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Serial clinical observation in early neonatal sepsis: insights from a national portuguese survey

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Abstract

Introduction and Objective: Early-onset neonatal sepsis (EOS) is a significant cause of neonatal morbidity and mortality. However, its incidence has declined in high-income countries due to improvements in maternal care and intrapartum antibiotic prophylaxis (IAP). This study aims to assess current practices in the management of asymptomatic, at-risk newborns in Portugal, three years after publication of the 2022 Portuguese Neonatal Society (SPN) consensus on EOS. **Methods:** An anonymous electronic questionnaire was distributed to 51 Portuguese neonatal units in 2025. Data regarding local protocols, adherence to the SPN consensus, assessment strategies, empirical antibiotic use, and implementation challenges were analyzed. The results were then compared to those of a national survey conducted in 2021 using the same methodology. **Results:** 45 neonatal units (88% of all units) responded in 2025. Most (75.6%) reported implementing the 2022 SPN consensus. The use of less invasive strategies, such as serial clinical observation in asymptomatic neonates with EOS risk factors, increased from 8.8% (3/34) in 2021 to 31.1% (14/45) in 2025. However, categorical risk-factor approaches remain prevalent. Barriers to adopting serial observation included concerns about workload, lack of confidence in clinical surveillance, and resistance to change. **Conclusions:** Portuguese units are increasingly aligning with national EOS guidance. Although the use of serial clinical observation has increased since 2021, it has not been widely adopted. Ongoing efforts are needed to address implementation barriers, such as resource allocation and training, to further reduce unnecessary antibiotic exposure in newborns at risk of EOS.

Keywords: Early-onset neonatal sepsis. Clinical surveillance. Neonatal guidelines. Antibiotic stewardship.

Vigilância clínica seriada na sépsis neonatal precoce: dados de um inquérito nacional em portugal

Resumo

Introdução e Objetivo: A sepsis neonatal de início precoce (EOS) é uma causa significativa de morbidade e mortalidade neonatal, embora a sua incidência tenha diminuído em países desenvolvidos devido a melhorias nos cuidados maternos e à profilaxia antibiótica intraparto (IAP). O objetivo é avaliar a abordagem de recém-nascidos assintomáticos com fatores de risco para sépsis precoce em Portugal, três anos após a publicação do consenso da Sociedade Portuguesa de Neonatologia (SPN) em 2022. **Métodos:** Em 2025, foi enviado um questionário eletrónico anonimizado a 51 unidades neonatais

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portuguesas. Foram colhidos dados sobre os protocolos locais, adesão ao consenso de 2022, estratégias de avaliação, uso empírico de antibióticos e dificuldades de implementação. Os resultados foram comparados com os de um inquérito nacional realizado em 2021 com a mesma metodologia. **Resultados:** Em 2025 responderam 45 unidades neonatais (88% do total). A maioria (75,6%) referiu ter implementado o consenso da SPN de 2022. A utilização da vigilância clínica seriada em recém-nascidos assintomáticos com fatores de risco para sépsis aumentou de 8.8% (3/34) em 2021 para 31% (14/45) em 2025. No entanto, continuam a prevalecer abordagens baseadas na categorização de fatores de risco. As principais barreiras à adoção da vigilância clínica incluíram preocupações com a carga de trabalho, falta de confiança na avaliação clínica e resistência à mudança por parte das equipas. **Conclusões:** As unidades portuguesas mostram uma adesão crescente às orientações nacionais para a sépsis neonatal precoce (EOS). Embora a utilização da vigilância clínica seriada tenha aumentado desde 2021, a sua implementação continua limitada. São necessários esforços adicionais para ultrapassar barreiras à implementação — como a afetação de recursos e a formação — de modo a reduzir ainda mais a exposição desnecessária a antibióticos em recém-nascidos com risco de EOS.

Palavras-chave: Sépsis neonatal precoce. Vigilância clínica. Diretrizes neonatais. Uso racional de antibióticos.

Keypoints

What is known

- EOS is rare in term newborns due to intrapartum prophylaxis, but many uninfected infants still receive antibiotics.
- Risk-based strategies or structured clinical observation reduce unnecessary treatments and are endorsed by international guidelines.
- Evidence suggests that these strategies safely reduce antibiotic exposure without compromising neonatal outcomes.

What is added

- In 2025, 75.6% of Portuguese units reported adopting the national EOS consensus, improving protocol uniformity.
- Use of serial clinical observation has increased substantially, indicating growing acceptance of less invasive EOS management.
- Most units still use categorical risk approaches, citing limitations in staffing, the reliability of clinical assessments, and resistance to change.

Introduction

Early-onset neonatal sepsis (EOS) is a significant cause of neonatal morbidity and mortality. However, its incidence has declined in high-income countries due to improvements in maternal care and intrapartum antibiotic prophylaxis (IAP)[1–3]. In term and near-term newborns, the incidence of EOS is particularly low, often estimated to be below 1 per 1,000 live births in developed countries[1,4,5]. Despite the low incidence of the disease, empirical antibiotic use in EOS risk scenarios remains disproportionately high, with potential consequences for future health and antimicrobial resistance[6–9].

Historically, many neonatal units have employed categorical risk-based approaches that often lead to the overuse of laboratory testing and antibiotics in asymptomatic newborns[4,5].

In recent years, international recommendations have advocated for more selective EOS management strategies, such as the use of multivariate risk prediction calculators or structured serial clinical observation protocols[1,5,10–14]. Implementing these strategies can be challenging as it requires clinical training, workflow adjustments, and tools to support consistent documentation and decision-making.

The available evidence suggests that the EOS calculator and serial clinical observation are both effective in reducing unnecessary antibiotic exposure in well-appearing term and near-term newborns with EOS risk factors[1,5,10,15–20]. However, these strategies differ substantially in design and outcomes. Serial clinical observation involves close and structured monitoring of all at-risk infants, regardless of their estimated sepsis probability. Antibiotics are initiated only if clinical signs develop. This approach allows for broad surveillance coverage and extremely low antibiotic usage rates (often < 1%) without compromising safety[5]. Conversely, the EOS calculator estimates the individual sepsis risk based on perinatal factors and clinical findings from a neonatal examination, guiding the decision of whether the newborn should receive antibiotics, undergo clinical observation, or receive no intervention. This model reduces the number of infants exposed to interventions, though it may still result in empiric antibiotics for around 2–5% of infants[1,18]. Therefore, while both approaches aim to minimize overtreatment, serial clinical observation may ensure greater safety and efficacy by identifying all symptomatic cases early and avoiding antibiotic use in asymptomatic infants.

In 2022, the Portuguese Society of Neonatology (SPN) issued a national consensus guideline for EOS risk management. This guideline aimed to standardize practice across Portugal while prioritizing less invasive management strategies for asymptomatic term and near-term infants with EOS risk factors[21].

The present study describes current national practices for managing EOS risk in asymptomatic newborns three years after the SPN consensus was published. We interpret our findings in light of the results of a previous national survey conducted in 2021, prior to the consensus. This comparison offers insight into changes in practice and the impact of the consensus on clinical behavior[22].

Methods

We conducted a cross-sectional survey to describe the current management strategies for EOS risk in term and late preterm infants (≥ 35 weeks' gestation) in Portuguese neonatal units. An anonymized electronic questionnaire was developed using a web-based application for survey design and data management. It addressed several domains, including: (1) the primary management strategy for asymptomatic term and near-term newborns with EOS risk factors; (2) the duration of postnatal hospitalization in neonates with EOS risk factors; (3) the duration of empirical antibiotics in asymptomatic infants with negative blood cultures; (4) the details of how serial clinical observation is conducted in units that use this strategy (e.g. monitoring protocols, responsible staff, frequency of observations); and (5) the perceived concerns, difficulties, and barriers to implementing serial observation in practice.

The survey included yes/no questions, multiple-choice items, and open-ended comment fields. The questionnaire was distributed between April and June 2025 via email to the director or lead neonatologist of 51 public and private neonatal units in Portugal. Instructions were provided to ensure that each unit submitted one response reflecting the most commonly used approach by that team. Participation was voluntary and responses were anonymized.

We performed a descriptive analysis of the survey results. Responses from 2025 were compared to those obtained in a similar national survey conducted in 2021, which had used the same methodology[22]. The 2021 survey results, published prior to the SPN consensus implementation, serve as a baseline for assessing practice changes. Given the descriptive, repeated cross-sectional nature of the comparison, no formal statistical hypothesis testing was applied, and the data are presented as percentages or absolute numbers for each option. Missing responses were excluded from denominators.

This study did not involve patient-level data and was exempt from formal ethics committee review.

Results

Respondent characteristics

A total of 45 neonatal units (88.2% out of the 51 total units) completed the 2025 survey. These included 6 Highly Differentiated Perinatal Centers, 18 Differentiated Perinatal Support Hospitals, and 21 Basic Perinatal Centers, according to the Portuguese Neonatal College categorization. Together they accounted for approximately 69,263 live births in 2024.

Approach to asymptomatic term newborns with EOS risk factors

most responding units (75.6%, 34/45) reported that their local EOS protocol for term or near-term infants was updated to align with the 2022 SPN consensus recommendations. The remaining 24.4% (11/45) indicated that they still follow protocols developed internally.

The majority of units (82.2%, 37/45) keep asymptomatic newborns with perinatal risk factors in hospital for at least 48 hours after birth. A small proportion (8.9%, 4/45) discharge between 36–48 hours, and the remaining 8.9% (4/45) require a minimum of 72 hours of observation before discharge. No unit reported routinely discharging at-risk infants before 36 hours of age.

Adoption of less invasive strategies was reported by 31.1% of units (14/45). Specifically, 24.4% of all units (11/45) now use structured serial clinical observation as the default approach for these infants, 4.4% (2/45) use a multivariate EOS risk calculator tool, and 2.2% (1/45) employ periodic clinical monitoring without a formally established protocol. The remaining 68.9% of units (31/45) continue to use a conventional categorical risk assessment approach as their primary strategy.

Categorical risk factor assessment strategy

Among the 31 units (68.8%) still using categorical risk assessment strategies, laboratory evaluation is performed in the presence of more than one risk factor or chorioamnionitis in 61.3% (19/31), when more than one risk factor was present in 35.5% (11/31) and in the presence of any risk factor in one (3.2%).

When empirical antibiotics are initiated in asymptomatic infants, most units in this group (77.4%, 24/31) transfer the newborn to a neonatal unit or special care nursery for the duration of treatment, while 22.6% (7/31) allow the infant to remain rooming-in with the mother. Regarding the duration of antibiotic therapy when blood cultures are negative, only 13.3% (4/30 units that provided data) reported stopping antibiotics at 48 hours in this scenario. Meanwhile 50% (15/30) stopped at 72 hours, and 36.7% (11/30) continued a full 5-day course of antibiotics.

In the case of chorioamnionitis, only five units (5/45, 11.1%) reported initiating empirical antibiotic therapy regardless of the newborn's clinical status or laboratory findings. The remaining units opted for laboratory evaluation, either alone or in combination with clinical surveillance.

The majority (71%, 22/31) of units that still use the conventional categorical approach expressed that it would be feasible to transition to a serial observation strategy. The main barriers identified were a shortage of human resources to conduct frequent observations, mentioned by 51.6% (16/31), the perceived subjective or unreliable nature of clinical assessments (16.1%, 5/31), and concerns about staff training, competence, or motivation to adopt a new protocol (12.9%, 4/31).

Serial clinical observation

Fourteen units in our sample (31.1% of respondents) indicated that they used less invasive strategies as the initial management for asymptomatic at-risk newborns. Among these, 11 units have a structured surveillance protocol in place (e.g., a standardized vital sign chart and examination schedule), two units apply the EOS calculator, whereas one unit use an unstructured approach (relying on routine nursery checks or individual clinical judgement without a formal protocol). Monitoring practices under serial surveillance typically involve frequent vital sign measurements and clinical assessments. The most commonly monitored parameters are oxygen saturation, heart rate, and axillary temperature, followed by respiratory rate (Table 1). Registered clinical signs include skin color and perfusion, respiratory effort, general well-being, and tone. Among the units that reported using serial clinical observation, two described partial deviations from structured protocols: one unit relied entirely on scheduled yet unstructured assessments for both vital signs and clinical evaluation, while the other followed a structured protocol for vital signs but used unstructured clinical assessments.

Table 1. Frequency of vital signs and clinical parameters monitored in units adopting serial clinical observation
n = 11

Vital sign	Frequency (n;%)
SpO_2	10 (90.9%)
Heart rate	10 (90.9%)
Axillary temperature	9 (81.8%)
Respiratory rate	7 (63.6%)
Non-structured clinical checks	4 (36.4%)
Rectal temperature	2 (18.1%)
Perfusion index	2 (18.1%)
Clinical parameter	
Color	9 (81.8%)
Signs of respiratory distress	9 (81.8%)
General condition	9 (81.8%)
Tonus	8 (72.7%)

Responsibility for carrying out serial observations was shared between medical and nursing staff in 57.1% of these units (8/14), while 42.9% (6/14) relied solely on nurses. The most frequently cited challenges to implementing of serial clinical observation were resistance to changing established practices and limited engagement of nursing staff.

Discussion

This national survey offers a comprehensive overview of EOS risk-management practices in Portugal. With a high response rate and broad national coverage (~82% of annual births – 84 788 births in 2024)[23], the findings are likely representative of current clinical practice. Conducted three years after the publication of the SPN consensus[21], the survey suggests that most units (75.6%) have incorporated the guideline into their local protocols, reflecting substantial national alignment and improvement compared with the pre-consensus landscape reported in 2021[22]. It also provides an opportunity to consider the impact of the consensus and to identify areas where further improvement is needed. The findings indicate a shift toward more evidence-based and standardized approaches to EOS management.

Despite this progress, the adoption of less invasive approaches such as serial clinical observation remains limited. Only 31.1% of units reported using less

invasive strategies as their initial management for asymptomatic newborns with EOS risk factors. Although this proportion has increased substantially since the previous national survey (8.8% in 2021)[22], serial clinical observation continues to be underutilized despite national and international recommendations and extensive evidence supporting its safety and effectiveness[10–14].

Several perceived barriers continue to hinder the broader implementation of serial clinical observation. The most common concern is the belief that serial examinations require more staff time and could overburden units that are already short-staffed. However, this may be a misperception. In our experience, caring for infants on antibiotics also consumes staffing resources (for IV access, drug administration, and monitoring in NICU), whereas structured observation uses short periodic assessments that, can be integrated into routine care with efficient organization. Furthermore, based on the reported incidence of perinatal risk factors[24], only a small number of asymptomatic at-risk newborns are typically born per day even in busy centers. With appropriate scheduling, serial observation can be feasible without significantly increasing the workload.

Another concern is the subjectivity and reliability of clinical monitoring. Admittedly, clinical signs of neonatal sepsis can be subtle, but current evidence indicates that changes in vital signs and newborn observations are the earliest and among the most sensitive indicators of EOS in this population[10,25]. Tools such as standardized scoring sheets and newborn assessment training can improve reliability further. In fact, the consensus emphasizes education in recognizing abnormal observations. Our experience suggests that what is needed is smarter allocation of existing resources and confidence in clinical skills rather than more resources.

A further barrier is resistance to change. Some staff may prefer with traditional, investigation-driven approaches or be concerned about risk and liability if antibiotics are not administered. Consistent training, clear protocols, and demonstrating positive outcomes can help reassure even the most skeptical.

Among the units that adopted serial clinical observation, most implemented structured protocols with systematic monitoring of vital signs and clinical parameters. Most of these units favored direct clinical observation over the EOS calculator, an approach that seems well-suited to the Portuguese context. Given that many centers likely maintain empirical antibiotic treatment rates close to 3% (except those treating all infants exposed to chorioamnionitis)[10,18,26], significant reductions may only be achievable through strategies targeting antibiotics exclusively for symptomatic infants[10]. Structured clinical observation aligns with this goal, offering broader monitoring coverage and prioritizing antibiotic use based on clinical signs rather than probabilistic models.

As most units reported adherence to the current national consensus, indicating a willingness to follow centralized guidance, and as the majority considered serial clinical observation feasible, these results may encourage revising the national recommendations to more assertively endorse this strategy as the preferred approach. Similar shifts have already been made in several European countries[10,13,14], where structured clinical observation has become the standard for managing asymptomatic neonates with EOS risk factors. This aligns with the growing evidence suggesting that categorical risk factor assessment lacks discriminatory power and thus leads to the overtreatment of many uninfected newborns[2,7,18,27,28].

Globally, the use of empirical antibiotics in neonates remains a concern[9]. The practice of administering antibiotics to every newborn exposed to chorioamnionitis —regardless of clinical signs or laboratory results— persists in 11.1% of Portuguese units (5/45), although this represents a significant improvement from 2021, when it was reported by 35% of units[22]. Furthermore, many centers report continuing antibiotic therapy beyond 48 hours despite negative blood culture results. These practices contribute to unnecessary antibiotic exposure, prolonged hospitalization, and potential disruption of the neonatal microbiome[6–9].

This study has a number of limitations inherent to survey-based designs. First, data were self-reported at the unit level, without patient-level verification, and a single response per unit may not fully capture intra-unit variability in daily practice. In addition, the survey was not linked to EOS incidence, antibiotic exposure rates, or clinical outcomes, which limits interpretation of the clinical impact of reported practices. Finally, because this was a descriptive, repeated cross-sectional comparison, no formal statistical testing was performed; therefore, differences between the 2021 and 2025 surveys should be interpreted with caution.

Conclusion

There is increasing reported adoption of less invasive strategies and broader alignment with the national consensus. However, serial clinical observation remains under-used despite supportive international evidence. These findings may assist units and guideline developers in considering how best to implement such

strategies and highlight the need for future work incorporating patient-level data and clinical outcomes. Overall, this survey reflects gradual progress in EOS risk management in Portugal while underscoring the importance of continued efforts to promote safe, consistent, and minimally invasive approaches in clinical practice.

Author contributions

I. Sampaio: bibliographical search, study design, data collection, analysis and interpretation of results, drafting and reviewing of the article; R. Gouveia: analysis and interpretation of results, critical reviewing of the content of the article.

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Conflicts of interest

None.

Ethical considerations

Protection of human subjects and animals. The authors declare that no experiments on humans or animals were performed for this research.

Confidentiality, informed consent, and ethical approval. The authors have followed their institution's confidentiality protocols, obtained informed consent from all patients, and secured approval from the Ethics Committee. SAGER guidelines have been followed as applicable to the nature of the study.

Declaration on the use of artificial intelligence. The authors declare that no generative artificial intelligence was used in the writing or creation of the content of this manuscript.

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