Statement

Prevention of congenital cytomegalovirus (CMV) infection

This statement has been developed by the Women's Health Committee (WHC) in 2019, and an interim update of the statement approved by the Women's Health Committee (Appendix A). Conflict of Interest disclosures have been received from all members of this committee (Appendix C)
The interim update to this statement has been developed and reviewed by the Women's Health Committee and the RANZCOG Council.

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 (Appendix D).

Objectives:	To provide guidance for maternity care providers and the community on the prevention of maternal cytomegalovirus (CMV) infection during pregnancy in order to reduce mother to child transmission (MTCT) of virus, fetal infection and clinical sequelae (symptomatic congenital CMV); and to provide a general overview of the diagnosis and management of congenital CMV
Target audience:	All registered health professionals responsible for providing maternity care, pregnant women and the general community. [i]See: RANZCOG's Interim statement on gendered language (below)
Background:	This statement was first developed by Women's Health Committee in March 2019 and reviewed in June 2023 (interim review) to ensure the guidance remains current. (Appendix C) It was approved by the Women's Health Committee in July 2023.
Funding:	The development and review of this statement was funded by RANZCOG.

[i] RANZCOG currently uses the term 'woman' in its documents to include all individuals needing obstetric and gynaecological healthcare, regardless of their gender identity. The College is firmly committed to inclusion of all individuals needing O&G care, as well as all its members providing care, regardless of their gender identity

Contents

1. Plain language summary

Cytomegalovirus (CMV) is a common virus that can be passed from person-to-person without their knowledge, usually via close contact. The most common sources of CMV infection are young children, as they are more likely to shed high levels of virus in their saliva, urine or nasal secretions for long periods. Women who catch CMV infection while pregnant may pass the virus to their unborn child. If infected, some of these children may have health problems such as hearing loss, developmental delay and learning problems. The most serious cases may end in stillbirth, infant death, or the severe condition of cytomegalic inclusion disease (CID).

Pregnant women can reduce their risk of being infected with CMV if given the following advice:

- Do not share food drinks, or utensils used by children (under the age of 3 years)
- Do not put a child's dummy / soother in your mouth
- Avoid contact with saliva when kissing a child ("kiss on the forehead not on the lips")
- Thoroughly wash your hands with soap and water for 15-20 seconds especially after changing nappies or feeding a young child or wiping a young child's nose or saliva
- Clean toys, countertops and other surfaces that come into contact with children's urine or saliva.

2. Summary of recommendations

Recommendation 1	Consensus- based recommendation
All pregnant women and women trying to conceive, should be given information about CMV prevention as part of routine antenatal or pre-pregnancy care.[1]	
Recommendation 2	**Consensus-based recommendation**
Hygiene practices to reduce infection should be recommended to all pregnant women and women trying to conceive, regardless of their CMV serology status. While the greatest risk of adverse perinatal outcome occurs with maternal primary infection, congenital infection with similar levels of severity can also occur with maternal non-primary infections [1]	
Recommendation 3	**Consensus-based recommendation**
The specific recommended hygiene measures are1: • Do not share food, drinks, or utensils used by young children (less than 3 years of age) • Do not put a child's dummy in your mouth • Avoid contact with saliva when kissing a child • Attention to hand hygiene, when changing nappies or when in contact with urine. Thoroughly wash hands with soap and water for 15-20 seconds, especially after changing nappies, feeding a young child, or wiping a young child's nose or saliva • Clean toys, countertops and other surfaces that come into contact with children's urine or saliva, • Do not share a toothbrush with a young child.[1]	
Recommendation 4	**Consensus-based recommendation**
Universal routine serological screening for CMV in pregnancy is not recommended. [1-4]	
Recommendation 5	**Consensus-based recommendation**
Pre-pregnancy or early pregnancy screening with CMV IgG may be considered for women who are high risk of infection (e.g. women caring for young children). Early determination of CMV serostatus may aid in distinguishing between primary infection and reactivation/reinfection during pregnancy if clinically indicated, but does not remove the need to follow recommended hygiene measures.[1-3]	

Recommendation 6	Consensus-based recommendation
Women with suspected CMV infection in pregnancy should have CMV serology testing for IgG and IgM, and IgG avidity if CMV IgG and IgM are positive. [2,5]	
Recommendation 7	**Consensus-based recommendation**
Diagnosis of primary CMV is based upon: • The new appearance of CMV-specific IgG in a woman who was previously seronegative or • The detection of CMV IgM antibody with low IgG avidity.	
Recommendation 8	**Consensus-based recommendation**
When congenital CMV infection is suspected on the basis of maternal serology or fetal ultrasound abnormalities, a referral to a maternal fetal medicine specialist, or specialist with expertise in perinatal infections is recommended.	
Recommendation 9	**Consensus-based recommendation**
All babies of mothers diagnosed with primary CMV infection during pregnancy, should have CMV testing performed with a CMV PCR of saliva or urine with the first 3 weeks of life.[1]	
Recommendation 10	**Consensus-based recommendation**
If an infant is diagnosed with congenital CMV, discussion with a paediatrician with experience in infectious diseases is recommended for further assessment and management.	

3. Introduction

Cytomegalovirus (CMV) is the commonest cause of congenital infection[6] and affects 0.2-2.2% of births.[7] Most (90%) babies who are infected with CMV before birth are healthy at birth and have normal development. However, 10-15% of all infected infants who are healthy at birth may still develop health problems in later childhood. Congenital CMV is the most important infective cause of sensorineural hearing loss and disability and is also associated with stillbirth[8], cerebral palsy, learning problems and impaired school performance.[9] There is currently no effective vaccine to prevent maternal CMV infection, and no proven therapy to prevent or treat fetal infection.[10,11]

4. Discussion and recommendations

4.1 Transmission

a. Child to mother:

CMV is excreted in the saliva or urine of those with infection. Excretion of virus, particularly at high titre, occurs more frequently in children under two, particularly children in day care[12]. The virus can continue to be excreted for months to years.[13] CMV can be transmitted from urine and saliva to hands then to mucosal surfaces (e.g. mouth) or directly to the mucosal surfaces.[14] High risk groups include parents with a child in daycare (23% risk of seroconversion per year if they have children who are shedding CMV)[13]. Parental excretion of CMV occurs from the cervix, in semen, and in other bodily fluids.

b. Mother to fetus:The highest likelihood of adverse perinatal outcome occurs following maternal primary infection during the first trimester.

This is associated with a 30-40% risk of intrauterine transmission, and of the infected fetuses, around one third (~10% overall) will have some disease.[15] The consequences of CMV infection may be present in utero or at birth.[1] Fetal and newborn manifestations of congenital CMV include growth restriction, microcephaly, cerebral ventriculomegaly, intracerebral calcifications, ascites/hydrops, hepatosplenomegaly, chorioretinitis, thrombocytopenia, anaemia, stillbirth and neonatal death. Long

term sequelae that may not be evident until later childhood include sensorineural hearing loss, delayed psychomotor development, cerebral palsy, and visual impairment. In cases of maternal reinfection with CMV or reactivation of latent infection, the risk of fetal infection is lower (1-3%)[16] although, when fetal infection occurs, the potential for and severity of fetal morbidity is similar to cases of primary infection. On a population-basis, the majority of the health burden of congenital CMV is attributable to non-primary maternal infection, as the seropositivity (and hence latent infection) rate of the child bearing Australian population is 40-60%.[17-19] Therefore, any public health strategy should also address nonprimary infection as well as primary infection during pregnancy.

Simple hygiene measures have been shown to reduce the risk of maternal CMV infection in pregnancy.[9-11] International consensus guidelines1 and Australian Federal and State health departments recommend that pregnant women are given information on simple hygiene measures to prevent CMV infection. However, the level of awareness about CMV infection in maternity care providers[20] and pregnant women in Australia and New Zealand is very low. (ref Lazzaro 2018 unpublished). A 2015 survey of RANZCOG members/fellows/diplomates and VIC and NSW midwives reported that less than 10% of maternity care providers routinely provided education on CMV prevention.[20]

Recommendation 1	Consensus- based recommendation
All pregnant women and women trying to conceive, should be given information about CMV prevention as part of routine antenatal or pre-pregnancy care.[1]	
Recommendation 2	**Consensus-based recommendation**
Hygiene practices to reduce infection should be recommended to all pregnant women and women trying to conceive, regardless of their CMV serology status. While the greatest risk of adverse perinatal outcome occurs with maternal primary infection, congenital infection with similar levels of severity can also occur with maternal non-primary infections [1]	
Recommendation 3	**Consensus-based recommendation**
The specific recommended hygiene measures are1: • Do not share food, drinks, or utensils used by young children (less than 3 years of age) • Do not put a child's dummy in your mouth • Avoid contact with saliva when kissing a child • Attention to hand hygiene, when changing nappies or when in contact with urine. Thoroughly wash hands with soap and water for 15-20 seconds, especially after changing nappies, feeding a young child, or wiping a young child's nose or saliva • Clean toys, countertops and other surfaces that come into contact with children's urine or saliva, • Do not share a toothbrush with a young child.[1]	

4.2 Serological testing for CMV

Universal routine serological screening for CMV in pregnancy is not recommended, as past infection with CMV does not confer complete protection against reinfection or congenital CMV.[1-4] Pre-pregnancy or early pregnancy screening with CMV IgG may be considered for women who are high risk of infection (e.g. young children at home or in childcare, or childcare workers). Some studies have shown women who are aware that they are susceptible to primary CMV infection on the basis of known seronegativity are more likely to practice hygiene measures.[21,22] Pre-pregnancy CMV serology may also aid in distinguishing between primary infection or nonprimary infections during pregnancy if clinically indicated, but does not remove the need to follow recommended hygiene measures.

The majority of women with acute CMV infection have no symptoms. However, serological and virological testing for CMV should be considered if a woman presents with flu-like illness, malaise, fever, and lymphadenopathy, or if fetal signs of CMV have been detected on ultrasound (i.e. case-finding, rather than screening).

Recommendation 4	**Consensus-based recommendation**
Universal routine serological screening for CMV in pregnancy is not recommended. [1-4]	
Recommendation 5	**Consensus-based recommendation**
Pre-pregnancy or early pregnancy screening with CMV IgG may be considered for women who are high risk of infection (e.g. women caring for young children). Early determination of CMV serostatus may aid in distinguishing between primary infection and reactivation/reinfection during pregnancy if clinically indicated, but does not remove the need to follow recommended hygiene measures.[1-3]	
Recommendation 6	**Consensus-based recommendation**
Women with suspected CMV infection in pregnancy should have CMV serology testing for IgG and IgM, and IgG avidity if CMV IgG and IgM are positive. [2,5]	

4.3 Diagnosis of primary CMV infection

Diagnosis of primary CMV should be based on appearance of CMV IgG during pregnancy in a woman who was previously seronegative; or detection of CMV IgM with low IgG avidity, if previous serology is unknown.[2, 5] (See Table 1). In general, the former is usually not available, as prior testing is often unavailable. Interpretation of CMV serology can be difficult as the IgM response may last up for 16 weeks post infection, may reappear with reactivation or reinfection and false positives occur due to cross reaction with other viruses.[24] CMV IgG avidity is more useful for timing maternal infection if primary infection during pregnancy is suspected. A low CMV IgG avidity is suggestive of recent infection (<3 months); high avidity suggests infection >3 months ago; Intermediate avidity – is not informative for assessing timing of infection. The IgG avidity testing is now standard and comparable within a laboratory, although differences in the avidity index depend on the kit/ technique the laboratory used and serial results from different laboratories should be compared with caution.[24]

All laboratories in Australia are required to store serum from pregnant women following diagnostic testing for 12 months. Retrospective testing of stored sera from first trimester booking bloods can be useful to determine if a primary infection has occurred during pregnancy.

Recommendation 7	Consensus-based recommendation
Diagnosis of primary CMV is based upon: • The new appearance of CMV-specific IgG in a woman who was previously seronegative or • The detection of CMV IgM antibody with low IgG avidity.	
Recommendation 8	**Consensus-based recommendation**
When congenital CMV infection is suspected on the basis of maternal serology or fetal ultrasound abnormalities, a referral to a maternal fetal medicine specialist, or specialist with expertise in perinatal infections is recommended.	

Table 1. Interpretation of CMV serology

Serology			Interpretation of serology	
IgM	IgG	IgG avidity	Interpretation	Action
-	-		Susceptible/ no evidence of recent infection	Educate about transmission. Consider repeat serology in 2-3 weeks if clinical suspicion of recent infection
+	-		Possible recent infection or false positive IgM	Repeat serology in 2 weeks and perform avidity if IgG then positive
+	+	Low	Recent primary infection	Refer – likely primary infection
+	+	Intermediate	Possible recent primary infection	Test stored sera, or manage as recent primary
+	+	High	Past infection	Refer- Non-primary (reinfection/ reactivation

4.4 Diagnosis of fetal infection

Fetal risk is dependent on the gestation at which maternal infection occurred, and whether it is primary infection or reactivation/ reinfection. The greatest risks are in first trimester with primary infection. However, timing of infection is often difficult to ascertain as the majority of infections are asymptomatic.

Prenatal diagnosis of fetal infection is performed with CMV nucleic acid tests (generally with PCR) on an amniocentesis sample. For optimal sensitivity and specificity, the amniocentesis needs to be performed >8 weeks after the suspected infection[20] and usually >21 weeks gestation.[1, 2, 24] Earlier amniotic fluid samples have a high falsely negative rate.[25]

4.5 Management of suspected or proven congenital CMV infection

Guidelines for the investigation and management of infections in pregnancy including CMV are available from the Australian Society of Infectious Diseases (ASID)[5] and the International Consensus guidelines.[1] When congenital CMV infection is suspected on the basis of maternal serological findings or fetal ultrasound abnormalities, a referral to a maternal fetal medicine specialist, or specialist with expertise in perinatal infections is recommended.

There is no established or recommended treatment to prevent fetal infection after maternal primary infection.[1, 26, 27] Treatment options for fetuses with CMV confirmed on amniocentesis are currently evolving.[1, 10, 11, 28]

Serial ultrasound surveillance +/- MRI are recommended when cCMV is proven on amniocentesis to monitor for fetal growth restriction and structural abnormalities, in particular brain abnormalities.[2, 24] When both ultrasound and MRI are normal, the prognosis is generally good.[29]

4.6 Neonatal investigation and management

All babies of mothers diagnosed with primary CMV infection during pregnancy, should have CMV testing performed at birth with a CMV PCR of saliva or urine within the first 3 weeks of life.[1] Testing must be performed within the first three weeks of life to distinguish congenital from postnatal CMV infection. If an infant is diagnosed with congenital CMV, discussion with a paediatrician with experience in infectious diseases is recommended for further assessment and management.[1] Long term follow up of hearing is recommended, regardless of the results of the infant hearing screen.

Testing for congenital CMV should be considered for infants that have an abnormal newborn hearing screen result.[30]

Breastfeeding should be encouraged. There is no evidence to suggest that postnatal CMV transmission during breastfeeding has any adverse effects on healthy infants.

Recommendation 9	Consensus-based recommendation
All babies of mothers diagnosed with primary CMV infection during pregnancy, should have CMV testing performed with a CMV PCR of saliva or urine with the first 3 weeks of life.[1]	
Recommendation 10	**Consensus-based recommendation**
If an infant is diagnosed with congenital CMV, discussion with a paediatrician with experience in infectious diseases is recommended for further assessment and management.	

3. References

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4. Suggested reading

Congenital CMV Australia website: http://www.cmv.org.au

Australian Government, Department of Health and Aged Care: https://www.health.gov.au/resources/pregnancy-care-guidelines/part-g-targeted-maternal-health-tests/cytomegalovirus

Australasian Society for Infectious Diseases (ASID). Guidelines on the Management of Perinatal Infections, Third Edition. November 2022. Editors P Palasanthiran, M Starr, C Jones, ML Giles ML. Available at: https://asid.net.au/publications

He Puna Waiora (Healthify): Cytomegalovirus (CMV): https://healthify.nz/health-a-z/c/cytomegalovirus-cmv/

5. Links to other College statements

Pre-pregnancy Counselling (C-Obs 3a)

Routine antenatal assessment in the absence of pregnancy complications (C-Obs 3b)

Pre-pregnancy and Pregnancy Vaccinations (C-Obs 44)

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

6. Patient information

A range of RANZCOG Patient Information Pamphlets can be viewed at: https://ranzcog.edu.au/resource-hub/?resource_audience=for-public
and ordered via:
https://ranzcog.zhpro.com.au/DSF/SmartStore.aspx?6xni2of2cF3ZE6Vkp5312HLCKdyzRw/RlmVRsVdzDflA7ud2OCsqiD4C7i9UTKPF#!/Storefront

Appendices

Appendix A Women's Health Committee Membership

Name	Position on Committee
Dr Scott White	Chair
Dr Gillian Gibson	Deputy Chair, Gynaecology
Dr Anna Clare	Deputy Chair, Obstetrics
Associate Professor Amanda Henry	Member and Councillor
Dr Samantha Scherman	Member and Councillor
Dr Marilla Druitt	Member and Councillor
Dr Frank O'Keeffe	Member and Councillor
Dr Kasia Siwicki	Member and Councillor
Dr Jessica Caudwell-Hall	Member and Councillor
Dr Sue Belgrave	Member and Councillor
Dr Marilyn Clarke	Aboriginal and Torres Strait Islander Representative
Professor Kirsten Black	SRHSIG Chair
Dr Nisha Khot	Member and SIMG Representative
Dr Judith Gardiner	Diplomate Representative
Dr Angela Brown	Midwifery Representative, Australia
Ms Adrienne Priday	Midwifery Representative, New Zealand
Ms Leigh Toomey	Community Representative
Dr Rania Abdou	Trainee Representative
Dr Philip Suisted	Māori Representative
Prof Caroline De Costa	Co-opted member (ANZJOG member)
Dr Steve Resnick	Co-opted member

Appendix B

The Women's Health Committee acknowledges the significant contribution of Associate Professor Lisa Hui MBBS PhD FRANZCOG CMFM in the interim update of this statement.

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

i. Steps in developing and updating this statement

This statement was first developed by Women's Health Committee in March 2019 and updated by the author in July 2023 ahead of approval by the Women's Health Committee. The Women's Health Committee carried out the following steps in reviewing this statement:

- Declarations of interest were sought from all members prior to reviewing this statement.
- Review of the statement content, with minor updates to recommendations agreed.
- Interim updates to the statement approved.

ii. Declaration of interest process and management

Declaring interests is essential in order to prevent any potential conflict between the private interests of members, and their duties as part of the Women's Health Committee.

A declaration of interest form specific to guidelines and statements was developed by RANZCOG and approved by the RANZCOG Board in September 2012. The Women's Health Committee members were required to declare their relevant interests in writing on this form prior to participating in the review of this statement.

Members were required to update their information as soon as they become aware of any changes to their interests and there was also a standing agenda item at each meeting where declarations of interest were called for and recorded as part of the meeting minutes.

There were no significant real or perceived conflicts of interest that required management during the process of updating this statement.

iii. 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 D Full Disclaimer

Purpose

This Statement has been developed to provide general advice to practitioners about women's health issues concerning the prevention of congenital cytomegalovirus (CMV) infection 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 person. 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 person and the particular circumstances of each case.

Quality of information

The information available in this statement is intended as a guide and provided for information purposes only. The information is based on the Australian/New Zealand context using the best available evidence and information at the time of preparation. While the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) have endeavoured 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. The use of this information is entirely at your own risk and responsibility.

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These terms and conditions will be constructed according to and are governed by the laws of Victoria, Australia.

Version	Date of Version	Pages revised / Brief Explanation of Revision
v1.0	Mar / 2019	RANZCOG Women's Health Committee
V1.2	July / 2023	Interim update approved by RANZCOG Women's Health Committee, and correction of footnote
V2.0		

Policy Version:	Version 1.2
Policy Owner:	Women's Health Committee
Policy Approved by:	RANZCOG Council
Review of Policy:	Mar / 2024