

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Aneurin Bevan University Health Board Antimicrobial Working Group	Guideline	012	014	1.6.8: There is quite a difference in coverage between amoxicillin and co-amoxiclav as options for Po switch, therefore if amoxicillin will suffice, as evidenced by current practice across a number of UK sites, why include co-amoxiclav as an option?	Thank you for the comment. The committee has revised the recommendation so that it now specifies amoxicillin as the first-choice oral antibiotic, informed by the antibiotic regimen used in the UK quality improvement initiatives and their clinical experience. The committee noted that the dose of co-amoxiclav used in the RAIN randomised controlled trial (Keij, 2022) was higher than the BNFC recommended dose and that the UK quality improvement initiatives that initially used co-amoxiclav have transitioned to using amoxicillin. Therefore, co-amoxiclav has been removed from the recommendation as suggested. The recommendation wording also clarifies that other antibiotics may be used when local microbiological surveillance data indicate different resistance patterns.
Aneurin Bevan University Health Board Antimicrobial Working Group	Guideline	012	014	1.6.8: Furthermore to the antimicrobial stewardship challenge to include co-amoxiclav is a safety concern of the increased risk of cholestatic jaundice / acute liver toxicity that is six times greater with co-amoxiclav than with amoxicillin alone which is one of the reasons that co-amoxiclav is only rarely used in neonatal ICUs (Neonatal Formulary, 7 th edition, 2015 Wiley Blackwell / BMJ Books – accessed 4/3/26 via Neonatal Formulary 7: Drug Use in Pregnancy and	Thank you for the comment. The committee has revised the recommendation so that it now specifies amoxicillin as the first-choice oral antibiotic, informed by the antibiotic regimen used in the UK quality improvement initiatives and their clinical experience. The committee noted that the dose of co-amoxiclav used in the RAIN randomised controlled trial (Keij, 2022) was higher than

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				the First Year of Life). I would suggest that the guideline recommends just amoxicillin empirically for these reasons.	the BNFC recommended dose and that the UK quality improvement initiatives that initially used co-amoxiclav have transitioned to using amoxicillin. Therefore, co-amoxiclav has been removed from the recommendation as suggested. The recommendation wording also clarifies that other antibiotics may be used when local microbiological surveillance data indicate different resistance patterns.
BNF Partnership	Guideline	012	014	Amoxicillin and co-amoxiclav SPCs do not include indications for neonatal infection and dosing for neonates younger than 7 days is not clearly stated; twice daily dosing is suggested in section 5.2 “For very young children (including preterm newborns) in the first week of life the interval of administration should not exceed twice daily administration due to immaturity of the renal pathway of elimination”. For these reasons, consider if inclusion of an off-label statement is warranted for oral step-down treatment of suspected early-onset neonatal infection.	Thank you for your comment. We are not including a dosage in the recommendation as we are aware the BNF is reviewing this. We have added an off-label statement based on advice from the MHRA
BNF Partnership	Guideline	012	014-016	1.6.8 We are concerned that the current recommendation may inadvertently imply that amoxicillin and co-amoxiclav are therapeutically equivalent and interchangeable. In the UK, amoxicillin is classified within the “Access” group of antibiotics, whereas co-amoxiclav is categorised as a “Watch” antibiotic because of its broader spectrum	Thank you for the comment. The committee has revised the recommendation so that it now specifies amoxicillin as the first-choice oral antibiotic, informed by the antibiotic regimen used in the UK quality improvement initiatives and their clinical experience. The committee noted that the dose of co-

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>of activity and greater potential to drive antimicrobial resistance. Co-amoxiclav is also associated with a higher incidence of gastrointestinal adverse effects compared with amoxicillin alone.</p> <p>Although one of the studies (RAIN study Keij et al) included in the systematic review used co-amoxiclav, the investigators themselves acknowledged that it was selected to provide broader coverage against both Gram-positive and Gram-negative organisms and questioned whether such breadth was necessary. The risk of a clinically significant, asymptomatic Gram-negative infection in the context of negative cultures is likely to be very low.</p> <p>Furthermore, resistance rates of <i>Escherichia coli</i> to co-amoxiclav are high in many regions, potentially limiting its effectiveness—particularly when prescribed at the UK-licensed dose, which is lower than the substantially higher dose used in the trial. If there are specific clinical scenarios in which co-amoxiclav should be preferred over amoxicillin, it would be helpful for these to be clearly defined. Explicitly outlining such indications would support antimicrobial stewardship and reduce the risk of unintended overuse of broader-spectrum agents.</p>	<p>amoxiclav used in the RAIN randomised controlled trial (Keij, 2022) was higher than the BNFC recommended dose and that the UK quality improvement initiatives that initially used co-amoxiclav have transitioned to using amoxicillin. Therefore, co-amoxiclav has been removed from the recommendation as suggested. The recommendation wording also clarifies that other antibiotics may be used when local microbiological surveillance data indicate different resistance patterns.</p>

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
British Association of Perinatal Medicine	General	011	026	Comment 1: Recommendation 1.6.7 (page 11, line 26) It would be helpful to clarify that this recommendation applies to babies for whom a decision has already been made to continue antibiotics beyond 36 hours. While this is implied in the surrounding recommendations, it is not currently stated explicitly and could lead to ambiguity in interpretation.	Thank you for your comment. The wording of this recommendation has been amended for clarity.
British Association of Perinatal Medicine	General	023	015	Comment 2: Evidence Review R, section 1.1.8.2 (page 23, line 15) There remain uncertainties and variation in clinical practice regarding the use of oral antibiotics in postnatal babies with suspected infection. Further prospective audit or service evaluation would help define appropriate clinical parameters, including CRP thresholds and gestational age criteria, to support safe implementation.	Thank you for your comment. The committee recognised the uncertainty and variation in current clinical practice regarding the use of oral antibiotics in postnatal babies with suspected infection. The committee agreed that further evidence is needed to clarify the clinical parameters required for safe and consistent implementation. To address this gap, the committee made a research recommendation comparing the effectiveness and safety of switching to oral antibiotics with continuing intravenous antibiotics in babies with suspected early-onset neonatal infection (see Appendix K in Evidence Review R).
British Association	General	Eligibility	Eligibility	Comment 3: Recommendation 1.6.7 (eligibility criteria)	Thank you for your comment. The committee noted that CRP thresholds for switching to oral antibiotics varied across the UK sites

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
of Perinatal Medicine				<p>The IV-to-oral switch pathway is currently being implemented with variation in eligibility criteria, including gestational age thresholds and the CRP levels considered acceptable for switching treatment. The guideline refers to CRP levels being “elevated” initially and subsequently “reassuring”, but does not define the thresholds or trends that should guide these decisions.</p> <p>Further prospective service evaluation, audit and research—ideally coordinated across neonatal networks or nationally—would help define appropriate gestational age criteria, CRP thresholds and other clinical parameters, and strengthen the evidence base for assessing the safety and efficacy of this approach across NHS neonatal settings.</p>	<p>trials the oral switch approach presented by the expert witness testimony and only one of the published studies reported a CRP threshold for switching to oral antibiotics. In addition, the committee agreed that an elevated CRP is not specific to infection. Therefore, the committee decided not to specify a CRP threshold and added a new recommendation stating that decisions about starting, stopping or continuing antibiotic treatment for suspected neonatal infection should not be based on CRP results alone.</p> <p>The committee also agreed with the need for further research and decided to include a research recommendation comparing the effectiveness and safety of switching to oral antibiotics with continuing IV antibiotics in babies with suspected early-onset neonatal infection (see Appendix K in Evidence Review R).</p>
British Association of Perinatal Medicine	General	General	General	<p>The British Association of Perinatal Medicine (BAPM) represents healthcare professionals involved in perinatal care across the UK, including neonatologists, neonatal nurses, allied health professionals and those working within neonatal networks. BAPM works to improve standards of</p>	<p>Thank you for your comments.</p>

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>perinatal care through guidance, quality improvement and collaboration across maternity and neonatal services.</p> <p>BAPM welcomes the opportunity to comment on the draft guideline Neonatal infection: antibiotics for prevention and treatment, specifically the new recommendations on switching from intravenous to oral antibiotics when treating early-onset neonatal infection (recommendations 1.6.7 to 1.6.10).</p>	
British Association of Perinatal Medicine	General	General	General	<p>We note that the recommendation to switch from intravenous to oral antibiotics and discharge babies home is presented as a broadly applicable recommendation despite a limited evidence base within the NHS healthcare system. The rationale indicates that the recommendation is informed partly by expert witness testimony and experience from a small number of neonatal units that have trialled this approach. While these experiences are valuable, they may not be sufficient to support uniform implementation across diverse NHS settings without further systematic evaluation.</p> <p>The Equality and Health Inequalities Assessment notes that no research recommendations were made because very large studies would be required to detect rare but serious adverse outcomes. However,</p>	<p>Thank you for your comment. The committee acknowledged that the evidence base for switching from intravenous to oral antibiotics is relatively limited. The recommendations were informed by available published evidence (including a randomised controlled trial) and UK real-world evidence presented through expert witness testimony from 3 quality improvement initiatives across 9 sites in England. The committee agreed that this was sufficient to support a cautious and well qualified recommendation. However, the committee agreed on the need for further research and decided to include a research recommendation comparing the effectiveness and safety of switching to oral antibiotics with continuing IV antibiotics in</p>

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>the need for large sample sizes should not preclude evaluation of this change in practice. Given the rarity of important adverse outcomes, coordinated national or network-level data collection would be particularly valuable.</p> <p>BAPM therefore suggests that the guideline should encourage prospective service evaluation, audit and research at a national or neonatal network level, enabling data from multiple units to be combined. Such an approach would allow meaningful evaluation of safety, effectiveness and implementation while capturing rare outcomes that may not be detectable within individual centres.</p>	babies with suspected early-onset neonatal infection (see Appendix K in Evidence Review R).
British Infection Association	Guideline	013	001	<p>Rec 1.6 – Would this guideline consider the appropriateness of recommending less than 7 days antibiotic treatment for some babies after a review? Usual practice in many (not all) centres (including Liverpool Womens' Hospital) is to discharge babies after 5 days of antibiotics rather than 7 provided they are well. These babies are inpatients so get reviewed prior to discharge. Would this update consider whether course lengths of less than 7 days would ever be appropriate for babies discharged on oral antibiotics. We are concerned that it may actually be a backwards stewardship step in some cases as it could potentially increase the course</p>	<p>Thank you for your comment. Recommendation 1.21.4 already recommends that babies who continue intravenous antibiotics for more than 36 hours despite negative blood cultures are reviewed every 24 hours to consider whether it is appropriate to stop antibiotic treatment. The committee also amended the new recommendation (1.22.6) to emphasise that follow-up consultations for babies continuing oral antibiotics at home should include an assessment of whether continued antibiotic therapy is still required. We have also added</p>

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				length for some babies (who will generally be the least unwell ones to meet criteria for discharge on orals).	a link to the NICE antimicrobial stewardship guideline (NG15) to support clinicians in applying good stewardship principles within neonatal care.
British Infection Association	Guideline	013	001	Rec 1.6.10 – We are not aware of anywhere doing 2 follow up reviews and several centres have successfully implemented oral antibiotics. The NOAH study and protocol does not require 2 reviews. We are concerned that requiring 2 may be a barrier to implementation.	Thank you for your comment. We understand your concern about the potential practical challenge of requiring two follow-up consultations. Although the UK sites trialling switching babies with suspected early-onset infection to oral antibiotics presented by the expert witnesses only included 1 follow-up consultation, the committee decided to adopt a more cautious approach and recommended at least 2 follow-up consultations to ensure safety after sending a baby home, including assessment of the baby's wellbeing and the need for ongoing antibiotic therapy. This was based on committee consensus and the number of follow-up appointments in the published evidence. Under current practice, these babies would remain in hospital on IV antibiotics and receive daily reviews, which is more resource-intensive than providing 2 follow-up consultations. Local services can determine how to implement these consultations to reduce barriers to

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					implementation (e.g. via telephone, video call or face to face).
London Neonatal ODN	General	General	General	<p>Thank you for the Draft guideline and we are pleased to see that NICE has endorsed transitioning home on oral antibiotics. St Georges Hospital have safely practiced this since September 2024 and the committee has considered their publication: (https://ep.bmj.com/content/early/2025/11/11/archdischild-2025-329226).</p> <p>The draft guideline covers the broad principles well. We appreciate the guideline will not cover all details of practice implementation & leave some aspects open to local services. We would like to highlight areas where unfamiliar clinicians may ask for clarification & mention areas of practice that support safer smooth home oral transition.</p>	Thank you for your comment.
London Neonatal ODN	Guideline	011	000	<p>1.6.7. “the baby has been reviewed by a senior neonatologist or paediatrician (consultant or similar level)”</p> <p>We agree that senior review is important. The Draft does not define how this review should take place. St Georges guideline is that the baby has been clinically seen by the neonatal medical doctor and then discussed with the neonatal consultant who needs to agree that the baby is suitable for home oral antibiotics.</p> <p>“The level of CRP is now reassuring”</p>	Thank you for your comment. The committee agreed that it is important that a senior neonatologist or paediatrician agrees to oral switch approach, including sending the baby home. However, their view was that this level of detail regarding how the senior review of the baby should take place is better determined locally, as services are expected to incorporate such processes into their own implementation arrangements.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				We understand why NICE has pragmatically agreed not to define CRP levels. This question does frequently come up. Practice guideline at St Georges is that if the baby's peak CRP is ≥ 100 the baby would usually be expected to continue with intravenous therapy for greater than 36 hours, until the CRP trends are reassuring and all clinical symptoms and signs of suspected sepsis have resolved. Switching to oral antibiotic therapy may be appropriate later in the course of treatment. St George's routinely takes only an initial CRP and one subsequent trend CRP; however, it is important to note that the CRP levels used by St Georges NICU has not been agreed across the whole network. (Some units use a threshold of CRP 50 to initially exclude oral antibiotics. There are units that may repeat the CRP twice to demonstrate down trending, we find this unnecessary)	The committee noted that CRP thresholds for switching to oral antibiotics varied across the UK sites trialling the oral switch approach presented by the expert witness testimony and that only one of the published studies reported a CRP threshold for switching to oral antibiotics. In addition, the committee agreed that an elevated CRP is not specific to infection. For these reasons, the committee decided not to specify a CRP threshold for switching to oral antibiotics. Instead, a new recommendation was added stating that decisions about starting, stopping or continuing antibiotic treatment for suspected neonatal infection should not be based on CRP results alone.
London Neonatal ODN	Guideline	012	000	1.6.9. "Before sending a baby home on oral antibiotics..." The draft does not mention written parent information/ parent information leaflet (PIL) to support safe discharge. St Georges and the NOAH programme (https://healthinnovationsouthwest.com/programmes/noah-neonatal-oral-antibiotics-at-home/) use a PIL that standardise and supports safety netting. The PIL	Thank you for your comment. The committee acknowledged that tools such as written parent information leaflets, safety netting guidance and discharge materials like those used in local initiatives such as St George's and the NOAH programme can play an important role in supporting consistent communication and safe practice. While the guideline does not prescribe specific

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				includes detailed instructions on how to administer the medicine, QR code with a video, what to do if the baby vomits, when and who exactly to contact to seek help post discharge. This underpins the face to face training parents received in the hospital giving the first dose and provides referenced support at home so "parents know when and how to seek medical help from the neonatal team". Clear written discharge information makes health professionals in the community (especially community midwives, GPs) who are less familiar with this newer practice aware of why the baby is on antibiotics and how long oral antibiotics will continue (they use a pre-printed sticker in the 'Red Book' for this at St Georges).	materials, the committee agreed that local services should incorporate this level of detail as part of their implementation processes to ensure that parents and community healthcare professionals receive the information they need. Sections 1.1 to 1.5 of the guideline cover 'information and support for parents and carers' and for example refers to the foundational recommendations on communication, which emphasise providing parents and carers with clear, accessible information to support shared decision-making and safe care, including providing both oral and written information.
London Neonatal ODN	Guideline	012	000	1.6.9. "Before sending a baby home on oral antibiotics..." The draft does not mention written parent information/ parent information leaflet (PIL) to support safe discharge. St Georges and the NOAH programme (https://healthinnovationsouthwest.com/programmes/noah-neonatal-oral-antibiotics-at-home/) use a PIL that standardise and supports safety netting. The PIL includes detailed instructions on how to administer the medicine, QR code with a video, what to do if the baby vomits, when and who exactly to contact to	Thank you for your comment. The committee acknowledged that tools such as written parent information leaflets, safety netting guidance and discharge materials like those used in local initiatives such as St George's and the NOAH programme can play an important role in supporting consistent communication and safe practice. While the guideline does not prescribe specific materials, the committee agreed that local services should incorporate this level of detail as part of their implementation processes to

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>seek help post discharge. This underpins the face to face training parents received in the hospital giving the first dose and provides referenced support at home so “parents know when and how to seek medical help from the neonatal team”.</p> <p>Clear written discharge information makes health professionals in the community (especially community midwives, GPs) who are less familiar with this newer practice aware of why the baby is on antibiotics and how long oral antibiotics will continue (they use a pre-printed sticker in the ‘Red Book’ for this at St Georges).</p>	<p>ensure that parents and community healthcare professionals receive the information they need. Sections 1.1 to 1.5 of the guideline are about ‘information and support for parents and carers’ and refers to the foundational recommendations on communication, which emphasise providing parents and carers with clear, accessible information to support shared decision-making and safe care, including providing both oral and written information.</p>
London Neonatal ODN	Guideline	013	000	<p>1.6.10. “If switching to oral antibiotics and sending baby home, provide at least 2 follow up consultations, including 1 at the end of treatment” Agreement that review post discharge is important to support parents and audit safety of the local program. The Draft does not completely specify when the first review should be done, who does the reviews and how. Practice guideline is that the community midwifery visit on day 5 is emphasized and ensured in place with midwifery teams aware of the antibiotic details (see point above with the information in the red book) and the neonatal doctor telephones the parents on day 5-7. (As part of initial safety auditing, the QI team at St Georges would also phone the parents > 28 days age)</p>	<p>Thank you for your comments. Regarding providing details of follow-up appointments, the committee’s view was that this level of detail regarding how the follow-up consultations of babies should take place is not required in the guideline because local services should incorporate this as part of their implementation processes.</p> <p>Regarding removing the text about the summary of product characteristics from recommendation 1.20.4, this relates to dosing for intravenous gentamicin, which was outside the scope of this update. Therefore,</p>

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>Page 9 – lines 9 & 10 – suggest removing ‘the summary of product characteristics recommends a dosage of 4 to 7 mg/kg/day administered in a single dose’</p> <p>Risks causing confusion? Line 11 & 12 suggest 5mg/kg every 36 hours, which is a practical dosing recommendation.</p> <p>Page 12 – lines 14-16 – no dosing recommendations supplied for oral antibiotics (amoxicillin/co-amoxicillin) – seems odd, as dosing recommendations have been provided for IV antibiotics (Benzylpenicillin & Gentamicin). For sake of consistency, they should be included?</p> <p>Page 13 – lines 10-17 – is it worth mentioning which IV antibiotics would be suitable for at home administration? A common choice is ceftriaxone, due to its dosing frequency being once daily.</p> <p>Is it worth mentioning that you wouldn't want to administer Abx multiple times a day at home, as most services wouldn't have the nursing capacity to support this?</p> <p>There is nothing in this draft of the guideline regarding giving antifungal agents alongside Abx to prevent candidiasis – has this recommendation been intentionally removed? Think it appeared in previous draft?</p>	<p>no change has been made to this recommendation.</p> <p>Regarding oral antibiotics dosing, the committee has revised the recommendation so that it now specifies amoxicillin as the first-choice oral antibiotic and co-amoxiclav has been removed from the recommendation.</p> <p>NICE no longer routinely specifies dosing regimens in recommendations because it is expected that clinicians refer to the dosages recommended by the British National Formulary (BNF). The committee were aware that there is not currently a BNF for Children (BNFC) recommended oral dose of amoxicillin for babies less than 7 days of age. NICE are liaising with the BNFC who are in the process of reviewing the evidence to make a recommendation for the most appropriate dose for this age group.</p> <p>Thank you for the suggestion of suitable IV antibiotics for home administration. However, specifying which IV antibiotics may be</p>

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					<p>suitable for home use is outside the scope of this update.</p> <p>Section 'Antifungals to prevent fungal infection during antibiotic treatment for late-onset neonatal infection' covers recommendations about administering anti-fungal agents with antibiotics (section 1.26), which was not updated as part of this update. Please note that the recommendations in this section relate to late-onset neonatal infection (not early-onset neonatal infection which was the focus of this update). The draft guideline document which was consulted on did not include the entire guideline content. As written on p1 of the draft guideline document "The consultation draft includes the new recommendations and some existing recommendations for context. It does not include all recommendations, for example, those on late-onset neonatal infection and treating meningitis."</p>
Maternity and Newborn Investigations	Guideline	003	022	We feel this needs to include 'in an accessible manner'.	Thank you for your comment. The information and support section for parents and carers of all babies is outside the scope of this update and therefore no changes will be made to this recommendation.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Maternity and Newborn Investigations	Guideline	007	014	This should include a recommendation that observations are based on NEWTT2 (Neonatal Early Warning Track and Trigger version 2)	Thank you for your comment. The committee were unable to include a recommendation as NEWTT2 (Neonatal Early Warning Track and Trigger version 2) is outside the of scope of this update and they did not review evidence for this. However, we will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.
Maternity and Newborn Investigations	Guideline	008	010	When talking about completed observations we feel it should agin be specific that these relate to NEWTT2 documentation	Thank you for your comment. The committee were unable to add a recommendation on NEWTT2 (Neonatal Early Warning Track and Trigger version 2) as this is out of scope for the update and they did not review evidence for this. However we will pass on the suggestion to look at NEWTT2 to the NICE surveillance team.
Mid Cheshire Hospitals NHS Foundation Trust	Guideline	5	Red Flags box	We are aware that the following has not been reviewed but wish to highlight concerns with the wording following a neonatal death case. The wording 'Clinical diagnosis of chorioamnionitis' caused confusion between the neonatal and obstetric teams, leading to the decision not to screen the baby on the basis that chorioamnionitis was never confirmed. Most cases are treated on a suspision of in the absnence of identifying other causes of symptoms.	Thank you for your comment and raising this patient safety issue with us. The wording of the risk factor for chorioamnionitis in box 1 was amended in 2021 to 'clinical diagnosis of chorioamnionitis' based on the committees view that chorioamnionitis is typically diagnosed from clinical signs. However, the committee recognises the concerns raised in your comment and has changed the risk factor back to its original wording of

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				Our obstetric and neonatal teams propose the wording is changed to Clinical diagnosis of and/or treated for chorioamnionitis.	'suspected or confirmed chorioamnionitis' to avoid confusion in clinical practice.
Neonatal and Paediatric Pharmacy Group	Guideline	008 - 009	016	1.5.1 Does there need to be a recognition of an increased use of amikacin, rather than gentamicin, in centres with multi-resistant bacteria issue and if so, should dosing and monitoring information be included?	Thank you for your comment. The intravenous antibiotics for suspected early-onset infection section is out of scope for this update and therefore no changes will be made to this recommendation.
Neonatal and Paediatric Pharmacy Group	Guideline	08	15	Section 1.5 - I don't think we can comment on this section but it seems like an opportunity was missed to provide a link to the NICE Genedrive MT-RNR1 ID kit HTG665 along with a statement in section 1.5 on considering screening for detecting the genetic variant m.1555A>G to guide antibiotic use, but it is not a directive, – e.g. something similar to the section that is included on the potential use of the KP calculator.	Thank you for your comment. A link to the HTG665 has now been added to the guideline, see the 'Investigations before starting antibiotics for early- or late-onset neonatal infection' section.
Neonatal and Paediatric Pharmacy Group	Guideline	11	026	For babies born from 35 weeks' gestation: Would be helpful to express gestation as weeks and days for clarity? e.g 35+0 or 36+0 as this often trips people up as to whether they mean 35 weeks completed gestation or from 35+0. They have used weeks and days in the section on the KP calculator - so keep the same format throughout the guideline	Thank you for your comment. We have amended the recommendation to specify gestation as weeks and days.
Neonatal and Paediatric	Guideline	12	014	Regarding the recommendations for choice of oral antibiotic - it would seem sensible to recommend	Thank you for the comment. The committee has revised the recommendation so that it

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Pharmacy Group				amoxicillin as the preferred choice, and only in combination with clavulanic acid if local resistance patterns suggest there is a need. It is the clavulanic acid component of the combined medicine that limits the dose, by using amoxicillin alone you can use a higher dose, which counters the slower rate of absorption of penicillins in newborns to some extent and allows a quicker attainment of therapeutic levels.	now specifies amoxicillin as the first-choice oral antibiotic, informed by the antibiotic regimen used in the UK quality improvement initiatives and their clinical experience. The committee noted that the dose of co-amoxiclav used in the RAIN randomised controlled trial (Keij, 2022) was higher than the BNFC recommended dose and that the UK quality improvement initiatives that initially used co-amoxiclav have transitioned to using amoxicillin. Therefore, co-amoxiclav has been removed from the recommendation as suggested. The recommendation wording also clarifies that other antibiotics may be used when local microbiological surveillance data indicate different resistance patterns.
Neonatal and Paediatric Pharmacy Group	Guideline	12	014	It would be helpful to standardise the proposed oral amoxicillin regimen.	Thank you for your comment. NICE no longer routinely specifies dosing regimens in recommendations because it is expected that clinicians refer to the dosages recommended by the British National Formulary (BNF). The committee were aware that there is not currently a BNF for Children (BNFC) recommended oral dose of amoxicillin for babies less than 7 days of age. NICE are liaising with the BNFC who are in the process of reviewing the evidence to make a

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					recommendation for the most appropriate dose for this age group.
Neonatal and Paediatric Pharmacy Group	Guideline	12	017	<p>1.6.9 - I don't think the highlighted text from the evidence review comes across strongly enough in the guideline with respect to amoxicillin alone being a good first line choice UNLESS co-amoxiclav is more clinically appropriate OR local microbiological data suggests a different antibiotic is indicated."</p> <p>Suggest adding bullet points along the lines of:</p> <ul style="list-style-type: none"> · Parents and carers know what action to take if their baby vomits within 30 minutes of an oral antibiotic dose · Parents and carers know how to store the oral antibiotics appropriately 	<p>Thank you for your comment. The committee has revised the recommendation so that it now specifies amoxicillin as the first-choice oral antibiotic, informed by the antibiotic regimen used in the UK quality improvement initiatives and their clinical experience. The committee noted that the dose of co-amoxiclav used in the RAIN randomised controlled trial (Keij, 2022) was higher than the BNFC recommended dose and that the UK quality improvement initiatives that initially used co-amoxiclav have transitioned to using amoxicillin. Therefore, co-amoxiclav has been removed from the recommendation as suggested. The recommendation wording also clarifies that other antibiotics may be used when local microbiological surveillance data indicate different resistance patterns.</p> <p>The committee acknowledged the importance of parents and carers knowing what to do if their baby vomits after being given oral antibiotics and how to store antibiotics. The committee's view was that this level of detail was not required in the</p>

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					guideline because local services should incorporate this as part of their implementation processes to ensure that parents and carers are provided with the information they need to manage their baby's oral antibiotic treatment safely at home.
Neonatal and Paediatric Pharmacy Group	Guideline	13	015	The amendments relating to the introduction of an oral antibiotic switch are helpful.	Thank you for your comment.
Neonatal and Paediatric Pharmacy Group	Guideline	General	General	Question as to how this guideline fits into NG195 which covers early and late onset infection and antifungals. This update seems to just address early onset sepsis – is that correct? NG195 replaced CG149 (Neonatal infection: (early onset): antibiotics for prevention and treatment). The document scope says that NICE are updating NG195. Question as to whether the other aspects of NG195 that are not covered in this update going to be reviewed at another time point?	Thank you for your comment. Recommendations on late-onset infection (sections 1.23 to 1.25 in 'Antibiotics for late-onset neonatal infection') and antifungals (section 1.26 in 'Antifungals to prevent fungal infection during antibiotic treatment for late-onset neonatal infection') remain in the guideline, but they were not updated as part of this update. The draft guideline document which was consulted on did not include the entire guideline content. As written on p1 of the draft guideline document "The consultation draft includes the new recommendations and some existing recommendations for context. It does not include all recommendations, for example,

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					those on late-onset neonatal infection and treating meningitis." The NICE surveillance team monitor key developments relevant to the guideline and any such developments identified will be considered for inclusion in future updates of the guideline. This update focuses on switching from intravenous to oral antibiotics for suspected early onset neonatal bacterial infection and on the timing of prelabour rupture of membranes to birth and the associated risk of early-onset neonatal infection. Any additional aspects of NG195 not covered in this update will be considered at a later time if new evidence or priorities are identified.
Neonatal and Paediatric Pharmacy Group	Guideline	General	General	I think there should be a recognition of further research comparing babies that are switched to oral antibiotics compared with stopping antibiotics completely. I think there is still something to be addressed around 'what' we are actually treating in these babies?	Thank you for your comment. As we did not review evidence comparing switching to oral antibiotics with stopping antibiotics altogether, we are unable to make a research recommendation in this area. The scope of this update focused on comparing intravenous and oral antibiotic treatment and considerations about whether antibiotics are needed at all are beyond the scope of this update.
Neonatal and Paediatric	Guideline	General	General	Please could we ask for dose recommendations also be added? The RAIN study used a co-amoxiclav	Thank you for your comment. The committee has revised the recommendation so that it

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Pharmacy Group				formulation with a different amoxicillin-to-clavulanic acid ratio compared with currently licensed UK preparations, so this may need clarification.	<p>now specifies amoxicillin as the first-choice oral antibiotic, informed by the antibiotic regimen used in the UK quality improvement initiatives and their clinical experience. The committee noted that the dose of co-amoxiclav used in the RAIN randomised controlled trial (Keij, 2022) was higher than the BNFC recommended dose and that the UK quality improvement initiatives that initially used co-amoxiclav have transitioned to using amoxicillin. Based on consultation feedback and committee's further consideration, co-amoxiclav has been removed from the recommendation. The recommendation wording also clarifies that other antibiotics may be used when local microbiological surveillance data indicate different resistance patterns.</p> <p>NICE no longer routinely specifies dosing regimens in recommendations because it is expected that clinicians refer to the dosages recommended by the British National Formulary (BNF). The committee were aware that there is not currently a BNF for Children (BNFC) recommended oral dose of amoxicillin for babies less than 7 days of age.</p>

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					NICE are liaising with the BNFC who are in the process of reviewing the evidence to make a recommendation for the most appropriate dose for this age group.
Neonatal and Paediatric Pharmacy Group	Guideline	General	General	Did not find mention of checking blood cultures & CRP before commencing antibiotics.	Thank you for your comment. Investigations before starting antibiotics in babies who may have early onset infection, including checking blood cultures and CRP, are covered in recommendations in section 'Investigations before starting antibiotics for early- or late-onset neonatal infection'.
Neonatal and Paediatric Pharmacy Group	Evidence Review R	22	03	1.6.8 - Comment: Did the committee consider the outcomes of the Oracle I trial where use of co-amoxiclav for PPRM was associated with a statistically significant increase in risk of NEC in the offspring? I would suggest 1.6.8 reads as use amoxicillin as the oral antibiotic, unless microbiological surveillance data show local bacterial resistance patterns that indicate the need for co-amoxiclav or different antibiotic. [2026]	Thank you for the comment. The Oracle I trial was not relevant to this update because the review focused on babies with suspected early-onset infection switching from IV to oral antibiotics, whereas the ORACLE I trial included mothers with PROM and not babies with suspected early-onset infection. Please note that based on consultation feedback, the committee has revised the recommendation so that it now specifies amoxicillin as the first-choice oral antibiotic, informed by the antibiotic regimen used in the UK quality improvement initiatives and their clinical experience. The committee noted that the

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					dose of co-amoxiclav used in the RAIN randomised controlled trial (Keij, 2022) was higher than the BNFC recommended dose and that the UK quality improvement initiatives that initially used co-amoxiclav have transitioned to using amoxicillin. Therefore, co-amoxiclav has been removed from the recommendation as suggested. The recommendation wording also clarifies that other antibiotics may be used when local microbiological surveillance data indicate different resistance patterns.
NHS England	Guideline	000	000	pre-birth: the presenting symptoms of mothers with a learning disability or autistic mothers with infection may be different and diagnostic overshadowing is a risk	Thank you for your comment. The committee agree maternal factors are important considerations, but this is beyond the scope of this guideline update.
NHS England	Guideline	000	000	- neonates with congenital disorders associated with learning disability e.g. Down Syndrome, Fragile X Syndrome are more likely to function in the learning disability range. Independently, people with such diagnoses may be predisposed to contracting neonatal infections because of physical problems such as failure to thrive, poor sucking ability, seizure disorders in the neonatal period.	Thank you for your comment. The evidence reviewed for this update focused specifically on babies without pre-existing health conditions. No evidence was identified that evaluated switching to oral antibiotics in babies with underlying conditions such as Down syndrome or other congenital disorders. The included studies in the evidence review recruited term or late-preterm infants with probable infection

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update


**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					but explicitly excluded babies with complex underlying conditions or congenital abnormalities. Similarly, UK real-world evidence presented by expert witnesses did not include babies with disabilities or complex underlying conditions. Because there was no relevant evidence for babies with underlying health conditions, the committee was unable to make recommendations for this group.
NHSE Patient Safety Team	Draft Guideline	General	General	The National Patient Safety Team identified several reports in which preparations of the benzathine benzylpenicillin formulation, intended for IM administration, were confused with preparations of benzylpenicillin sodium formulations, and inadvertently administered via the IV route. Details of our concerns were shared with the RCPCH and NPPG Joint Medicines Committee (November 2023) who subsequently issued advice to designated clinical teams clarifying that it is not necessary to hold stock of the different salt formulations of benzylpenicillin in clinical areas treating paediatric and neonatal patients:	Thank you for your comment. Based on the advice of our medicines optimisation team, we have amended the wording in the guideline recommendations to say 'benzylpenicillin sodium' instead of 'benzylpenicillin'. Regarding your second suggestion, this was considered to be outside the scope of the guideline so we have not included this.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				 <p>Confusion over Salts of Benzylpenici</p> <p>We would suggest that</p> <ol style="list-style-type: none"> 1. All references to “benzylpenicillin” should specify the intended salt (benzylpenicillin sodium or benzathine benzylpenicillin). 2. Consideration is given to include information to reflect the recommendations of RCPCH and NPPG Medicines Committee: <ol style="list-style-type: none"> a. As benzathine benzylpenicillin is not critically urgent, this formulation should not be kept as a <i>stock</i> item in areas treating neonatal patients or on neonatal transport services. <p>In those areas where benzathine benzylpenicillin may be required for <i>specific named patients</i>, it must be stored away from Benzylpenicillin Sodium</p>	
NHSE Patient Safety Team	Guideline	005	Box 1	There is no reference to early maternal postnatal infection / sepsis as a risk factor for neonatal infection.	Thank you for your comment. The risk factor of ‘intrapartum fever higher than 38°C if there is suspected or confirmed bacterial infection’ in Box 1 has now been changed to ‘suspected or confirmed sepsis in the intrapartum or early postpartum period’. This

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					change is to clarify that maternal sepsis in the intrapartum as well as in the early postpartum period is the risk factor for neonatal infection. It also emphasises suspected sepsis rather than a specific temperature measurement, recognising that other signs or symptoms may also indicate maternal sepsis.
UK Health Security Agency	Guideline	011	000	<p>The prompt switch from IV to oral antibiotics, where antibiotics are deemed necessary, is much welcome. However, the evidence supporting this change is limited; for this to be recommended in a national guidance document, results of robust pilot data in UK centres would have been ideal.</p> <p>The concern is the missed opportunity to stop antibiotics that were not necessary in the first place – in which case, PO antibiotics would cause unnecessary harm.</p> <p>My suggestion is to schedule a review of this recommendation in the next 6-12 months, meanwhile collating robust information regarding neonatal clinical outcomes and changes in prescribing rates in units implementing this change.</p>	<p>Thank you for your comment.</p> <p>This update specifically focused on switching from intravenous to oral antibiotics for babies who had already started antibiotic treatment for suspected early-onset infection. As such, recommendations relating to when antibiotics should be initiated were outside the scope of this update. However, the committee recognised the importance of minimising unnecessary antibiotic exposure and agreed to strengthen recommendation 1.21.3 to stop antibiotics at 36 hours if deemed appropriate. In addition, recommendation 1.21.4 already recommends that babies who continue intravenous antibiotics for more than 36 hours despite negative blood cultures are reviewed every 24 hours to consider whether it is appropriate to stop antibiotic treatment. The committee also amended the new</p>

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					<p>recommendation (1.22.6) to emphasise that follow-up consultations for babies continuing oral antibiotics at home should include an assessment of whether continued antibiotic therapy is still required. We have also added a link to the NICE antimicrobial stewardship guideline (NG15) to support clinicians in applying good stewardship principles within neonatal care.</p> <p>The committee agreed with the need for further research and decided to include a research recommendation comparing the effectiveness and safety of switching to oral antibiotics with continuing IV antibiotics in babies with suspected early-onset neonatal infection (see Appendix K in Evidence Review R).</p> <p>The NICE surveillance team monitor key developments relevant to the guideline and any such developments identified will be considered to determine whether the guideline should be updated in the future.</p>
UK Health Security Agency	Guideline	012	000	Please indicate the evidence-based threshold for “local bacterial resistance patterns that indicate the need for a different antibiotic” to prevent confusion.	Thank you for your comment. The committee did not review evidence on thresholds for local bacterial resistance patterns indicating

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					that a different antibiotic is appropriate. Therefore, we cannot make a recommendation regarding a specific threshold that should be used.
UKCPA – Infection Network	Guideline	009	008	There's no description of whether gentamicin genotyping for hearing loss should be done (https://www.nice.org.uk/news/articles/nice-recommends-genetic-test-to-prevent-newborn-babies-going-deaf) There's no recommendation about how to do therapeutic drug monitoring of gentamicin in neonates. Is this something that NICE should recommend research in	Thank you for your comment. NICE HTG655 covers Genedrive MT-RNR1 ID Kit for detecting a genetic variant to guide antibiotic use and prevent hearing loss in babies: early value assessment. A link to HTG665 has now been added to the guideline, see the 'Investigations before starting antibiotics for early- or late-onset neonatal infection' section. 'Therapeutic drug monitoring for babies receiving gentamicin' is covered in sections 1.35 to 1.36 of the neonatal infection guideline NG195.
UKCPA – Infection Network	Guideline	012	001	Can we specify a course length – above was 7 days but can be extended, but this is not mentioned here	Thank you for your comment. Recommendation 1.21.2 recommends considering continuing antibiotic treatment for more than 7 days for babies with a positive blood culture or negative blood culture if sepsis has been strongly suspected if the baby has not yet fully recovered or it is indicated by the pathogen on the blood culture. This recommendation does not apply to babies who are switched to oral antibiotics because they would not meet the eligibility

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					criteria to switch to oral antibiotics if they had a positive blood culture or if they have clinical indicators of ongoing infection. The committee have revised the new recommendation (1.22.1) to specify that the course length for babies who switch to oral antibiotics is up to 7 days in total, inclusive of treatment with IV and oral antibiotics.
UKCPA – Infection Network	Guideline	012	003	Regards oral switch should people be sign posted to the national IVOS tool and should the recommendations for such as switch be the same.	Thank you for your comment. The committee discussed the IVOS tool and it is referenced in the committee discussion section of Evidence Review R. Although the overall principles of safe antimicrobial switching are broadly aligned, some IVOS criteria differ from the recommendations in this guideline because of the population. The IVOS tool acknowledges that there may be special considerations for neonates.
University Hospitals Dorset	General	000	000	<p><i>Would it be challenging to implement of any of the draft recommendations? Please say why and for whom. Please include any suggestions that could help users overcome these challenges (for example, existing practical resources or national initiatives).</i></p> <p>As with any new practice this would take staff education and confidence to roll out IV to oral switch</p>	Thank you for your comment. The committee has revised the recommendation so that it now specifies amoxicillin as the first-choice oral antibiotic, informed by the antibiotic regimen used in the UK quality improvement initiatives and their clinical experience. The committee noted that the dose of co-amoxiclav used in the RAIN randomised controlled trial (Keij, 2022) was higher than

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				in newborn babies. The NICE guideline does not give a suggested dosage of amoxicillin or co amoxiclav and I know there have been discrepancies in appropriate dosing of the co amoxiclav in the NOAH project where the babies were underdosed. This need to be clarified so this does not happen in practice.	<p>the BNFC recommended dose and that the UK quality improvement initiatives that initially used co-amoxiclav have transitioned to using amoxicillin. Based on consultation feedback and committee's further consideration, co-amoxiclav has now been removed from the recommendation. The recommendation wording also clarifies that other antibiotics may be used when local microbiological surveillance data indicate different resistance patterns.</p> <p>NICE no longer routinely specifies dosing regimens in recommendations because it is expected that clinicians refer to the dosages recommended by the British National Formulary (BNF). The committee were aware that there is not currently a BNF for Children (BNFC) recommended oral dose of amoxicillin for babies less than 7 days of age. NICE are liaising with the BNFC who are in the process of reviewing the evidence to make a recommendation for the most appropriate dose for this age group.</p>
University Hospitals Dorset	General	000	000	<i>Would implementation of any of the draft recommendations have significant cost implications?</i>	Thank you for your comment. This update specifically focused on switching from intravenous to oral antibiotics for babies who

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>No, the cost implications are in not amending other areas of this guideline, for example giving clearer guidance on which babies to start antibiotics on and being able to stop antibiotic sooner. Neonatal early onset infection is unnecessarily overtreating newborn babies currently which causes a high cost to hospitals and causes patient flow problems. IV to oral switch goes some way to address patient flow but if we could improve the number of babies starting antibiotics in the first place by using Kaiser Permanente sepsis screening calculator or by serial examination then there would be less cost implication for this workstream in the first place.</p>	<p>had already started antibiotic treatment for suspected early-onset infection. As such, recommendations relating to when antibiotics should be initiated were outside the scope of this update. However, the committee recognised the importance of minimising unnecessary antibiotic exposure and agreed to strengthen recommendation 1.21.3 to stop antibiotics at 36 hours if deemed appropriate. In addition, recommendation 1.21.4 already recommends that babies who continue intravenous antibiotics for more than 36 hours despite negative blood cultures are reviewed every 24 hours to consider whether it is appropriate to stop antibiotic treatment. The committee also amended the new recommendation (1.22.6) to emphasise that follow-up consultations for babies continuing oral antibiotics at home should include an assessment of whether continued antibiotic therapy is still required. We have also added a link to the NICE antimicrobial stewardship guideline (NG15) to support clinicians in applying good stewardship principles within neonatal care.</p>

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
University Hospitals Dorset	Guideline	005	Box 1	Thank you for clarifying that this is the time between ruptured membranes and birth rather than pre labour ROM. This makes much more sense and is what has been happening in practice anyway.	Thank you for your comment. We appreciate your feedback and support of the updated risk factor.
University Hospitals Dorset	Guideline	011	003	<p>1.6.3. The NICE neonatal infection guideline previously recommended a CRP threshold of 10mg/L but any guidance on a specific number or threshold level was removed in the 2021 iteration. Despite removing the number 10 the NICE guideline continues to recommend testing it for early onset infection a) at baseline when starting antibiotic treatment and b) 18 to 24 hours after presentation. NICE then recommends stopping antibiotics if the blood culture is negative, if the baby has no clinical indicators of infection and <i>“the levels and trends of C-reactive protein concentration are reassuring”</i>. In practice many clinicians will extend antibiotic courses if CRPs are deemed ‘high’, though what constitutes this will vary by centre and clinician. The previous NICE threshold of 10mg/L mean that clinicians often consider levels above this as requiring longer courses of treatment.</p> <p>CRP is a non-specific marker of infection, rising in any inflammatory state, and has been shown to be normally raised in infants following birth. Stocker et</p>	Thank you for your comment. The committee did not review evidence on CRP thresholds for starting antibiotics, which was outside of the scope of this update. However, the committee agreed that CRP level on its own is not necessarily a good marker for infection and need for antibiotic treatment in neonates and agreed to include a new recommendation stating that decisions about starting, stopping or continuing antibiotic treatment for suspected neonatal infection should not be based on CRP results alone.

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>al measured CRP in healthy term infants between 48-72 hours of life and found that CRP levels above 20mg/L are quite common [1 in 5 had a CRP \geq10mg/L and 1 in 14 had CRP \geq20mg/L]. Low CRP has a good negative predictive value, but it is a poor positive predictor of infection. We note that in a Norwegian setting they use a CRP threshold of 30mg/L and in Denmark a CRP of up to 50mg/L to stop antibiotics in well infants.</p> <ol style="list-style-type: none"> 1. Kuzniewicz MW, Puopolo KM, Fischer A, et al. A Quantitative, Risk-Based Approach to the Management of Neonatal Early-Onset Sepsis. JAMA Pediatr. 2017 Apr 1;171[4]:365-371 2. Ishibashi M, Takemura Y, Ishida H et al. C-reactive protein kinetics in newborns: application of a high sensitivity analytic method in its determination. Clin chemistry 2002;48:1103-6. 3. Stocker M, van Herk W, El Helou S, et al. NeoPInS Study Group. Procalcitonin-guided decision making for duration of antibiotic therapy in neonates with suspected early-onset sepsis: a multicentre, randomised 	

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>controlled trial [NeoPIs]. Lancet 2017;390[10097]:871-881.</p> <p>4. Vatne A, Klingenberg C, Oymar K et al. Reduced Antibiotic Exposure by Serial Physical Examinations in Term Neonates at Risk of Early-onset Sepsis. The Pediatric Infectious Disease Journal 2020;39[5]</p> <p>5. Malchau Carlsen, E. L., Schultz Dungu, K. H., Lewis, A., et al. Oral antibiotics for neonatal infections: A systematic review and meta-analysis. Journal of Antimicrobial Chemotherapy 2023;74[10], 3150–3161.</p> <p>[This text was identified as confidential and has been removed].</p>	
University Hospitals Dorset	Guideline	011	026	<p>1.6.7 – 1.6.10</p> <p>We are concerned that this recommendation for IV to oral switch takes the antibiotic stewardship focus away from firstly reducing the number of infants started on unnecessary antibiotics and secondly from stopping them as soon as you can. IV to oral switch just shifts the problem to the community. There is good evidence to show that broad spectrum antibiotics in early life have lasting effects on the developing microbiome and can lead to chronic</p>	<p>Thank you for your comment. This update specifically focused on switching from intravenous to oral antibiotics for babies who had already started antibiotic treatment for suspected early-onset infection. As such, recommendations relating to when antibiotics should be initiated were outside the scope of this update. However, the committee recognised the importance of minimising unnecessary antibiotic exposure and agreed</p>

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>diseases later on. By using IV to oral switch a newborn baby is subjected to up to 4 different types of antibiotic in the first days of life (benzylpenicillin, gentamicin, cefotaxime, amoxicillin, clavulanic acid).</p> <p>This guideline could offer more to support more rational use of antibiotics in newborn babies via the use of serial physical examination for asymptomatic babies with risk factors which has been shown to work well in other countries. This examination of the infant would be covered by use of the NEWTT2 tool for the first 24 hours of life and if the infant remained asymptomatic then the chance of early onset infection is very low.</p> <ol style="list-style-type: none"> 1. McDonnell L, Gilkes A, Ashworth M et al. Association between antibiotics and gut microbiome dysbiosis in children: systematic review and meta-analysis. <i>Gut Microbes</i>. 2021; 13 2. Do Nascimento, S., Theodosiou, A.A. & Sergaki, C. Microbiotoxicity: an under-recognised player in drug efficacy, toxicity, and health outcomes. <i>npj Antimicrob Resist</i> 3, 102 (2025). https://doi.org/10.1038/s44259-025-00165-5 	<p>to strengthen recommendation 1.21.3 to stop antibiotics at 36 hours if deemed appropriate. In addition, recommendation 1.21.4 already recommends that babies who continue intravenous antibiotics for more than 36 hours despite negative blood cultures are reviewed every 24 hours to consider whether it is appropriate to stop antibiotic treatment. The committee also amended the new recommendation (1.22.6) to emphasise that follow-up consultations for babies continuing oral antibiotics at home should include an assessment of whether continued antibiotic therapy is still required. We have also added a link to the NICE antimicrobial stewardship guideline (NG15) to support clinicians in applying good stewardship principles within neonatal care.</p> <p>The committee were unable to add a recommendation on NEWTT2 (Neonatal Early Warning Track and Trigger version 2) as this is out of scope for the update and they did not review evidence for this. However we will pass on the suggestion to look at NEWTT2 to the NICE surveillance team.</p>

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>3. Vatne A, Klingenberg C, Oymar K et al. Reduced Antibiotic Exposure by Serial Physical Examinations in Term Neonates at Risk of Early-onset Sepsis. The Pediatric Infectious Disease Journal 2020;39[5]</p> <p>Stocker M, Rosa-Mangeret F, Agyeman PKA, McDougall J, Berger C, Giannoni E. Management of neonates at risk of early onset sepsis: a probability-based approach and recent literature appraisal : Update of the Swiss national guideline of the Swiss Society of Neonatology and the Pediatric Infectious Disease Group Switzerland. Eur J Pediatr. 2024 Dec;183(12):5517-5529. doi: 10.1007/s00431-024-05811-0. Epub 2024 Oct 17. PMID: 39417838; PMCID: PMC11527939.</p>	
University Hospitals Dorset	Guideline	011	026	<p>1.6.7 – 1.6.10</p> <p>The recent NOAH IV to oral switch project only has UK information about term babies >37 weeks whereas the NICE guideline is recommending this for infants >35 weeks. This is a bold move for the vulnerable 35 and 36 week population. There seems to be limited, low quality information about efficacy and harms of oral antibiotics in late preterm infants. Switching to oral antibiotics in this group is unlikely to make much impact on patient flow as they will need to stay in hospital for other reasons. It would be</p>	<p>Thank you for your comment. The RAIN randomised controlled trial (Keij 2022) included babies ≥35 weeks gestation. Late pre-term babies were also included in the UK quality improvement projects presented by the expert witnesses (≥35 weeks in PEARL and ≥36 weeks in KSS). Therefore, the committee agreed to recommend considering switching to oral antibiotics for babies born from 35 weeks gestation.</p>

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				<p>better for antibiotic stewardship to improve recommendations about serial examination and observation of late preterm infants with risk factors (rather than premature + PROM = antibiotics) and also stopping antibiotics as soon as possible at 36 hours rather than switch to oral.</p>	<p>The committee agreed that babies meeting the criteria for switching to oral antibiotics who need to stay in hospital for reasons other than infection should be eligible to switch to oral antibiotics and remain in hospital. The recommendations have been amended accordingly to specify this.</p> <p>This update specifically focused on switching from intravenous to oral antibiotics for babies who had already started antibiotic treatment for suspected early-onset infection. As such, recommendations relating to when antibiotics should be initiated were outside the scope of this update. However, the committee recognised the importance of minimising unnecessary antibiotic exposure and agreed to strengthen recommendation 1.21.3 to stop antibiotics at 36 hours if deemed appropriate. In addition, recommendation 1.21.4 already recommends that babies who continue intravenous antibiotics for more than 36 hours despite negative blood cultures are reviewed every 24 hours to consider whether it is appropriate to stop antibiotic treatment. The committee also amended the new recommendation (1.22.6) to emphasise that</p>

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					follow-up consultations for babies continuing oral antibiotics at home should include an assessment of whether continued antibiotic therapy is still required. We have also added a link to the NICE antimicrobial stewardship guideline (NG15) to support clinicians in applying good stewardship principles within neonatal care.
University Hospitals Dorset	Evidence review Whole guideline	016	021	<p>In the evidence review there is acknowledgement of the problems of unnecessary overprescribing: <i>“There are potential risks with switching to oral antibiotics, such as overprescribing and unnecessary use of antibiotics, contributing to antimicrobial resistance. A key concern is that clinicians may prescribe oral antibiotics as a precaution, rather than restricting this approach to cases where continuation of antibiotics is clinically indicated. Inappropriate use could result in babies receiving antibiotics without need, thereby increasing the risk of antimicrobial resistance. These concerns can be mitigated by establishing strict eligibility criteria and ensuring parental agreement before discharge. Clear guidance and ongoing monitoring will be essential to maintain safety and effectiveness”</i></p> <p>NICE need to heed their own statement here and please ensure that the neonatal infection guideline</p>	<p>Thank you for your comment. This update specifically focused on switching from intravenous to oral antibiotics for babies who had already started antibiotic treatment for suspected early-onset infection. As such, recommendations relating to when antibiotics should be initiated were outside the scope of this update. However, the committee recognised the importance of minimising unnecessary antibiotic exposure and agreed to strengthen recommendation 1.21.3 to stop antibiotics at 36 hours if deemed appropriate. In addition, recommendation 1.21.4 already recommends that babies who continue intravenous antibiotics for more than 36 hours despite negative blood cultures are reviewed every 24 hours to consider whether it is appropriate to stop antibiotic treatment. The committee also amended the new</p>

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Neonatal infection: antibiotics for prevention and treatment - update

**Consultation on draft guideline - Stakeholder comments table
19/02/2026 to 04/03/2026**

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				has language that gives support to the clinicians using it to make choices to improve antibiotic stewardship. The current language in the guideline is very defensive/low threshold for starting antibiotics, low threshold for continuing them and DOES LEAD TO OVERPRESCRIBING.	recommendation (1.22.6) to emphasise that follow-up consultations for babies continuing oral antibiotics at home should include an assessment of whether continued antibiotic therapy is still required. We have also added a link to the NICE antimicrobial stewardship guideline (NG15) to support clinicians in applying good stewardship principles within neonatal care.

**None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.*

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees