorised health education resource provider or public health unit.

5.4.2 Is there a difference in rates of HBV infections between breast-fed infants and formula-fed infants?

While HBV has been detected in the breastmilk of HBsAg-positive women, a recent meta-analysis of 32 studies has reported no differences in rates of HBV infections in breast-fed infants, when compared to formula-fed infants, provided appropriate immunoprophylaxis has been given at birth.[20]

5.4.3 What long-term follow-up care should HBsAg-positive women receive?

HBsAg-positive women should be closely monitored for several months postpartum as there is an increased risk of hepatitis flares during this time.[10] Lifelong follow-up should also be offered to monitor for complications of liver disease and hepatocellular carcinoma.

Recommendation 4	Grade and reference
<u>Postpartum:</u> *In Australia:* • As part of the Australian childhood vaccination program, it is recommended that all newborn infants receive a monovalent paediatric formulation of hepatitis B vaccine at birth (within 24 hours). Following this birth dose, 3 doses of a hepatitis-B-containing combination vaccine are recommended for all children, at 2, 4 and 6 months of age. • If an infant has not received a birth dose within the 1st 7 days of life, a primary 3-dose course of a hepatitis B-containing combination vaccine should be given, at 2, 4 and 6 months of age; catch-up of the birth dose is not necessary. • In addition to routine vaccination, infants born to HBsAg-positive mothers should receive passive immunisation with HBIG at birth (preferably within 12 hours and certainly within 48 hours). • Anti-HBs antibody and HBsAg levels should be measured in infants born to mothers with chronic hepatitis B infection 3 to 12 months after completing the primary vaccine course. Referral to a paediatrician with expertise in viral hepatitis is recommended if HBsAg positive. *In New Zealand:* • All infants are offered routine HBV vaccination at birth, 6 weeks, 3 months and 5 months as per the Immunisation schedule. • As in Australia, infants born to HBsAg-positive mothers should also receive passive immunisation with HBIG at birth (preferably within 12 hours). • It is recommended for infants for HBsAg-positive mothers to have serology testing at 9 months of age, and referral to a specialist if HbsAg positive. <u>*Breastfeeding*</u> Provided appropriate immunoprophylaxis has been given at birth, breastfeeding by HBsAg-positive women has not been shown to increase rates of perinatal transmission. Breastfeeding is not contraindicated in women with HBV receiving tenofovir (Grade B) <u>*Postpartum and long term follow up*</u> HBsAg-positive women receiving antiviral therapy in pregnancy should be monitored closely for several months post-partum for hepatitis flares. Lifelong follow up should be offered to HBsAg-positive women for monitoring of complications such as liver disease and hepatocellular carcinoma (Grade A).	Consensus-based recommendation References 7 8, 22 23 2

6. Links to other College statements

Evidence-based Medicine, Obstetrics and Gynaecology (C-Gen 15)
https://www.ranzcog.edu.au/RANZCOG_SITE/media/RANZCOG-MEDIA/Women%27s%20Health/Statement%20and%20guidelines/Clinical%20-%20General/Evidence-based-medicine,-Obstetrics-and-Gynaecology-(C-Gen-15)-Review-March-2016.pdf?ext=.pdf

7. Patient information

A range of RANZCOG patient information pamphlets can be ordered via:

https://www.ranzcog.edu.au/Womens-Health/Patient-Information-Guides/Patient-Information-Pamphlets

8. References

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Appendices

Appendix A Women's Health Committee Membership

Name	Position on Committee
Professor Yee Leung	Chair and Board Member
Dr Gillian Gibson	Deputy Chair, Gynaecology
Dr Scott White	Deputy Chair, Obstetrics and Subspecialties Representative
Associate Professor Ian Pettigrew	Member and EAC Representative
Dr Kristy Milward	Member and Councillor
Dr Will Milford	Member and Councillor
Dr Frank O'Keeffe	Member and Councillor
Professor Steve Robson	Member
Professor Sue Walker	Member
Dr Roy Watson	Member and Councillor
Dr Susan Fleming	Member and Councillor
Dr Sue Belgrave	Member and Councillor
Dr Marilyn Clarke	ATSI Representative
Associate Professor Kirsten Black	Member
Dr Thangeswaran Rudra	Member
Prof Steve Robson	Member
Dr Nisha Khot	Member and SIMG Representative
Dr Judith Gardiner	Diplomate Representative
Dr Angela Brown	Midwifery Representative, Australia
Ms Adrienne Priday	Consumer Representative, New Zealand
Ms Ann Jorgensen	Community Representative
Dr Rebecca Mackenzie-Proctor	Trainee Representative
Prof Caroline De Costa	Co-opted member (ANZJOG member)
Dr Christine Sammartino	Observer

Appendix B Overview of the development and review process for this statement

i. Steps in developing and updating this statement

This statement was originally developed in November 1990 and was most recently reviewed in November 2019. The Women's Health Committee carried out the following steps in reviewing this statement:

- Structured clinical questions were developed and agreed upon.
- An updated literature search to answer the clinical questions was undertaken.
- At the October 2019 committee meeting, the existing consensus-based recommendations were reviewed and updated (where appropriate) based

on the available body of evidence and clinical expertise. Recommendations were graded as set out below in Appendix B part ii).

ii. Grading of recommendations

Each recommendation in this College statement is given an overall grade as per the table below, based on the National Health and Medical Research Council (NHMRC) Levels of Evidence and Grades of Recommendations for Developers of Guidelines. Where no robust evidence was available but there was sufficient consensus within the Women's Health Committee, consensus-based recommendations were developed or existing ones updated and are identifiable as such. Consensus-based recommendations were agreed to by the entire committee. Good Practice Notes are highlighted throughout and provide practical guidance to facilitate implementation. These were also developed through consensus of the entire committee.

Recommendation category		Description
Evidence-based	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	The body of evidence is weak and the recommendation must be applied with caution
Consensus-based		Recommendation based on clinical opinion and expertise as insufficient evidence available
Good Practice Note		Practical advice and information based on clinical opinion and expertise

Appendix C Full Disclaimer

This information is intended to provide general advice to practitioners, and should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any patient.

This information has been prepared having regard to general circumstances. It is the responsibility of each practitioner to have regard to the particular circumstances of each case. Clinical management should be responsive to the needs of the individual patient and the particular circumstances of each case.

This information has been prepared having regard to the information available at the time of its preparation, and each practitioner should have regard to relevant information, research or material which may have been published or become available subsequently.

Whilst the College endeavours to ensure that information is accurate and current at the time of preparation, it takes no responsibility for matters arising from changed circumstances or information or material that may have become subsequently available.