CATEGORY: CLINICAL GUIDANCE STATEMENT

Term Prelabour Rupture of Membranes (Term PROM)

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: July 2010
Current: July 2021
Review due: July 2026

Objectives: To provide advice on the management of Term (≥37 weeks gestation) Prelabour Rupture of Membranes (Term PROM)

Options: Expectant management versus active management with induction of labour.

Outcomes: To improve maternal and fetal outcomes of those women undergoing Term Prelabour Rupture of Membranes (PROM)

Target audience: All health practitioners providing maternity care and patients.

Evidence: Medline was searched for randomised trials and cohort studies comparing expectant management versus active management with induction of labour.

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

Validation: This statement was compared with RCOG , ACOG and NICE guidelines on this topic.

Funding:. The development and review of this statement was funded by RANZCOG.

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1. Plain language Summary

In about one in 12 pregnancies, after 37 weeks, the fetal membranes around the baby will break before labour begins (breaking of the waters). Sometimes it is not clear that the waters have actually broken, and additional tests might have to be done to find the answer. Many women will start labour on their own after the waters break, but if not, induction of labour within 24 hours reduces infections for the woman and her baby.

If women are known to carry the bacteria group B streptococcus (GBS), they should be treated with antibiotics to help protect the baby against infection, and have labour induced straight away. Women who stay at home to await the onset of labour after their waters break need to monitor for signs of infection.

2. Summary of recommendations

Recommendation 1	Grade
Initial assessment of women presenting with term PROM should include confirmation of the diagnosis, confirmation of gestation, confirmation of presentation and assessment of maternal and fetal wellbeing. Where there is diagnostic uncertainty, a sterile speculum examination should be performed. If uncertainty remains regarding the diagnosis, tests for the presence of amniotic fluid proteins in vaginal fluid (e.g. Amnisure) may be used.	Consensus-based recommendation[1]
Recommendation 2	**Grade**
In women known to have vaginal Group B streptococcus (GBS) colonisation, or who are being treated as positive for GBS, prophylactic antibiotics and early planned birth is recommended.	Grade A[2, 3]
Recommendation 3	**Grade**
In women with ruptured membranes at term, induction of labour within 24 hours is recommended, where practical	Grade A[2, 3]
Recommendation 4	**Grade**
In women with ruptured membranes at term, who are negative for GBS, and where timely induction of labour is planned, antibiotics should not be prescribed as part of routine care.	Grade A[4]
Recommendation 5	**Grade**
Induction of labour with oxytocin is the usual method of induction, but in women with an unfavourable cervix, prostaglandins may be used.	Grade B[3]

3. Introduction

Term Prelabour Rupture of Membranes (term PROM) is defined as rupture of the membranes prior to the onset of labour at or beyond 37 weeks gestation.

The incidence of term PROM is 8%. Most women (70%) will commence labour spontaneously within 24 hours, but some women will have significant latency from PROM to delivery if managed expectantly. 85% of women with term PROM will labour spontaneously within 48 hours while 95% will labour spontaneously within 96 hours.

The immediate, but uncommon, risks of rupture of membranes include cord prolapse, cord compression and placental abruption.

Delayed risks include maternal and neonatal infection. Neonatal infection can result in devastating sequelae including death, chronic lung disease and cerebral palsy. Chorioamnionitis has been implicated as a cause of cerebral palsy in term infants[5].

4 How should women with term PROM be assessed?

Initial assessment of women presenting with term PROM should include confirmation of the diagnosis, of gestation, of presentation and assessment of maternal and fetal wellbeing. Where there is diagnostic uncertainty, a sterile speculum examination should be performed. If uncertainty remains regarding the diagnosis, tests for the presence of amniotic fluid proteins in vaginal fluid (e.g. Amnisure) may be used. Clinicians must be aware that false-positive test results may occur in the presence of blood or semen, alkaline antiseptics, certain lubricants, trichomonas, or bacterial vaginosis. Alternatively, false-negative test results may occur with prolonged membrane rupture and minimal residual fluid. False-positive test result rates of 19-30% have also been reported in women with clinically intact membranes and symptoms of labour[6].

All biochemical tests to confirm or refute the presence of ruptured membranes have a low but measurable false positive and false negative rate, and test findings should be interpreted in conjunction with clinical findings. The USFDA has recently issued a warning regarding overreliance on these tests and subsequent adverse outcomes. These tests should not be used as part of routine assessment of women with ruptured membranes[7].

Tests to diagnose the presence of amniotic fluid based on pH, rather than detection of amniotic fluid proteins, are less reliable.

Digital vaginal examination should be avoided unless immediate induction is planned as this has been shown to increase the rate of neonatal infection.

Recommendation 1	Grade
Initial assessment of women presenting with term PROM should include confirmation of the diagnosis, confirmation of gestation, confirmation of presentation and assessment of maternal and fetal wellbeing. Where there is diagnostic uncertainty, a sterile speculum examination should be performed. If uncertainty remains regarding the diagnosis, tests for the presence of amniotic fluid proteins in vaginal fluid (e.g. Amnisure) may be used.	Consensus-based recommendation

5. Management

5.1 How should women with term PROM be managed ?

Management of term PROM requires discussion between the woman, her partner and caregivers regarding the benefits and risks of expectant management versus active management with induction of labour.

5.2 What are the differences in outcome between expectant management and induction of labour?

A large metaanalysis reviewed the outcomes from published randomised controlled trials of immediate induction of labour, defined as within 24 hours, compared to expectant management. Overall, outcomes were improved, or showed a trend to improvement in women in whom labour was induced compared to expectant management. The quality of the evidence was low, and there was heterogeneity regarding timing to start of induction, use of antibiotics and inclusion of women with GBS carriage[2]. The findings were similar to, and strongly influenced by, the TermPROM trial[3] which contributed around half the participants. In this trial, women who were GBS positive were not managed differently to women without GBS.

	Planned birth	Expectant managment	
Maternal chorioamnionitis	54/1000	110/1000	RR 00.49; 95% CI 0.33 to 0.72
definite or probable early-onset neonatal sepsis	30/1000	41/1000	RR 0.73; 95% CI 0.58 to 0.92
caesarean section rate	126/1000	150/1000	RR 0.84, 95% CI 0.69-1.04
Neonate receiving antibiotics	85/1000	126/1000	RR 0.61; 95% CI 0.44 to 0.84
Neonatal admission to a neonatal special care or intensive care unit	129/1000	160/1000	RR 0.75, 95% CI 0.66-0.85

Women in the planned early birth group had more positive experiences compared with women in the expectant management group.

A post hoc analysis of the term PROM study concluded that expectant management at home was associated with an increase in neonatal infection (OR 1.97 95% CI 1.00, 3.90, P =. 05), compared to expectant care in hospital, noting that women were not randomised to home or hospital care[8].

5.2.1 Active management

Active management i.e. commencement of induction of labour or delivery by caesarean section, should be commenced within 24 hours, where practical, in women who are GBS negative or unknown.

In women who are GBS positive (or being treated as GBS positive), induction of labour should commence as soon as practical after diagnosis of rupture of membranes. Timing of caesarean section in this setting will depend on local service capability, and women should be given intravenous antibiotics, according to the "Maternal Group B Streptococcus in pregnancy: screening and management" guideline.

Recommendation 2	Grade
In women known to have vaginal Group B streptococcus (GBS) colonisation, prophylactic antibiotics and early planned birth is recommended.	Grade A

Recommendation 3	Grade
In women with ruptured membranes at term, induction of labour within 24 hours is recommended.	Grade A

5.2.2 Expectant management

Some women may choose expectant management, after counselling regarding the increased risks of this decision. Routine antibiotic prophylaxis may reduce rates of maternal infection in these women[4]. Ideally, these women would be/have:

- Fixed cephalic presentation.
- Negative Group B streptococcus (GBS) status and no prior history of a baby with EOGBS infection.
- No signs of infection (maternal tachycardia, fever, uterine tenderness).
- Normal CTG and fetal movements.
- Clear amniotic fluid
- Adequate resource/staffing to provide support as an outpatient or inpatient.
- Commitment to regular assessment of maternal temperature, vaginal loss and fetal movements. (4-hourly temperature check during waking hours is recommended).
- Access to reliable transport.
- Clearly documented plan for review

5.3 What is the role of antibiotics in term PROM?

a) Women known to be GBS negative

Meta-analysis does not show any benefit for women or neonates from routine antibiotic administration prior to labour in women with ruptured membranes in whom timely induction of labour is planned[9].

b) Women in whom GBS status is unknown.

Antibiotic prophylaxis should be used in line with guidance from RANZCOG guideline, "Maternal Group B Streptococcus in pregnancy: screening and management".

c) Chorioamnionitis

If chorioamnionitis is diagnosed or suspected, delivery should be expedited and broad spectrum antibiotics should be administered.

Recommendation 4	Grade and reference
In women with ruptured membranes at term, who are negative for GBS, and where timely induction of labour is planned, antibiotics should not be prescribed as part of routine care.	Grade A[4]

5.4 Should induction of labour be undertaken with oxytocin or prostaglandins?

The usual method of induction of labour in Australia is with oxytocin. Oxytocin or oral prostaglandins are used in New Zealand[10]. Prostaglandins were used in the TermPROM trial and, in this trial and a number of further small trials, including Australian data, there was no difference in outcome compared to the use of oxytocin for induction of labour. In women with an unfavourable cervix, the use of prostaglandins may have a role. Mechanical methods of induction eg. balloon catheters, are associated with an increased risk of infection, however the data is limited.

Recommendation 5	Grade and reference
Induction of labour with oxytocin is the usual method in Australia but oxytocin or oral prostaglandins are used in New Zealand. Prostaglandins may also be used in women with an unfavourable cervix.	Grade B[3]

6. Conclusion

Planned early birth leads to reduced maternal infections, reduced neonatal infections and greater maternal satisfaction without an increase in caesarean section.

7. References

1. Prelabor Rupture of Membranes: ACOG Practice Bulletin, Number 217. Obstetrics and gynecology. 2020;135(3):e80-e97.
2. Middleton P, Shepherd E, Flenady V, McBain RD, Crowther CA. Planned early birth versus expectant management (waiting) for prelabour rupture of membranes at term (37 weeks or more). Cochrane Database of Systematic Reviews. 2017(1).
3. Hannah ME, Ohlsson A, Farine D, Hewson SA, Hodnett ED, Myhr TL, et al. Induction of labor compared with expectant management for prelabor rupture of the membranes at term. TERMPROM Study Group. N Engl J Med. 1996;334(16):1005-10.
4. Saccone G, Berghella V. Antibiotic prophylaxis for term or near-term premature rupture of membranes: metaanalysis of randomized trials. American journal of obstetrics and gynecology. 2015;212(5):627.e1-9.
5. Wu YW, Escobar GJ, Grether JK, Croen LA, Greene JD, Newman TB. Chorioamnionitis and cerebral palsy in term and near-term infants. Jama. 2003;290(20):2677-84.
6. Lee SM, Lee J, Seong HS, Lee SE, Park JS, Romero R, et al. The clinical significance of a positive Amnisure test in women with term labor with intact membranes. J Matern Fetal Neonatal Med. 2009;22(4):305-10.
7. FDA. Risks Associated with Use of Rupture of Membranes Tests - Letter to Health Care Providers 2018 [updated 08/09/2018]. Available from: https://www.fda.gov/medical-devices/letters-health-care-providers/risks-associated-use-rupture-membranes-tests-letter-health-care-providers.
8. Hannah ME, Hodnett ED, Willan A, Foster GA, Di Cecco R, Helewa M. Prelabor rupture of the membranes at term: expectant management at home or in hospital? The TermPROM Study Group. Obstetrics and gynecology. 2000;96(4):533-8.
9. Wojcieszek AM, Stock OM, Flenady V. Antibiotics for prelabour rupture of membranes at or near term. The Cochrane database of systematic reviews. 2014(10):Cd001807.
10. Kerr RS, Kumar N, Williams MJ, Cuthbert A, Aflaifel N, Haas DM, et al. Low-dose oral misoprostol for induction of labour. The Cochrane database of systematic reviews. 2021;6(6):Cd014484.

8. Links to other College statements

Routine Intrapartum Care in the absence of Pregnancy Complications (C-Obs 31)

Intrapartum Fetal Surveillance Clinical Guidelines - Fourth Edition

Maternal Group B Streptococcus in pregnancy: screening and management (C-Obs 19)

Evidence-based medicine, obstetrics and gynaecology (C-Gen 15)

9. Patient information

A range of RANZCOG Patient Information Pamphlets can be ordered via the RANZCOG website

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
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
Prof 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
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 Rebecca Mackenzie-Proctor	Trainee Representative
Dr Leigh Duncan	Maori Representative
Prof Caroline De Costa	Co-opted member (ANZJOG member)
Dr Christine Sammartino	Observer

Appendix B Contributing Authors

The Women's Health Committee acknowledges the contribution of Dr Alexis Shub to 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 developed in July 2016 and reviewed recently in July 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 July 2021 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 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. 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

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Appendix D Full Disclaimer

Purpose

This Statement has been developed to provide general advice to practitioners about women's health issues concerning term prelabour rupture of membranes 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 with a term prelabour rupture of membranes. 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 with a prelabour rupture of membranes at term and the particular circumstances of each case.

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The information available in Term Prelabour Rupture of Membranes 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 andNew 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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