National Institute for Health and Care Excellence

Draft for consultation

Intrapartum care for healthy women and babies

[B] Initial assessment of women reporting prelabour rupture of membranes

NICE guideline number CG190 (update)

Evidence review underpinning recommendations 1.7.1, 1.7.2, 1.7.6, 1.7.7 and 1.7.11 in the NICE guideline April 2023

Draft

Disclaimer

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The recommendations in this guideline are not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

Local commissioners and/or providers have a responsibility to enable the guideline to be applied when individual health professionals and their patients or service users wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with compliance with those duties.

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Initial assessment after prelabour rupture of membranes

3 Review question

4 What is the optimum timeframe between a mother reporting possible prelabour rupture of the 5 membranes and face-to-face clinical review?

6 Introduction

Pre-labour rupture of membranes (PRoM) occurs in 8% of pregnancies and around 60% of
these women will begin labour spontaneously within 24 hours. There are serious, but
uncommon risks associated with PRoM, such as cord prolapse, cord compression, placental
abruption and neonatal infection. It is therefore important that women with suspected PRoM
are assessed by a maternity care professional, but there is variation in practice and no
current guidance about the nature or timing of this review.

13 The aim of this review is to determine how soon after the membranes have ruptured an in-14 person clinical review of the woman should be carried out.

15 Summary of the protocol

See Table 1 for a summary of the Population, Intervention, Comparison and Outcome(PICO) characteristics of this review.

18 Table 1: Summary of the protocol (PICO table)

19

	 Women who are pregnant with a single baby, who go into labour at preterm (< 37+ 0) or term (37 to 42 weeks of pregnancy)
	 Women who have had a previous caesarean birth or are having a planned caesarean birth
	 Women whose baby has not been identified before labour to be at high risk of adverse outcomes
Population	 Singleton babies born at term (37 to 42 weeks of pregnancy) with no previously identified problems (for example congenital malformations, genetic anomalies, intrauterine growth restriction, placental problems)
Intervention	Face-to-face clinical review advised as soon as possible (< 3 hours) after a mother telephoning to report PRoM
Comparison	Face-to-face clinical review delayed between the timeframes stated below after a mother telephoning to report PRoM
	• 3 to < 6 hours
	• 6 to < 12 hours
	• 12 < 18 hours
	• 18 to 24 hours
	• > 24 hours

Outcome Critical

- Maternal admission to ITU or high-dependency area
- Mode of birth (spontaneous vaginal, instrumental vaginal, caesarean birth)
- Requirement for antibiotics
- Important
- Induction of labour
- Evidence of maternal infection including maternal pyrexia, other signs of chorioamnionitis and sepsis
- Women's experience of labour and birth
- Neonatal admission (includes NICU and SCBU)

1 ITU: intensive therapy unit; NICU: neonatal intensive care unit; PRoM: pre-labour rupture of membranes; SCBU: 2 special care baby unit

3 For further details see the review protocol in appendix A.

4 Methods and process

- 5 This evidence review was developed using the methods and process described in
- 6 <u>Developing NICE guidelines: the manual</u>. Methods specific to this review question are
- described in the review protocol in appendix A and the methods document (supplementarydocument 1).
- 9 Declarations of interest were recorded according to NICE's conflicts of interest policy.
- 10 The committee agreed that only studies conducted in high-income countries (as defined by
- 11 the Organisation for Economic Co-operation and Development [OECD]) should be
- 12 considered for inclusion because clinical monitoring following suspected rupture of
- 13 membranes is likely to vary between high and low/middle income countries.
- 14 The protocol makes reference to 'face-to-face clinical review', whereas the recommendations
- 15 and discussion of the evidence use the terminology 'in-person (clinical review)'. The
- 16 committee preferred the latter wording as the former could be taken to mean a video call.

17 Effectiveness

18 Included studies

- A systematic review of the literature was conducted but no studies were identified whichwere applicable to this review question.
- 21 See the literature search strategy in appendix B and study selection flow chart in appendix C.

22 Excluded studies

Studies not included in this review are listed, and reasons for their exclusion are provided inappendix J.

25 Summary of included studies

No studies were identified which were applicable to this review question (and so there are no
evidence tables in Appendix D). No meta-analysis was conducted for this review (and so
there are no forest plots in Appendix E).

29 Summary of the evidence

No studies were identified which were applicable to this review question (and so there are no
 GRADE tables in Appendix F).

1 Economic evidence

2 Included studies

A systematic review of the economic literature was conducted but no economic studies were identified which were applicable to this review question.

5 Economic model

6 No economic modelling was undertaken for this review because the committee agreed that 7 other topics were higher priorities for economic evaluation.

8 The committee's discussion and interpretation of the evidence

9 The outcomes that matter most

10 The committee chose maternal admission to intensive therapy unit (ITU) or high-dependency area, mode of birth and requirement for antibiotics as the critical outcomes for this review. As 11 both maternal admission and requirement for antibiotics are common negative outcomes for 12 women associated with PRoM, the committee agreed that these were the best indicators to 13 understand the differential effectiveness of different timeframes between a woman reporting 14 possible PRoM and an in-person clinical review. The committee also wanted to find out 15 whether different timeframes would impact the mode of birth and agreed that this was a 16 meaningful outcome for making recommendations, both in terms of the woman and the 17 18 health system.

19 The committee also agreed on the important outcomes for this review. As induction of labour is recommended 24 hours after PRoM due to an increased risk of infection, the committee 20 21 wanted to include induction of labour and evidence of maternal infection as important 22 outcomes as these are likely to be impacted by different timeframes between a woman reporting PRoM and an in-person face-to-face clinical review. They also agreed that it was 23 also important to find out about women's experience of labour and birth. The committee 24 25 recognised the great importance of women's experience of labour and birth in the presence of suspected PRoM, but they were aware that data on this outcome was likely to be sparse 26 and unlikely to inform decision-making in a meaningful way, so they prioritised other 27 outcomes as critical. 28

Finally, the committee chose neonatal admission as an important outcome as this would indicate whether there are any risks for the baby associated with different timeframes

31 between a woman reporting PRoM and a face-to-face clinical review.

32 The quality of the evidence

33 No evidence was identified which was applicable to this review question.

34 Benefits and harms

35 The committee noted that the protocol had included women with preterm PRoM (less than 37

36 weeks) but that the NICE guidelines on Preterm labour and birth already included

37 recommendations on the management of preterm PRoM and so they restricted their

discussions and recommendations to women with PRoM at term (37 to 42 weeks) which is aligned with the scope of the Intrapartum care guidance.

40 No evidence was identified for the timeframe between a woman reporting possible PRoM

41 and an in-person clinical assessment, so the committee based the recommendations on their 42 experience and expertise. The committee agreed that while the recommendations would

reflect current practice in many Trusts, the recommendations would help to reduce variation
 in practice and reliance on women's knowledge and perception of risk.

3 The committee discussed the triage of women reporting possible PRoM and agreed that in practice, the urgency of an in-person clinical assessment should be based on the presence 4 of risk factors. The committee agreed that a list of risk factors would be useful in determining 5 the urgency of an in-person clinical assessment and decided that a woman should be seen 6 7 immediately if any one of these factors is present. The committee noted that some of these factors would require women to be offered immediate induction, for example, if she has a 8 9 positive group B streptococcus test, and that recommendations relating to the timing of induction were already present in the NICE guideline on Inducing labour and the NICE 10 guideline on Neonatal infection. The committee therefore included these recommendations in 11 12 the guideline and cross-referenced to these other relevant NICE guidelines.

13 The committee agreed that women who do not have any risk factors should be seen within 6 14 hours or as soon as possible if the woman has any concerns or wishes to be induced immediately. The committee discussed the timeframe and agreed that there was no clinical 15 16 reason there should be a delay in an in-person clinical assessment, but they agreed that for this lower risk group, the benefits of urgency should be balanced with the preferences of the 17 woman, for example wanting to spend the night at home or taking time to arrange childcare 18 19 and agreed that 6 hours would be a reasonable pragmatic time to allow this. The committee 20 agreed that the in-person assessment of a woman without risk factors could be carried out at the woman's intended place of birth, be that at home, in a midwifery-led unit or an obstetric 21 unit. The committee noted that the deployment of community midwives may be needed in 22 cases where the woman was unable to reach the maternity unit within 6 hours, however, they 23 24 decided not to make a recommendation on this as this would be determined at the local 25 level.

The committee discussed whether to make a research recommendation as no evidence had been identified but agreed that as a risk assessment was necessary for women presenting with PRoM (as they had advised in their recommendations), and as this was an area where maternal preference and planned place of birth also had a large impact on the decision, a study randomising women to different times for assessment would be unlikely to be conducted.

32 Cost effectiveness and resource use

33 The committee agreed that the recommendation for women with risk factors is in line with 34 current practice. However, the recommendation for women without risk factors may result in 35 more women being seen in-person within a shorter timeframe than current practice, as some units currently advise longer delays than this. The committee agreed that this is unlikely to 36 37 have a significant impact on resources as it is only bringing the time of review for some 38 women earlier by a few hours. However, although no clinical evidence was identified, the committee made a qualitative assessment that the recommendations based on their 39 40 expertise and experience would represent a cost-effective use of NHS resources.

41 Recommendations supported by this evidence review

42 This evidence review supports recommendations 1.7.1, 1.7.2, 1.7.6, 1.7.7 and 1.7.11.

43 **References – included studies**

44 Effectiveness

- 45 No evidence was identified which was applicable to this review question.
- 46

1 Appendices

2 Appendix A Review protocols

- 3 Review protocol for review question: What is the optimum timeframe between a mother reporting possible PRoM and
- 4 face-to-face clinical review?

5 Table 2: Review protocol

Field	Content		
PROSPERO registration number	CRD42021266237		
Review title	Initial assessment of women reporting pre-labour rupture of membranes (PRoM)		
Review question	What is the optimum timeframe between a mother reporting possible PRoM and face-to-face clinical review?		
Objective	To make recommendations for the optimum timeframe between a mother reporting possible PRoM and face-to-face clinical review		
Searches	The following databases will be searched:		
	Cochrane Central Register of Controlled Trials (CENTRAL)		
	Cochrane Database of Systematic Reviews (CDSR)		
	• Embase		
	MEDLINE & MEDLINE In-Process		
	International Health Technology Assessment (IHTA) database		
	Searches will be restricted by:		
	No date limitations		
	English language studies		
	Human studies		
	Other searches:		

Field	Content
	Inclusion lists of systematic reviews
	The full search strategies for the MEDLINE database will be published in the final review. For each search, the principal database search strategy is quality assured by a second information scientist using an adaptation of the PRESS 2015 Guideline Evidence-Based Checklist.
Condition or domain being studied	Labour and birth
Population	 Women who are pregnant with a single baby, who go into labour at preterm (< 37+ 0) or term (37 to 42 weeks of pregnancy) Women who have had a previous caesarean birth or are having a planned caesarean birth
	 Women whose baby has not been identified before labour to be at high risk of adverse outcomes
	 Singleton babies born at term (37 to 42 weeks of pregnancy) with no previously identified problems (for example congenital malformations, genetic anomalies, intrauterine growth restriction, placental problems)
Intervention	Face-to-face clinical review advised as soon as possible (< 3 hours) after a mother telephoning to report PRoM
Comparator	Face-to-face clinical review delayed between the timeframes stated below after a mother telephoning to report PRoM
	• 3 to < 6 hours
	• 6 to < 12 hours
	• 12 < 18 hours
	• 18 to 24 hours
	• > 24 hours
Types of study	Include published full-text papers:
to be included	Systematic reviews of RCTs
	Parallel RCTs (individual or cluster)
	If not enough evidence from RCTs is found:
	Prospective and retrospective cohort studies
	Note: prospective and retrospective studies must make adjustment for confounding factors in their analysis
	Conference abstracts will not be included because these do not typically have sufficient information to allow full critical appraisal.

Field	Content
Other exclusion	Population:
criteria	• Women who are identified before labour to be at high risk, or whose baby is at high risk, of complications or adverse outcomes
	Women with non-cephalic presentation
	Women with an intrauterine fetal death
	Women pregnant with multiple babies
	Setting:
	Countries other than high income countries (as defined by the OECD)
	If any study or systematic review includes <1/3 of women with the above characteristics/ who received care in the above setting, it will be considered for inclusion but, if included, the evidence will be downgraded for indirectness.
Context	The population of this guideline may overlap with the population of women included in other NICE guidelines (such as caesarean birth or preterm labour and birth)
Primary	 Maternal admission to intensive therapy unit (ITU) or high-dependency area
outcomes (critical	 Mode of birth (spontaneous vaginal, instrumental vaginal, caesarean birth)
outcomes)	Requirement for antibiotics
Secondary	Induction of labour
outcomes	 Evidence of maternal infection including maternal pyrexia, other signs of chorioamnionitis and sepsis
(important outcomes)	Women's experience of labour and birth
outcomecy	 Neonatal admission (includes neonatal intensive care unit [NICU] and special care baby unit [SCBU])
Data extraction	All references identified by the searches and from other sources will be uploaded into EPPI and de-duplicated. Titles and
(selection and	abstracts of the retrieved citations will be screened to identify studies that potentially meet the inclusion criteria outlined in the
coding)	review protocol. Duplicate screening will not be undertaken for this question. Full versions of the selected studies will be obtained for assessment. Studies that fail to meet the inclusion criteria once the full
	version has been checked will be excluded at this stage. Each study excluded after checking the full version will be listed, along
	with the reason for its exclusion.
	A standardised form will be used to extract data from studies. The following data will be extracted: study details (reference, country where study was carried out, type and dates), participant characteristics, inclusion and exclusion criteria, details of the
	interventions if relevant, setting and follow-up, relevant outcome data and source of funding. One reviewer will extract relevant

Field	Content
	data into a standardised form, and this will be quality assessed by a senior reviewer.
Risk of bias	Quality assessment of individual studies will be performed using the following checklists:
(quality)	ROBIS tool for systematic reviews
assessment	Cochrane RoB tool v.2 for RCTs
	 Cochrane RoB tool v.2 for cluster randomised controlled trials
	 ROBINS-I tool for non-randomised (clinical) controlled trials and cohort studies
	The quality assessment will be performed by one reviewer and this will be quality assessed by a senior reviewer.
Strategy for data synthesis	Quantitative findings will be formally summarised in the review. Where multiple studies report on the same outcome for the same comparison, meta-analyses will be conducted using Cochrane Review Manager software.
	A fixed effect meta-analysis will be conducted and data will be presented as risk ratios if possible or odds ratios when required (for example, if only available in this form in included studies) for dichotomous outcomes, and mean differences or standardised mean differences for continuous outcomes. Heterogeneity in the effect estimates of the individual studies will be assessed using the I2 statistic. Alongside visual inspection of the point estimates and confidence intervals, I2 values of greater than 50% and 80% will be considered as significant and very significant heterogeneity, respectively. Heterogeneity will be explored as appropriate using sensitivity analyses and pre-specified subgroup analyses. If heterogeneity cannot be explained through subgroup analysis then a random effects model will be used for meta-analysis, or the data will not be pooled.
	The confidence in the findings across all available evidence will be evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group: http://www.gradeworkinggroup.org/
	Minimally important differences:
	 Validated scales/continuous outcomes: published MIDs where available
	 All other outcomes & where published MIDs are not available: 0.8 and 1.25 for all relative dichotomous outcomes ; +/- 0.5x control group SD for continuous outcomes
Analysis of	Evidence will be stratified by:
subgroups	BMI thresholds on booking:
	○ Underweight range: <18.5 kg/m ²
	◦ Healthy weight range: 18.5 to 24.9 kg/m ²
	○ Overweight range: 25 to 29.99 kg/m ²
	◦ Obesity range 1: 30 to 34.99 kg/m²

Field	Content	
	 Obesity range 2: 	35 to 39.99 kg/m ²
	 Confirmed vs susp 	ected PRoM
	Stratifications will be PRoM)	dealt with in a hierarchy (this is, first by BMI thresholds on booking and then by confirmed vs suspected
	Evidence will be sub	grouped by the following only in the event that there is significant heterogeneity in outcomes:
	• Age of woman (<3	
	 Ethnicity ○ White 	
	 Asian/Asian Britis 	sh
	• • • • • • • • • • • • • • • • • • • •	ribbean/Black British
	 Mixed/Multiple et 	hnic groups
	 Other ethnic grou 	lp
	 Women with disabi 	lity vs not
	 Deprived socioecor 	nomic group vs not
	should be made for c interventions in distin	tratified or subgrouped the committee will consider on a case by case basis if separate recommendations distinct groups. Separate recommendations may be made where there is evidence of a differential effect of act groups. If there is a lack of evidence in one group, the committee will consider, based on their experience, ble to extrapolate and assume the interventions will have similar effects in that group compared with others.
Type and	\boxtimes	Intervention
method of		Diagnostic
review		Prognostic
		Qualitative
		Epidemiologic
		Service Delivery
		Other (please specify)
Language	English	

Field	Content
Country	England
Anticipated or actual start date	14/07/2021
Anticipated completion date	22/03/2023
Named contact	5a. Named contact
	Guideline Development Team National Guideline Alliance (NGA)
	5b. Named contact e-mail
	IPCupdate@nice.org.uk
	5c. Organisational affiliation of the review
	Guideline Development Team NGA, Centre for Guidelines, National Institute for Health and Care Excellence (NICE)
Review team	From the Guideline Development Team NGA:
members	Senior Systematic Reviewer
	Systematic Reviewer
Funding sources/sponsor	This systematic review is being completed by the Guideline Development Team NGA, Centre for Guidelines, which is part of the National Institute for Health and Care Excellence (NICE).
Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.
Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of <u>Developing NICE guidelines: the manual</u> . Members of the guideline committee are available on the NICE website: https://www.nice.org.uk/guidance/cg190
Other registration	None

Field	Content
details	
URL for published protocol	https://www.crd.york.ac.uk/PROSPERO/display_record.php?RecordID=266237
Dissemination	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as:
plans	 notifying registered stakeholders of publication
	 publicising the guideline through NICE's newsletter and alerts
	 issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.
Keywords	Pre-labour rupture of membranes; timeframe; clinical review
Details of existing review of same topic by same authors	Not applicable
Additional information	None
Details of final publication	www.nice.org.uk

CDSR: Cochrane Database of Systematic Reviews; CENTRAL: Cochrane Central Register of Controlled Trials; GRADE: Grading of Recommendations Assessment, Development and Evaluation; IHTA: International Health Technology Assessment; MID: minimally important difference; NGA: National Guideline Alliance; NHS: National health service; NICE: National Institute for Health and Care Excellence; OECD: Organisation for Economic Co-operation and Development; PRESS: peer review of electronic search strategies; PRoM: Pre-labour rupture of membranes; RCT: randomised controlled trial; ROBINS-I: Risk of bias in non-randomised studies on interventions; RoB(IS): risk of bias (in systematic reviews); SD: standard deviation

12345 6

Appendix B Literature search strategies

Literature search strategies for review question: What is the optimum timeframe between a mother reporting possible PRoM and face-to-face clinical review?

Review question search strategies

Database: Medline - OVID interface

Date of last search: 06/12/2022

#	Searches
1	FETAL MEMBRANES, PREMATURE RUPTURE/
2	((prelabo?r or pre-labo?r or preterm or pre-term or premature*) adj3 ruptur* adj3 membrane?).ti,ab.
3	((prelabo?r or pre-labo?r or preterm or pre-term or premature) adjo tuptar adjo memorane () ti,ab.
4	PPROM.ti,ab.
5	(water* adj10 break* adj10 (prelabo?r or pre-labo?r or preterm or pre-term or premature*)).ti,ab.
6	or/1-5
7	(fluid? adj3 (gush* or trickl* or leak*)).ti,ab.
8	(feel* adj3 (wet* or damp*)).ti,ab.
9	((urinat* or wee*) adj3 (sensation? or feel* or need*)).ti,ab.
10	or/7-9
11	PREGNANCY/
12	pregnan*.ti,ab.
13	or/11-12
14	10 and 13
15	6 or 14
16	"REFERRAL AND CONSULTATION"/
17	clinical\$ review\$.ti,ab.
18	face to face.ti,ab.
19	consultation?.ti,ab.
20	meeting?.ti,ab.
21	clinical\$ examin\$.ti,ab.
22	(examin* adj3 (patient? or wom?n)).ti,ab.
23	(contact* adj5 (healthcare professional? or medic? or doctor? or consultant? or specialist? or obstetrician? or gyn?ecologist? or midwife? or midwive? or GP or GPs or nurse? or hospital? or ward? or department?)).ti,ab.
24	TRIAGE/
25	triag*.ti,ab.
26	HOTLINES/
27	exp TELEPHONE/
28	(hotline? or phone? or telephone? or phoning or phoned).ti,ab.
29	or/16-28
30	15 and 29
31	FETAL MEMBRANES, PREMATURE RUPTURE/di [Diagnosis]
32	TIME FACTORS/
33	31 and 32
34	30 or 33
35	limit 34 to english language
36	LETTER/
37	EDITORIAL/
	NEWS/
38 39	
	exp HISTORICAL ARTICLE/ ANECDOTES AS TOPIC/
40	
41	COMMENT/
42	CASE REPORT/
43	(letter or comment*).ti.
44	
45	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.
46	44 not 45
47	ANIMALS/ not HUMANS/
48	exp ANIMALS, LABORATORY/
49	exp ANIMAL EXPERIMENTATION/
50	exp MODELS, ANIMAL/
51	exp RODENTIA/
52	(rat or rats or mouse or mice).ti.

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#	Searches
53	or/46-52
54	35 not 53
55	META-ANALYSIS/
56	META-ANALYSIS AS TOPIC/
57	(meta analy* or metanaly* or metaanaly*).ti,ab.
58	((systematic* or evidence*) adj2 (review* or overview*)).ti,ab.
59	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
60	(search strategy or search criteria or systematic search or study selection or data extraction) ab.
61	(search* adj4 literature).ab.
62	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
63	cochrane.jw.
64	or/55-63
65	randomized controlled trial.pt.
66	controlled clinical trial.pt.
67	pragmatic clinical trial.pt.
68	randomi#ed.ab.
69	placebo.ab.
70	randomly.ab.
71	CLINICAL TRIALS AS TOPIC/
72	trial.ti.
73	or/65-72
74	COHORT STUDIES/
75	FOLLOW-UP STUDIES/
76	LONGITUDINAL STUDIES/
77	PROSPECTIVE STUDIES/
78	RETROSPECTIVE STUDIES/
79	((cohort* or follow-up or follow?up or longitudinal* or prospective* or retrospective*) adj1 (stud* or research or analys*)).tw.
80	(incidence? adj (stud* or research or analys*)).tw.
81	(longitudinal* adj1 (survey* or evaluat*)).tw.
82	(prospective* adj method*).tw.
83	(retrospective* adj design*).tw.
84	or/74-83
85	54 and 64
86	54 and 73
87	54 and 84
88	or/85-87

Database: Embase - OVID interface

Date of last search: 06/12/2022

#	Searches		
1	PREMATURE FETUS MEMBRANE RUPTURE/		
2	((prelabo?r or pre-labo?r or preterm or pre-term or premature*) adj3 ruptur* adj3 membrane?).ti,ab.		
3	((prelabo?r or pre-labo?r or preterm or pre-term or premature*) adj3 ROM).ti,ab.		
4	PPROM.ti,ab.		
5	(water* adj10 break* adj10 (prelabo?r or pre-labo?r or preterm or pre-term or premature*)).ti,ab.		
6	or/1-5		
7	(fluid? adj3 (gush* or trickl* or leak*)).ti,ab.		
8	(feel* adj3 (wet* or damp*)).ti,ab.		
9	((urinat* or wee*) adj3 (sensation? or feel* or need*)).ti,ab.		
10	or/7-9		
11	PREGNANCY/		
12	pregnan*.ti,ab.		
13	or/11-12		
14	10 and 13		
15	6 or 14		
16	CONSULTATION/		
17	PATIENT REFERRAL/		
18	clinical\$ review\$.ti,ab.		
19	face to face.ti,ab.		
20	consultation?.ti,ab.		
21	meeting?.ti,ab.		
22	clinical\$ examin\$.ti,ab.		
23	(examin* adj3 (patient? or wom?n)).ti,ab.		
24	(contact* adj5 (healthcare professional? or medic? or doctor? or consultant? or specialist? or obstetrician? or gyn?ecologist? or midwife? or midwive? or GP or GPs or nurse? or hospital? or ward? or department?)).ti,ab.		

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#	Searches	
# 25	triag*.ti,ab.	
26	HOTLINE/	
27	TELEPHONE/	
28	exp MOBILE PHONE/	
29	(hotline? or phone? or telephone? or phoning or phoned).ti,ab.	
30	or/16-29	
31	15 and 30	
32	PREMATURE FETUS MEMBRANE RUPTURE/di [Diagnosis]	
33	TIME FACTOR/	
34	32 and 33	
35	31 or 34	
36	limit 35 to english language	
37	LETTER/	
38	EDITORIAL/ NEWS/	
39 40	exp HISTORICAL ARTICLE/	
40	ANECDOTES AS TOPIC/	
42	COMMENT/	
43	CASE REPORT/	
44	(letter or comment*).ti.	
45	or/37-44	
46	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.	
47	45 not 46	
48	ANIMALS/ not HUMANS/	
49	exp ANIMALS, LABORATORY/	
50	exp ANIMAL EXPERIMENTATION/	
51	exp MODELS, ANIMAL/	
52	exp RODENTIA/	
53	(rat or rats or mouse or mice).ti.	
54	or/47-53	
55 56	36 not 54 SYSTEMATIC REVIEW/	
57	META-ANALYSIS/	
58	(meta analy* or metanaly* or metaanaly*).ti,ab.	
59	((systematic or evidence) adj2 (review* or overview*)).ti,ab.	
60	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.	
61	(search strategy or search criteria or systematic search or study selection or data extraction).ab.	
62	(search* adj4 literature).ab.	
63	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.	
64	((pool* or combined) adj2 (data or trials or studies or results)).ab.	
65	cochrane.jw.	
66	or/56-65	
67	random*.ti,ab.	
68	factorial*.ti,ab.	
69 70	(crossover* or cross over*).ti,ab. ((doubl* or singl*) adj blind*).ti,ab.	
70	(assign* or allocat* or volunteer* or placebo*).ti,ab.	
72	CROSSOVER PROCEDURE/	
73	SINGLE BLIND PROCEDURE/	
74	RANDOMIZED CONTROLLED TRIAL/	
75	DOUBLE BLIND PROCEDURE/	
76	or/67-75	
77	COHORT ANALYSIS/	
78	FOLLOW UP/	
79	LONGITUDINAL STUDY/	
80	PROSPECTIVE STUDY/	
81	RETROSPECTIVE STUDIES/	
82	((cohort* or follow-up or follow?up or longitudinal* or prospective* or retrospective*) adj1 (stud* or research or analys*)).tw.	
83	(incidence? adj (stud* or research or analys*)).tw.	
84	(longitudinal* adj1 (survey* or evaluat*)).tw.	
85 86	(prospective* adj method*).tw. (retrospective* adj design*).tw.	
86 87	(retrospective" adj design").tw. or/77-86	
88	55 and 66	
89	55 and 66	
90	55 and 87	
91	or/88-90	

Databases: Cochrane Central Register of Controlled Trials; and Cochrane Database of Systematic Reviews – Wiley interface

Date of last search: 06/12/2022

# #1			
H	Searches MeSH descriptor: [Fetal Membranes, Premature Rupture] this term only		
#2	((prelabor or prelabour or pre-labor or pre-labour or preterm or pre-term or premature*) near/3 ruptur* near/3 membrane*):ti,ab		
#3	((prelabor or prelabour or pre-labor or pre-labour or preterm or pre-term or premature*) near/3 ROM):ti,ab		
#4	PPROM:ti,ab		
#5	(water* near/10 break* near/10 (prelabor or prelabour or pre-labor or pre-labour or preterm or pre-term or premature*)):ti,ab		
#6	#1 or #2 or #3 or #4 or #5		
#7	(fluid* near/3 (gush* or trickl* or leak*)):ti,ab		
#8	(feel* near/3 (wet* or damp*)):ti,ab		
#9	((urinat* or wee*) near/3 (sensation* or feel* or need*)):ti,ab		
#10	#7 or #8 or #9		
#11	MeSH descriptor: [Pregnancy] this term only		
#12	pregnan*:ti,ab		
#13	#11 or #12		
#14	#10 and #13		
#15	#6 or #14		
#16	MeSH descriptor: [Referral and Consultation] this term only		
#17	"Clinical* review*":ti,ab		
#18	"face to face":ti,ab		
#19	consultation*:ti,ab		
#20	meeting*:ti,ab		
#21	"clinical" examin*":ti,ab		
#22	(examin* near/3 (patient or patients or woman or women)):ti,ab		
#23	(contact* near/5 ("healthcare professional*" or medic or medics or doctor or doctors or consultant* or specialist* or obstetrician* or gynecologist* or gynaecologist* or midwife* or midwive* or GP or GPs or nurse* or hospital or hospitals or wards or department or departments)):ti,ab		
#24	MeSH descriptor: [Triage] this term only		
#25	triag*:ti,ab		
#26	MeSH descriptor: [Hotlines] this term only		
#27	MeSH descriptor: [Telephone] explode all trees		
#28	(hotline* or phone* or telephone* or phoning or phoned):ti,ab		
#29	#16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28		
#30	#15 and #29		
#31	MeSH descriptor: [Fetal Membranes, Premature Rupture] this term only and with qualifier(s): [diagnosis - DI]		
#32	MeSH descriptor: [Time Factors] this term only		
#33	#31 and #32		
#34	#30 or #33		

Database: International Health Technology Assessment

Date of last search: 06/12/2022

Searches All: "Fetal Mem

All: "Fetal Membranes, Premature Rupture"[mh]
OR All: (rupture) AND (membranes)
OR AII: (PPROM)
OR All: (waters) AND (breaking)

Health economics search strategies

Database: Medline - OVID interface

Date of last search: 06/12/2022

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#	Searches		
1	FETAL MEMBRANES, PREMATURE RUPTURE/		
2	((prelabo?r or pre-labo?r or preterm or pre-term or premature*) adj3 ruptur* adj3 membrane?).ti.ab.		
3	((prelabo?r or pre-labo?r or preterm or pre-term or premature*) adj3 ROM).ti,ab.		
4	PPROM.ti.ab.		
5	(water* adj10 break* adj10 (prelabo?r or pre-labo?r or preterm or pre-term or premature*)).ti,ab.		
6	(water" adj10 break" adj10 (prelabo?r or pre-labo?r or preterm or pre-term or premature")).ti,ab.		
7			
8	(fluid? adj3 (gush* or trickl* or leak*)).ti,ab.		
	(feel* adj3 (wet* or damp*)).ti,ab.		
9	((urinat* or wee*) adj3 (sensation? or feel* or need*)).ti,ab.		
10	or/7-9		
11	PREGNANCY/		
12	pregnan*.ti,ab.		
13	or/11-12		
14	10 and 13		
15	6 or 14		
16	"REFERRAL AND CONSULTATION"/		
17	clinical\$ review\$.ti,ab.		
18	face to face.ti,ab.		
19	consultation?.ti,ab.		
20	meeting?.ti,ab.		
21	clinical\$ examin\$.ti,ab.		
22	(examin* adj3 (patient? or wom?n)).ti,ab.		
23	(contact* adj5 (healthcare professional? or medic? or doctor? or consultant? or specialist? or obstetrician? or		
	gyn?ecologist? or midwife? or midwive? or GP or GPs or nurse? or hospital? or ward? or department?)).ti,ab.		
24	TRIAGE/		
25	triag*.ti,ab.		
26	HOTLINES/		
27	exp TELEPHONE/		
28	(hotline? or phone? or telephone? or phoning or phoned).ti,ab.		
29	or/16-28		
30	15 and 29		
31	FETAL MEMBRANES, PREMATURE RUPTURE/di [Diagnosis]		
32	TIME FACTORS/		
33	31 and 32		
33 34			
	30 or 33		
35	limit 34 to english language		
36			
37	EDITORIAL/		
38	NEWS/		
39	exp HISTORICAL ARTICLE/		
40	ANECDOTES AS TOPIC/		
41	COMMENT/		
42	CASE REPORT/		
43	(letter or comment*).ti.		
44	or/36-43		
45	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.		
46	44 not 45		
47	ANIMALS/ not HUMANS/		
48	exp ANIMALS, LABORATORY/		
49	exp ANIMAL EXPERIMENTATION/		
50	exp MODELS, ANIMAL/		
51	exp RODENTIA/		
52	(rat or rats or mouse or mice).ti.		
53	or/46-52		
54	35 not 53		
55	ECONOMICS/		
56	VALUE OF LIFE/		
57	exp "COSTS AND COST ANALYSIS"/		
58	exp ECONOMICS, HOSPITAL/		
59	exp ECONOMICS, HOSFIAL/		
60	exp RESOURCE ALLOCATION/		
61	ECONOMICS, NURSING/		
62	ECONOMICS, NORSING/ ECONOMICS, PHARMACEUTICAL/		
63	exp "FEES AND CHARGES"/		
63 64	exp BUDGETS/		
65 66	budget*.ti,ab.		
66 67	cost*.ti,ab.		
67	(economic* or pharmaco?economic*).ti,ab.		
68	(price* or pricing*).ti,ab.		
69	(financ* or fee or fees or expenditure* or saving*).ti,ab.		

Searches

- 70 (value adj2 (money or monetary)).ti,ab.
- 71 resourc* allocat*.ti,ab.
- 72 (fund or funds or funding* or funded).ti,ab.
- 73 (ration or rations or rationing* or rationed).ti,ab.
- 74 ec.fs.
- 75 or/55-74
- 76 54 and 75

Database: Embase - OVID interface

Date of last search: 06/12/2022

#	Saarahaa		
# 1	Searches PREMATURE FETUS MEMBRANE RUPTURE/		
2	((prelabo?r or pre-labo?r or preterm or pre-term or premature*) adj3 ruptur* adj3 membrane?).ti,ab.		
3	((prelabo?r or pre-labo?r or preterm or pre-term or premature*) adj3 ROM).ti,ab.		
4	PPROM.ti,ab.		
5	(water* adj10 break* adj10 (prelabo?r or pre-labo?r or preterm or pre-term or premature*)).ti,ab.		
6	(water adjito break adjito (prelabo i or pre-labo i or preterm or pre-term or premature)).tr,ab.		
7			
8	(fluid? adj3 (gush* or trickl* or leak*)).ti,ab. (feel* adj3 (wet* or damp*)).ti,ab.		
9	((urinat* or wee*) adj3 (sensation? or feel* or need*)).ti,ab.		
10	or/7-9		
11	PREGNANCY/		
12	pregnan*.ti,ab.		
13	or/11-12		
14	10 and 13		
15	6 or 14		
16	CONSULTATION/		
17	PATIENT REFERRAL/		
18	clinical\$ review\$.ti,ab.		
19	face to face.ti.ab.		
20	consultation?.ti,ab.		
21	meeting?.ti,ab.		
22	clinical\$ examin\$.ti,ab.		
23			
23	(examin* adj3 (patient? or wom?n)).ti,ab.		
	(contact* adj5 (healthcare professional? or medic? or doctor? or consultant? or specialist? or obstetrician? or gyn?ecologist? or midwife? or midwive? or GP or GPs or nurse? or hospital? or ward? or department?)).ti,ab.		
25	triag*.ti,ab.		
26	HOTLINE/		
27	TELEPHONE/		
28	exp MOBILE PHONE/		
29	(hotline? or phone? or telephone? or phoning or phoned).ti,ab.		
30	or/16-29		
31	15 and 30		
32	PREMATURE FETUS MEMBRANE RUPTURE/di [Diagnosis]		
33	TIME FACTOR/		
34	32 and 33		
35	31 or 34		
36	limit 35 to english language		
37			
38			
39			
40	exp HISTORICAL ARTICLE/		
41	ANECDOTES AS TOPIC/		
42	COMMENT/		
43	CASE REPORT/		
44	(letter or comment*).ti.		
45	or/37-44		
46	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.		
47	45 not 46		
48	ANIMALS/ not HUMANS/		
49	exp ANIMALS, LABORATORY/		
50	exp ANIMAL EXPERIMENTATION/		
51	exp MODELS, ANIMAL/		
52	exp RODENTIA/		
53	(rat or rats or mouse or mice).ti.		
54	or/47-53 36 not 54		
55	30 Hot 34		

#	Searches
56	HEALTH ECONOMICS/
57	exp ECONOMIC EVALUATION/
58	exp HEALTH CARE COST/
59	exp FEE/
60	BUDGET/
61	FUNDING/
62	RESOURCE ALLOCATION/
63	budget*.ti,ab.
64	cost*.ti,ab.
65	(economic* or pharmaco?economic*).ti,ab.
66	(price* or pricing*).ti,ab.
67	(financ* or fee or fees or expenditure* or saving*).ti,ab.
68	(value adj2 (money or monetary)).ti,ab.
69	resourc* allocat*.ti,ab.
70	(fund or funds or funding* or funded).ti,ab.
71	(ration or rations or rationing* or rationed).ti,ab.
72	or/56-71
73	55 and 72

Database: Cochrane Central Register of Controlled Trials – Wiley interface

Date of last search: 06/12/2022

#	Searches		
#1	MeSH descriptor: [Fetal Membranes, Premature Rupture] this term only		
#2	((prelabor or prelabour or pre-labor or pre-labour or preterm or pre-term or premature*) near/3 ruptur* near/3 membrane*):ti,ab		
#3	((prelabor or prelabour or pre-labor or pre-labour or preterm or pre-term or premature*) near/3 ROM):ti,ab		
#4	PPROM:ti,ab		
#5	(water* near/10 break* near/10 (prelabor or prelabour or pre-labor or pre-labour or preterm or pre-term or premature*)):ti,ab		
#6	#1 or #2 or #3 or #4 or #5		
#7	(fluid* near/3 (gush* or trickl* or leak*)):ti,ab		
#8	(feel* near/3 (wet* or damp*)):ti,ab		
#9	((urinat* or wee*) near/3 (sensation* or feel* or need*)):ti,ab		
#10	#7 or #8 or #9		
#11	MeSH descriptor: [Pregnancy] this term only		
#12	pregnan*:ti,ab		
#13	#11 or #12		
#14	#10 and #13		
#15	#6 or #14		
#16	MeSH descriptor: [Referral and Consultation] this term only		
#17	"Clinical* review*":ti,ab		
#18	"face to face":ti,ab		
#19	consultation*:ti,ab		
#20	meeting*:ti,ab		
#21	"clinical* examin*":ti,ab		
#22	(examin* near/3 (patient or patients or woman or women)):ti,ab		
#23	(contact* near/5 ("healthcare professional*" or medic or medics or doctor or doctors or consultant* or specialist* or obstetrician* or gynecologist* or gynaecologist* or midwife* or midwive* or GP or GPs or nurse* or hospital or hospitals or ward or wards or department or departments)):ti,ab		
#24	MeSH descriptor: [Triage] this term only		
#25	triag*:ti,ab		
#26	MeSH descriptor: [Hotlines] this term only		
#27	MeSH descriptor: [Telephone] explode all trees		
#28	(hotline* or phone* or telephone* or phoning or phoned):ti,ab		
#29	#16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28		
#30	#15 and #29		
#31	MeSH descriptor: [Fetal Membranes, Premature Rupture] this term only and with qualifier(s): [diagnosis - DI]		
#32	MeSH descriptor: [Time Factors] this term only		
#33	#31 and #32		
#34	#30 or #33		
#35	MeSH descriptor: [Economics] this term only		
#36	MeSH descriptor: [Value of Life] this term only		
#37	MeSH descriptor: [Costs and Cost Analysis] explode all trees		
#38	MeSH descriptor: [Economics, Hospital] explode all trees		
#39	MeSH descriptor: [Economics, Medical] explode all trees		
#40	MeSH descriptor: [Resource Allocation] explode all trees		
#41	MeSH descriptor: [Economics, Nursing] this term only		

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#	Searches		
#42	MeSH descriptor: [Economics, Pharmaceutical] this term only		
#43	MeSH descriptor: [Fees and Charges] explode all trees		
#44	MeSH descriptor: [Budgets] explode all trees		
#45	budget*:ti,ab		
#46	cost*:ti,ab		
#47	(economic* or pharmaco?economic*):ti,ab		
#48	(price* or pricing*):ti,ab		
#49	(financ* or fee or fees or expenditure* or saving*):ti,ab		
#50	(value near/2 (money or monetary)):ti,ab		
#51	resourc* allocat*:ti,ab		
#52	(fund or funds or funding* or funded):ti,ab		
#53	(ration or rations or rationing* or rationed):ti,ab		
#54	#35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 or #43 or #44 or #45 or #46 or #47 or #48 or #49 or #50 or #51 or #52 or #53		
#55	#34 and #54		

Database: International Health Technology Assessment

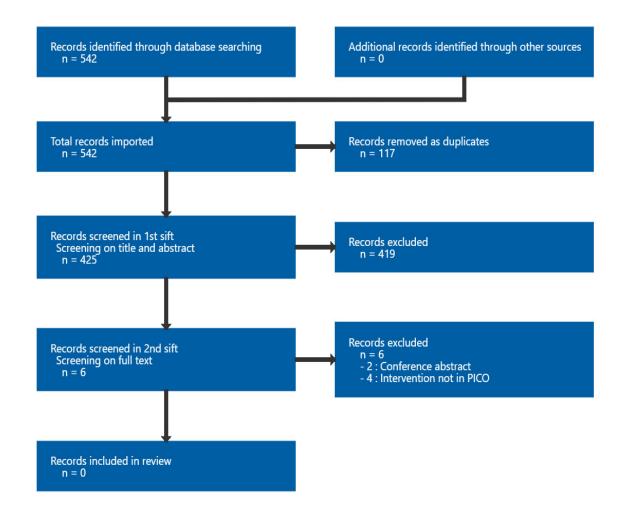
Date of last search: 06/12/2022

#	Searches
	All: "Fetal Membranes, Premature Rupture"[mh]
	OR All: (rupture) AND (membranes)
	OR All: (PPROM)
	OR All: (waters) AND (breaking)

Appendix C Effectiveness evidence study selection

Study selection for: What is the optimum timeframe between a mother reporting possible PRoM and face-to-face clinical review?

Figure 1: Study selection flow chart



Appendix D Evidence tables

Evidence tables for review question: What is the optimum timeframe between a mother reporting possible PRoM and face-to-face clinical review?

No evidence was identified which was applicable to this review question.

Appendix E Forest plots

Forest plots for review question: What is the optimum timeframe between a mother reporting possible PRoM and face-to-face clinical review?

No meta-analysis was conducted for this review question and so there are no forest plots.

Appendix F GRADE tables

GRADE tables for review question: What is the optimum timeframe between a mother reporting possible PRoM and face-to-face clinical review?

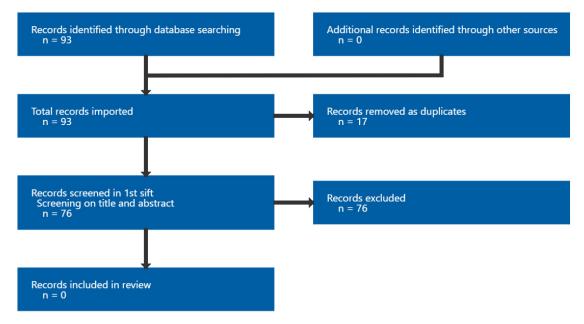
No evidence was identified which was applicable to this review question.

Appendix G Economic evidence study selection

Study selection for: What is the optimum timeframe between a mother reporting possible PRoM and face-to-face clinical review?

No economic evidence was identified which was applicable to this review question.

Figure 2: Study selection flow chart



Appendix H Economic evidence tables

Economic evidence tables for review question: What is the optimum timeframe between a mother reporting possible PRoM and face-to-face clinical review?

No evidence was identified which was applicable to this review question.

Appendix I Economic model

Economic model for review question: What is the optimum timeframe between a mother reporting possible PRoM and face-to-face clinical review?

No economic analysis was conducted for this review question.

Appendix J Excluded studies

Excluded studies for review question: What is the optimum timeframe between a mother reporting possible PRoM and face-to-face clinical review?

Excluded effectiveness

Table 3: Excluded studies and reasons for their exclusion		
Study	Reason for exclusion	
Carlan, S. J., O'Brien, W. F., Parsons, M. T. et al. (1993) Preterm premature rupture of membranes: a randomized study of home versus hospital management. Obstetrics and gynecology 81(1): 61-4	- Intervention not in PICO Study compares latency periods of women diagnosed with PRoM randomised to home or hospital management. Study does not report timeframe from presentation/ reporting of possible PRoM to clinical assessment/ review	
Chacon, Kelly M.; Bryant Mantha, Allison S.; Clapp, Mark A. (2021) Outpatient Expectant Management of Term Prelabor Rupture of Membranes: A Retrospective Cohort Study. American journal of perinatology 38(7): 714-720	- Intervention not in PICO Study compares latency periods of women diagnosed with PRoM randomised to home or hospital management. Study does not report timeframe from presentation/ reporting of possible PROM to clinical assessment/ review	
Munson, L. A., Graham, A., Koos, B. J. et al. (1985) Is there a need for digital examination in patients with spontaneous rupture of the membranes?. American journal of obstetrics and gynecology 153(5): 562-3	- Intervention not in PICO Study compares two methods of membrane examination. Study does not report timeframe from presentation/ reporting of possible PRoM to clinical assessment/ review	
Papadakis, K. and Pande, B. (2017) The role of Actim PROM in the clinical diagnosis of PPROM. BJOG: An International Journal of Obstetrics and Gynaecology 124(supplement1): 138-139	- Conference abstract	
Singhal, Seema; Puri, Manju; Gami, Neha (2012) An analysis of factors affecting the duration of latency period and its impact on neonatal outcome in patients with pprom. International Journal of Infertility and Fetal Medicine 3(3): 87-91	- Intervention not in PICO Prospective cohort study reporting factors associated with length of latency period in women with PPRoM. Study does not report timeframe from presentation/ reporting of possible PRoM to clinical assessment/ review	
Warwar, Rachel E., Kuss, Brittany N., Elliott, John O. et al. (2019) Financial Analysis of Expectant Management of Preterm Premature Rupture of Membranes to Term in a Community Hospital. Obstetrics and Gynecology 133(suppl1)	- Conference abstract	

Excluded economic studies

No economic evidence was identified for this review.

Appendix K Research recommendations – full details

Research recommendations for review question: What is the optimum timeframe between a mother reporting possible PRoM and face-to-face clinical review?

No research recommendations were made for this review question.