

CLINICAL PRACTICE **13** GUIDELINE



Management of **Prelabour Rupture of Membranes** at term

2019 Update



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Ontario **Midwives**
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CLINICAL PRACTICE GUIDELINE NO.13

Management of Prelabour Rupture of Membranes at Term 2019 Update

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The views expressed in this guideline are strictly those of the Association of Ontario Midwives. No official endorsement by the Ministry of Health and Long-Term Care is intended nor should be inferred. Endorsement by the Ministry of Health and Long-Term Care is intended or should be inferred.

The AOM is committed, through our statement on Gender Inclusivity and Human Rights, to reflect and include trans, genderqueer and intersex communities in all aspects of our work.

In this document, there are references to sources that use gendered language to refer to populations of pregnant and birthing people. In order to accurately represent these sources, we may have maintained gendered language. Furthermore, this CPG employs the use of the term “digital vaginal exams”, which we have maintained in referencing the literature, and in our recommendations and summary statements to accurately reflect this method of examination.

We support research and knowledge translation that engages and reflects the entire childbearing population.

This guideline reflects information consistent with the best evidence available as of the date issued and is subject to change. The information in this guideline is not intended to dictate a course of action, but inform clinical decision-making. Local standards may cause practices to diverge from the suggestions within this guideline. If practice groups develop practice protocols that depart from a guideline, it is advisable to document the rationale for the departure.

Midwives recognize that client expectations, preferences and interests are an essential component in clinical decision-making. Clients may choose a course of action that may differ from the recommendations in this guideline, within the context of informed choice. When clients choose a course of action that diverges from a clinical practice guideline and/or practice group protocol, this should be well documented in their charts.

This guideline was approved by the AOM Board of Directors: January 25, 2011

An updated version of this guideline was approved by the AOM Board of Directors: September 25, 2019

This document replaces AOM Clinical Practice Guideline No. 13: Management of Prelabour Rupture of Membranes at Term. The original guideline was published in 2011.

Statement of purpose

The goal is to provide an evidence-based clinical practice guideline (CPG) that is consistent with the midwifery philosophy and model of care. Midwives are encouraged to use this CPG as a tool in clinical decision-making.

Objective

The objective of this CPG is to provide a critical review of the research literature on the management of prelabour rupture of membranes (PROM) at term gestation. Evidence relating to the following will be discussed:

- Impact of PROM at term on birthing parent and neonatal outcomes
- Diagnosis and assessment of PROM at term
- Management options for PROM at term

Outcomes of interest

1. Birthing parent outcomes: infection rates, mode of delivery, satisfaction with care
2. Neonatal outcomes: perinatal morbidity, perinatal mortality

Methods

A search of the MEDLINE database and the Cochrane Library from 1994 to 2009 was conducted using the keywords: prelabour or preterm rupture of membranes, pregnancy, and management. Additional search terms were used to provide more detail on individual topics as they related to term PROM. Older studies were accessed in cases of seminal research, commonly cited sources for incidence rates, and significant impacts on clinical practice.

This CPG has been updated to reflect literature published from 2010 to 2018. The Cochrane Library, MEDLINE and CINAHL databases were searched using the keywords: prelabour (or preterm or premature) rupture of membranes, pregnancy, and management (expectant or latent period). An initial literature review was conducted for all research questions. However, revisions to this current edition of the guideline were only made where new evidence has prompted a change.

Recommendations and summary statements in this updated CPG have been marked with one of the following labels: [new 2019], [2019] or [2011]. These labels appear at the end of the recommendation or summary statement. See the table below (Key to Partial Update Labelling for Recommendations/Summary Statements) for an explanation of these labels. Table 1 in the Appendix provides a detailed list of the updated recommendations and summary statements (i.e., [new 2019] statements) in this guideline, along with an explanation for these changes.

Key to Partial Update Labelling for Recommendations and Summary Statements	
Recommendation or summary statement label	Meaning of label
[new 2019]	<p>New recommendation/summary statement as of 2019</p> <ul style="list-style-type: none"> Indicates that the recommendation or summary statement is new as of 2019. New evidence has prompted a change to or the addition of a recommendation or summary statement. An explanation of this change is provided in the Appendix (Table 1).
[2019]	<p>Reaffirmed recommendation/summary statement as of 2019</p> <ul style="list-style-type: none"> Indicates that the recommendation or summary statement is consistent with new evidence as of 2019. New evidence has not prompted a change to the original statement. Small changes may have been made to the wording of this statement, but these wording changes do not affect the meaning of the statement.
[2011]	<p>Unchanged recommendation/summary statement from 2011</p> <ul style="list-style-type: none"> Indicates that the recommendation or summary statement has not been updated since 2011. New evidence has not been reviewed. Small changes may have been made to the wording of this statement, but these wording changes do not affect the meaning of the statement.

Review

The original 2010 CPG was reviewed using a modified version of the AGREE instrument (1) and the Values-based Approach to CPG Development (2), as well as consensus of the CPG Committee, the Insurance and Risk Management Program and the AOM Board of Directors. The original CPG critically appraised the available evidence based on the Canadian Task Force of Preventive Health Care. See the table below, Key to evidence statements and grading of recommendations, from the Canadian Task Force on Preventive Health Care).

The updated (current) version of the CPG was reviewed by the CPG Committee, and the Quality, Insurance and Risk Management Committee, and approved by the Board of Directors.

Key to Evidence Statements and Grading of Recommendations, from the Canadian Task Force on Preventive Health Care*

Evaluation of evidence criteria		Classification of recommendation criteria	
I	Evidence obtained from at least one properly randomized controlled trial	A	There is good evidence to recommend the clinical preventive action.
II-1	Evidence from well-designed controlled trials without randomization	B	There is fair evidence to recommend the clinical preventive action.
II-2	Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group	C	The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making.
II-3	Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category	D	There is fair evidence to recommend against the clinical preventive action.
III	Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees	E	There is good evidence to recommend against the clinical preventive action.
		L	There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making.

*The evidence in this guideline was originally appraised using the Canadian Task Force on Preventive Health Care's (CTFPHC) key to evidence statements and grading of recommendations. (3) The CTFPHC has since adopted the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to grading the quality of evidence and strength of recommendations. In light of the partial nature of this CPG update, we have not amended our appraisal protocol at this time.

Abbreviations

BMI	body mass index	PPROM	preterm prelabour rupture of membranes
EOGBSD	early-onset group B streptococcal disease	PROM	prelabour rupture of membranes
IAP	intrapartum antibiotic prophylaxis	RCT	randomized controlled trial
MSAF	meconium-stained amniotic fluid	ROM	rupture of membranes
NICU	neonatal intensive care unit	RR	relative risk
OR	odds ratio	SROM	spontaneous rupture of membranes
PEB	planned early birth		

INTRODUCTION

Prelabour rupture of membranes (PROM) is a common variant of normal in term pregnancy. Despite the rarity of major complications, PROM is associated with increased morbidity for the birthing parent and neonate. Disagreement exists among health-care providers about the optimal management of individuals with PROM, particularly the need for and timing of induction. Midwives providing care for clients with PROM aim to avoid unnecessary interventions while facilitating the best possible outcomes for clients and newborns. The midwifery management of PROM includes: diagnosing PROM, assessing fetal and birthing parent well-being, and determining the need for and timing of induction.

Definition and terms

PROM is defined as the rupture of membranes before the onset of regular uterine contractions at term gestation ($\geq 37+0$ weeks' gestation). In the research literature, PROM has also been referred to as “premature rupture of the membranes,” which causes confusion, as this term also implies neonatal prematurity. In this document, PROM < 37 weeks' gestation is referred to as “preterm prelabour rupture of the membranes” (PPROM). The “latent period” is the interval between membrane rupture and the onset of active labour. Expectant management, sometimes referred to as “conservative management,” involves waiting for labour to begin spontaneously. Induction, also referred to as “planned management,” “planned early birth” or sometimes “active management,” involves inducing individuals with PROM within a short time following membrane rupture.

Prevalence

PROM occurs in approximately 10% of all pregnancies (from 2.7 to 17%), with 60% to 80% of cases occurring at term. (4–6) The latest available data from the Better Outcomes Registry and Network for PROM among midwifery clients in Ontario reports an incidence of 3.3% (compared with the Ontario-wide rate of 1.6%) (7).

Approximately 75% of individuals with PROM will give birth within 24 hours, 90% within 48 hours and 95% by 72 hours. (5,8–10) Approximately 3% to 4% of individuals with PROM do not begin labour within seven days from membrane rupture. (8)

Etiology

The etiology of PROM is poorly understood. Most research investigating the causes of PROM has focused on PPRM or has failed to differentiate between PPRM and PROM. Researchers have hypothesized that PPRM and PROM are products of different mechanisms, speculating that PPRM is associated with pathological mechanisms such as infection; signs of acute chorioamnionitis have been found in roughly 26% to 50% of placentas delivered following PPRM. Conversely, it is posited that PROM may simply be a result of normal parturition, including uterine contractions and fetal movement. (5,11) More recent research suggests that PROM may be a result of a “programmed weakening process,” in which the membranes weaken prior to labour, potentially due to a decrease in collagen content (which is believed to contribute to the strength of the membranes). (5,12–14) Other proposed mechanisms for PROM include membranes being weakened by mechanical forces, such as polyhydramnios, and multiple gestation. (5,15) Small case-control studies investigating the etiology of both PPRM and PROM have repeatedly found that PROM at different gestations appears to have different origins. (16–18) It has been surmised that individuals with PROM who do not go into spontaneous labour after a long latent period may have deficient prostaglandin production or prostanoid biosynthesis pathways. (19)

Associated factors

An American cohort of more than 5000 participants at 12 different sites found that a history of PROM was the strongest predictor of PROM in a subsequent pregnancy. This study examined the risk factors for PROM in participants with two successive singleton pregnancies, in an attempt to control for genetic factors. Twenty-six percent of participants who experienced PROM in their second pregnancy had PROM in their previous one. When the first pregnancy went to term without PROM, only 17% of the subsequent pregnancies had PROM ($p < 0.001$). (20) This study also found a positive association between cigarette smoking and PROM ($p < 0.05$). Two small case-control studies have questioned the importance of a number of potential risk factors for PROM. (17,18) Cases were differentiated as PPRM and PROM and were compared with controls without PROM who delivered at more than 39 weeks' gestation. In one study, involving 220 cases of PROM and 220

controls, there was an association between prior PROM and current PROM (OR 2.35, 95% CI 1.21-4.58). (17) However, no associations were found between PROM and other socio-demographic factors (education, income, adequacy of prenatal care) or behavioural factors (smoking, drug use). Medical factors from the index pregnancy, including urinary tract infection, chorioamnionitis, chlamydial or gonorrhoeal infections and lower respiratory infections, had no effect on PROM. No association was shown between PROM and prior therapeutic abortions, fetal loss/miscarriage or preterm births. (18)

Two randomized control trials explored the effects of vitamin C and E supplementation in pregnancy and their association with PROM. Participants in both trials were randomized to either a treatment arm (which

consisted of daily supplementation with vitamins C and E) or a placebo arm. (21,22) Both studies found a statistically significant association between vitamin C and E supplementation and PROM at term (RR 1.89, CI 1.11-3.23 and RR 1.65, CI 1.23-2.22, respectively). However, because the studies included participants who had supplemented with both vitamins (1000 mg of vitamin C with 400 IU of vitamin E), it is difficult to draw conclusions about associations of either vitamin on its own with the observed increased risk of PROM at term. (21,22)

A summary of factors associated with PROM \geq 37 weeks is provided in Table 1. More research, with larger sample sizes, is still needed to determine which individuals are at a higher risk for PROM.

Table 1: Factors associated with PROM occurring \geq 37 weeks' gestation

Factors associated with PROM	Association not found with PROM
<ul style="list-style-type: none"> History of PROM (18,20,23) Cigarette smoking (20) Vitamin C and E supplementation (simultaneously, 1000 mg of vitamin C with 400 IU of vitamin E during pregnancy) (21,22) 	<ul style="list-style-type: none"> Socio-demographic factors (17) Adequacy of prenatal care (17) Prior miscarriage/fetal loss/therapeutic abortion (18) Urinary tract infection (18,24) Cervical infections (gonorrhoea, chlamydia) (18,24) BMI (16)

Protective factors

Vitamin C

Although vitamin C, when supplemented along with vitamin E has been found to be associated with an increased risk for PROM at term (see *Associated factors*), the reverse has been observed when pregnant people supplemented with vitamin C without vitamin E. One RCT (n = 170), wherein participants supplemented with 100 mg of vitamin C daily, found that significantly fewer people in the supplementation group experienced PROM at term (18.8%) compared with those who supplemented with a placebo (34.1%) (RR 0.55, CI 0.32-0.94, p < 0.05). (25) It is important to note, however, that participants in this trial also supplemented daily with folic acid and iron. Furthermore, because the study authors did not assay the serum levels of vitamin C, understanding its impact on observed outcomes (separate from that of folic acid and iron) is difficult. Moreover, trial

participants were only required to supplement with 100 mg of vitamin C, whereas participants in the two aforementioned trials (21,22) were required to supplement daily with 1000 mg of vitamin C – a marked difference in dosage.

Another RCT (N = 109), wherein participants supplemented daily with 100 mg of vitamin C beyond 20 weeks' gestation, reported a significant reduction in the incidence of PROM. (13) The incidence of PROM was 7.69% in the supplementation group and 24.5% in the placebo group (RR 0.26, CI 0.078-0.837, p = 0.018). Although the mean gestational age at delivery was 38 weeks for both the intervention and control groups, the gestational ages at which PROM actually occurred were not specified.

It is believed that vitamin C supplementation during pregnancy may have a protective effect against PROM

by playing a role in collagen metabolism or reducing oxidative stress. (26) Collagen is believed to help maintain the strength of the membranes. (13,14) However, due to the small nature of these trials, it is difficult to draw conclusions about these observed associations between vitamin C supplementation in pregnancy and PROM at term.

Zinc

A 2015 Cochrane meta-analysis explored the effects of zinc supplementation on various pregnancy and infant outcomes. A positive but non-significant association was found between PROM at term and supplementation with zinc (20 mg) during pregnancy, based on two trials that reported on this outcome (n = 1691, RR 0.93, CI 0.78-1.11, p = 0.43). (27) An RCT (n = 92) published later on the effects of zinc supplementation (40 mg) on pregnancy outcomes further supports this finding. Fewer participants in the zinc sulphate supplementation group (14.6%) experienced PROM at term, in comparison with those in the control group (17.6%), although this finding is also not statistically significant (OR 0.800, CI 0.259-2.467, p = 0.697). (28)

SUMMARY STATEMENTS

Supplementing with 100 mg of vitamin C (without vitamin E) during pregnancy may reduce the risk of PROM at term. However, more research with larger sample sizes is needed. [new 2019]

There is evidence to suggest that zinc may be protective against PROM at term. However, more research with larger sample sizes is needed. [new 2019]

Complications associated with PROM

Infection in the birthing parent and the neonate is the foremost concern with PROM. Once the protective barrier of the amniotic sac is no longer intact, risk of infection may increase as bacteria ascend the vagina into the uterine cavity.

Although cord compression is generally cited as a concern, no studies investigating its incidence with PROM were found.

Table 2: Complications Associated with PROM

	Associated complication	Overall incidence	Incidence with PROM
Birthing parent complications	Chorioamnionitis	1%-4% (9,29,30)	1.2%-11% (5,31,32)
	Endometritis	After vaginal delivery: < 3% (33)	3.2% (34)
Fetal/ neonatal complications	Cord prolapse	0.002% (35)	All gestations: 0.3%-1.7% (4)
	Early-onset neonatal sepsis	Canada: 0.0002% (36)	2% (confirmed) to 6% (confirmed and suspected) (37,38)

MANAGEMENT OF PROM: EARLY INDUCTION OF LABOUR VS. EXPECTANT MANAGEMENT

Debate continues regarding the optimal management of PROM at term. Early reports from the 1960s suggested that PROM for longer than 24 hours resulted in an increase in morbidity and mortality for both the birthing parent and neonate. (31) For instance, one 1965 study showed alarming rates of maternal infection (28%)

and perinatal mortality (6.1%) among individuals with PROM ≥ 24 hours. However, researchers did not differentiate PPROM from PROM, and there was no discussion of other confounding factors, such as fever, meconium or other non-reassuring signs with PROM. (39) Based on these results, many practitioners began to recommend immediate induction for PROM.

More current research has not replicated these dramatically increased rates of adverse outcomes

with PROM. (40) Early research has limited relevance today, as few antibiotics were available at the time. Advances in treatment of infection and neonatal care have significantly improved outcomes related to birthing parent and neonatal infection for pregnancies with PROM. As the impact of infection decreased significantly over time compared with rates in these early studies, a policy of immediate induction with PROM was questioned in the face of increasing rates of caesarean section, operative delivery and use of birth technology.

More recent research has examined whether a policy of immediate induction of labour with PROM was associated with increased caesarean section rates, renewing debate about the optimal strategy for birthing parents and neonates. (8,41)

The TermPROM Study

The TermPROM Study is the largest to date focusing on the management of PROM. (6) Researchers sought to determine whether a policy of expectant management or induction of labour for individuals with PROM was preferable in terms of the risks of birthing parent and fetal infection as well as caesarean section, and whether one method of induction was superior to the other. This multi-centre RCT involved 72 institutions in six countries (Canada, the UK, Austria, Sweden, Denmark and Israel) and followed 5041 participants.

Individuals with PROM ≥ 37 weeks' gestation, as confirmed by nitrazine or fern tests, were randomized into four groups: immediate induction with vaginal prostaglandin (PGE₂); immediate induction with oxytocin; and expectant management with induction, if necessary, with prostaglandin; or with oxytocin. Study participants in the expectant management groups were induced if complications arose, or if labour did not begin spontaneously within four days (96 hours) of membrane rupture.

Overall, the TermPROM Study investigators concluded that strategies of expectant management and induction were both reasonable options for birthing parents with PROM. Neither approach was found to be clearly superior. (6) The study's findings have been instrumental in guiding best practices regarding the optimal management of people with PROM, and they comprised a majority of the participants included in the Cochrane

meta-analysis (updated in 2017) that informs much of this CPG.

Cochrane review

The updated 2017 Cochrane review examined differences in outcomes (summarized below) for individuals at ≥ 37 weeks' gestation with PROM, who were randomized into two groups: planned early birth (induction within 24 hours); and expectant management (no planned induction within 24 hours). (42) The review analyzed 23 trials (involving 8615 participants), with the TermPROM Study comprising 58.5% of total participants. Methods of induction included intravenous oxytocin (10 trials), prostaglandins (12 trials), caulophyllum (one trial) and acupuncture (one trial).

Maternal and neonatal outcomes of interest

Chorioamnionitis

The risk of maternal infection, defined as chorioamnionitis and endometritis, was lower for participants in the planned early-birth group compared with the expectant management group (6% and 11%, respectively; RR 0.47, CI 0.31-0.72, $p = 0.0003$). For chorioamnionitis specifically (suspected or proven), participants in the planned early-birth group were at lower risk than those in the expectant management group (6% vs. 11%; RR 0.55, CI 0.37-0.82, $p = 0.0037$). (42)

It is important to note that the TermPROM Study, which comprises 73% of this sub-analysis on chorioamnionitis, diagnosed most cases of chorioamnionitis based on two instances of temperature ≥ 37.5 °C occurring intrapartum (6), rather than the now more commonly used 38°C. The effect of epidural analgesia on intrapartum fever was not examined in the TermPROM Study, representing another potential confounding factor related to chorioamnionitis.

Endometritis

The updated Cochrane review investigated endometritis as a secondary outcome. Findings from one RCT reported no clear difference between the planned early-birth and expectant management groups (RR 0.25, CI 0.05-1.14, $p = 0.074$). (42)

Postpartum fever

The TermPROM Study did not investigate the outcome of endometritis. However, it did measure the incidence of postpartum fever, which implies the presence of infection. The study found a non-significant trend toward an increased incidence of postpartum fever in the expectant management group (oxytocin and prostaglandin), as opposed to the induction group (oxytocin and prostaglandin) (RR 0.75, CI 0.55-1.04, $p = 0.08$). (6)

Neonatal infection

The Cochrane review found that infants born to participants in the planned early-birth group were at a lower risk of developing definite or probable early-onset neonatal sepsis, compared with those born to participants in the expectant management group (3% vs. 4%; RR 0.73, CI 0.58-0.92, $p = 0.0071$). However, it is important to note that the absolute risk of early-onset neonatal sepsis was ultimately low in both groups. (42)

Experiences with types of care

The Cochrane review also reported on findings from two studies that evaluated individuals' experiences of planned early birth and expectant management. Participants reported more positive experiences with planned early birth. (42) However, as they were randomized to these two types of management, the results do not necessarily reflect the views of individuals who actively choose expectant management within the context of informed choice. Additionally, it is difficult to determine whether worries about their personal and/or baby's health would apply to clients in midwifery care who choose expectant management, as they have access to their midwives by phone/pager, as well as scheduled check-ins and assessments throughout their latent periods.

Other birthing parent and neonatal outcomes

There were no differences reported between the planned early-birth and expectant management groups for other outcomes, such as caesarean births, serious illnesses, maternal mortality, definite infection or death of the newborn (see Table 5). (42)

Factors that increase the risk of infection with PROM

Within the population of individuals with PROM and their newborns, certain factors can increase the risk of infection.

Digital vaginal exams

Frequent vaginal exams have been shown to present a significant risk factor for maternal infection. (43–45) Nearly all of the trials included in the Cochrane review (20 out of 23) involved participants who received digital vaginal exams upon study entry and prior to active labour. Only three of the trials (Shalev 1995, Ayaz 2008 and Selmer-Olsen 2007) reported that participants did not receive routine vaginal exams prior to active labour. (42)

Results from the Cochrane meta-analysis that stratified study participants according to whether they received a digital vaginal exam showed little to no difference in maternal infection rates (for both chorioamnionitis and endometritis) between the planned early-birth and expectant management groups. In fact, when participants did not undergo a digital vaginal exam prior to the onset of active labour, there no longer appeared to be clear benefits favouring planned early-birth (RR 0.45, CI 0.05-3.86). (42) This finding further supports a secondary analysis of results from the TermPROM Study, in that a high frequency of vaginal exams proved to be the strongest predictor of chorioamnionitis with PROM. Having more than eight vaginal exams following PROM increased the risk of developing chorioamnionitis (OR 5.07, 95% CI 2.51-10.25). (31)

The Cochrane review also reported no difference in rates of neonatal infection (definite early-onset neonatal sepsis and definite or probable early-onset neonatal sepsis) between the planned early-birth and expectant management groups when a strict protocol of avoiding digital vaginal exams was applied. Furthermore, a secondary analysis of the TermPROM Study found that seven to eight vaginal exams were significantly associated with neonatal infection (OR 2.37, 95% CI 1.03-5.43). (46)

Midwives endeavour to avoid digital vaginal exams during the latent period with PROM, and to minimize the number of vaginal exams during active labour. This will likely mitigate the slightly increased rates of infection for the birthing parent and the neonate associated with expectant management, as observed in the Cochrane review.

SUMMARY STATEMENTS

Chorioamnionitis and endometritis are associated with PROM at term. However, no difference was found in rates of infection between the planned early-birth and expectant management groups for PROM at term in trials where a strict protocol of avoiding digital vaginal exams was enforced. [new 2019]

A high frequency of vaginal exams is the strongest independent predictor of chorioamnionitis with PROM. It is also significantly associated with neonatal infection. [new 2019]

Neonatal infection is associated with PROM at term. However, no difference in rates of infection was found between planned and expectant management for PROM at term in trials where a strict protocol of avoiding digital exams was enforced. [2019]

Other factors that increase the risk of infection

Not explored in the Cochrane review, but reported in two secondary analyses of the TermPROM Study, are a series of factors that increase the risk of infection with term PROM (see Tables 3 and 4).

Infection in the pregnant and postpartum person

Factors that increase the risk of postpartum fever > 38 °C with PROM

In a secondary analysis of the TermPROM trial data, researchers found the risk of postpartum fever > 38 °C increased with the following factors (31):

- Chorioamnionitis (OR 5.37, 95% CI 3.60-8.00)
- Caesarean delivery (OR 3.97, 95% CI 2.20-7.20)
- Operative delivery (OR 1.86, 95% CI 1.15-3.00)
- Group B Streptococcus (GBS) status (OR 1.88, 95% CI 1.18-3.00)
- Receiving antibiotics before delivery (OR 1.94, 95% CI 1.06-3.57)
- Duration of active labour

Factors that increase the risk of chorioamnionitis with PROM

In a secondary analysis of the TermPROM trial data, researchers found the risk of chorioamnionitis increased with a series of factors (see Table 3).

Table 3: Factors That Increase Risk of Chorioamnionitis with PROM at Term (31)

Risk factor	Estimated odds ratio of chorioamnionitis (95% CI, p < 0.05)
3-4 vaginal exams	2.06 (1.07-3.97)
5-6 vaginal exams	2.62 (1.35-5.08)
7-8 vaginal exams	3.80 (1.92-7.53)
> 8 vaginal exams	5.07 (2.51-10.25)
Meconium-stained amniotic fluid	2.28 (1.67-3.12)
Nulliparity	1.80 (1.29-2.51)
GBS status	1.71 (1.23-2.38)
Active labour 6-9 hours (vs. < 3 hrs)	1.97 (1.18-3.25)
Active labour 9-12 hours (vs. < 3 hrs)	2.94 (1.75-4.94)
Active labour ≥ 12 hours (vs. < 3hrs)	4.12 (2.46-6.9)
Latent period 24-48 hours	1.77 (1.27-2.42)
Latent period ≥ 48 hours	1.76 (1.21-2.55]

SUMMARY STATEMENT

The main predictors of infection in the pregnant and postpartum person with PROM include: frequent vaginal exams, meconium-stained amniotic fluid, nulliparity, GBS-positive status, active labour > 6 hours and a latent period > 24 hours. [new 2019]

Neonatal infection

The risk of neonatal infection appears to rise with particular factors in combination with PROM (see Table 4).

Risk factor	Estimated odds ratio of neonatal infection (95% CI, p < 0.05)
Chorioamnionitis	5.89 (3.68-9.43)
GBS status	3.08 (2.02-4.68)
Latent period of 24-48 hours	1.97 (1.11-3.48)
Latent period ≥ 48 hours	2.25 (1.21-4.18)
Administration of antibiotics before delivery (due to suspected or actual chorioamnionitis)	1.63 (1.01-2.62)

SUMMARY STATEMENTS

The main predictors of neonatal infection include: chorioamnionitis, GBS-positive status, increased frequency of vaginal exams, and a latent period > 24 hours. [new 2019]

COMPARING USE OF PAIN MEDICATION FOR INDUCTION OF LABOUR VS. EXPECTANT MANAGEMENT WITH PROM

The Cochrane meta-analysis included a sub-analysis that examined the use of epidural analgesia, which included five trials (n = 585). There was no difference found in the administration of epidural analgesia for participants in the planned early-birth and expectant management groups (22.7% vs. 21.7%, p = 0.65). (42)

The TermPROM Study similarly found no difference in the rate of analgesia use between the induction (oxytocin) and expectant management (oxytocin) groups (40.5% vs. 40.8%, p = 0.87). (6)

Table 5 provides a summary of outcomes for PROM management strategies.

RECOMMENDATIONS

- 1. For clients with PROM > 37+0 weeks, discuss the risks and benefits of both expectant management and induction of labour. In the absence of abnormal findings and when digital vaginal exams are avoided before the onset of active labour, expectant management and induction are both appropriate options. [I-A] [new 2019]**
- 2. Inform clients with PROM who choose expectant management that they have the option to revisit their management plan and may choose induction of labour if they no longer desire expectant management. [III-A] [2019]**
- 3. To reduce the risk of infection, avoid digital vaginal exams for clients with PROM whenever possible, until active labour or upon induction. [I-A] [2019]**

Table 5: Summary of Outcomes for Planned Early Birth vs. Expectant Management of PROM

Outcome	Planned early birth	Risk ratio
Chorioamnionitis (suspected or proven)	Decreased risk (p < 0.05)	0.55 (0.37-0.82)
Chorioamnionitis and/or endometritis People who did not receive a digital vaginal exam before onset of active labour	No difference (p = 0.46)	0.45 (0.05-3.86)
Endometritis	No difference (p = 0.074)	0.25 (0.05-1.14)
Assisted delivery	No difference (p = 0.90)	1.03 (0.67-1.59)
Caesarean section	No difference (p = 0.10)	0.84 (0.69-1.03)
Neonatal infection (definite early-onset neonatal sepsis)	No difference (p = 0.19)	0.57 (0.24-1.33)
Neonatal infection (definite or probable early-onset neonatal sepsis)	Decreased risk (p < 0.05)	0.73 (0.58-0.92)
Neonatal infection (definite or probable early-onset neonatal sepsis) People who did not receive a digital vaginal exam before onset of active labour	No difference (p = 0.49)	0.70 (0.25-1.94)
Use of epidural analgesia	No difference (p = 0.65)	1.07 (0.80-1.42)
Use of antibiotics	Lower rate of use (p < 0.05)	0.61 (0.44-0.84)
Time from rupture of membranes to birth (hours)	Shorter time from ROM to birth (p < 0.05)	-10.10 (-12.15 to -8.06)

Table 6: Abnormal findings with PROM

- Meconium in amniotic fluid
- Frank vaginal bleeding
- Fever (T > 38.0 °C)
- Evidence of infection (foul-smelling amniotic fluid, uterine tenderness)
- Abnormal fetal heart rate, tachycardia
- Decreased fetal movement

ANTEPARTUM MANAGEMENT

Informed choice

Given the quantity of information about PROM management and the factors that can affect decision-making around this event, having a discussion of the management options in the event that PROM does occur during the prenatal period may help prepare clients and their families for these decisions.

Information sharing regarding signs and symptoms of PROM, as well as when and how to notify the midwife in cases of suspected PROM, will ideally occur during the prenatal period, before it presents.

Diagnosis and initial assessment

Although a client's report of ruptured membranes must be taken seriously, it is important for the midwife to confirm PROM so appropriate management can be planned. Other fluids, such as urine, vaginal discharge, copious bloody show and/or semen, may be mistaken for amniotic fluid. (47)

Phone assessment

Midwives are available to their clients on a 24-hour basis. Therefore, clients usually report signs and symptoms of PROM by phone. No research was found to recommend or reject phone assessment for PROM history-taking and initial management. Despite the limited evidence, assessment by phone for suspected PROM seems like a reasonable first step for midwives.

During the assessment, the midwife should ask the client about the following: time of suspected rupture; colour, smell and amount of fluid; whether or not the fluid continues to leak; whether or not the fetus has been active since the suspected rupture; GBS status (if known); engagement of presenting part documented at the most recent prenatal visit; vaginal bleeding; and the presence and pattern of contractions.

The midwife should do a prompt in-person assessment if there are any abnormal signs or symptoms present. If the client's history is clear and all signs and symptoms are normal (clear fluid, presence of fetal movement, GBS negative or GBS positive), and they choose a period of expectant management, the midwife would usually

do an in-person assessment within 24 hours from the time of membrane rupture. If the history is unclear, the midwife should assess as soon as is practical, to confirm or rule out PROM. They should inform the client during the phone conversation of the signs and symptoms of chorioamnionitis and how to monitor for signs of infection. The client should be made aware of when to contact the midwife for a more timely assessment in the case of abnormal findings or the onset of active labour.

In-person assessment

Location of assessment

Midwives offer assessments at the client's home, in a clinic or in the hospital. All of these options are reasonable, provided that the midwife carries the appropriate tools to confirm or rule out PROM, and that the client's history excludes any urgent need to be hospitalized for assessment. In the absence of circumstances that warrant an immediate PROM assessment, there is no evidence to recommend a particular location for an in-person assessment of PROM.

RECOMMENDATION

4. **Initial assessment for PROM may take place by phone or in person.**
 - a. **If no abnormal signs or symptoms are present during history-taking by phone for suspected PROM, conduct an in-person assessment to confirm PROM. Following the phone assessment, make a management plan within 24 hours after membrane rupture. Ensure that the client is aware of when and how to contact the midwife to arrange an earlier assessment in the event that abnormal signs develop: presence of meconium in amniotic fluid, frank vaginal bleeding, fever > 38 °C, foul-smelling amniotic fluid or decreased fetal movement. [III-A] [2011]**
 - b. **If abnormal signs or symptoms are present during history-taking related to PROM, an immediate in-person assessment is warranted. [III-A] [2011]**

DIAGNOSIS OF PROM

Three main methods are currently used to confirm PROM: a sterile speculum exam, a nitrazine test and/or a fern test. These have been utilized for over 60 years, and they remain the standard for assessing PROM. Despite this, diagnosing PROM remains a common problem, as there is no single universally accepted method for confirming rupture of membranes. (48)

Although newer procedures have been developed to diagnose rupture of membranes, these remain less widely used than the standard tests, due to a combination of lower sensitivities, slower results and higher cost. With all tests for PROM, it is imperative that midwives employ sterile technique and avoid performing any vaginal exams, to minimize the risk of infection in the birthing parent and/or the neonate. When results from any of the tests are uncertain, multiple tests, along with the midwife's clinical judgment, should be used to obtain a clearer clinical picture.

Sterile speculum exam

A sterile speculum exam, without lubrication, confirms PROM through the observation of amniotic fluid trickling from the cervix and pooling in the speculum. (15) If no fluid is initially visible, the client may be encouraged to cough or strain. A sterile speculum exam also permits visualization of possible cord prolapse. Although the visualization of fluid issuing from the cervix is a commonly used method to diagnose PROM, the absence of visualized fluid may produce a false negative result. One study found the speculum exam to have a false negative rate of 12%. In this study, no information was provided about the false positive rate. (48)

A sterile speculum exam may also be an effective option for assessing the dilation and effacement of the cervix, avoiding a digital exam in cases where this information is deemed necessary to formulating a management plan. A prospective study that included 133 participants compared the accuracy of speculum exams with digital vaginal exams when assessing the dilation and effacement of the cervix. Good correlation was noted, with less than 20% mean variation between digital and speculum exams. (49)

Nitrazine test

The nitrazine test confirms PROM by detecting an alteration in the vaginal pH level. The pH of amniotic fluid ranges from 7.1 to 7.3, while normal vaginal fluids usually have a pH of 4.5 to 6.0. The yellow nitrazine swab changes to a dark blue when the pH is greater than 7.0, as in the presence of amniotic fluid. (9) Blood, semen, alkaline antiseptics, vaginitis and cervicitis may result in false positive results. (47) False negative results may occur with prolonged fluid leakage where minimal residual fluid is observed. (50) A study in the late 1960s involving 100 participants reported that the nitrazine test had a false positive rate of 17.4% and a false negative rate of 9.7%. (47)

Fern test

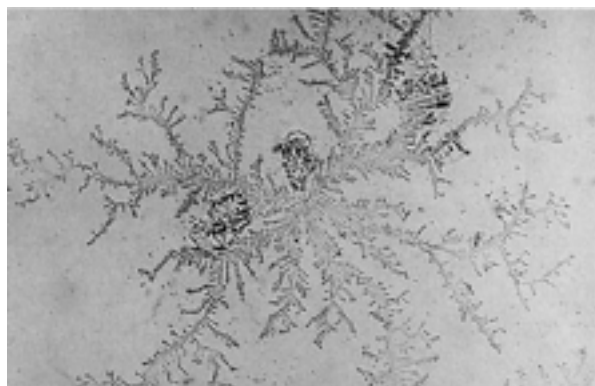
The fern test (also known as arborization) involves swabbing the amniotic fluid and smearing it on a microscope slide. Once the fluid has air dried (after approximately 10 minutes), it exhibits a characteristic fern-like crystallization pattern visible under low magnification (see Fig. 1). This test is not affected by dilute concentrations of blood. However, a high concentration of blood or meconium may give a false negative result. (51) The fern test has a false positive rate of 3% to 6% and a false negative rate of 3.75% to 12.9%. (47,51) Because the fern test has a higher sensitivity, a positive fern test should be considered evidence of ROM, even if a nitrazine test is negative. Access to a microscope may not be possible for in-home assessments; however, the fern test is only indicated if the other methods prove insufficient to make a diagnosis. Midwives can carry slides to a home visit and return to the office or hospital for evaluation, if necessary.

See Table 7 for a summary of the sensitivities and specificities of PROM diagnostic tests.

Table 7: Sensitivity and Specificity of PROM Diagnostic Tests

Test	False positive rate	False negative rate
Sterile speculum exam	N/A	12% (48)
Nitrazine test	17.4% (47)	9.7% (47)
Fern test	3-6% (47,51)	3.75%-12.9% (47,51)

Figure 1: Positive Fern Test (52)



Ultrasound

Ultrasound may be used to document oligohydramnios, but it is not diagnostic of PROM. (50) However, it can be a useful tool when history is unclear and diagnostic tests are equivocal, since the presence of a normal amount of amniotic fluid decreases the likelihood of a PROM diagnosis. (53)

Timing of PROM diagnosis

No studies were identified that assessed the efficacy of PROM diagnostic tests at different intervals following suspected PROM.

SUMMARY STATEMENTS

Other than circumstances that warrant an immediate PROM assessment in hospital (lack of fetal movement, meconium-stained amniotic fluid, signs of infection), there is no evidence to recommend a particular location for the in-person assessment of PROM, which may take place in the client's home, at a clinic or in the hospital. [2011]

No single PROM diagnostic test has been found to be completely accurate, with all methods producing false positive and false negative results. [2011]

RECOMMENDATIONS

5. Diagnosis of PROM may be performed with one or more of the following: a sterile speculum exam, a nitrazine test and/or a fern test. Results should be interpreted in combination with a client's history of PROM. [II-2-B] [2011]
6. When results from any of the tests are uncertain, multiple methods (a sterile speculum exam, a nitrazine test and/or a fern test), as well as the

midwife's clinical judgment, should be used to obtain a clearer clinical picture. Decision-making may be supported by ultrasound evaluation of the amniotic fluid volume in instances when PROM results are uncertain, following other diagnostic tests. [III-B] [2011]

PRACTICAL ASPECTS OF PROM MANAGEMENT

Monitoring well-being during expectant management

None of the studies reviewed have confirmed an ideal regimen for monitoring of the birthing parent and the neonate during expectant management of PROM. Any abnormal findings should be regarded as contraindicating expectant management. The frequency and rigour of monitoring varies considerably between studies, and there is no ideal process for monitoring.

No research was found that compared different protocols for expectant management monitoring. Given the low rates of morbidity and mortality among all participants, these studies approximate what types of monitoring may be considered as reasonable for practice (see Table 8 for examples of monitoring protocols used in PROM studies of expectant management). Until studies are published that evaluate and compare monitoring protocols, it will be difficult to make best practice recommendations for the expectant management of clients with PROM at term. It would seem reasonable, however, for midwives to conduct daily in-person assessments to monitor the well-being of the birthing parent and the fetus for clients with PROM who choose expectant management. No research was found regarding the efficacy of using a non-stress test for evaluation of fetal well-being during the latent period for individuals with PROM.

Table 8: Monitoring Protocols Used in PROM Studies of Expectant Management

Trial	Starting week	Birth parent and fetal monitoring protocols
Hannah, 1996 (54)	37	<ul style="list-style-type: none"> • Checked temperature twice daily • Checked colour and odour of amniotic fluid
Natale, 1994 (55)	37	<ul style="list-style-type: none"> • Daily white blood cell count and differential • Temperature q4h while awake • Fetal heart rate q4h • Daily non-stress test
Duff, 1984 (10)	36	<ul style="list-style-type: none"> • Temperature q4h • Fetal heart rate q4h • White blood cell count upon admission and q24h
Kappy, 1982 (8)	36	<ul style="list-style-type: none"> • Daily complete blood count and differential • Temperature q4h while awake • Daily evaluation of uterine tenderness • Weekly non-stress test
Maqbool, 2014 (56)	37	<ul style="list-style-type: none"> • Uterine activity monitored • Sterile pad, antibiotic cover and fetal heart rate monitoring
Shah, 2012 (57)	37	<ul style="list-style-type: none"> • Uterine contractions monitored for 24h

RECOMMENDATIONS

7. Ensure that clients with PROM who choose expectant management are aware of when and how to contact their midwife for support should complications develop. [III-A] [2011]

- When is the ideal time to start intrapartum antibiotic prophylaxis (IAP)?
- When is the ideal time to induce labour?

8. For clients with PROM who choose expectant management, the midwife should conduct a daily in-person assessment in the client's home, at a clinic or in the hospital. This should include: monitoring vital signs of the birthing parent and the fetus and examining the amniotic fluid, as well as a discussion of the client's emotional well-being. If the midwife notes any contraindications to expectant management during the physical exam, or if any other emotional or psychological concerns arise, they may offer induction of labour. [III-B] [2011]

No prospective studies have been designed to examine either of these questions. The most relevant published evidence comes from secondary analyses of data collected as part of the TermPROM Study. Of the 5041 participants, 4834 were cultured for GBS at delivery. Researchers found a non-significant trend suggesting that GBS carriers were at lower risk of early-onset group B streptococcal disease (EOGBSD) if they were induced with oxytocin rather than managed expectantly (OR 0.29, 95% CI 0.08-1.05, p = 0.06). (46) This study has led the Society of Obstetricians and Gynaecologists of Canada (SOGC) to recommend that individuals with term PROM be offered induction immediately. (58)

PROM and GBS

The combination of PROM and GBS-positive status raises two significant questions for care providers:

Although the TermPROM Study points to a correlation between GBS status and neonatal infection, this RCT predates implementation of the IAP screening and treatment strategy. The GBS status of many participants

in the TermPROM Study was not known until after delivery. Additionally, despite the study's protocol to give IAP to participants known to be GBS positive upon entry to the trial, antibiotics were administered to a minority of participants, which may have contributed to higher neonatal infection rates. The TermPROM Study does not provide sufficient evidence to compare the strategy of immediate induction of labour with induction after a moderate waiting period or with ongoing expectant management within the context of universal prenatal screening and IAP for all who tested positive for GBS. Further research into the timing of induction for GBS-positive individuals with PROM is warranted.

One 1999 publication reanalyzed previously published data to establish odds ratios for factors associated with increased risk for EOGBSD in neonates. This new analysis calculated the OR of EOGBSD at stratified time periods from the data of three studies (59–61) (see Table 9), revealing higher risk of EOGBSD with increased length of ruptured membranes. (62) It is important to note that these figures relate to the timing of amniotic membrane rupture and not specifically to PROM. They are not reflective of current practices for administering IAP. Because this was a secondary analysis of data collected prior to the introduction of universal screening and IAP, it is difficult to determine whether or not the calculated risks remain valid today.

Table 9: ORs for EOGBS Stratified by Duration of Amniotic Membrane Rupture* (62)

Duration of ROM (hrs)	OR (95% CI)	P All groups	P Groups ≤ 18 hrs	References
0-6	1.0	0.24	0.76	(60)
6-12	1.33 (0.28-6.30)			
12-18	2.05 (0.42-9.73)			
> 18	7.32 (2.24-23.8)			
0-6	1.0	< 0.001	0.089	(59)
7-12	2.43 (1.12-5.32)			
13-18	2.00 (0.76-5.30)			
19-24	7.48 (3.48-16.0)			
25-48	11.4 (5.32-24.4)			
> 48	14.3 (6.39-32.1)			
0-9	1.0	< 0.001	0.71	(61)
10-19	1.60 (0.25-10.1)			
20-29	26.5 (8.95-78.2)			
30+	28.8 (10.1-82.1)			
Pooled data for patients with ROM ≤ or > 18 h or < or ≥ 20 h from above studies				
≤ 18	1.0	0.0025		(60)
> 18	5.92 (2.1-16.1)			
≤ 18	1.0	< 0.001		(59)
> 18	7.23 (4.42-12.0)			
< 20	1.0	< 0.001		(61)
≥ 20	26.2 (10.7-63.9)			

* Regardless of whether rupture of membranes occurred during labour or prior to labour

Studies related to administering antibiotics prior to active labour for GBS-positive individuals with term PROM during expectant management were not found. In the absence of literature on this topic, midwives are currently using various approaches to ensure adequate administration of IAP for these clients; however, further research is necessary. These gaps in research, along with the range of approaches to PROM and GBS management and variations in local community standards, should be thoroughly discussed with clients as part of an informed choice discussion.

For a full discussion related to management of GBS, please see AOM CPG 11, Group B Streptococcus: Prevention and Management in Labour.

RECOMMENDATIONS

- 9. Inform clients of the research gaps regarding the most effective approach to preventing EOGBSD in infants born to GBS carriers who experience term PROM. [III-B] [2011]**
- 10. Offer a choice between expectant management and immediate induction of labour with oxytocin to clients with a positive GBS swab result at term who experience PROM for < 18 hours and have no other risk factors [III-B]. [2011]**
- 11. Recommend induction of labour with oxytocin to GBS-positive clients with PROM \geq 18 hours [III-B]. IAP should be offered upon initiation of induction. [2011]**
- 12. Offer GBS-positive clients with PROM who choose expectant management a range of options for prophylactic antibiotic administration:**
 - a. IAP in active labour [II-2-B] [2011]**
 - b. IAP in the latent phase [III-C] [2011]**
 - c. IAP upon initiation of induction of labour [III-B] [2011]**

Note: Recommendations 9-12 differ from those of the SOGC. The AOM recognizes the existing research gaps pertaining to the appropriate management of individuals with term PROM who present with group B streptococcus, particularly in light of changes to the implementation of the IAP screening and treatment strategy. Given these gaps in the evidence, rigorous information-sharing with clients is essential, to assist them in making decisions about their course of care.

Expectant management: home or hospital?

Midwives routinely offer clients with PROM the option of expectant management at home, rather than requiring hospital admission prior to the onset of active labour. Very little research has been done to compare the outcomes of expectant management in the home versus in the hospital.

In a secondary analysis of findings from the TermPROM Study, 1670 participants assigned to expectant management also had information collected about their location of management. It is important to note that individuals were not randomly allocated to home or hospital, but that the location of management followed particular hospital routines or were made by individual physicians. (63) With multiple regression analysis, it was found that participants managed at home were more likely to have neonates with infection (OR 1.97, CI 1.00-3.90). Primiparas managed at home were more likely to receive antibiotics (OR 1.52, CI 1.04-2.24), and GBS-negative participants managed at home were more likely to deliver by caesarean section (OR 1.48, CI 1.03-2.14). (63) While the authors concluded that it was “generally safer” for individuals with PROM to remain in hospital for expectant management, several factors suggest caution in assuming that these findings should inform midwifery practice. First, it is possible that the outcomes may have differed if participants were randomly allocated to home or hospital. Second, despite an attempt to avoid vaginal exams in the study, the analysis did not control for this factor, which is known to be a strong predictor of infection. Finally, it is unclear whether or not the participants allocated to expectant management at home received care similar to that offered by Ontario midwives, including routine explanation of practices to minimize risk of infection, regular in-person care

to evaluate well-being of the birthing parent and the fetus, and good access to a health-care provider in the event of questions or concerns. Secondary analysis of findings from the TermPROM Study also showed that individuals who had already given birth were more likely to positively evaluate care if expectant management took place at home rather than in the hospital, indicating that this group preferred to remain at home. (63)

Other studies that appear to address non-hospital expectant management are very small, non-randomized designs. A prospective Swedish study examined the outcomes of 176 primiparas with PROM who were expectantly managed at home or in clinic. The results were compared with those for a historical group, and they found no differences in instrumental delivery or rates of maternal or neonatal infection. (64)

SUMMARY STATEMENT

Existing evidence to recommend expectant management in hospital for individuals with PROM is weak. Remaining at home during the latent period is recommended. In some circumstances, for example where clients planning hospital births must travel long distances, in-hospital management may be a more practical strategy for the latent period. [2011]

RECOMMENDATIONS

13. For clients who choose expectant management following PROM at term, remaining at home during the latent period is recommended, provided that daily in-person assessments take place and that the client is aware of how and when to contact the midwife. In-person assessments should include: monitoring vital signs of the birthing parent and the fetus and examining the amniotic fluid, as well as a discussion of the client's emotional well-being. [III-B] [2011]

Timing of induction for PROM: when is the latent period too long?

There is no definitive length of the latent period at which the risks of PROM significantly increase. Four studies were found that addressed the length of the latent period during expectant management of PROM and the risk of infection for the birthing parent and/or the neonate.

Secondary analyses of the TermPROM Study showed that clinical chorioamnionitis occurred in 6.7% of study participants, or 335/5028 participants. (31) The absolute risk of clinical chorioamnionitis from time of rupture of membranes to onset of active labour was:

- 1.3% < 12 hours
- 1.5% from 12 to < 24 hours
- 2.3% from 24 to < 48 hours
- 1.35% ≥ 48 hours

The key single predictive factor for chorioamnionitis was multiple vaginal exams. (31)

The TermPROM Study did not show any significant difference in the overall rate of neonatal infection between the expectant management and induction groups. In a secondary analysis of the TermPROM Study, the absolute risks of neonatal infection at different time intervals from rupture of membranes to onset of labour were: (46)

- 0.77% from 12 to < 24 hours
- 0.82% from 24 to < 48 hours
- 0.54% ≥ 48 hours

This secondary analysis notes that the key single predictive factor for neonatal infection was the presence of chorioamnionitis (OR 5.89, $p < 0.0001$). (46)

A randomized prospective study done in Israel assigned 566 participants with PROM to expectant management with a limit of 12 or 72 hours. (65) It excluded anyone who had undergone a digital vaginal exam prior to active labour, and it had a strict policy to restrict vaginal exams to active labour or onset of induction. There was no significant difference in the incidence of clinical chorioamnionitis between the 12-hour group (11.7%) and the 72-hour (12.7%) group (RR 0.9, 95% CI 0.6-1.5, $p = 0.83$). In addition, no significant differences between the groups were found in rates of caesarean delivery or neonatal sepsis. (65) Without significant differences in maternal or neonatal outcomes, these results support individuals who choose expectant management for up to 72 hours. It should be noted that the study population had a median gravidity of 3, which may make the findings less applicable to the Canadian population.

A 2013 meta-analysis examined the risk of early-onset neonatal infection resulting from maternal infection or colonization. (66) It included a sub-analysis on the duration of ruptured membranes and the newborn's risk for neonatal infection. Neonates born to participants whose membranes were ruptured for ≥ 18 to 24 hours had 2.2 times the infection risk found in newborns of individuals with membranes that ruptured for < 18 hours, although this finding was not statistically significant (95% CI 0.6-7.4). (66)

An observational cohort study done in Italy examined differences in outcomes, including chorioamnionitis, for individuals with term PROM who experienced spontaneous birth within 48 hours or who were induced > 48 hours; 1315 participants met the inclusion criteria for term PROM. (5) Labour occurred spontaneously for 84% of these individuals, and 16% of them were eventually induced. Overall, 76.5% of participants experienced active labour within 24 hours, and 90% within 48 hours. The majority who experienced spontaneous labour delivered vaginally (97.5%). The study authors noted that this was likely due to the extra time allowed for cervical ripening. These participants also experienced fewer caesarean sections (2.5%) compared with those who were induced (15.5%).

Length of term PROM > 24 or > 48 hours was not significantly associated with maternal and neonatal infection rates. The overall rate of chorioamnionitis was 1.2%; however, when participants who delivered within 24 hours were excluded, the infection rate rose slightly, to 2.3%. Similarly, the overall neonatal infection rate was 2.5%, although when participants who delivered within 24 hours were excluded, a slight rise in neonatal infections was observed (2.8%). The factors positively associated with maternal infections included more than eight vaginal exams and induction of labour, whereas neonatal infection was associated with chorioamnionitis (OR 12.48, CI 5.58-27.9, $p < 0.001$) and more than eight digital vaginal exams during labour (OR 3.32, CI 1.54-7.15, $p < 0.00039$).

Length of term PROM was not found to be associated with caesarean section. Of the 140 participants who experienced term PROM > 48 hours, only 18 underwent caesarean sections. (5)

RECOMMENDATIONS

- 14. In the absence of signs of infection in the birthing parent or the fetus, inform clients who are GBS negative and who choose expectant management that it is reasonable to wait for up to 96 hours before induction of labour. [I-A] [2011]**
- 15. As part of an informed choice discussion regarding expectant management and the length of the latent period, inform clients that chorioamnionitis and neonatal infection rates increase ≥ 24 hours after PROM. [II-2-B] Inform clients that avoiding vaginal exams until the onset of active labour appears to mitigate this risk, and it is therefore an important part of an expectant management approach. [I-A] [new 2019]**
- 16. Inform clients who choose expectant management beyond 96 hours that no available research quantifies any potential increase in the risk of infection in the birthing parent or the neonate. [III-B] [2019]**

Prophylactic Antibiotics for PROM at Term

As PROM may increase the risk of infection for the birthing parent and the neonate, it has been suggested that the administration of prophylactic antibiotics such as ampicillin could reduce the occurrence of infection. A small but growing body of research exists regarding the routine administration of prophylactic antibiotics for individuals with PROM at term.

A Cochrane meta-analysis from 2014 assessed four trials that involved a total of 2639 participants at ≥ 36 weeks' gestation. (67) Trials were included if they compared the use of antibiotics during labour to no antibiotics or a placebo for individuals with PROM at term. The use of antibiotics resulted in little to no difference in the risk of maternal infection, defined as chorioamnionitis or endometritis (RR 0.48, CI 0.20-1.15, $p = 0.10$). No serious maternal outcomes (which the study defined as death, cardiac arrest, respiratory arrest, anaphylaxis or admission to an intensive care unit) were reported in any of the included trials. (67)

Furthermore, no clear benefit was observed for neonates of birthing parents who were administered prophylactic antibiotics. Little to no difference was observed between

groups for probable early-onset neonatal sepsis (RR 0.69, CI 0.21-2.33, $p = 0.55$), definite early-onset neonatal sepsis (RR 0.57, CI 0.08-4.26, $p = 0.58$), or stillbirth (two of the three trials that reported on this outcome did not observe any cases of stillbirth) (RR 3.00, CI 0.61-14.82, $p = 0.18$). (67)

A subsequent meta-analysis (2015) that reported on findings from four of the trials included in the 2014 Cochrane review contained a sub-group analysis that examined outcomes for birthing parents with PROM with a latent period > 12 hours. Among these participants, rates of maternal infection (chorioamnionitis and endometritis) were lower for those who were administered prophylactic antibiotics in comparison with participants who did not receive antibiotics: chorioamnionitis 36/1324 (2.7%) vs. 49/1315 (3.7%), and endometritis 5/1324 (0.4%) vs. 13/1315 (0.9%). At least one-third of participants among the studies covered by the sub-analysis had no treatment protocol for GBS. The potential presence in the control group of GBS that was untreated and uncontrolled for may have been a factor in the higher infection rates for those with longer latent periods. As such, this sub-analysis should be interpreted with caution.

This evidence must also be considered within the wider context of risks associated with use of antibiotics in the intrapartum period, which can increase the risk of antibiotic resistance for both the parturient and the fetus or neonate, thus complicating treatment for common infections (67,68). Ampicillin, an antibiotic commonly administered during the intrapartum period (and used in three of the trials reported in the aforementioned meta-analyses), is an independent risk factor for ampicillin-resistant *Escherichia coli* early-onset sepsis. (68,69) The use of antibiotics in the intrapartum period has also been linked to the development of allergies and illnesses in children, as they have the potential to disrupt the development of the newborn's gut microbiota. (68,70)

Furthermore, antibiotic use may (very rarely) result in anaphylactic shock, which can result in serious life-threatening outcomes for the labouring person, as well as the fetus or newborn, who may experience oxygenation impairment. (67,68) As governments and key stakeholders in health care worldwide increasingly

address the immediate and long-term impacts of antibiotic overuse and misuse, including antibiotic resistance, midwives must prudently weigh the benefits and drawbacks of antibiotic use in the intrapartum period.

SUMMARY STATEMENT

In the absence of signs of infection in the birthing parent, inform clients with term PROM that there is no evidence that the use of prophylactic antibiotics reduces rates of infectious morbidity in the birthing parent (chorioamnionitis or endometritis) or neonatal infections. [new 2019]

More research is needed on the use of prophylactic antibiotics to reduce infectious morbidity for those with PROM with a latent period of > 12 hours. [new 2019]

INTRAPARTUM MANAGEMENT

Baths

Having ruptured membranes could put individuals at increased risk for infection during baths, because water entering the vagina could facilitate the passage of microorganisms into the uterine cavity. Microorganisms may originate from the birthing parent or may already be present in the tub. (71) Midwives often recommend warm baths during labour, as they promote relaxation and may reduce pain during labour. (72,73)

Two studies were identified that examined whether or not a warm bath during labour increases the risk of infection in the birthing parent with PROM or the neonate. (71,74) In one non-randomized study of 1385 individuals with PROM > 34 weeks' gestation (538 of whom wanted a bath during labour and 847 who did not), no differences in maternal or neonatal infectious morbidity were detected between the bath group and the reference group. The authors analyzed the incidence of maternal or neonatal infectious morbidity for those with PROM < 24 hours and with PROM ≥ 24 hours. No differences were found between the two subgroups. (74) A retrospective cohort study ($n = 178$) also found no differences in maternal or neonatal infection rates between groups. No information related to the number of vaginal exams or the interval from the first digital exam until birth was available. (71)

SUMMARY STATEMENT

Evidence shows that taking a warm bath during labour with PROM is not associated with infectious morbidity in the birthing parent or the neonate. Warm baths during labour may be recommended for clients with PROM. [2011]

Intrapartum fetal monitoring with PROM

No research literature was found to suggest that PROM or prolonged PROM in the absence of any evidence of fetal compromise is an indication for continuous electronic fetal monitoring (EFM).

In its clinical practice guideline on fetal health monitoring, the SOGC notes that the use of continuous EFM may be beneficial with PROM > 24 hours. (75) The SOGC states that due to insufficient evidence to suggest which situations (including PROM > 24 hours) would benefit from EFM, that it may be beneficial. The SOGC does note that in comparison with intermittent auscultation, EFM in labour is associated with increased rates of caesarean section and instrumental vaginal birth. Attention to fetal heart rate is important for detecting fetal tachycardia, one of the first signs of clinical chorioamnionitis. However, this difference in associated outcomes is important to consider when making a decision regarding the appropriate fetal monitoring method.

RECOMMENDATION

17. In the absence of meconium staining of the amniotic fluid and any signs of infection in the birthing parent or the fetus, it is appropriate for midwives to use intermittent auscultation as a method of intrapartum fetal monitoring for clients with PROM. [III-B] [2011]

POSTPARTUM MANAGEMENT

Treatment of the newborn

PROM is associated with neonatal infection; therefore, care of the newborn following pregnancies affected by PROM includes monitoring for neonatal infection. The following is a summary of research related to PROM and neonatal infection rates:

- Newborns born to participants in the planned early-birth group were at a lower risk of developing definite or probable early-onset neonatal sepsis compared with newborns born to participants in the expectant management group (RR 0.73, CI 0.58-0.92, $p = 0.0071$). However, no significant difference was found in definite early-onset neonatal sepsis rates between the planned early-birth and expectant management groups (RR 0.57, CI 0.24-1.33, $p = 0.19$).
- Upon secondary analysis of the TermPROM Study, certain factors in combination with PROM appear to be associated with a higher risk of neonatal infection: chorioamnionitis (OR 5.89, 95% CI 3.68-9.43, $p < 0.0001$), GBS-positive status (OR 3.08, 95% CI 2.02-4.68, $p < 0.0001$), a latent period ≥ 48 hours (OR 2.25, 95% CI 1.21-4.18, $p = 0.01$) and more frequent vaginal exams (seven to eight) (OR 2.37, 95% CI 1.03-5.43, $p = 0.04$) (46) (II-2).
- In studies where a strict protocol was used of avoiding digital exams until induction of labour or active labour, there was no difference in neonatal infection rates (42,43,65) (I).
- The well newborn whose birthing parent is GBS negative and healthy may be assessed as usual, based on clinical signs and symptoms of infection. Diagnostic evaluation for sepsis is unnecessary for the clinically well neonate born to this group.
- As always, if the neonate has any signs or symptoms of infection upon newborn exam or any subsequent exam, a prompt consultation with a physician is recommended.

Refer to AOM Clinical Practice Guideline No. 11 Group B Streptococcus: Prevention and Management in Labour (2014) for recommendations on neonatal follow-up for newborns whose gestational parent had PROM and is GBS positive, and where IAP has been administered fully, partially or not at all.

RECOMMENDATION

18. The healthy infant born to clients with PROM who are GBS negative may be assessed by the midwife as usual, based on clinical signs and symptoms of infection. (III-A) [2011]

CONCLUSION

Overall, PROM presents a number of issues for practising midwives. While it is a common event, amid a growing body of evidence there continues to be debate regarding how best to manage individuals with PROM \geq 37+0 weeks' gestation.

Clients must consider the slightly increased risk of infection in the birthing parent and the newborn with expectant management versus the risks associated with induction of labour, while also taking their personal preferences into account. However, there is little to no difference in infection rates for expectant management and active management with PROM when vaginal exams are limited to active labour.

According to the Canadian Association of Midwives, “the concept of normality rests on the physiology of labour and the capacity of women to give birth with their own power.” (76) As there is no clear evidence regarding best practice for managing clients with PROM, and poor outcomes are relatively rare, midwives need to balance the expectation that care providers must “do something” with the knowledge that such interventions may be unnecessary and may contribute to greater use of technological intervention in childbirth.

Given the trade-offs between different approaches to PROM, midwives should discuss both expectant management and induction of labour with their clients. Ultimately, clients who experience PROM are best suited to decide which option is best for them by weighing the risks and benefits within the context of their own values and interests.

SUMMARY OF RECOMMENDATIONS

1. For clients with PROM > 37+0 weeks, discuss the risks and benefits of both expectant management and induction of labour. In the absence of abnormal findings and when digital vaginal exams are avoided before the onset of active labour, expectant management and induction are both appropriate options. [I-A] [new 2019]
2. Inform clients with PROM who choose expectant management that they have the option to revisit their management plan and may choose induction of labour if they no longer desire expectant management. [III-A] [2019]
3. To reduce the risk of infection, avoid digital vaginal exams for clients with PROM whenever possible, until active labour or upon induction. [I-A] [2019]
4. Initial assessment for PROM may take place by phone or in person.
 - a. If no abnormal signs or symptoms are present during history-taking by phone for suspected PROM, conduct an in-person assessment to confirm PROM. Following the phone assessment, make a management plan within 24 hours after membrane rupture. Ensure that the client is aware of when and how to contact the midwife to arrange an earlier assessment in the event that abnormal signs develop: presence of meconium in amniotic fluid, frank vaginal bleeding, fever > 38 °C, foul-smelling amniotic fluid or decreased fetal movement. [III-A] [2011]
 - b. If abnormal signs or symptoms are present during history-taking related to PROM, an immediate in-person assessment is warranted. [III-A] [2011]
5. Diagnosis of PROM may be performed with one or more of the following: a sterile speculum exam, a nitrazine test and/or a fern test. Results should be interpreted in combination with a client's history of PROM. [II-2-B] [2011]
6. When results from any of the tests are uncertain, multiple methods (a sterile speculum exam, a nitrazine test and/or a fern test), as well as the midwife's clinical judgment, should be used to obtain a clearer clinical picture. Decision-making may be supported by ultrasound evaluation of the amniotic fluid volume in instances when PROM results are uncertain, following other diagnostic tests. [III-B] [2011]
7. Ensure that clients with PROM who choose expectant management are aware of when and how to contact their midwife for support, should complications develop. [III-A] [2011]
8. For clients with PROM who choose expectant management, the midwife should conduct a daily in-person assessment in the client's home, at a clinic or in the hospital. This should include: monitoring vital signs of the birthing parent and the fetus and examining the amniotic fluid, as well as a discussion of the client's emotional well-being. If the midwife notes any contraindications to expectant management during the physical exam, or if any other emotional or psychological concerns arise, they may offer induction of labour. [III-B] [2011]
9. Inform clients of the research gaps regarding the most effective approach to preventing EOGBSD in infants born to GBS carriers who experience term PROM. [III-B] [2011]
10. Offer a choice between expectant management and immediate induction of labour with oxytocin to clients with a positive GBS swab result at term who experience PROM for < 18 hours and have no other risk factors. [III-B] [2011]

- 11.** Recommend induction of labour with oxytocin to GBS-positive clients with PROM \geq 18 hours [III-B]. IAP should be offered upon initiation of induction. [2011]
- 12.** Offer GBS-positive clients with PROM who choose expectant management a range of options for prophylactic antibiotic administration:
 - a.** IAP in active labour [II-2-B] [2011]
 - b.** IAP in the latent phase [III-C] [2011]
 - c.** IAP upon initiation of induction of labour [III-B] [2011]
- 13.** For clients who choose expectant management following PROM at term, remaining at home during the latent period is recommended, provided that daily in-person assessments take place and that the client is aware of how and when to contact the midwife. In-person assessments should include: monitoring vital signs of the birthing parent and the fetus and examining the amniotic fluid, as well as a discussion of the client's emotional well-being. [III-B] [2011]
- 14.** In the absence of signs of infection in the birthing parent or the fetus, inform clients who are GBS negative and who choose expectant management that it is reasonable to wait for up to 96 hours before induction of labour. [I-A] [2011]
- 15.** As part of an informed choice discussion regarding expectant management and the length of the latent period, inform clients that chorioamnionitis and neonatal infection rates increase \geq 24 hours after PROM. [II-2-B] Inform clients that avoiding vaginal exams until the onset of active labour appears to mitigate this risk, and it is therefore an important part of an expectant management approach. [I-A] [new 2019]
- 16.** Inform clients who choose expectant management beyond 96 hours that no available research quantifies any potential increase in the risk of infection in the birthing parent or the neonate. [III-B] [2019]
- 17.** In the absence of meconium staining of the amniotic fluid and any signs of infection in the birthing parent or the fetus, it is appropriate for midwives to use intermittent auscultation as a method of intrapartum fetal monitoring for clients with PROM. [III-B] [2011]
- 18.** The healthy infant born to clients with PROM who are GBS negative may be assessed by the midwife as usual, based on clinical signs and symptoms of infection. (III-A) [2011]

APPENDIX

Table 1: Updated 2019 Recommendations/Summary Statements and Explanation of Changes

Original Recommendation or Summary Statement from 2011	Updated Recommendation or Summary Statement [new 2019]	Explanation of Change(s)
Protective factors		
<p>Summary statement</p> <p>None</p>	<p>Summary statement</p> <p>Supplementing with 100 mg of vitamin C (without vitamin E) during pregnancy may reduce the risk of PROM at term. However, more research with larger sample sizes is needed. [new 2019]</p>	<ul style="list-style-type: none"> Evidence from a new RCT (2013) further supports previous research that found that when supplemented without vitamin E, vitamin C is associated with a protective effect against PROM at term.
	<p>There is evidence to suggest that zinc may be protective against PROM at term. However, more research with larger sample sizes is needed. [new 2019]</p>	<ul style="list-style-type: none"> New evidence is available from an updated Cochrane review (2015) and a new RCT on zinc supplementation in pregnancy. Findings from both studies suggest that zinc supplementation is associated with a protective effect against PROM at term
Management of PROM: early induction of labour vs. expectant management		
<p>Summary statement</p> <p>Maternal complications associated with PROM include chorioamnionitis and postpartum infection.</p>	<p>Summary statement</p> <p>Chorioamnionitis and endometritis are associated with PROM at term. However, no difference was found in rates of infection between the planned early-birth and expectant management groups for PROM at term in trials where a strict protocol of avoiding digital vaginal exams was enforced. [new 2019]</p>	<ul style="list-style-type: none"> New evidence included from an updated sub-analysis on digital vaginal exams for birthing parent infection rates. New evidence supports finding that when vaginal exams are avoided before onset of active labour, little to no difference is observed for rates of maternal and neonatal infection between expectant management and induction groups.
<p>Summary statement</p> <p>A high frequency of vaginal exams is the strongest independent predictor of chorioamnionitis with PROM.</p>	<p>Summary statement</p> <p>A high frequency of vaginal exams is the strongest independent predictor of chorioamnionitis with PROM. It is also significantly associated with neonatal infection. [new 2019]</p>	<ul style="list-style-type: none"> Summary statement updated to highlight evidence from an updated Cochrane meta-analysis that included a sub-analysis on digital vaginal exams and the risk of infection with PROM at term. A higher frequency of vaginal exams is also associated with neonatal infection, based on updated evidence.

Table 1: Updated 2019 Recommendations/Summary Statements and Explanation of Changes

Original Recommendation or Summary Statement from 2011	Updated Recommendation or Summary Statement [new 2019]	Explanation of Change(s)
Management of PROM: early induction of labour vs. expectant management		
<p>Summary statement</p> <p>None</p>	<p>Summary statement</p> <p>The main predictors of infection in the pregnant and postpartum person with PROM include: frequent vaginal exams, meconium-stained amniotic fluid, nulliparity, GBS-positive status, active labour > 6 hours and a latent period > 24 hours. [new 2019]</p>	<ul style="list-style-type: none"> • New summary statement included to summarize the main factors that increase the risk of infection for those with PROM at term. • This summary statement now matches one included in the section on neonatal infection, which highlights the main predictors of infection in the newborn if the birthing parent has experienced PROM at term.
<p>Summary statement</p> <p>The main predictors of neonatal infection include: maternal chorioamnionitis, GBS status and increased frequency of vaginal exams.</p>	<p>Summary statement</p> <p>The main predictors of neonatal infection include: chorioamnionitis, GBS-positive status, increased frequency of vaginal exams, and a latent period > 24 hours. [new 2019]</p>	<ul style="list-style-type: none"> • Minor change made to summary statement to include all main predictors of infection in the newborn if the birthing parent has experienced PROM at term.
<p>Summary statement</p> <p>1. Offer clients with PROM > 37+0 weeks' gestation the option of induction or expectant management. In the absence of abnormal findings (see Table 5), expectant management is as appropriate as induction of labour. [I-A]</p>	<p>Summary statement</p> <p>1. For clients with PROM > 37+0 weeks, discuss the risks and benefits of both expectant management and induction of labour. In the absence of abnormal findings and when digital vaginal exams are avoided before the onset of active labour, expectant management and induction are both appropriate options. [I-A] [new 2019]</p>	<ul style="list-style-type: none"> • Updated Cochrane meta-analysis found an association between induction and a decreased risk for chorioamnionitis, endometritis and neonatal infection. • However, a sub-analysis of digital vaginal exams within this meta-analysis found that when a strict policy of avoiding vaginal exams before the onset of active labour was employed, no statistical difference between induction and expectant management was observed for all important outcomes, particularly chorioamnionitis, endometritis and neonatal infection.

Table 1: Updated 2019 Recommendations/Summary Statements and Explanation of Changes

Original Recommendation or Summary Statement from 2011	Updated Recommendation or Summary Statement [new 2019]	Explanation of Change(s)
Timing of induction for PROM: when is the latent period too long?		
<p>Recommendation</p> <p>15. As part of an informed choice discussion regarding expectant management and the length of the latent period, inform clients that according to a secondary analysis of the TermPROM Study, when compared with a latent period of 12 hours, the OR of chorioamnionitis and neonatal infection increases ≥ 24 hours after PROM. [II-2-B] Inform clients that avoiding vaginal exams until active labour appears to mitigate this risk, and it is therefore an important part of an expectant management approach. [I-A]</p>	<p>Recommendation</p> <p>15. As part of an informed choice discussion regarding expectant management and the length of the latent period, inform clients that chorioamnionitis and neonatal infection rates increase ≥ 24 hours after PROM. [II-2-B] Inform clients that avoiding vaginal exams until the onset of active labour appears to mitigate this risk, and it is therefore an important part of an expectant management approach. [I-A] [new 2019]</p>	<ul style="list-style-type: none"> • New evidence suggests a stronger association between a longer latent period and an increased risk for chorioamnionitis (> 24 hours) and neonatal infection ($\geq 18-24$ hours). Findings support evidence that was previously reported in this CPG from a secondary analysis of the TermPROM Study.
Prophylactic antibiotics for PROM at term		
<p>Summary statement</p> <p>Insufficient evidence exists to recommend antibiotics for all clients with term PROM.</p>	<p>Summary statement</p> <p>In the absence of signs of infection in the birthing parent, inform clients with term PROM that there is no evidence that the use of prophylactic antibiotics reduces rates of infectious morbidity in the birthing parent (chorioamnionitis or endometritis) or neonatal infections. [new 2019]</p>	<ul style="list-style-type: none"> • Findings from an updated Cochrane meta-analysis suggest that there is now little to no difference in birthing parent rates of infection (chorioamnionitis and endometritis) for those with PROM who were administered antibiotics in comparison with participants who did not receive antibiotics.
	<p>Summary statement</p> <p>More research is needed on the use of prophylactic antibiotics to reduce infectious morbidity for those with PROM with a latent period of > 12 hours. [new 2019]</p>	<ul style="list-style-type: none"> • New evidence available for and against the administration of antibiotics for clients depending on the length of the latency period (whether $>$ or $<$ 12 hours). Evidence suggests that antibiotics may be protective against infection in the birthing parent for those with latent period > 12 hours.

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