National Institute for Health and Care Excellence

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Neonatal infection: antibiotics for prevention and treatment

[D2] Evidence review for timing of prelabour rupture of membranes to birth and risk of early-onset neonatal infection

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NICE guideline NG195

Evidence underpinning a risk factor in box 1 (about rupture of membranes at term). Box 1 is referenced in recommendations 1.3.1, 1.3.3 and 1.3.5.

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Neonatal infection: prelabour rupture of membranes

1.1 Review question

This evidence review summarises the evidence for:

What is the risk of early onset neonatal infection at different time intervals between prelabour rupture of membranes (PROM) and birth for singleton pregnancies at term?

1.1.1 Summary of the protocol

A summary of the review protocol is available in **Table 1**.

Table 1: Summary of the protocol

Population	Inclusion: • Women and people with confirmed prelabour rupture of membranes (PROM) at term (37 to 42 weeks gestation) with singleton pregnancies • Babies born at term following PROM Exclusion: • Women and people with PROM with multiple pregnancies • Women and people with PROM at pre-term (<37 weeks gestation) • Babies born pre-term following PROM (also known as preterm, prelabour rupture of membranes PPROM) • Babies with confirmed or suspected non-bacterial infections • Babies with localised infections

Prognostic factors	Time between PROM and birth at the following intervals: • <12 hours • ≥18 hours to <24 hours • ≥24 to <36 hours • ≥36 to <48 hours • ≥48 hours to <72 hours Include all time intervals as reported in the studies.
Comparators/Reference groups	• Comparing PROM to birth at different time intervals (listed above) to those without PROM. • Comparing PROM to birth interval to a PROM to birth interval of < 12 hours • Comparing one PROM to birth interval to another (e.g., >36 hours vs. 24 hours)
Outcomes	• Culture-proven infection (blood or cerebrospinal fluid (CSF)) from a sample taken within 72 hours following birth or within the timeframe defined by the study for early-onset neonatal infection (this outcome may be reported as neonatal sepsis) • Culture negative suspected neonatal infection within 72 hours of birth where available or within the timeframe defined by the study for early onset neonatal infection (in such cases baby is unwell or having elevated CRP but is not culture positive). • Admission to NICU for suspected infection within 72 hours of birth or within the timeframe defined by the study for early onset neonatal infection • Neonatal mortality associated with early onset infection • Meningitis within 72 hours of birth or within the timeframe defined by the study for early onset neonatal infection • Early onset pneumonia within 72 hours of birth or within the timeframe defined by the study for early onset neonatal infection (note: pneumonia may not be captured by blood or CSF culture)
Study type	• Prospective cohort studies • Retrospective cohort studies • Systematic reviews of cohort studies

	Cohort studies will only be included if they adjust for any covariate(s) in their analysis. Only studies with multivariable analysis will be included.

Abbreviations: CRP: C-reactive protein; CSF: cerebrospinal fluid; NICU: neonatal intensive care unit; PROM: prelabour rupture of membranes; ROM: rupture of membranes

For the full protocol see **appendix A** in the technical appendices document.

1.1.2 Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual. Methods specific to this review question are described in the review protocol and in **appendix J** in the technical appendices document.

Declarations of interest were recorded according to NICE's conflicts of interest policy.

1.1.2.1 Search methods

The searches for the effectiveness evidence were run on 08/10/2025. The following databases were searched: Cochrane Central Register of Controlled Trials (CENTRAL) (Wiley); Cochrane Database of Systematic Reviews (CDSR) (Wiley); Embase (Ovid); Epistemonikis (https://www.epistemonikos.org/); MEDLINE (Ovid); Limits were applied to remove animal studies, editorials, conference abstracts, empty registry entries and references not published in the English language.

The database searches were supplemented with additional search methods. Forward citation searching was conducted on Lens.org using seed references identified from the scoping searches.

The searches for the cost effectiveness evidence were run on 08/10/2025. The following databases were searched: Embase (Ovid); International HTA Database (https://database.inahta.org); MEDLINE ALL (Ovid). Limits were applied to remove animal studies, editorials, conference abstracts, empty registry entries and references not published in the English language. Filters were used to limit to economic evaluations.

A NICE Senior Information Specialist (SIS) conducted the searches. The MEDLINE strategy was quality assured by another NICE SIS. All translated search strategies were peer reviewed to ensure their accuracy. Both procedures were adapted from the 2015 PRESS Guideline Statement. Further details and full search strategies for each database are provided in Appendix B.

1.1.2.2 Protocol deviations

At full text sifting it became apparent that there were very few studies that matched the full inclusion and exclusion criteria. A decision was made to allow the inclusion of secondary analyses that are not prespecified in the original study publication.

1.1.3 Prognostic evidence

1.1.3.1 Included studies

Study selection

A systematic search was carried out to identify potentially relevant studies as detailed in appendix J in the technical appendices document. See **appendix B** in the technical appendices document for the literature search strategy.

The study selection process is presented as a PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) flow diagram in **appendix C** in the technical appendices document.

Three papers were included in this review, 2 retrospective cohort studies (Herbst 2007, Zhuang 2020) and a secondary analysis study of an included study (Zhuang 2022). The included studies are summarised in Table 2.

Outcomes that were not captured in any studies were admission to NICU for suspected infection within 72 hours of birth, neonatal mortality associated with early-onset infection and meningitis within 72 hours of birth.

One study (Herbst 2007) reported association data for rupture of membranes (ROM) to birth time with neonatal sepsis in increasing timeframes up to 72

hours as a continuous variable using 0 hours to 6 hours ROM to birth time as a reference. This study did not report the timing the onset of neonatal infection.

One study reported association data for prelabour rupture of membranes (PROM) with early-onset neonatal sepsis, early-onset pneumonia (both within 72 hours) and neonatal infectious diseases onset within 7 days, comparing to neonates born without PROM (Zhuang, 2020). The study reported that the median duration between PROM to delivery was 26.38 hours (Q1-Q3: 10.15–40.87 h), however, this variable was not included in the model analysis. An additional outcome neonatal infectious disease was also included from the study, as it included relevant protocol outcomes such as neonatal sepsis and bacterial meningitis.

The secondary analysis study (Zhuang 2022) utilised the data only from those neonates born following PROM from the original publication as described above (Zhuang 2020). This study reported association data for PROM to birth at different time intervals for early-onset neonatal sepsis within 72 hours and early-onset pneumonia for both 72 hours and 7 days for timeframes ranging from 10 hours to more than 22 hours, and compared those born before the specified PROM to birth time to those born after.

No same confounder was adjusted for in all three studies. Two studies adjusted for chorioamnionitis, mode of delivery, amniotic fluid pollution (defined as degree I, II and II meconium-stained amniotic fluid), and location of hospital, (Zhuang 2020, Zhuang 2022), 2 studies adjusted for maternal age and infant gender (Herbs 2007, Zhuang 2022), and 2 studies adjusted for multiparity (Zhuang 2020, Herbst 2007).

The association data from each study could not be pooled for several reasons:

- Different PROM to birth time intervals were reported across the studies.

- Outcome definitions were varied. For example, two studies defined early-onset neonatal infection as culture-proven sepsis from blood or cerebrospinal fluid (CSF) within 72 hours, whereas the third study defined it as culture-proven sepsis (blood or CSF) or clinical signs combined with elevated C-reactive protein levels, without specifying a timeframe for onset.
- Studies adjusted for different set of covariates.
- Reference groups were not consistent across the studies.

Subgroup analysis could not be conducted because of insufficient evidence.

1.1.3.2 Excluded studies

Details of studies excluded at full text, along with reasons for exclusion, are given in **appendix I**.

1.1.4 Summary of studies included in the prognostic evidence

Table 2 Summary of studies included in the prognostic evidence

Study details	Population	Prognostic factors	Reference groups	Covariates	Outcomes
Herbst 2007 Study type: Retrospective cohort Follow-up time: Not reported Setting: Registry data Location: Sweden	n = 113568 mothers n = 113568 singleton infants born at term	Rupture of membranes to birth intervals as a continuous variable 6.1 hours to 12 hours 12.1 hours to 18 hours 18.1 hours to 24 hours 24.1 hours to 48 hours 48.1 hours to 72 hours	Rupture of membranes to birth from 0 hours to 6 hours	• Maternal age (continuous) • multiparity (yes/no) • infant gender • gestational age (continuous) • birth weight (continuous) • duration of labour	Neonatal sepsis (blood positive culture or typical clinical signs with elevated C-reactive protein). Timeframe of neonatal sepsis not reported
Zhuang 2020 Study type: Retrospective cohort	n = 15926 participants with a diagnosis of PROM, gestation age of < 24 weeks and ≥42	PROM to birth Duration between PROM to delivery: median, 26.38 hours;	No PROM	• City where the hospital locates • Mode of delivery (caesarean	• Early-onset neonatal sepsis within 72 hours • Early-onset neonatal

Study details	Population	Prognostic factors	Reference groups	Covariates	Outcomes
Follow-up time: 7 days Setting: 3 hospital sites Location: China	weeks. Pregnancies without PROM but with the same gestational week, admission date ± 3 days and maternal age ± 5 years as those with PROM n = 16353 neonates Includes neonates from 212 twin pregnancies and one triplet pregnancy	Q1-Q3, 10.15–40 .87 h		section or vaginal delivery) • Clinical or subclinical chorioamnionitis • Large or small for gestational age • Amniotic fluid pollution • Gestational hypertensive • Essential hypertension • Diabetes mellitus arising in pregnancy • Multiparity Multiple birth	pneumonia within 72 hours • Neonatal infectious diseases onset within 7 days Neonatal sepsis confirmed by clinical symptoms and a positive blood or CSF culture
Zhuang 2022	N=7019 participants with a diagnosis of PROM at term N = 7015 singleton neonates	Time threshold of PROM to birth (hours); from 0 hours to ≥ 10 hours	Time threshold of PROM to birth (hours); < 10 hours < 12 hours	• City where the hospital locates • Maternal age • Education level • Chorioamnionitis	• Early-onset neonatal sepsis within 72 hours • Early-onset neonatal pneumonia within 72 hours

Study details	Population	Prognostic factors	Reference groups	Covariates	Outcomes
Study type: Secondary analysis, not prespecified Follow-up time: 7 days Setting: 3 hospital sites Location: China	4 neonates were stillborn	from 0 hours to ≥ 12 hours from 0 hours to ≥ 14 hours from 0 hours to ≥ 16 hours from 0 hours to ≥ 18 hours from 0 hours to ≥ 20 hours from 0 hours to ≥ 22* hours	< 14 hours < 16 hours < 18 hours < 20 hours < 22 hours	• Induction of labour • Prenatal antibiotic treatment • Mode of delivery (caesarean section or vaginal delivery) • Neonate's sex Apgar score	• Early-onset neonatal pneumonia within 7 days Neonatal sepsis confirmed by clinical symptoms and a positive blood or CSF culture

Abbreviations: CSF: cerebrospinal fluid; PROM: prelabour rupture of membranes

* No upper threshold of PROM reported

See **appendix D** for full evidence tables.

1.1.5 Summary of prognostic evidence

PROM to birth compared to no PROM

Risk factor and reference group	Outcomes	Risk	Certainty
PROM to birth compared to no PROM (median duration between PROM to birth 26.38 hours; not included in the model)	Culture positive early-onset sepsis (timeframe: within 72 hours of life).	Increased risk	Very low
PROM to birth compared to no PROM (median duration between PROM to birth 26.38 hours; not included in the model)	Early-onset pneumonia (timeframe: within 72 hours of life)	Increased risk	Very low
PROM to birth compared to no PROM (median duration between PROM to birth 26.38 hours; not included in the model)	Neonatal infectious diseases (timeframe: within 7 days of life). Method of diagnosis NR.	Increased risk	Very low

Abbreviations: NR: not reported; PROM: prelabour rupture of membranes

PROM to birth compared to other PROM to birth time intervals

Risk factor and reference group	Outcomes	Risk	Certainty
PROM to birth ≥10 hours compared to <10 hours	Culture positive early-onset sepsis (timeframe: within 72 hours of life)	Uncertain risk	Very low
PROM to birth ≥12 hours compared to <12 hours	Culture positive early-onset sepsis (timeframe: within 72 hours of life)	Uncertain risk	Very low
PROM to birth ≥14 hours compared to <14 hours	Culture positive early-onset sepsis (timeframe: within 72 hours of life)	Uncertain risk	Very low
PROM to birth ≥16 hours compared to <16 hours	Culture positive early-onset sepsis (timeframe: within 72 hours of life)	Uncertain risk	Very low
PROM to birth ≥18 hours compared to <18 hours	Culture positive early-onset sepsis (timeframe: within 72 hours of life)	Uncertain risk	Very low
PROM to birth ≥20 hours compared to <20 hours	Culture positive early-onset sepsis (timeframe: within 72 hours of life)	Uncertain risk	Very low

PROM to birth ≥22 hours compared to <22 hours**	Culture positive early-onset sepsis (timeframe: within 72 hours of life)	Uncertain risk	Very low
ROM to birth 6 per hour interval compared to ROM to birth 0 to 6 hours	Culture positive* neonatal sepsis (timeframe for sepsis not reported)	Increased risk	Very low
PROM to birth ≥10 hours compared to <10 hours	Early-onset pneumonia (timeframe: within 72 hours of life)	Uncertain risk	Very low
PROM to birth ≥12 hours compared to <12 hours	Early-onset pneumonia (timeframe: within 72 hours of life)	Uncertain risk	Very low
PROM to birth ≥14 hours compared to <14 hours	Early-onset pneumonia (timeframe: within 72 hours of life)	Uncertain risk	Very low
PROM to birth ≥16 hours compared to <16 hours	Early-onset pneumonia (timeframe: within 72 hours of life)	Increased risk	Very low
PROM to birth ≥18 hours compared to <18 hours	Early-onset pneumonia (timeframe: within 72 hours of life)	Increased risk	Very low
PROM to birth ≥20 hours compared to <20 hours	Early-onset pneumonia (timeframe: within 72 hours of life)	Increased risk	Very low
PROM to birth ≥22 hours compared to <22 hours**	Early-onset pneumonia (timeframe: within 72 hours of life)	Uncertain risk	Very low

PROM to birth ≥10 hours compared to <10 hours	Early-onset pneumonia (timeframe: within 7 days of life)	Uncertain risk	Very low
PROM to birth ≥12 hours compared to <12 hours	Early-onset pneumonia (timeframe: within 7 days of life)	Uncertain risk	Very low
PROM to birth ≥14 hours compared to <14 hours	Early-onset pneumonia (timeframe: within 7 days of life)	Uncertain risk	Very low
PROM to birth ≥16 hours compared to <16 hours	Early-onset pneumonia (timeframe: within 7 days of life)	Increased risk	Very low
PROM to birth ≥18 hours compared to <18 hours	Early-onset pneumonia (timeframe: within 7 days of life)	Increased risk	Very low
PROM to birth ≥20 hours compared to <20 hours	Early-onset pneumonia (timeframe: within 7 days of life)	Increased risk	Very low
PROM to birth ≥22 hours compared to <22 hours**	Early-onset pneumonia (timeframe: within 7 days of life)	Increased risk	Very low

Abbreviations: NR: not reported; PROM: prelabour rupture of membranes

*Culture positive or clinical signs of sepsis plus elevated C-reactive protein

** No upper threshold of PROM reported

See **appendix F** for full GRADE tables.

1.1.6 Economic evidence

1.1.6.1 Included studies

A search was performed to identify published economic evaluations of relevance to this review question. See the literature search strategy in **appendix B** in the technical appendices document.

No economic studies were identified which were applicable to this review question. (see economic study selection flow chart in **appendix G** in the technical appendices document).

1.1.6.2 Excluded studies

See **appendix I** in the technical appendices document for a list of excluded economic studies, with reason for exclusion.

1.1.7 Economic model

No original economic modelling was completed for this review question.

1.1.8 Committee discussion and interpretation of the evidence

1.1.8.1 Is the problem a priority

The current NICE guideline on neonatal infection (NG195) lists various risk factors for early onset neonatal infection, including pre labour rupture of membranes (PROM) for more than 24 hours before the onset of labour. However, this definition does not align with clinical practice, where the interval from PROM to birth is considered more relevant than the time before labour begins. This is because the amniotic sac provides a protective barrier, and once it ruptures, the fetus is exposed to potential pathogens or ascending infection from the genital tract. Therefore, the total duration of this exposure is relevant, while the timing of labour itself has little impact on the risk of infection. The evidence underpinning the existing recommendation is outdated and does not address this PROM to birth interval, resulting in inconsistencies in maternal counselling, induction decisions, neonatal monitoring and management.

In 2023, there were 591,072 live births in England and Wales, with 92% at term (544,931). PROM occurs in about 8% of term pregnancies (~48,456 cases annually), and around 14% of these, approximately 6,784 cases, remain prolonged beyond 24 hours before birth (ONS 2024; Cammu 1990). Revising this risk factor can clarify and standardise practice in terms of when rupture of membranes should be considered a risk factor for early onset neonatal infection.

The committee agreed that an evidence review could help determine the association between PROM to birth interval and the risk of early onset neonatal infection and inform revisions to the wording of this risk factor.

1.1.8.2 Certainty of evidence and balance of effects

All of the evidence was assessed with GRADE and was rated as very low certainty. The risk of bias and directness was evaluated using the QUIPS tool. Risk of bias was assessed to be high for 2 studies: one study did not report a

description of how time from ROM to birth was measured or the timeframe of sepsis onset (Herbst 2007); the second failed to report a description of how time from ROM to birth was measured and also reported secondary analysis data not outlined in the original publication (Zhuang 2022). The third study was assessed to be of moderate risk because there was no reporting of how time from PROM to birth was measured (Zhuang 2020).

All evidence comparing different time intervals between PROM and birth for association with infection was downgraded for very serious or serious imprecision in GRADE. Two outcomes were downgraded for indirectness because they did not match those specified in the protoocol; neonatal infectious disease includes both non-bacterial and localised infections; and early-onset pneumonia within 7 days surpasses the 72 hour timeframe used for early-onset infection definition. All outcomes were also downgraded for inconsistency because they were based on single studies.

Whilst all studies adjusted for multiple confounders, no single confounder was adjusted for in all three studies.

The committee considered all available evidence on the association between the duration of PROM to birth and early onset neonatal infection. One study reported an increased risk of early onset sepsis, early onset pneumonia, and neonatal infectious disease among babies born to women with PROM in term singleton pregnancies. The median PROM to birth interval in this study was 26.38 hours; however, the analysis did not include PROM to birth time as a variable in the model, limiting its usefulness for determining a specific threshold.

Two other studies examined PROM to birth intervals using different time thresholds, but the associations were inconsistent. For early onset sepsis within 3 days of life, there was uncertain risk across thresholds such as >10, >12, >14, >16, >18, >20 and >22 hours compared with <10, <12, <14, <16, <18, <20 and <22 hours respectively. For early-onset pneumonia at 3 days, evidence suggested increased risk at intervals >16, >18, and >20 hours (compared with <16, <18, and <20 hours respectively), while risk remained

uncertain at shorter thresholds >10, >12, >14, and >22 hours (compared with <10, <12, <14, and <22 hours). A similar pattern was observed for pneumonia at 7 days, with increased risk at >16 to >22 hours (compared to <16 to <22 hours respectively) and uncertain risk at >10, >12, >14 (compared with <10, <12, <14 hours respectively).

One study also reported a linear increase in culture positive septicaemia risk per 6 hour increment, estimating approximately a 29% higher risk per 6 hour increment compared with a 0–6 hour reference. Although this finding aligned with clinical experience, the continuous nature of the analysis made it difficult to identify a discrete threshold.

The committee acknowledged several limitations in the evidence base, including variations in PROM to birth interval thresholds, heterogeneity in outcome definitions, differences in covariate adjustment, and inconsistent reference groups. Some studies combined culture positive sepsis with clinically diagnosed culture-negative cases, and some only reported on culture-positive cases. Overall, the certainty of evidence for all outcomes was very low.

Despite these limitations, the committee agreed that the overall evidence indicated that the risk of early onset infection increases as the PROM to birth interval lengthens. In the absence of a definitive evidence based threshold, the committee relied on clinical experience and current practice, which commonly considers a PROM to birth interval of 24 hours or more as a risk factor for early-onset infection. Adopting this threshold was judged to be clinically pragmatic, consistent with current practice, and likely to reduce variation in care across the UK. While this change may slightly increase the number of neonates requiring assessment, it is expected to clarify and improve clinical practice, thereby enhancing the identification of babies at risk of infection. For example, under the previous definition of this risk factor (PROM for 24 hours before the onset of labour), a baby would not have been considered at risk if active labour began 8 hours after membrane rupture but lasted for 24 hours, making the total length of exposure time of 34 hours

between PROM and birth. The new definition of the risk factor should address this inconsistency.

The committee noted that although all 3 studies investigated prelabour rupture of membranes, none reported how the onset of labour was defined. The committee also discussed that whether rupture of membranes occurrs prior to or after the onset of labour is irrelevant when assessing the risk of neonatal infection. Therefore, the committee agreed to remove the word ‘prelabour’ from the risk factor to make it clear that all rupture of membranes at term, whether prelabour or not, is important for assessing the risk of early-onset infection.

1.1.8.3 Resources and cost-effectiveness

There was no published economic evidence to support the committee’s decision making. Therefore the committee made a qualitative assessment of the cost-effectiveness of amending the risk factor for early-onset recommendation to confirmed rupture of membranes for more than 24 hours before a term birth. The risk factor had previously been described as the confirmed prelabour rupture of membranes at term for more than 24 hours before the onset of labour. The committee considered that the revised wording of the risk factor could potentially increase the number of neonates requiring monitoring for early-onset infection. They balanced this against the possibility of a higher number of missed infection cases if the recommendations remained unchanged.

However, the committee also noted that current practice was aligned with the revised wording of the risk factor, especially as the timing of onset of labour is often not recorded. Therefore, no significant resource impact is anticipated from the revised wording of the risk factor.

1.1.8.4 Equity

No equality and health inequalities issues related to PROM were identified in the evidence.

The committee noted that some research suggests that ethnicity may influence neonatal outcomes, but there is limited direct evidence linking ethnicity to worse outcomes specifically following PROM. However, social factors such as access to healthcare and socio-economic status often overlap with ethnicity and may contribute to differences in outcomes, including neonatal infections. These factors could affect monitoring and management plans following PROM. The committee highlighted that recommendations should be sensitive to these challenges and include strategies to support equitable implementation, such as culturally appropriate communication and consideration of local service provision.

1.1.8.5 Acceptability

The committee noted that in practice, 24 hours between rupture of membranes and birth was already widely used as a prompt to assess the baby for risk of infection.

1.1.8.6 Feasibility

The committee agreed that adopting PROM to birth interval as a risk factor is feasible, as PROM to birth intervals are already incorporated into routine neonatal risk assessment. Neonates delivered after more than 24 hours of ruptured membranes are routinely monitored by midwives and paediatricians, regardless of labour status which supports this amendment.

1.1.8.7 Other considerations

The committee considered what effect changing the risk factor will have on counselling women and pregnant people presenting with PROM at term regarding their choice of expectant management for up to 24 hours or induction of labour as soon as possible. They highlighted that the evidence reviewed for this update showed that the risk of neonatal infection increases over time and providing this information may impact the woman’s or pregnant person’s choice of PROM management. The committee noted that this is covered in the section regarding prelabour rupture of membranes at term in

the intrapartum care guideline (NG235) and the relevant recommendation (1.7.5) will be amended accordingly.

1.1.9 Recommendations supported by this evidence review

This evidence review supports a risk factor for early-onset neonatal infection in box 1 (about rupture of membranes at term). Box 1 is referenced in recommendations 1.3.1, 1.3.3 and 1.3.5.

1.1.10 References

Effectiveness evidence

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