CATEGORY: BEST PRACTICE STATEMENT

The use of misoprostol in obstetrics and gynaecology

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.
Disclosure statements have been received from all members of this committee.

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 2001
Current: November 2021
Review due: November 2026

Objectives: To provide advice on the use of misoprostol in obstetrics and gynaecology.

Target audience: All health practitioners providing Obstetrical and Gynaecological 23 care.
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 Women's Health Committee in November 2001 and last reviewed in November 2019.
Funding: The development and review of this statement was funded by RANZCOG.

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1. Plain language summary

Misoprostol is a medication that is available in Australia and New Zealand. It is used as part of the treatment for miscarriage (early pregnancy loss) and stillbirth, for abortion, and may also be used for the control of excessive bleeding after birth. Misoprostol is also used for induction of labour in New Zealand. When used in these settings misoprostol is safe and effective, and can provide important benefits for women. These should be discussed with the doctor providing care.

2. Summary of recommendations

Recommendation 1	Grade
Misoprostol is appropriate for use, and demonstrates advantages over available alternatives, in the medical management of miscarriage and in combination with mifepristone for abortion in the first trimester.	Consensus-based recommendation
Recommendation 2	**Grade**
Under current TGA guidelines in Australia misoprostol is registered for use in a composite pack with mifepristone for abortion up to 63 days. There is no approved use beyond 63 days gestation or for other obstetric or gynaecological procedures. Where practical any "off-label" use should occur after obtaining and documenting informed consent from the woman.	Consensus-based recommendation
Recommendation 3	**Grade**
Misoprostol is used in combination with mifepristone for abortion and management of some miscarriages. Detailed information about this indication can be found in the College statement *The use of mifepristone for medical termination of pregnancy (C-Gyn 21).*	Consensus-based recommendation

3. Introduction

There is considerable evidence in published studies about the use of misoprostol in obstetrics. There are in excess of 200 randomised controlled trials included in Cochrane Systematic Reviews, involving more than 35,000 women where misoprostol has been administered for obstetric or gynaecological indications.

4. Discussion and recommendations

Recommendation 1	Grade
Misoprostol is appropriate for use, and demonstrates advantages over available alternatives, in the medical management of miscarriage and in combination with mifepristone for abortion in the first trimester.	Consensus-based recommendation

4.1 Use in first and second trimesters

In general, the evidence demonstrates advantages of misoprostol over available alternatives for use in medical management of miscarriage. The advantages are that it is at least as effective as alternatives, has fewer side effects, is more practical to use and is cheaper. Compared to surgical evacuation of the uterus, misoprostol is associated with a slightly higher rate of retained products of conception, vomiting and

diarrhoea, but patient satisfaction is similar. There is no clear evidence that any route of administration or dosage regimen is superior to others[1].

Misoprostol is safe and effective for management of second trimester fetal death in utero. There is now clear evidence that the addition of mifepristone to misoprostol reduces the time to delivery in women with fetal death in utero between 14 and 28 weeks' gestation compared to misoprostol alone[2].

In 2012 misoprostol was registered in Australia for use orally or buccally in combination with mifepristone for abortion up to 49 days gestation. From February 2015 a composite pack containing both misoprostol and mifepristone was introduced with a new indication of abortion up to 63 days gestation. This has been found to be effective and associated with few side-effects.

The Therapeutic Goods Administration approved product information and evidence based guidelines should be consulted for detailed information about appropriate regimens.[3]

Misoprostol has been shown to be superior to other methods of cervical preparation for surgical abortion in the first trimester[4].

4.2 Use in third trimester

4.2.1 Induction of labour[5-12]

Misoprostol is used extensively in the third trimester in countries other than Australia, including in New Zealand. Advantages include that it is relatively inexpensive, can be stored at room temperature and has a long shelf life. However, in Australia, use of misoprostol is less common after the first trimester and, under current TGA guidelines, the use of misoprostol for abortion after 63 days gestation or for other obstetric or gynaecological procedures is not an approved indication.

There is considerable literature evaluating the use of misoprostol for cervical ripening and induction of labour. Both vaginal and oral administration of misoprostol are effective methods for cervical ripening and for induction of labour. As with other prostaglandins, misoprostol can cause uterine hypertonicity. Misoprostol is an effective uterotonic and can achieve sustained uterine contraction in the third stage.

Misoprostol is a safe and effective method of induction of labour for fetal death in utero or abortion. Dosage should be adjusted according to gestation, presence of uterine scars (including caesarean section), and fetal death, with these factors influencing myometrial responsiveness and the risk of uterine rupture. Uterine rupture may occur with misoprostol induction of labour, as with other uterotonic agents, and its use in women with uterine scars, particularly those with multiple or upper uterine segment scars, should be under close supervision in a facility adequately equipped to manage this rare but serious complication.

The table below suggests a reasonable regimen, but this should be considered a general guide and may require modification depending on other clinical circumstances or local considerations.

Clinical context[13-15]	Misoprostol dose		Maximal doses before review
	Initial	Subsequent	
Medical abortion 14 to 22 weeks gestation[a]	400 to 800mcg	400mcg 4-hourly	6 doses
Medical abortion 22-27 weeks gestation	400mcg	400mcg 4-hourly	6 doses
Medical abortion 22-27 weeks with prior uterine surgery	200mcg	200mcg 4-hourly	6 doses
Induction of labour from 28 weeks[b] Induction of labour with a live fetus	25 to 100mcg 25mcg	25 to 100mcg 2-hourly to 6-hourly 2hrly	24 hours 8 doses
[a] Consider reducing dose in women with prior uterine surgery after 20 weeks [b] Use lower doses at later gestations, in parous women, and with fetal death in utero. Use only with caution in women with prior uterine surgery and generally not with a live fetus and a uterine scar.			

4.2.2 Third stage management [16-20]

There is insufficient evidence to recommend misoprostol over conventional injectable uterotonics in prophylactic management in the third stage of labour, particularly in women considered to be at low risk for severe postpartum haemorrhage.

Misoprostol may be used for the management of postpartum haemorrhage. This is covered in more detail in the College statement Management of *Postpartum Haemorrhage (C-Obs 43).* FIGO recommends misoprostol for management of PPH in low resource settings due to its low cost and easy storage[21], however there is insufficient evidence to recommend its use over injectable uterotonics in routine practice in Australia and New Zealand at this stage[22].

4.2.3 Use in Gynaecology

Misoprostol administration prior to hysteroscopy has been shown to reduce the need for mechanical dilatation, and reduces the incidence of intra-operative complications (cervical laceration, false-track formation[23-25]). Vaginal administration, compared to oral, appears to reduce the time required for the priming to be effective and to reduce gastrointestinal side effects[26].

4.2.4 Registration status of misoprostol

In Australia misoprostol is now only registered for use in obstetrics and gynaecology in a composite pack with Mifepristone and solely for the purpose of abortion up to 63 days gestation.

The use of misoprostol after 63 days gestation or for other obstetric or gynaecological indications is not currently an approved indication.

Misoprostol is included in the regimen for early medical abortion in the New Zealand Medsafe datasheet for mifepristone, but misoprostol itself is not registered there for obstetric and gynaecological indications and therefore is used as not an approved indication.

The company which markets the widely used formulation of misoprostol which is registered for gastrointestinal indications has not researched, and does not support, its use in pregnancy, and has not expressed any intention to do so.

4.5 Use in clinical practice

Recommendation 2	Grade
Under current TGA guidelines in Australia misoprostol is registered for use in a composite pack with mifepristone for abortion up to 63 days. There is no approved use beyond 63 days gestation or for other obstetric or gynaecological procedures. Where practical any "off-label" use should occur after obtaining and documenting informed consent from the woman.	Consensus-based recommendation
Recommendation 3	**Grade**
Misoprostol is used in combination with mifepristone for abortion and management of some miscarriages. Detailed information about this indication can be found in the College statement *The use of mifepristone for medical termination of pregnancy (C-Gyn 21).*	Consensus-based recommendation

Particular caution is recommended with the use of misoprostol for cervical ripening and induction of labour. The potential risks and benefits in each individual case should be carefully evaluated and attention paid to the published information regarding minimisation of dosage. As with all prostaglandin preparations, caution is recommended with the use of misoprostol in the presence of a uterine scar.

5. Conclusion

There is reasonable evidence from peer reviewed literature attesting to the efficacy of misoprostol as a therapeutic agent in treating a number of conditions in Obstetrics and Gynaecology. Practitioners should be aware that when they prescribe it, they will generally be using it 'off label' and, apart from in time-critical emergency settings, should only use it in clinical situations after obtaining and documenting informed consent from the woman.
The references which follow include information about dosage regimens evaluated.

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7. Other suggested reading

National Consensus Guideline for Treatment of Postpartum Haemorrhage
http://www.health.govt.nz/publication/national-consensus-guideline-treatment-postpartum-haemorrhage

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8. Links to other College statements

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

The use of mifepristone for medical termination of pregnancy (C-Gyn 21)

Birth after previous Caesarean Section (C-Obs 38)

Management of postpartum haemorrhage (C-Obs 43)

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
Dr Jared Watts	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
Ms Adrienne Priday	Midwifery Representative, New Zealand
Ms Ann Jorgensen	Community Representative
Dr Ashleigh Seiler	Trainee Representative
Dr Leigh Duncan	Maori 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 July 1992 and was most recently reviewed in November 2021. 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.
- Structured clinical questions were developed and agreed upon.
- An updated literature search to answer the clinical questions was undertaken.
- At the September 2021 teleconference, 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 iii)

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.[13] 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

Purpose

This Statement has been developed to provide general advice to practitioners about women's health issues concerning use of misoprostol 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 while using misoprostol and circumstances of each case.

Quality of information

The information available in Use of misoprostol in obstetrics and gynaecology (C-Obs 12) 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) had endeavoured to ensurethat 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
v1.1	Nov / 2001	Developed by WHC
v2.1	Nov / 2003	Reviewed by WHC
v3.1	Nov / 2005	Reviewed by Working party (WHC)
v4.1	Nov/2007	Reviewed by WHC
v5.1	Nov/2010	Reviewed by WHC
v6.1	Nov/2012	Reviewed by WHC
v7.1	Mar/2016	Reviewed by Sexual and Reproductive Health Advisory Group

Policy Version:	Version 8.1
Policy Owner:	Women's Health Committee
Policy Approved by:	RANZCOG Council/Board
Review of Policy:	Nov / 2026