



OBSTETRICS & GYNAECOLOGY DIRECTORATE Clinical Practice Guideline

Infections in obstetrics: Hepatitis C

This document should be read in conjunction with this **Disclaimer**

Contents

Background	2
Risk factors	2
Screening for HCV	2
Interpreting HCV results	3
Patient information regarding HCV	4
Planned invasive procedures	4
Intrapartum management	4
Postpartum management	5
Neonatal management	5
Appendix 1: RANZCOG Clinical Statement: Management of	
Hepatitis C in Pregnancy (C-Obs 51)	1

Aims

- To offer antenatal screening for the hepatitis C virus (HCV) to all women
- Provide education to women positive for HCV regarding disease management during pregnancy, intrapartum and the postpartum periods
- Provide information to HCV positive women about strategies to prevent transmission of HCV and ensure postnatal follow-up for the mother and the neonate



Background

For background information, epidemiology and prevalence, see Appendix 1: RANZCOG Clinical Statement: Management of Hepatitis C in Pregnancy (C-Obs 51); and Department of Health Australia: Pregnancy Care Guidelines.

Risk factors

Prevalence is estimated at 0.9% of the Australian population¹, however this level may rise as high as 80% in high-risk behaviour groups.² In Australia transmission predominantly occurs in people with a history of injecting drug use and people in prison.³

Risk factors for contracting HCV include:

- injecting drugs and sharing of equipment, 1, 3 use of intranasal cocaine 3
- incarceration^{1, 3}
- tattooing or body piercing^{1, 3}
- working in environments where there is contact with bodily fluids³ (e.g. needle stick injuries¹)
- country of origin high-prevalence region (e.g. Africa, central and east Asia,³
 Egypt, Pakistan, Mediterranean and Eastern Europe)¹
- received blood transfusions or organ transplant³ (prior to 1990)¹
- participation in overseas invasive procedures³
- sharing of equipment with a person with HCV (e.g. sex toys,¹ razor, toothbrush)
- sexual partners of a HCV infected person (higher risk if partner has sex with men and people with HCV-HIV coinfection)¹ and practicing unsafe sex where blood may be present¹ (although the contribution of sexual transmission in the acquisition of HCV infection is controversial)
- children born to HCV infected mothers¹
- people infected with HIV or hepatitis B virus (HBV), or evidence of liver disease¹

Screening for HCV

Pre-pregnancy screening- Consider screening women pre-pregnancy so the woman may make an informed choice regarding treatment prior to planned pregnancy. Existing treatment options for hepatitis C are not recommended during pregnancy or breastfeeding.²

Screening during pregnancy

1. All antenatal women should have their HCV status reviewed at the booking visit. Women who have not been screened should be counselled, and the test performed if informed consent is given.^{2, 3}

- There is no intervention to preventing mother to baby transmission of HCV (apart from avoidance of invasive procedures), or recommended treatments during pregnancy, but if the woman is HCV PCR positive, then the woman and neonate will require follow-up. Treatment of the woman post- partum will reduce the risk of HCV in subsequent pregnancies.³
- 2. The initial screening test assesses for the presence of antibodies to HCV. The laboratory then will perform a confirmatory test. It may take 3 months from the time of infection until antibodies are detected.⁴ People may naturally clear the virus, however can still have antibodies present which may persist for life.¹
 - Should a woman test positive to antibodies for HCV then a blood test for HCV RNA Polymerase Chain Reaction (PCR) should be ordered² to detect the presence or absence of the virus in the blood, the viral load, and the genotype.
 - Liver function tests (LFTs) should be performed at the same time when testing for HCV RNA status.²
 - All HCV positive patients should be screened for other blood borne viruses which may be co- transmitted (HBV, HIV).⁴
- 3. All newly diagnosed HCV infections require completion of the mandatory Health Department of Western Australia Notification Form for Infectious Diseases.⁴

Interpreting HCV results

Test	Result	Interpretation	Additional information
Anti-HCV (antibodies) - enzyme immunoassay (EIA or ELISA)	Positive	Detects exposure to HCV in the present or the past.	The person may have cleared the virus naturally, or have an ongoing infection. A negative result usually indicates infection is not present, however the 'window-period' should be taken into account especially in high-risk circumstances, and repeat testing in 3 months may be required. ¹
HCV RNA	Positive	Confirms a person is currently positive for HCV	If HCV is present in 6 months, it is a chronic infection. ¹
PCR viral detection test	Negative	Infection has cleared	Follow-up in 6-12 months is required to checked sustained clearance. ⁴
HCV RNA PCR viral load		Measures the amount of virus in the blood	Useful in determining it a treatment is working.
HCV RNA viral		Determines genotype for	Seven different genotypes of HCV

genotype test	HCV	exist ¹ with antiviral treatment
		responding more effectively with
		some types than others. Genotype
		testing need not be delayed until
		specialist/ hepatology clinic review.

Patient information regarding HCV

Provide verbal and written information about HCV including:

- The course of the illness
- Mode of transmission of the virus
- Prevention of HCV transmission
- · Pregnancy and postnatal management
- Life-style changes e.g. Alcohol use, nutrition, fatigue and management of symptoms¹
- Management of the neonate including recommended follow-up testing
- Community support services in Western Australia
- Women can be referred to http://www.hepatitiswa.com.au or The Deen clinic for information
- Explain that effective treatments are now available. For PCR positive women treatment can be accessed post-partum through her GP, the Deen clinic 9227 9800 or a hepatology clinic

Planned invasive procedures

Amniocentesis in women infected with HCV does not appear to significantly increase the risk of vertical transmission but the evidence base is very limited on this issue³. Prior to planned amniocentesis or chorionic villus sampling (CVS), a hepatitis RNA test is recommended and if positive, non-invasive options for testing should be offered if suitable.²

Intrapartum management

- Standard precautions are utilised and should be implemented for all women.
 See KEMH Infection Prevention & Management Manual: <u>Standard Precautions</u>
- 2. Performing an elective caesarean section is not recommended as a way to prevent or reduce the incidence of vertical transmission of HCV.²
- 3. HIV co-infection significantly increases the risk of vertical transmission of HCV.3
- 4. Risk of vertical transmission of HCV increases with prolonged rupture of membranes, use of internal fetal monitoring, invasive procedures, and if the mother has a higher HCV viral load during labour or birth.^{2, 3}

- 5. Where possible avoid procedures that may increase risk of vertical transmission of HCV including:
 - Fetal blood sampling³
 - Fetal scalp electrode use³
 - Early artificial rupture of membranes
 - If assisted delivery required, use of soft cup vacuum extraction (e.g. Kiwi) or forceps is preferred over a metal cup which poses increased risk for scalp injury⁵
 - Episiotomy³

Postpartum management

- 1. Encourage breastfeeding (<u>Hepatitis C and Breastfeeding</u> information available):
 - Breastfeeding is not contra-indicated for women with HCV infection.
 However, if the nipples are damaged, cracked or bleeding it is recommended the milk is expressed and discarded until the nipples are healed.²
- 2. Educate the mother about:
 - breastfeeding prevention techniques to avoid nipple damage, checking of nipples following each feed
 - how to express breast milk in case of damaged or bleeding nipples. See
 Newborn Feeding guidelines: Breastfeeding: Nipple Trauma; Expressing
 - prevention of transmission of the HCV in the home environment
 - follow-up testing for the neonate
- 3. Follow-up: For PCR positive mothers, discuss preferences for GP, Deen clinic or Hepatology Clinic follow up.
- 4. Encourage women with chronic HCV to have immunisations for Hepatitis A and B if non-immune.¹

Neonatal management

- The neonate should be bathed to remove maternal body fluids prior to intramuscular (IM) injections e.g. Vit K²
- It is recommended that a child at risk of perinatal transmission for HCV should be tested for HCV antibodies after the appropriate time interval has passed.².
 Refer to <u>CAHS Neonatal Postnatal Ward guidelines</u>: HCV: Care of the Infant Born to HCV Positive Women and quick reference guide.
- Postnatal review of the neonate will be conducted by the paediatrician who
 will generate a letter to the GP indicating appropriate neonatal follow-up
 testing for HCV. Options for follow up include serology at 18 months, or HepC
 RNA at 3 months of age.

References

- 1. Hepatitis C Virus Infection Consensus Statement Working Group. Australian recommendations for the management of hepatitis C virus infection: a consensus statement (January 2017)Melbourne: Gastroenterological Society of Australia 2017. Available from: https://www.hepatitiswa.com.au/wp-content/uploads/2019/05/HCV-Consensus-Statement-Jan-2017.pdf
- 2. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists. C Obs 51: Management of hepatitis C in pregnancy: RANZCOG; 2020. Available from: https://ranzcog.edu.au/statements-guidelines
- 3. Department of Health. Part F: Routine maternal health tests: 35- Hepatitis C. 2019 (last updated March 2020). In: Clinical Practice Guidelines: Pregnancy Care [Internet]. Canberra: Australian Government Department of Health. Available from: https://www.health.gov.au/resources/pregnancy-care-guidelines/part-f-routine-maternal-health-tests/hepatitis-c
- 4. Sexual Health and Blood-borne Virus Program. Hepatitis C. 2019. In: Silver book A guide for managing sexually transmitted infections and blood-borne viruses [Internet]. Communicable Disease Control Directorate, Department of Health Western Australia. Available from: https://ww2.health.wa.gov.au/Silver-book
- 5. O'Mahony F, Hofmeyr GL, Menon V. Choice of instruments for assisted vaginal delivery. **The Cochrane Database of Systematic reviews**. 2010 (11).

Related WNHS policies, procedures and guidelines

- CAHS Neonatal Postnatal Ward guidelines: <u>Hepatitis C Virus (HCV): Care of Infant Born to HCV Positive Women</u> and <u>Hepatitis C Virus (HCV): Quick Reference Guide</u>
- KEMH Infection Prevention & Management Manual: <u>Standard Precautions</u>

Useful resources (including related forms)

Department of Health website: <u>Hepatitis C and Breastfeeding</u>

Hepatitis Australia: Hepatitis C Guides for GPs and Patients and in other languages

Silver book: Hepatitis C and STI Screening Recommendations for High Risk Populations

Keywords:	hepatitis C, HCV, sexually transmitted infection, STI, vertical transmission, perinatal transmission, seroconversion, viral load		
Document owner:	Obstetrics & Gynaecology Directorate		
Author / Reviewer:	Microbiology Consultant & Head of Obstetrics		
Date first issued:	September 2008		
Reviewed dates: (since Jan 2015)	Jan 2015; Sept 2020	Next review date:	Sept 2023
Supersedes:	This Sept 2020 version supersedes the Jan 2015 version		
Endorsed by:	Obstetrics & Gynaecology Directorate Management Committee [OOS approved with Medical and Midwifery Co directors]	Date:	29/09/2020
NSQHS Standards (v2) applicable: 1 Governance, 2 Partnering Consumers, 3 Preventing and Controlling Infection, 5 Comprehensive Care, 6 Communicating			
Printed or personally saved electronic copies of this document are considered uncontrolled.			

Access the current version from the WNHS HealthPoint website.

This document can be made available in alternative formats on request for a person with a disability.

© North Metropolitan Health Service 2020

Copyright to this material is vested in the State of Western Australia unless otherwise indicated. Apart from any fair dealing for the purposes of private study, research, criticism or review, as permitted under the provisions of the Copyright Act 1968, no part may be reproduced or re-used for any purposes whatsoever without written permission of the State of Western Australia.

www.nmhs.health.wa.gov.au

Appendix 1: RANZCOG Clinical Statement: Management of Hepatitis C in Pregnancy (C-Obs 51)

Acknowledgment: Sourced and reproduced with permission from RANZCOG



CATEGORY: CLINICAL STATEMENT

Management of Hepatitis C in pregnancy

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

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: June 1998 Current: March 2020 Review due: March 2023 Objectives: To provide advice on the management of Hepatitis C in pregnancy.

Target audience: All health practitioners providing maternity care. In addition, this may provide useful information for those working in Aboriginal communities.

Outcomes: Reduce the transmission of Hepatitis C from infected mothers to infants.

Evidence: A literature search was undertaken to identify articles relating to the management of Hepatitis C 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 June 1998 and was most recently revised in March 2020.

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

1. Plain language summary

Hepatitis C is a viral infection affecting approximately 1% of women of childbearing years. Hepatitis C is most commonly acquired following intravenous drug use, but is also more common in some immigrant groups and in some cases has been acquired medically. In 2016, effective treatments for Hepatitis C with cure rates of over 95% became readily available. For this reason, pre pregnancy screening of women for Hepatitis C should be considered so that treatment can be initiated and Hepatitis C cured prior to pregnancy. While the risk of mother-to-child transmission of Hepatitis C is extremely low for most women, treatment prior to pregnancy benefits the infected woman, her baby, and reduces occupational exposure for health workers. Among women already pregnant with Hepatitis C, treatment is not recommended during pregnancy, but treatment following pregnancy and completion of breast feeding should be discussed. Care of Women with Hepatitis C in pregnancy should be informed by a multidisciplinary team with special expertise in infectious disease. Although hepatitis C infection is not a reason not to breastfeed the newborn, when there is cracking or bleeding of the nipples, it is wise to express and discard the milk until any open wounds are healed. Appropriate follow-up should be arranged for both mother and baby where hepatitis C infection is known or suspected.

Recommendation 1	Grade and reference
Although not universally recommended, RANZCOG considers that all pregnant women should be screened for Hepatitis C so that risk stratification can be performed and measures taken to both reduce perinatal transmission and minimise occupational exposure. Knowledge of HCV status allows counselling for women who may be eligible for treatment prior to embarking on a future pregnancy (see section 8).	Consensus-based recommendation
Recommendation 2	Grade and reference
It is recommended that individuals who are HCV positive have a PCR test for HCV RNA, as the risk of perinatal transmission is dependent on the presence of HCV RNA. Liver function tests should be performed at the time of checking HCV RNA status. As HIV co-infection increases the risk of transmission, HIV status should be ascertained if not already performed.	Consensus-based recommendation
Recommendation 3	Grade and reference
Risk of vertical transmission is increased with high viral load, prolonged rupture of membranes and invasive procedures. Where possible, fetal scalp electrodes and fetal scalp sampling should be avoided in women with HCV.	Consensus-based recommendation
Recommendation 4	Grade and reference
Caesarean section is not recommended as a means of reducing perinatal transmission of Hepatitis C	Consensus-based recommendation



Recommendation 5	Grade and
	reference
As for all blood borne infections, it is recommended to bath the baby to remove any maternal body secretions and blood prior to IM injections e.g. vitamin K.	Consensus-based recommendation
Recommendation 6	Grade and reference
HCV infection is not a contraindication to breastfeeding except in the presence of cracked or bleeding nipples. In this instance, expression and discarding of the milk is advised whilst waiting for healing of the cracked nipple.	Consensus-based recommendation
Recommendation 7	Grade and reference
All infants of HCV positive mothers should be screened following delivery to determine whether they have been infected. Care should be taken to ensure the appropriate interval has passed for the neonate to become PCR+/- antibody positive.	Consensus-based recommendation
Recommendation 8	Grade and reference
Given that antiviral curative treatment for Hepatitis C is now readily available, consideration should be given to screening all women prior to pregnancy so that they are able to make an informed choice regarding treatment prior to embarking on pregnancy. Existing treatments for HCV are not recommended during pregnancy or breast feeding. In particular ribavirin is terratogenic (Category X). For all women and male partners receiving Ribaviran, reliable contraception must be used during treatment and for 6 months after completion of treatment.	Consensus-based recommendation
Recommendation 9	Grade and
	reference
All medical and para-medical personnel who are parenterally exposed to the blood or other body fluids of HCV carriers should be screened and followed as part of standard occupational health procedures.	Consensus-based recommendation

2. Epidemiology

Worldwide, 71 million people are estimated to be living with Hepatitis C infection. ¹The incidence of Hepatitis C Virus (HCV) carriage in women of childbearing age is estimated to be 1-2 per cent, but may be as high as 80 per cent in high risk behaviour groups such as injecting drug users and blood product dependent patients. While the incidence of Hepatitis C is falling, the prevalence is increasing, with the major at-risk groups being; older patients (more commonly immigrants or who have acquired Hepatitis C medically), and younger patients (mostly due to intravenous drug use). While Hepatitis C does not have the same chronic disease burden as other viral infections in pregnancy such as HIV and Hepatitis B, 15-30% of untreated patients with Hepatitis C will develop cirrhosis within 20 years, and 27% of these subsequently develop hepatocellular carcinoma within 10 years. Hepatitis C is now the commonest cause for liver transplantation. Although there is not universal support for Hepatitis C screening in pregnancy², RANZCOG considers all women should be screened so that risk stratification (ie HCV RNA status) can be assessed and measures taken to reduce the risk to the woman, her baby and those caring for her. In addition, effective treatment is now available and should be offered postpartum to minimise risks to the woman and Mother-tochild transmission (MTCT) in future pregnancies.

Recommendation 1	Grade and reference
Although not universally recommended, RANZCOG considers that all pregnant women should be screened for Hepatitis C so that risk stratification can be performed and measures taken to both reduce perinatal transmission and minimise occupational exposure. Knowledge of HCV status allows counselling for women who may be eligible for treatment prior to embarking on a future pregnancy (see section 8).	Consensus-based recommendation

3. Perinatal Transmission of Hepatitis C

Maternal HCV poses a small risk of vertical transmission of HCV to the newborn (approximately 5%), although the risk of vertical transmission is largely confined to those patients with maternal viraemia and/ or HIV co-infection.^{3, 4} Only rarely has perinatal transmission been reported from HCV-RNA negative mothers. Children that contract HCV at birth are usually asymptomatic, but at risk of long-term liver disease.

Among women requiring an invasive procedure such as amniocentesis or chorionic villous sampling (CVS) for prenatal diagnosis, HCV RNA status should be established prior to the procedure. In HCV-RNA positive women, non-invasive prenatal testing (NIPT) should be offered if this is a suitable alternative.

Good Practice Point

Women identified as being at high risk for an euploidy on screening will usually proceed to diagnostic testing with amniocentesis or CVS. Given the potential for MTCT among HCV RNA positive women, NIPT may be considered as a second-tier screening test, given its lower false positive rate, thus reducing the need for an invasive procedure.

Recommendation 2	Grade and reference
It is recommended that individuals who are HCV positive have a PCR test for HCV RNA, as the risk of perinatal transmission is dependent on the presence of HCV RNA. Liver function tests should be performed at the time of checking HCV RNA status. As HIV co-infection increases the risk of transmission, HIV status should be ascertained if not already performed.	A

4. Intrapartum care

While transmission may be antenatal, peripartum infection appears to be most common with most neonates taking several weeks to become HCV RNA positive. Fetal scalp electrode placement has been associated with increased transmission rates and should be avoided³, where possible.

Caesarean section is not recommended as a means of reducing perinatal transmission of Hepatitis C.

Recommendation 3	Grade and reference
Risk of vertical transmission is increased with high viral load, prolonged rupture of membranes and invasive procedures. Where possible, fetal scalp electrodes and fetal scalp sampling should be avoided in women with HCV.	A
Recommendation 4	Grade and reference

5. Postpartum care

As per all blood borne viral precautions, the baby should be bathed to remove any maternal body secretions and blood prior to IM injections e.g. vitamin K.

Recommendation 5	Grade and reference
As for all blood borne infections, it is recommended to bath the baby to remove any maternal body secretions and blood prior to IM injections e.g. vitamin K.	A

6. Breastfeeding

Recommendation 6	Grade and reference
HCV infection is not a contraindication to breastfeeding except in the presence of cracked or bleeding nipples. In this instance, expression and discarding of the milk is advised whilst waiting for healing of the cracked nipple.	A

7. Postnatal follow up

Follow up of children for evidence of perinatal transmission is necessary, and consideration should be given to postpartum treatment of women after breast feeding has completed (see section 8.)

Recommendation 7	Grade and reference
All infants of HCV positive mothers should be screened following delivery to determine whether they have been infected. Care should be taken to ensure the appropriate interval has passed for the neonate to become PCR+/- antibody positive.	A

8. Treatment of Hepatitis C and the place of pre pregnancy screening

<u>Pangenotypic</u> treatments for Hepatitis C that can achieve a sustained viral response (SVR) have been readily available since 2016. Treatment with Direct Acting Antivirals (DAA) can achieve cure (SVR: absence of DNA at 12-24 weeks) in over 90% of patients.

A sustained viral response at 12 weeks post treatment amounts to cure and produces hepatic histological improvement and lifelong health advantage.

Consideration should be given to screening all women pre pregnancy so that they are able to make an informed choice regarding treatment prior to embarking on pregnancy. Existing treatments for HCV are not recommended during pregnancy or breast feeding. In particular ribavirin is teratogenic (Category X). For all women and male partner receiving Ribaviran, reliable contraception must be used during treatment and for 6 months after completion of treatment.

Recommendation 8	Grade and reference
Given that antiviral curative treatment for Hepatitis C is now readily available, consideration should be given to screening all women prior to pregnancy so that they are able to make an informed choice regarding treatment prior to embarking on pregnancy. Existing treatments for HCV are not recommended during pregnancy or breast feeding . In particular ribavirin is teratogenic (Category X).	A



The risk of HCV infection from percutaneous needle stick injury is 1-3% and appears to be confined to those where the patient is HCV PCR positive. The risk from blood contact with mucous membranes appears very low. All medical and para-medical personnel who are parenterally exposed to the blood or other body fluids of HCV carriers should be screened and followed as part of standard occupational health procedures.

Recommendation 9	Grade and reference
All medical and para-medical personnel who are parenterally exposed to the blood or other body fluids of HCV carriers should be screened and followed as part of standard occupational health procedures.	A

9. References

- Guidelines for the care and treatment of persons diagnosed with chronic hepatitisC virus infection. Geneva: World Health Organization; 2018. Ligence: CC BY-NC-SA 3.0 IGO.
- 2. Prasad M. Hepatitis C Virus Screening in Pregnancy: Is It Time to Change Our Practice? Obstetrics and gynaecology. 2016.
- 3. Mast EE HL, Seto DS, Nolte FS, Nainan OV, Wurtzel H, Alter MJ. Risk factors for perinatal transmission of hepatitis C virus (HCV) and the natural history of HCV infection acquired in infancy. The Journal of infectious diseases. 2005 Dec 1;192(11):1880-9.
- 4. Benova L MY, Calvert C, Abu-Raddad LJ. Vertical transmission of hepatitis C virus: systematic review and meta-analysis. Clinical Infectious Diseases: an official publication of the Infectious Diseases Society of America. 2014 Sep 15;59(6):765-73.

10. Links to other College Statements

Pre-pregnancy counselling (C-Obs 03a)

Routine Antenatal Assessment in the absence of pregnancy complications (C-Obs 03b)

Evidence-based Medicine, Obstetrics and Gynaecology (C-Gen 15)

11. 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

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
	Deputy Chair, Obstetrics and
Dr Scott White	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 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
Dr Nisha Khot	Member and SIMG Representative
Dr Judith Gardiner	Diplomate Representative
Dr Angela Brown	Midwifery Representative, Australia
	Midwifery Representative, New
Ms Adrienne Priday	Zealand
Ms Ann Jorgensen	Community Representative
Dr Rebecca Mackenzie-Proctor	Trainee Representative
Dr Leigh Duncan	Maori Representative
	Co-opted member (ANZJOG
Prof Caroline De Costa	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 June 1998 and was most recently reviewed in March 2020. 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 March 2020 face-to-face 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	Α	Body of evidence can be trusted to guide practice
	В	Body of evidence can be trusted to guide practice in most situations
	С	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.