Health Innovation South West

Evaluation of the Early Adopters of the Neonatal Oral Switch Pathway in the UK

June 2026

NOAH Neonatal Oral Antibiotics at Home

NIHR | Applied Research Collaboration

Acknowledgements

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Our purpose is to improve the lives of the people in the South West through innovation, by improving health and care services, health outcomes, and economic growth.

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- Royal Devon University Hospital: Exeter site
- Royal Devon University Hospital: Barnstaple site
- Musgrove Park Hospital, Taunton
- St George's Hospital, Tooting
- St Peter's Hospital, Chertsey
- Darent Valley Hospital, Dartford
- Medway Maritime Hospital, Gillingham
- Maidstone and Tunbridge Wells Hospitals,
- East Surrey Hospital, Redhill
- Frimley Park Hospital, Camberley

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Background

In the UK, the standard approach to managing suspected early-onset neonatal infection (EOI) involves administering intravenous (IV) antibiotics for a minimum of 36 hours. Treatment is usually discontinued at that point if the baby remains clinically well, C-reactive protein (CRP) levels are reassuring, and any cultures taken are negative. When clinical concerns persist, however, IV antibiotic therapy is typically extended for up to 7 days.

Despite their widespread use, IV antibiotics are associated with a number of drawbacks. They often prolong hospital admission and require repeated cannulation attempts—procedures that are technically challenging, painful, and may result in babies being separated from their parents.

Historically, oral antibiotics have been used infrequently in high-resource settings to treat EOI due to concerns about their efficacy, particularly regarding neonatal gastrointestinal absorption. Nevertheless, emerging evidence now supports the safety of transitioning from IV to oral treatment in carefully selected infants with suspected EOI. Several high-quality studies have demonstrated that such a switch is effective, safe, and cost-efficient (Keij et al., 2022; Carlsen, 2024).

A meta-analysis examining oral antibiotic use in neonatal infections (Keij et al., 2019) found that although oral agents may reach peak concentrations more slowly and have reduced bioavailability, therapeutic levels are typically achieved. Crucially, no differences were identified in relapse rates or mortality when compared with IV therapy. Furthermore, studies assessing IV-to-oral switches have reported no increase in reinfection or adverse events (Keij et al., 2022; Carlsen et al., 2024).

Neonatal oral switch pathways have therefore been developed to support early transition from IV to oral antibiotics in infants with suspected early-onset bacterial infection, enabling treatment completion at home. Early adopters of these pathways aim to shorten hospital stays while maintaining clinical effectiveness. Although the traditional reliance on IV antibiotics has stemmed from concerns about oral drug absorption in neonates, growing evidence indicates that oral therapy can achieve comparable serum concentrations without increased risk.

Pharmacokinetic studies (Autret et al., 1988; Gras-Le Guen, 2007) show that oral amoxicillin can attain and maintain effective therapeutic levels in neonates without significant adverse effects. The multicentre RAIN trial (Keij et al., 2022) further confirmed that early switching to oral amoxicillin-clavulanic acid is safe and effective, substantially reducing the length of hospital stay without increasing adverse events, readmissions, or treatment failures. Similarly, a Danish cohort study by Carlsen et al., (2024) demonstrated that switching to oral antibiotics after 36–48 hours led to shorter admissions with no subsequent infection-related readmissions.

Supporting evidence from smaller studies (Gyllensvärd et al., 2020; Manzoni et al., 2009) highlights additional benefits, including reduced antibiotic duration, lower healthcare costs, and improved outcomes such as enhanced breastfeeding rates. A recent rapid evidence review from the Archives of Disease in Childhood (Gifford, 2024) concluded that transitioning to oral antibiotics is an appropriate option for term, clinically stable, well-feeding neonates with culture-negative early-onset infection, provided that robust outpatient monitoring is in place.

In summary, current evidence strongly supports the safety and efficacy of transitioning from IV to oral antibiotics in clinically stable neonates with suspected EOI. This approach reduces hospital stay length, facilitates earlier discharge, and does so without increasing the risk of adverse outcomes.

Building the evidence base

Early implementation of neonatal intravenous-to-oral antibiotic switch pathways represents a significant shift in the management of suspected early-onset infection in the UK. Although international studies have demonstrated the safety and effectiveness of early oral switch for clinically stable, culture-negative neonates, real-world evidence within NHS services remains limited. As more UK sites begin adopting these pathways, it is essential to build a robust national understanding of how they perform in practice, how consistently they are implemented, and what outcomes are being achieved for babies and families. Collecting national data enables the NHS to monitor safety at scale, identify rare adverse events that would not be visible within individual trusts, and assess the wider impact on service efficiency, antimicrobial stewardship, and parent-infant experience.

This report aims to build on the evidence available to support implementation of similar pathways across the UK by exploring the views of early adopter sites in the UK and examining the aggregate and routinely collected data on the babies on these pathways.

Evaluation of Early Adopters

Health Innovation South West have been working in collaboration with multiple sites across the UK to gather insights on early adopters' experience of implementing their oral switch pathway. Sites have also shared data on the impact of the new pathway on readmissions and reinfection rates.

The evaluation seeks to answer the following evaluation questions:

- Who has implemented a neonatal oral switch pathway, and how is the pathway working?
- What can be learned from the experience of implementation and delivery of the neonatal oral switch pathways?
- Which babies are being supported on the oral switch pathways, and does this vary across sites?
- What is the impact of the oral switch pathway on readmissions and ongoing infection concerns?

Methodology

To address the evaluation questions, a mixed-methods evaluation design was implemented between April 2025 and March 2026. Data was gathered from the following sources:

- Surveys from sites (n=9 sites)
- Rapid insights session (n=6 sites)
- Aggregate data extracted from patient records from 9 sites for the period of May 2024 and February 2026 (site dependent)

A total of 10 early adopter sites took part in the evaluation.

Rapid Insights Session

A rapid insights session was conducted in December 2025 to evaluate the implementation and experiences of the Neonatal Oral Switch Pathway. The session aimed to gather qualitative feedback from clinical teams on implementation experience, perceived safety, acceptability, enablers and barriers, via six structured open-ended questions and facilitated discussions. Participants provided written narrative responses to the following questions:

1. What has been your overall experience of switching babies onto oral antibiotics?
2. What were the barriers to implementation of the new pathway to switch babies to oral antibiotics?
3. What, if any, areas do you feel need more work to strengthen the pathway or process?
4. What has helped your implementation of the new pathway to switch babies to oral antibiotics?
5. What do you feel are the critical success factors in your running a successful oral switch pathway?
6. What benefits are you experiencing by switching babies to oral antibiotics at home? (For staff, the trust, parents, and babies).

Qualitative analysis

The rapid insights session was recorded and transcribed using Microsoft Teams' built-in transcription feature and edited by researchers, Written responses to the questions in the session were considered alongside the transcription. Thematic analysis was employed across the text. Emergent themes are discussed within the report.

Quantitative analysis

Descriptive statistics from the survey data and routinely collected system data are presented throughout the report, where applicable in the text.

Results

1. Who has implemented a neonatal oral switch pathway, and how is the pathway working?

Early Adopter Sites

Ten early adopters of the neonatal oral switch pathway agreed to participate in this evaluation. Nine sites submitted quantitative data, including three in the South West, five in the South East, and one in London. An additional site in the South East contributed to the implementation survey to share their protocols, but did not have data available at the time of extraction.

Variation in Oral Switch Pathways Across Sites

Survey responses from nine participating trusts demonstrated broad alignment in the principle of early oral antibiotic switch for suspected early-onset neonatal infection. Table 1 (below) summarises the variation in pathway implementation, alongside areas of consistency in core clinical practice.

While efforts were made to collect detailed and accurate information from all participation sites, the findings are based on self-reported data and may not capture the full complexity of local pathways. Some variation in reporting detail is likely, and elements of pathways may not have been fully described.

Core Clinical Criteria

All trusts reported that babies must be clinically well, with no ongoing signs of sepsis, and have negative blood cultures at approximately 36 hours prior to consideration of oral antibiotic switch. Adequate feeding was also consistently required. These findings indicate strong agreement on the core safety principles underpinning pathway use.

Eligibility Criteria

There was some variation in eligibility criteria across sites. Gestational age thresholds ranged from >35 weeks to >37 weeks. CRP interpretation was largely consistent, with most trusts using a threshold of <50 mg/L with a downward trend; however, one trust used a trend-based approach without a fixed numerical cut-off, and one used a higher cut off, of <100 mg/L.

Additional criteria were reported by most trusts, including minimum birth weight thresholds (>1800g or >2000g), no concerns about meningitis or osteomyelitis, requirement for consultant agreement, parental consent, and consideration of safeguarding, transport, and parental understanding. These additional factors reflect local adaptations to manage perceived risk.

Timing of Oral Switch

The timing of transition from intravenous to oral antibiotics varied slightly between sites. Most trusts reported switching at approximately 36 hours, aligned with blood culture results and CRP interpretation. However, one trust reported delayed switching until up to 48 hours, indicating variation in clinical decision-making thresholds.

Antibiotic Choice

There was limited variation in antibiotic selection. All trusts used co-amoxiclav or amoxicillin, reflecting broadly similar antimicrobial approaches. Total treatment duration was consistent across sites, typically 5-7 days.

There was some variation in how intravenous (IV) antibiotics were used prior to switching to oral therapy. Most trusts reported using a combination of benzylpenicillin and gentamicin, consistent with standard empirical treatment for suspected early-onset neonatal infection. However, in some trusts, ceftriaxone or cefotaxime were used for screening on the postnatal or labour ward.

In addition, there was variation in whether specific IV treatment requirements were defined prior to oral switch. Some trusts explicitly required completion of a minimum IV course, while others did not specify this within their pathway. This may reflect differences in local protocols, the level of prescriptive detail within guidelines, or that such requirements were in place but not explicitly reported within the documented pathway.

Sepsis Risk Assessment

Approaches to early-onset sepsis risk assessment varied, with trusts reporting use of:

- NICE-based frameworks
- The Kaiser Permanente (KP) calculator
- A combination of both

No trusts reported concerns regarding sepsis recognition within their chosen approach, and none reported use of procalcitonin (inflammatory marker test).

Safety, Monitoring and Follow-up

All trusts described structured post-discharge follow-up arrangements, although timing and delivery varied. Common approaches included daily telephone contact, or calls at approximately 24 hours post-discharge and/or at day 5-7, with some sites providing additional calls at antibiotic completion. At this stage, one site undertook a face-to-face review of the baby. Follow-up was delivered by a range of staff, including medical teams, consultants, advanced neonatal nurse practitioners, and outreach services.

Despite this variation, all pathways demonstrated a strong emphasis on safety-netting, accessibility, and ongoing monitoring.

Clinical Reviews

Pathways for review of babies who become unwell while receiving oral antibiotics were present across all sites but varied in structure and access points.

There was consistent emphasis on early escalation for clinical concern, particularly in the presence of recognised red flag symptoms. In such cases, parents were uniformly advised to seek urgent medical attention via the Emergency Department (ED), reflecting a shared low threshold for escalation. However, there was variation in how families were advised to seek non-urgent review. Depending on the site, reviews could occur via ED, Paediatric Assessment Unit (PAU), postnatal ward, or neonatal services. In some cases, the point of review was influenced by capacity or clinical factors, rather than a standardised pathway. This results in a flexible but non-uniform system, where similar clinical presentations may be managed differently across sites.

In addition, most services provided access to telephone advice, typically via neonatal or transitional care teams, enabling parents to seek guidance prior to attending hospital. This provides an important safety net and supports timely access to specialist input.

Routine follow-up processes were more consistent, including planned telephone reviews and ongoing community-based care through midwifery, health visiting, and primary care services. These mechanisms provide a structured safety net alongside reactive pathways.

A key feature across all pathways was reliance on parental recognition of clinical deterioration and appropriate help-seeking behaviour. Parents were routinely provided with verbal and written safety-netting information and encouraged to treat concerns as potentially significant. While this supports parental empowerment, it also introduces variability related to parental confidence, understanding, and access to support.

Overall, while the underlying principles of care were consistent, particularly around safety-netting, accessibility of advice, and escalation for acute illness, the operationalisation of pathways varies. Differences in access points, use of telephone triage, and local service configuration contribute to a lack of a single standardised model, with potential implications for consistency of patient experience and service utilisation.

Reported Concerns

Concerns across sites were primarily related to maintaining reliable communication with families following discharge. While most services reported successful follow-up in the majority of cases, difficulty contacting parents remained a recurring issue.

Approaches to managing unsuccessful contact varied, ranging from repeated telephone attempts to escalation via community midwifery teams for welfare checks. These findings highlight a reliance on telephone-based follow-up and parental engagement, with variation in the robustness of escalation processes when contact cannot be established.

Use of Supporting Resources

Two trusts reported using NOAH resources to support implementation of the oral switch pathway; of these, one had developed additional local materials to complement the existing resources.

One of these trusts provided additional feedback, highlighting the value of structured eligibility and exclusion criteria, standardised follow-up tools, and parent-facing safety-netting materials. However, it also identified gaps, including the need for clearer guidance on audit metrics (e.g., readmissions, missed follow-ups) and considerations related to equity, inclusion, and follow-up safety.

Domain	SW - Royal Devon (NOAH)	SW - Royal Devon (Barnstaple)	SW – Musgrove Park	St Georges (PEARL)	KSS - St Peter's	KSS - Darent Valley	KSS - Medway	KSS – Frimley Park	KSS - East Surrey	KSS - MTW *
Annual birth rate (approx.)	3497	1250	3625	4000	3280	4600	4500	5500	4300	6000
Gestational threshold	>37 weeks	>37 weeks	>37 weeks	>35 weeks	→36 weeks	→36 weeks	>36 weeks	→36 weeks	>36 weeks	→37 weeks
CRP criteria	<50 & falling	<50 & falling	Between 15 and <50 & falling	<100 & falling	<50 (if <40 avoid a third CRP)	<50 & falling	<50 & falling	1st and 2nd CRP <50 if <40 no need for 3rd	<50 & falling	Declining with no cut off
Blood culture	Negative at 36 hours	Negative at 36 hours	Negative at 36 hours	Negative at 36 hours	Negative at 36 hours	Negative at 36 hours	Negative at 36 hours	Negative at 36 hours	Negative at 36 hours	Negative at 36 hours
Birth weight	Not specified	Not specified	Not specified	>2000g	Not specified	Not specified	Not specified	Not specified	Not specified	>1.8kg
Tolerating feeds	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Other criteria	Yes*	Yes*	Yes*	Yes*	Yes*	Not specified	Not specified	nil	Yes*	Yes*
Earliest switch timing	After 36h	At 36h	At 36h	Minimum of 36h	Minimum of 36h	After 36h	48h	After 36h	After 36h	At 36h
IV requirement specified	Yes	Yes	No specified	Yes	Not specified	Yes	Yes	yes	Not specified	Not specified
IV antibiotic	Benzyl-penicillin & Gentamicin	Benzyl-penicillin & Gentamicin	Benzyl-penicillin & Gentamicin	Ceftriax-one	Cefotaxime Benzyl-penicillin & Gentamicin	Benzyl-penicillin & Gentamicin	Benzyl-penicillin & Gentamicin	Benzyl-penicillin & Gentamicin	Cefotaxime, Benzyl-penicillin & Gentamicin	Benzyl-penicillin & Gentamicin
Oral antibiotic	Amoxicillin (previously Co-amoxiclav)	Amoxicillin	Co-amoxiclav	Amoxicillin	Co-amoxiclav	Co-amoxiclav	Co-amoxiclav	Co-amoxiclav	Co-amoxiclav	Co-amoxiclav
Sepsis risk assessment	KP	NICE + KP	KP	KP	KP	NICE	NICE	KP	KP	NICE
Monitoring and follow-up	Day 5	Day 8	Daily + end of treatment	Day 5-7	End of treatment	24h + end of treatment	24h + end of treatment	24-48hrs then end of treatment	24h + end of treatment, review of record at 28-35 days	Daily

Table 1: Pathway Variation

*Some sites reported additional criteria. Due to variation in any additional criteria across sites, they are listed together here: Baby is clinically well without any ongoing symptoms of signs of sepsis, meningitis, osteomyelitis; Continue intravenous therapy if the baby has a condition that impacts their immune system; Consultant discussion; Parental consent; No safeguarding, transport, or parental comprehension concerns

2. What can be learned from the experience of site implementation and delivery of the neonatal oral switch pathways?

Rapid insights session

Responses to the six questions showed significant overlap. The analysis therefore focused on identifying six cross-cutting themes that reflect the main issues raised.

The six questions were:

1. What has been your overall experience of switching babies onto oral antibiotics?
2. What were the barriers to implementation of the new pathway to switch babies to oral antibiotics?
3. What, if any, areas do you feel need more work to strengthen the pathway or process?
4. What has helped your implementation of the new pathway to switch babies to oral antibiotics?
5. What do you feel are the critical success factors in your running a successful oral switch pathway?
6. What benefits are you experiencing by switching babies to oral antibiotics at home? (For staff, the trust, parents, and babies).

Strong Overall Acceptance and Perceived Benefits

The oral switch pathway was widely viewed as a positive and progressive development in neonatal care. Participants consistently reported strong parental acceptance among both staff and parents, with families particularly valuing earlier discharge and the ability to continue treatment at home. This was perceived to improve parent-child bonding, support breastfeeding, and reduce stress associated with prolonged hospital admission. No parental refusals were reported.

"Generally very positive, well received by staff and readily accepted by families"

"Overall very positive. The parents are very pleased to be going home earlier and being able to continue treatment at home. The staff on the postnatal ward are pleased to be able to allow babies and their families home"

"Happier parents, happier nurses, happier midwives. Shorter LOS [length of stay] of about 2 days = cheaper for trusts. Parents report less cannulations and that being home makes things like establishing breastfeeding easier"

Staff also reported increased satisfaction, improved patient flow, and reduced bed occupancy. Participants highlighted cost savings, reduced workload associated with intravenous therapy, and avoidance of repeated cannulation procedures. The pathway was described as safe in practice, with participants reporting no significant adverse events or readmissions in their local populations to date.

> **"In 11 months none of our babies have returned to the unit or the paediatric assessment unit"**
>
> **"Analysis of our data so far appears to suggest safe"**

Importance of Early Stakeholder Engagement, Leadership, and Clinical Buy-In

Early and sustained engagement of key stakeholders was identified as critical to successful implementation. Participants emphasised the importance of involving neonatal consultants, microbiology, pharmacy teams, midwives, nurses and governance teams from the outset.

Initial resistance was commonly reported, particularly among clinicians concerned about safety, antibiotic dosing, and unfamiliarity with the pathway. This cautious response was most commonly reported among more "conservative/ risk-averse" clinicians, while another described the pathway as "slow to start with initial clinician reservation". However, once stakeholders were engaged, and reassured by the evidence and governance processes, acceptance and confidence increased, and implementation progressed more smoothly.

The presence of clear leadership, including designated pathway leads and local champions across multidisciplinary teams, was identified as a key enabler. Champions played an important role in supporting staff confidence, promoting adherence, addressing concerns, and maintaining momentum.

> **"You need clear lead/co-leads and then champions. Our ANNPs [Advanced Neonatal Nurse Practitioners] were really proactive and really got the project off the ground, providing support to midwifery team and giving confidence around administration of oral antibiotics. Once everyone is comfortable with it, it gets its own momentum"**
>
> **"We found it really helpful getting all stakeholders involved in the guideline writing process, so everyone is on board to begin with (micro, pharmacy, midwives, transitional care nurse, neonatal teams). We allocated "champions" - resident doctors each 6-month rotation - to keep up the communication and oversight of the project on the ground"**

Clinical Safety Concerns and Ongoing Evidence

Clinical safety concerns was a key area of discussion. A key area of concern related to the potential impact of oral antibiotics on the neonatal gut microbiome. This concern influenced clinician confidence and contributed to a more cautious adoption in some organisations, or no adoption at all. Participants emphasised the importance of ongoing research and evidence to better understand long-term effects of antibiotic exposure in early life.

> **"It [gut microbiome] is something that comes up quite a lot for us. And I know in [region, hospital] for example, they have made an active decision not to be part of the oral switch project for exactly those concerns around the microbiome. So I think that's still something that needs some work"**
>
> **"It's quite complicated and there's not much [evidence] out there"**
>
> **"Everybody's asking about it and there's no evidence unfortunately. I believe giving probiotics in this context. So parents ask and they like it and I don't think there's any harm, but I don't think we can be actively saying there is evidence to say this will benefit your baby because I don't think that's there unfortunately"**

Uncertainty regarding antibiotic selection, dosing, and treatment duration was also identified as an important consideration. In particular, pharmacy teams and clinicians initially expressed concerns regarding co-amoxiclav and amoxicillin dosing recommendations that differed from standard reference sources such as the British National Formulary for Children (BNFc). These concerns were generally addressed through governance processes, multidisciplinary discussion, shared learning across sites, and growing clinical experience.

Participants also highlighted challenges relating to the interpretation and application of C-reactive protein (CRP) thresholds within the pathway. The initial NOAH, PEARL and St Peters protocols were informed by evidence from the RAIN study (Keij et al., 2022), which provided an important foundation for demonstrating the safety of oral antibiotic switch strategies. However, participants noted that translating evidence from an international research context into routine NHS England clinical practice required local adaption. In particular, clinicians reported uncertainty regarding CRP thresholds, including the significance of falling CRP values and appropriate duration of antibiotic treatment in babies with low or moderately elevated CRP levels.

Participants described how the pathway was refined iteratively as experience increased and areas of ambiguity became apparent in clinical practice. For example, clarification of CRP limits, and guidance on interpreting downward trends in CRP, were introduced following initial implementation, as variation in interpretation had led to uncertainty among staff. Some clinicians described variation in practice where antibiotic duration was shortened, or discontinued earlier, in babies with low peak CRP values and reassuring clinical features. This highlights the importance of clear and standardised criteria to support consistent clinical decision-making.

Despite these concerns, participants reported reassuring safety outcomes in practice, which helped to increase clinician confidence over time. However, continued research, national evaluation, and development of consensus guidance were noted as important, to strengthen the evidence base, improve consistency, and support wider adoption.

Operational and Logistical Systems as Key Enablers and Barriers to Successful Implementation

Operational and logistical factors played a key role in both enabling and challenging successful implementation. Pharmacy processes were frequently identified as a key operational consideration, particularly in relation to dispensing antibiotic doses outside standard reference ranges, and ensuring medication availability at the point of discharge. Some participants reported challenges with out-of-hours dispensing, or delays in medication supply, which required local process adaptations. In response, several teams implemented practical solutions, such as maintaining pre-labelled antibiotic stock on postnatal wards, to ensure that babies could be discharged safely without delays.

Follow-up and outcome monitoring systems also varied between organisations, and were recognised as an important but challenging component of the pathway. Participants described using a range of locally developed approaches, including electronic patient record (EPR) review, spreadsheets, and telephone follow-up with parents, to monitor babies for up to 28 days following discharge. However, these approaches were often labour-intensive and not fully reliable. Key limitations identified included: reliance on parental recall and engagement; the challenges of running follow-up telephone calls as part of an acute service; access to shared EPRs not being universally in place; and the inability to consistently capture re-presentations to other hospitals, particularly in regions with multiple neighbouring trusts. As one participant noted, while internal systems allowed identification of re-presentations within their own organisation, presentations to neighbouring hospitals or other services might not be detected.

Variation in follow-up responsibilities also influenced implementation. In some settings, follow-up was conducted by acute neonatal or medical teams, due to lack of dedicated outreach services. Participants highlighted that outreach teams would be well positioned to support follow-up and monitoring, and could provide a more sustainable and consistent model of care.

> **"I think once the babies had gone home, it was a bit out of sight, out of mind"**
>
> **"Concerns about losing babies to follow-up"**
>
> **"We had a problem with the follow-up calls being given to the most junior person in the team and then they got busy all day and we're trying to ring busy parents at bedtime and not getting any answers. So I think that comes back to this issue of out of sight out of mind and how babies who [we] are delivering hospital level care to at home probably need to sit under an outreach team really in my opinion"**

Additional operational and logistical challenges included translation of parent information materials into multiple languages, limitations in IT systems for remote monitoring, and the need to establish clear discharge documentation and communication processes. The development of standard workflows, accessible guidelines, and locally adapted operational solutions were critical in supporting safe and reliable implementation.

Workload, Workforce Capacity and Training

Workload was also identified as a key factor influencing successful implementation. Implementation and ongoing monitoring of the pathway required dedicated clinical time, which could place additional demands on individual clinicians and teams. One participant noted that implementation and follow-up represented "a lot of work", particularly where responsibilities were not formally supported within job planning. Limited outreach capacity also affected follow-up processes, with responsibility often falling to acute clinical teams. Participants identified dedicated outreach services as a key enabler for improving follow-up consistency.

Training was required across multidisciplinary teams, including midwives, neonatal nurses and medical staff, particularly in relation to antibiotic administration, discharge processes, and parental education. Participants highlighted that administering medications to newborns was not routine practice for midwives, which initially raised concerns about required targeted training and confidence building. Ongoing training and education, support from experienced staff, and the presence of local champions, were identified as important factors to support staff confidence and the successful implementation of the pathway.

The Importance of Governance and System-Level Support

The development of clear, standardised protocols, and maintaining clear clinical governance, were also highlighted as critical to successful implementation. Participants highlighted the importance of clearly defined eligibility criteria, accessible clinical guidance, and formal approval through governance structures, including microbiology and medicines management committees.

Several sites also described implementing prospective monitoring processes, including regular review of pathway data and outcomes, to ensure safe implementation and identify areas for improvement. This proactive approach enabled early identification of process gaps, such as incorrect antibiotic durations, or delays in medication provision at discharge. This continuous quality improvement approach was viewed as essential in supporting patient safety, strengthening pathway reliability, and building clinical confidence.

Summary

Overall, the oral switch pathway was viewed as a safe, effective, and beneficial innovation in neonatal care. The rapid insights session identified strong overall support for the pathway, with clear perceived benefits for families, clinical teams, and service delivery. Initial clinical concerns, particularly regarding safety, administering medication to newborns, and microbiome impact, were mitigated over time through training, experience and evidence-informed practice. Participants reported reassuring safety outcomes, with no significant adverse events or readmissions observed.

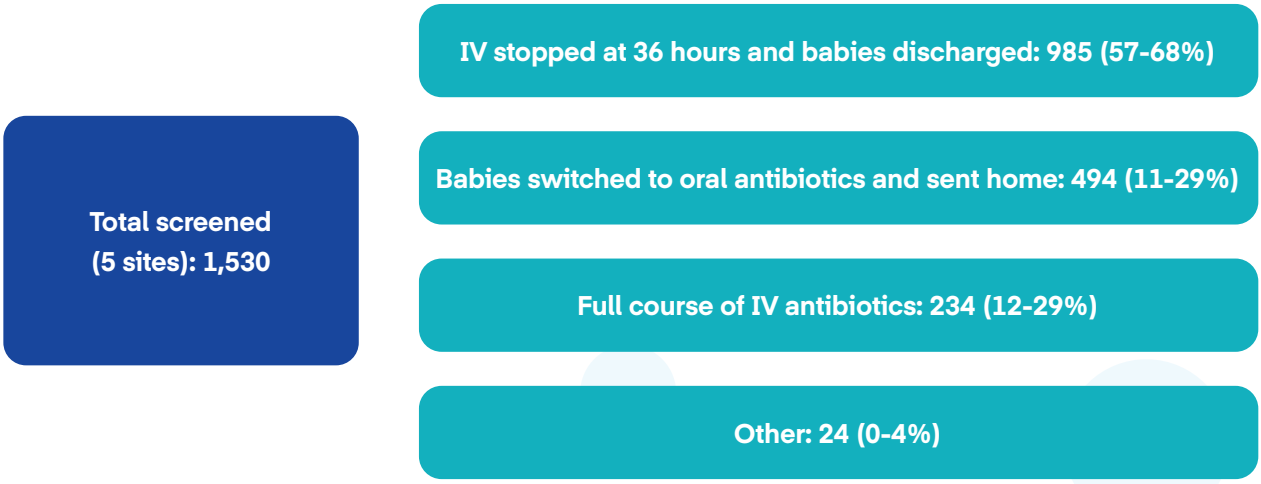
Successful implementation was supported by strong stakeholder engagement, clear leadership and 'champion' roles, training and clear governance. Operational infrastructure, workload and workforce capacity, and ongoing monitoring were critical to sustaining the pathway.

However, the need for national evaluation to support safety and capture readmissions data, as well as research to understand the impact on gut microbiome, were highlighted as important areas for future research and evaluation.

3. Who is being supported on the oral switch pathways and does this vary across sites?

Across the nine sites, 494 babies were supported on an oral switch pathway. This represents between 0.6 and 1.9% of the birth rate across trusts, with an overall average of 1.6%.

For the five sites who were able to report on the number of babies screened for infection, oral switch babies represented between 11% and 29% (average 19%) of babies screened for infection.



The majority of babies (57-68% across sites) screened for infection were considered well enough to send home at 36-48 hours without antibiotics. For one site where data was available, this proportion did not decrease with the introduction of the oral switch pathway. This suggests that pathway is unlikely to be increasing the proportion of babies receiving antibiotics.

3.1 Characteristics of Oral Switch Babies

Table 2 describes the characteristics of the babies across sites.

	Minimum	Maximum	Average (mean)
Gestation (weeks+days)	3497	1250	3625
Birth Weight (grams)	>37 weeks	>37 weeks	>37 weeks
Peak CRP (mg/l)	<50 & falling	<50 & falling	Between 15 and <50 & falling

Table 2. Baby characteristics

Baby characteristics represent the differences in eligibility criteria across sites. There is a broad range in gestation, birth weight and peak CRP levels across babies, across sites.

Interestingly, 8 of the 9 sites which submitted data reported their CRP threshold for eligibility for oral switch to be less than 50, and falling. However, all but one site reported babies on the pathway with CRP levels above 50. One site reported a max CRP level of over 100. This demonstrates pathway deviation in that babies with CRPs above the stated threshold are being switched to oral antibiotics.

Max value for Peak CRP	Number of Sites	Max CRPs reported
<50	1	43
50-75	4	52, 52, 53, 66
76-100	3	78, 94, 96
>100	1	139

Table 3. Max CRP values across sites.

In terms of gestational age of neonate, all trusts complied with their criteria, with a range of minimum gestations between 35+4 and 38+1. Maximum gestation ranged from 41+5 to 43.

Minimum birth weights varied from 2,050g to 3,290g, and maximum birth weights varied from 3,860g to 5,190g.

[1] *In 2022, 65% of babies screened were discharged home after 36 hours, since the oral switch pathway was introduced, 68% of babies have been sent home after 36 hours.*

4. What is the impact of the oral switch pathway on readmissions and ongoing infection concerns?

4.1 Activity across sites

Site / Project	Timeframe	Number screened for EOI	Number switched to oral antibiotics	Re-presentations (any reason)	Readmissions (any reason)	Readmission with presumed infection with negative cultures	Confirmed late sepsis within 28 days
SW - Royal Devon (NOAH)	20 months	539	91	19	3	2**	0
SW – Royal Devon (Barnstaple)	10 months	55	6	4	1	0	0
SW – Musgrove Park	12 months	283	40	3	2	0	0
St George's (PEARL)	16 months	450	96	17	2	0	0
KSS – St Peter's	21 months	203	57	0	0	0	0
KSS – Darent Valley	9 months	*	67	4	2	1***	0
KSS – Medway	12 months	*	45	1	0	0	0
KSS – East Surrey	9 months	*	52	*	3	3****	0
KSS – Medway	12 months	*	45	1	0	0	0
Frimley Park	12 months	*	40	3	1	0	0
Total	-	*	494	51	14	6	0

Table 4. Activity Across Sites

*Data not available
**One baby was admitted with suspected infection and was treated with IV antibiotics for 36 hours; all cultures were negative & CRPs were low.
One baby was Admitted at 18 days of life with nasal congestion, poor feeding and hypothermia. Peak CRP 17. Blood cultures negative. Chest Xray suggestive of pneumonia. Endocrine concerns ?adrenal suppression. Completed 5 days IV antibiotics
***One baby admitted on Day 25 RSV+ve Bronchiolitis. Partial sepsis screen, treated with IV antibiotics. Peak CRP 64.3, Blood culture negative.
****One baby admitted on Day 12, with vomiting/abnormal movements. Had a full septic screen, including a CT head which had no acute findings, and commenced on triple antimicrobials. Serial CRPs were < 1, blood + urine + CSF cultures were negative chest x-ray showed possible infective changes. Swabs for respiratory viruses and skin swabs for culture and HSV were negative. Baby was thought to have a reflex anoxic episode, received a five-day course of antibiotics.
One baby admitted on Day 18 with nasal congestion, intermittent periodic breathing and one temperature of 37.9C. Baby was suspected to have sepsis and was screened. Chest x-ray showed an infective process. Serial CRPs were negative and blood + CSF culture negative. A urine culture showed mixed growth. Antibiotics were discontinued after 48 hours as baby was well whilst admitted.
One baby admitted on Day 9 with coryzal symptoms and difficulty in breathing. Baby was well and only needed saline drops but was admitted for observation. CRP was < 1. Final diagnosis was mild viral illness.

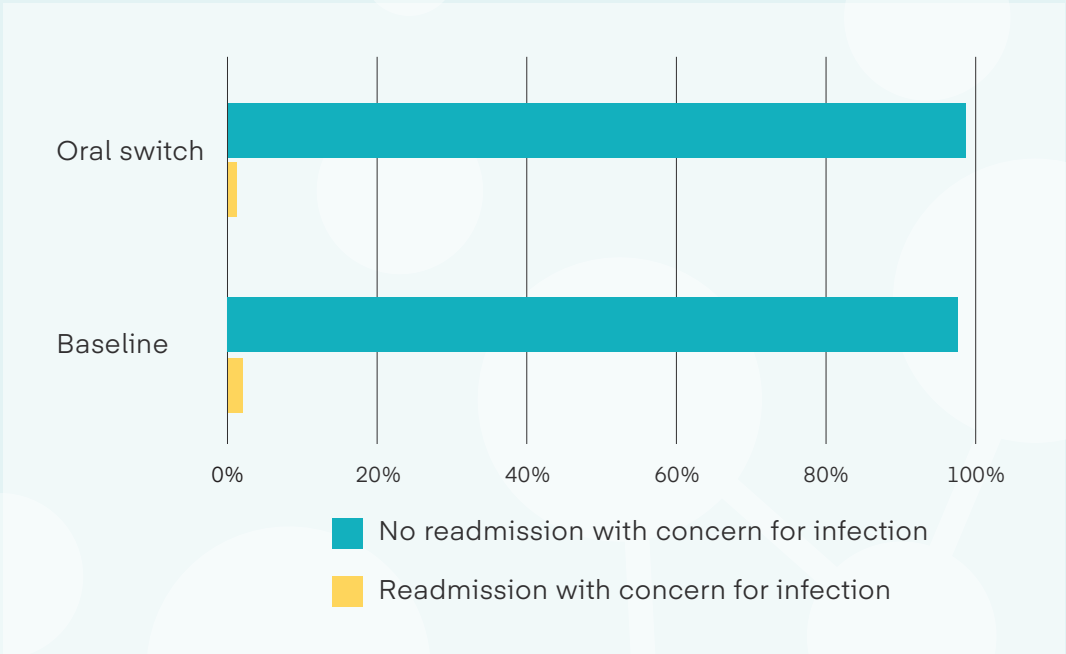
Pathway variations

Variations in criteria across sites likely reflects differing levels of risk tolerance across trusts, as well as the different pathways that the oral switch sits alongside. More evidence is needed to understand the impact of different criteria on patient outcomes.

Examination of criteria against outcomes currently offers no evidence that higher CRP tolerance of the pathway leads to less favourable outcomes (from this small amount of early data), with all six babies who were readmitted with infection concerns coming from sites whose maximum CRP levels were around 50, and zero coming from those with a higher peak CRP tolerance.

4.2 Readmission with infection concern

Of the 494 babies that were switched from IV to oral antibiotics, six (1%) were readmitted with further concerns of infection. Establishing the expected rate of neonatal re-admission up to 28 days of life is beyond the scope of this evaluation, however, a previous retrospective audit conducted prior to oral switch in RDUH (Exeter) showed 2% (of a small sample of 50 babies) of babies with initial suspected early onset infection were admitted within 28 days of life with infection concerns. Further research is needed to fully understand the impact of the pathway on readmissions within this cohort of babies.



5. Conclusion

This evaluation contributes important real-world evidence to the developing UK knowledge base on neonatal IV-to-oral antibiotic switch pathways. While international research, such as the RAIN trial and recent Danish cohort studies, has established the safety and efficacy of early oral switch, UK-specific evidence has been limited to date. By synthesising experiences from ten early adopter sites and analysing outcomes from 494 babies, this evaluation provides the first national picture of how oral switch pathways are working in routine NHS practice.

Despite variation in eligibility criteria, follow-up processes, and operational delivery, the core clinical principles (switching clinically well, culture negative babies to oral antibiotics with structured follow-up) were applied consistently. Early data indicates reassuring safety outcomes, with readmission and infection related concerns occurring at very low rates, and comparable to babies who remained on intravenous therapy. Implementation has been strengthened by strong leadership, multidisciplinary engagement, and iterative refinement of pathways as local learning emerged. At the same time, challenges around follow-up systems, workload, and ongoing evidence needs, particularly relating to the microbiome and long-term outcomes, highlight areas for further national coordination and research. As early adopters demonstrate the feasibility, acceptability, and potential benefits of these pathways, the findings provide an important foundation for wider scale-up across neonatal services.

Importantly, the evaluation also identifies the practical enablers and challenges that are unique to the UK context, such as local governance requirements, pharmacy processes, follow up capacity, and the need for consistent national guidance. In doing so, it provides actionable insights to support further spread, informs the development of more standardised pathways, and contributes to the growing evidence base needed to underpin national adoption of neonatal oral switch strategies.

6. References

Autret, E., LAUGER, J., Marimbu, J., Vaillant, M. C., Furet, Y., & Breteau, M. (1988). Comparison des concentrations plasmatiques d'amoxicilline par voie orale et intraveineuse dans les colonisations bactériennes néonatales. Archives françaises de pédiatrie, 45(9), 679-682.

Carlsen, E. L. M., Dungu, K. H. S., Lewis, A., Vissing, N. H., Aunsholt, L., Trautner, S., ... & Nygaard, U. (2024). Switch from intravenous-to-oral antibiotics in neonatal probable and proven early-onset infection: a prospective population-based real-life multicentre cohort study. Archives of Disease in Childhood-Fetal and Neonatal Edition, 109(1), 34-40.

Gifford, A., Wooding, E. L., & Ng, K. F. (2024). Is it safe for neonates with probable bacterial infection to be treated with oral antibiotics in high-income countries? Archives of disease in childhood, 109(8), 681–687

Gras-Le Guen C, Boscher C, Godon N, Caillon J, Denis C, Nguyen JM, Kergueris MF, Roze JC. (2007). Therapeutic amoxicillin levels achieved with oral administration in term neonates. Eur J Clin Pharmacol. 63(7):657-62.

Gyllensvärd, J., Ingemansson, F., Hentz, E., Studahl, M., & Elfvin, A. (2020). C-reactive protein- and clinical symptoms-guided strategy in term neonates with early-onset sepsis reduced antibiotic use and hospital stay: A quality improvement initiative. BMC Pediatrics, 20, 512

Keij, F., Kornelisse, R., Hartwig, N., Reiss, I., Allegaert, K. and Tramper-Stranders, G. (2019) Oral antibiotics for neonatal infections: a systematic review and meta-analysis. Journal of Antimicrobial Chemotherapy,; 74: 3150–3161

Keij, F. M., Kornelisse, R. F., Hartwig, N. G., Van der Sluijs-Bens, J., van Beek, R. H., van Driel, A., ... & Tramper-Stranders, G. A. (2022). Efficacy and safety of switching from intravenous to oral antibiotics (amoxicillin–clavulanic acid) versus a full course of intravenous antibiotics in neonates with probable bacterial infection (RAIN): a multicentre, randomised, open-label, non-inferiority trial. The Lancet Child & Adolescent Health, 6(11), 799-809.

Kent, A., Turner, M. A., Sharland, M., & Heath, P. T. (2014). Aminoglycoside toxicity in neonates: something to worry about? Expert review of anti-infective therapy, 12(3), 319-331.

Landersdorfer, C., Amanda Gwee, A. and Nation, R. (2023). Clinical pharmacological considerations in an early intravenous to oral antibiotic switch: are barriers real or simply perceived? Clinical Microbiology and Infection. 29(9), 1120-1125

Manzoni, P., Esposito, S., Gallo, E., Gastaldo, L., Farina, D., & Principi, N. (2009). Switch Therapy in Full-Term Neonates with Presumed or Proven Bacterial Infection. Journal of Chemotherapy, 21(1), 68–73.

Schacht, J., Talaska, A. E., & Rybak, L. P. (2012). Cisplatin and aminoglycoside antibiotics: hearing loss and its prevention. The Anatomical Record: Advances in Integrative Anatomy and Evolutionary Biology, 295(11), 1837-1850.

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