Clinical Audit

Audit of antibiotic prescribing patterns before and after ICMR STW implementation in neonatal sepsis

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Abstract

Background: Antibiotic overuse in neonatal intensive care units (NICUs) contributes significantly to antimicrobial resistance (AMR) and adverse clinical outcomes. In response, the Indian Council of Medical Research (ICMR) introduced Standard Treatment Workflows (STWs) in 2022 to promote rational antibiotic use in neonatal sepsis.

Objective: This audit aimed to compare antibiotic prescribing patterns before and after the implementation of the ICMR STW in a level III NICU.

Methods: We conducted a retrospective audit of NICU admissions over two six-month periods in 2024. The pre-implementation phase spanned from January to June, while the post-implementation phase covered July to December. The ICMR STW was operationalized using a structured proforma that guided documentation of clinical signs, indications for initiating antibiotics, culture testing, and escalation decisions. NICU nurses were actively involved in ensuring compliance through real-time monitoring.

Results: Among 216 neonates admitted during the study period, 109 were admitted before and 97 after STW implementation. The proportion of neonates receiving antibiotics declined from 31% in the pre-implementation phase to 18% post-implementation ($p = 0.023$). Culture-positive sepsis was observed only in the pre-intervention phase and was rare overall (1.4%). The use of higher antibiotics also decreased, from 41% to 29% ($p=0.43$), while the mean duration of antibiotic therapy remained consistent at 5 days.

Conclusion: The introduction of the ICMR STW improved antibiotic stewardship in our NICU by reducing both the number of prescriptions and the use of higher antibiotics. This success was achieved through structured documentation and active nursing engagement and may serve as a scalable model for other NICUs.

Key words: Antibiotic stewardship; Antibiotic prescribing pattern; Neonatal

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1. Introduction

Neonatal sepsis remains a leading cause of morbidity and mortality in developing countries, especially among preterm and low birth weight (LBW) infants. Due to the nonspecific nature of early clinical signs, empirical antibiotic therapy is often initiated even in the absence of confirmed infection. This practice can lead to the inappropriate or prolonged use of antibiotics, which is associated with increased risk of antimicrobial resistance (AMR), secondary fungal infections, necrotizing enterocolitis, and poor neurodevelopmental outcomes.

To address these concerns, the Indian Council of Medical Research (ICMR) developed Standard Treatment Workflows (STWs) in 2022, offering clinicians a structured approach to managing neonatal sepsis. These workflows emphasized clinical risk stratification, clear criteria for initiating antibiotics, mandatory culture testing, timely de-escalation or discontinuation, and reliance on objective clinical and laboratory findings.

This audit aimed to evaluate whether implementing the ICMR STW in our level III NICU resulted in more rational antibiotic prescribing and improved stewardship practices.

1.1. Methods

This audit was conducted retrospectively in the NICU of a tertiary care hospital that provides level III neonatal care, including mechanical ventilation and total parenteral nutrition. We reviewed NICU admissions during two consecutive six-month periods in 2024: the pre-implementation phase from January to June and the post-implementation phase from July to December.

The ICMR STW for neonatal sepsis was formally adopted in July 2024. Training sessions were conducted for medical and nursing staff. A structured proforma based on the STW was incorporated into daily clinical workflow to guide decision-making on antibiotic initiation, escalation, and de-escalation (Figure 1).

The STW emphasized initiating antibiotics based on clearly defined clinical signs and risk factors, obtaining blood cultures before starting treatment, standardizing the empirical regimen, and using predefined durations based on the type of sepsis. NICU nurses were trained to monitor compliance with the proforma and ensured real-time documentation and communication with physicians.

Data were extracted from NICU records and included demographic details such as gestation and birth weight, indications for antibiotic use, culture results, empirical and escalated antibiotic regimens, duration of therapy, and the use of higher antibiotics (including carbapenems, colistin, vancomycin, linezolid, and amphotericin B).

Primary outcomes included the proportion of neonates receiving antibiotics and the use of higher antibiotics. Secondary outcomes included antibiotic duration and culture positivity rates. Descriptive statistics were used, with categorical data analyzed using chi-square tests. A p-value of less than 0.05 was considered statistically significant.

This audit received approval from the Clinical Audit Committee of Kauvery Hospital, Radial Road. As only de-identified patient data were used and no direct patient contact was involved, the requirement for individual informed consent was waived.

NEWBORNS SEPSIS ANTIBIOTICS AUDIT

Please complete for all infants started on antibiotic for sepsis

Commencement of antibiotics- Date: …… Time: ……

Red flag signs

- Shock
- Hardening of skin – sclerema
- Bleeding from multiple sites
- Respiratory distress needing intubation (OR) SA score > 6
- Respiratory distress onset more than 6 hours of birth
- If age of baby is less than 7 days and mother has foul smelling discharge or chorioamnionitis

Yellow flag signs

- Seizures
- Refusal to feed
- Lethargy
- Feed intolerance
- HR > 160/minute for more than 1 hour
- Baby temperature <36.5 °C or ≥ 38 °C
- RR > 60/minute or apnea or respiratory distress
- Grunting, nasal flaring or recession
- Oxygen saturations <95%
- Altered responsiveness, persistent hypotonia

Maternal Risk factors

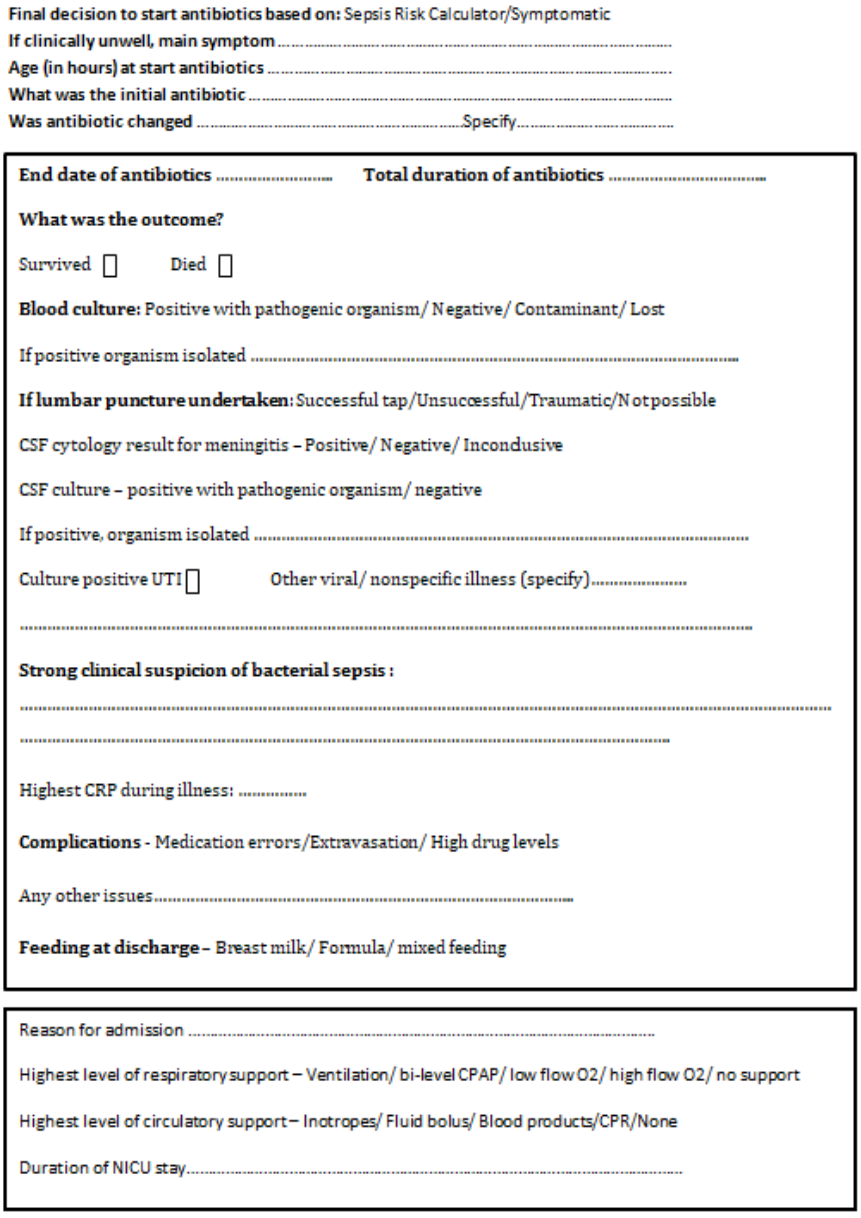
- Unclean vaginal examination
- Rupture of membranes > 18 hours
- Preterm premature rupture of membranes
- UTI
- Diarrhea
- Fever

HIGH PROBABILITY OF SEPSIS – Start treatment and investigate

- Any red flag sign is present
- Two yellow flag signs/ maternal risk factors are present
- One yellow sign or maternal risk factor is present and GA at birth ≤ 32 weeks

AT RISK/ SUSPECT SEPSIS OBSERVE – NO ANTIBIOTICS

- One yellow flag signs/ maternal risk factors are present AND
- GA at birth > 32 weeks



Final decision to start antibiotics based on: Sepsis Risk Calculator/Symptomatic
If clinically unwell, main symptom .....
Age (in hours) at start antibiotics .....
What was the initial antibiotic .....
Was antibiotic changed .....Specify.....

End date of antibiotics ..... **Total duration of antibiotics** .....

What was the outcome?

Survived ☐ Died ☐

Blood culture: Positive with pathogenic organism/ Negative/ Contaminant/ Lost

If positive organism isolated .....

If lumbar puncture undertaken: Successful tap/Unsuccessful/Traumatic/Not possible

CSF cytology result for meningitis – Positive/ Negative/ Incondusive

CSF culture – positive with pathogenic organism/ negative

If positive, organism isolated .....

Culture positive UTI ☐ Other viral/ nonspecific illness (specify).....

.....

Strong clinical suspicion of bacterial sepsis :

.....

.....

Highest CRP during illness: .....

Complications - Medication errors/Extravasation/ High drug levels

Any other issues.....

Feeding at discharge – Breast milk/ Formula/ mixed feeding

Reason for admission .....

Highest level of respiratory support – Ventilation/ bi-level CPAP/ low flow O2/ high flow O2/ no support

Highest level of circulatory support – Inotropes/ Fluid bolus/ Blood products/CPR/None

Duration of NICU stay.....

Fig (1): Proforma on antibiotic initiation, escalation and de-escalation

2. Results

A total of 216 neonates were admitted during the study period, with 109 admissions during the pre-implementation phase and 97 during the post-implementation phase. The baseline characteristics of the two groups were comparable (Table 1). Preterm neonates constituted 56% of the admissions in the pre-implementation phase and 50% in the post-implementation phase. Similarly, the proportion of low birth weight neonates was 57% before and 49% after STW implementation.

The proportion of neonates receiving antibiotics dropped from 34 out of 109 (31%) in the pre-implementation period to 17 out of 97 (18%) in the post-implementation period, reflecting a 42% relative reduction (p=0.023) (Table 2). Culture positivity rates were low in both periods, with all three culture-positive cases occurring in the pre-implementation phase. In the post-implementation group, one neonate was diagnosed with culture-negative meningitis.

most common empirical regimen in both periods was a combination of piperacillin–tazobactam and an aminoglycoside. Use of higher antibiotics, such as meropenem, colistin, vancomycin, linezolid and antifungals, declined from 41% before implementation to 29% afterward (p=0.43). The mean duration of antibiotic therapy remained unchanged at approximately 5 days, consistent with the STW recommendations for culture-negative sepsis.

Table 1. Demographic characteristics of the study population

Characteristics	**Jan–June 2024**	**July 2024–Dec 2024**	
No of NICU admissions	109	97	
Male sex	62	53	x
Birth weight categories			
>2.5 kg	46	50	
1.5-2.5 kg	48	37	
1-1.5 kg	11	7	
<1000 grams	4	4	
Low birth weight	62 (57%)	47 (49%)	x
Gestational age categories			
<28 wks	1	5	
28-31 wks	19	6	
32-33 wks	10	5	
34-36 wks	32	33	
> 37 wks	47	48	
Prematurity	60 (56%)	48 (50%)	
Culture-positive sepsis	3/109 (3%)	0/97	0.542
Culture-negative sepsis	31/109 (28%)	17/97 (18%)	
Early-onset sepsis (of all sepsis)	29/34 (85%)	16/17 (94%)	0.649
Late-onset sepsis (of all sepsis)	5/34(15%)	1/17 (6%)	

Meningitis	0/34	1/17 (6%)	0.444
Pneumonia	5/34(15%)	3/17 (18%)	
Culture sent, but antibiotics not started	5/109(5%)	2/97 (2%)	

Table 2: Antibiotic Prescribing Patterns

Characteristics	**Jan 2024–June 2024**	**July 2024–Dec 2024**	**P value**
Total NICU admissions	109	97	
Neonates receiving any antibiotics	34/109 (31%)	17/97 (18%)	0.023
First line (Ampicillin-amikacin)	2 /34	1/17	0.705
Second line (Piperacillin-Tazobactam-Amikacin)	18/34	11/17	
Reserve antibiotics (Meropenem, Vancomycin, Linezolid, Colistin, Amphotericin B)	14/34	5/17	
Mean duration of antibiotics (days)	5.4	5.9	

3. Discussion

The implementation of the ICMR STW resulted in a significant improvement in antibiotic stewardship practices within our NICU. The observed reduction in antibiotic use and a more judicious approach to escalating therapy were likely driven by multiple reinforcing factors.

First, the structured documentation process prompted clinicians to critically evaluate the necessity of antibiotics, reducing the tendency to initiate empirical therapy in the absence of clear indications. Second, nursing staff played an essential role in sustaining compliance with the protocol. Their active participation in real-time documentation and communication with the medical team fostered a collaborative and accountable care environment. Third, the STW provided clear and standardized thresholds for initiating, modifying, or discontinuing antibiotic therapy, which reduced uncertainty and minimized defensive prescribing.

Our post-intervention antibiotic usage rate (18%), although not statistically significant when compared to the pre-intervention period, is substantially lower than national averages reported by Chawla et al., reflecting the impact of the STW. Importantly, the reduction in antibiotic use was not associated with any increase in adverse clinical outcomes.

This supports the safety of restrictive prescribing strategies when guided by clinical algorithms.

This audit has several limitations. As it was retrospective, it relied on existing documentation, which may have introduced inaccuracies or missing data. The single-center design limits the generalizability of findings, as antibiotic prescribing practices and patient profiles may differ in other NICUs. The very low culture positivity rate (1.4%) restricted the ability to assess the appropriateness of antibiotic use based on microbiological confirmation. Additionally, the study focused only on immediate NICU outcomes, without evaluating long-term consequences such as readmissions or neurodevelopmental follow-up. Other unmeasured factors, including changes in staffing or infection control practices, may have influenced antibiotic use independently of the STW implementation.

The study highlights that structured antibiotic stewardship protocols, supported by nursing involvement, can safely reduce antibiotic overuse in NICUs. Future research should explore long-term outcomes and validate these findings across multiple centers.

4. Conclusion

Our audit demonstrates that the implementation of the ICMR Standard Treatment Workflow for neonatal sepsis led to a meaningful reduction in antibiotic prescriptions and the use of higher-tier antibiotics in a level III NICU. The success of this intervention was driven by structured documentation, active nursing involvement, and adherence to clinical algorithms. This stewardship model is potentially scalable and could benefit other NICUs striving to optimize antibiotic use while reducing the risk of antimicrobial resistance.

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