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Research Article

An Observational Study to Evaluate the Antibiotic Prescribing Pattern Using Who Access, Watch, Reserve (Aware) Criteria Among Pediatric Patients Admitted In Intensive Care Unit At Sir Padampat Institute Of Neonatology & Paediatric Health, Jaipur

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ABSTRACT
Background: Escalating antimicrobial resistance (AMR) threatens the effectiveness of life-saving antibiotics, particularly in low- and middle-income countries. The World Health Organization (WHO) introduced the Access, Watch, Reserve (AWaRe) framework to monitor and optimise antibiotic use. Robust paediatric data remain scarce, especially for Indian intensive-care settings.
Methods: We performed a descriptive, hospital-based observational study of consecutive new admissions to the Paediatric Intensive Care Unit (PICU) and Neonatal Intensive Care Unit (NICU) at Sir Padampat Institute of Neonatology & Paediatric Health (SPINPH), Jaipur. All children receiving at least one antibiotic were enrolled until the target sample of 400 was achieved (95 % CI, 10 % relative error). Prescriptions were analysed for drug, dose and adherence to Standard Treatment Guidelines (STG, 6th edition). Each molecule was mapped to the WHO AWaRe list (2021). Primary outcomes were the proportions of antibiotics in the Access, Watch and Reserve groups. Secondary outcomes included adverse-drug-reaction (ADR) incidence and culture-confirmed resistance patterns. Data were summarised as means ± SD or proportions; x^2 and paired t-tests were applied as appropriate.
Results: A total of 400 children (male: female = 2.1: 1; mean age 2.6 ± 3.6 years) received 838 antibiotic (mean 2.09 ± 0.63 per encounter). Watch agents predominated (65.2 %), surpassing Access (32.5 %) and Reserve (2.4 %) drugs (Figure 1). Amikacin (Access) was most frequent (22.7 % of all prescriptions), whereas cefotaxime and vancomycin led the Watch category (19.3 % and 16.0 %, respectively) (Figure 2). Ninety-seven per cent of agents were on the Indian Essential Medicines List and were prescribed generically. Adherence to STG exceeded 85 % for nine major drugs but fell below 60 % for azithromycin, aztreonam, linezolid and teicoplanin. Culture results were available for only 4.8 % of cases, isolating *Pseudomonas* spp. (32 %), *Acinetobacter* spp. and *E. coli* (each 21 %). ADRs occurred in 5 % of children, mostly mild, with no fatalities.
Conclusion: Two-thirds of antibiotic use in this ICU/NICU cohort derived from the Watch group, underscoring an urgent stewardship need to shift prescribing towards Access agents. Limited microbiological testing hampers rational escalation/de-escalation. Implementing real-time culture surveillance and AWaRe-based feedback could curb unnecessary exposure to broad-spectrum antibiotics and mitigate AMR.

Keywords: AWaRe; antibiotic stewardship; paediatric intensive care; neonatal intensive care; India; antimicrobial resistance

INTRODUCTION

Antibiotics revolutionised child survival, yet their indiscriminate use fuels antimicrobial resistance (AMR), now one of the gravest global health threats [1,2]. The WHO estimates that drug-resistant infections were directly responsible for 1.27 million deaths in 2019, with South-Asia bearing a disproportionate burden [3]. Paediatric populations are uniquely vulnerable: empirical broad-spectrum treatment is frequently initiated before culture confirmation because signs of sepsis are nonspecific, laboratory infrastructure is limited and clinicians adopt a low threshold for early

coverage [4]. Neonates, moreover, possess immature immunity and altered pharmacokinetics, necessitating special dosing considerations.

To promote judicious prescribing, WHO introduced the Access, Watch, Reserve (AWaRe) classification, first in 2017 and updated most recently in 2021 to include 258 molecules [1]. Access drugs are narrow-spectrum first or second-line therapies with lower resistance potential; Watch agents have higher resistance-selection risk and should be restricted; Reserve antibiotics are "last-resort" options for multidrug-resistant infections. WHO's Global Action Plan and the 13th General Programme of Work target ≥60 % of national consumption from Access agents by 2030, alongside verified stewardship structures [5].

Despite this, recent Indian hospital studies reveal continued dominance of third-generation cephalosporins, carbapenems and glycopeptides in paediatric intensive-care units (PICUs) [6, 7]. Scoping reviews indicate that paediatric stewardship programmes lag behind adult counterparts, constrained by staffing, surveillance and paediatric-specific breakpoints [8]. Moreover, metrics such as days of therapy (DOT) and defined daily doses are inconsistently applied, hampering comparison [9].

Jaipur, the capital of Rajasthan, serves a large referral population with rising AMR in Gram-negative pathogens.

Sir Padampat Institute of Neonatology & Paedi atric Health (SPINPH) is a tertiary centre affiliated to SMS Medical College. Prior internal audits suggested heavy reliance on Watch antibiotics but lacked systematic AWaRe mapping. Against this backdrop, we conducted an observational study to (i) characterise antibiotic prescribing patterns among new PICU/NICU admissions, (ii) quantify their distribution across AWaRe groups, (iii) assess concordance with national STG, and (iv) document ADRs and culture-proven resistance. By aligning institutional data with WHO benchmarks, our findings aim to inform local stewardship initiatives and contribute to the limited national evidence-base.

MATERIALS AND METHODS

Study design & setting

This hospital-based descriptive study was undertaken in the PICU and NICU of SPINPH, Jaipur, from November 2023 to August 2024, after approval by the Institutional Ethics Committee (Ref No. SPINPH/IEC/2023/127).

Participants

All consecutive children (0–12 y) of either sex admitted for ≥24 h who received at least one antibiotic were eligible. Exclusion criteria were parental refusal of consent or transfer/discharge before drug administration.

Sample size

Assuming 50 % of initial prescriptions fall in the Access category (maximising variance), 400 encounters were required for 95 % confidence and 10 % relative precision.

Data collection

A pre-validated case-record form captured demographics, weight, diagnosis, antibiotic details (generic name, dose, route, frequency, and duration), laboratory investigations, culture-sensitivity results and ADRs (WHO-UMC causality scale). Prescribers were blinded to the study to minimise Hawthorne bias.

Variables

Primary outcome: proportion of antibiotics in each AWaRe category (2021 list). Secondary outcomes: (i) number of agents per encounter; (ii) STG adherence (yes/no per prescription); (iii) ADR incidence; (iv) culture-confirmed resistance.

Statistical analysis

Data were entered into MS Excel and analysed with SPSS v25. Continuous variables are expressed as mean ± SD; categorical variables as frequencies/percentages. Differences in means used paired-sample t-tests; proportions used χ^2 tests. Two-tailed $p < 0.05$ was significant.

RESULTS

A total of 400 antibiotic-treated admissions (272 male, 128 female) were included (Table 1). Infants under one year constituted 64.5 % of cases; mean body-weight did not differ by sex ($p = 0.87$). Every encounter contained at least one injectable antibiotic, and the overall average was 2.09 agents.

AWaRe distribution

Of 838 prescriptions, 546 (65.2 %) were Watch, 272 (32.5 %) Access and 20 (2.4 %) Reserve (Figure 1, Table 3). Hence, the Access target of ≥60 % was unmet by a wide margin.

Antibiotic spectrum

Sixteen distinct molecules were ordered (Figure 2). Amikacin (22.7 %) topped the list, followed by cefotaxime (19.3 %), vancomycin (16.0 %) and ceftriaxone (12.6 %). Reserve class usage was restricted to aztreonam and linezolid (each 1.2 %).

Dose variability

Substantial inter-patient variation was observed for cefotaxime (mean 267 mg, SD 324 mg) and piperacillin-tazobactam (1383 ± 908 mg), reflecting weight-based or severity-guided titration.

Guideline adherence & diagnostics

Overall, STG concordance reached 87 %. Deviations centred on azithromycin (38 % non-adherent) and linezolid (60 %). Only 19 cultures (4.8 %) were retrieved—*Pseudomonas* spp. predominated—limiting opportunity for targeted therapy. Documented ADRs (rash, diarrhoea, nephrotoxicity) were noted in 20 children (5 %); all resolved with dose adjustment or withdrawal.

Tables

Table 1. Demographic Characteristics (N = 400)

Characteristic	Male (n = 272)	Female (n = 128)	Total (%)
Age < 1 y	178 (65.4)	80 (62.5)	258 (64.5)
Age 1–5 y	50 (18.4)	24 (18.8)	74 (18.5)
Age 5–10 y	22 (8.1)	8 (6.3)	30 (7.5)
Age > 10 y	22 (8.1)	16 (12.5)	38 (9.5)
Mean weight (kg)	8.95 ± 9.6	9.13 ± 10.6	–

Table 2. Who Core Prescribing Indicators

Indicator	Result
Average antibiotics per encounter	2.09 ± 0.63
% encounters with ≥1 antibiotic	100 %
% encounters with injection	100 %
% antibiotics prescribed generically	100 %
% antibiotics from Essential Medicines List	97 %

Table 3. Distribution By Aware Category

Category	No. prescriptions	% of total
Access	272	32.5 %
Watch	546	65.2 %
Reserve	20	2.4 %

Table 4. Top 10 Antibiotics Prescribed

Rank	Antibiotic	AWaRe class	n (%)
1	Amikacin	Access	190 (22.7)
2	Cefotaxime	Watch	162 (19.3)
3	Vancomycin	Watch	134 (16.0)
4	Ceftriaxone	Watch	106 (12.6)
5	Piperacillin-Tazobactam	Watch	52 (6.2)
6	Meropenem	Watch	52 (6.2)
7	Azithromycin	Watch	26 (3.1)
8	Gentamicin	Access	24 (2.9)
9	Ampicillin	Access	22 (2.6)
10	Doxycycline	Access	14 (1.7)

Figures

Figure 1. Distribution of Antibiotics by Who Aware Category

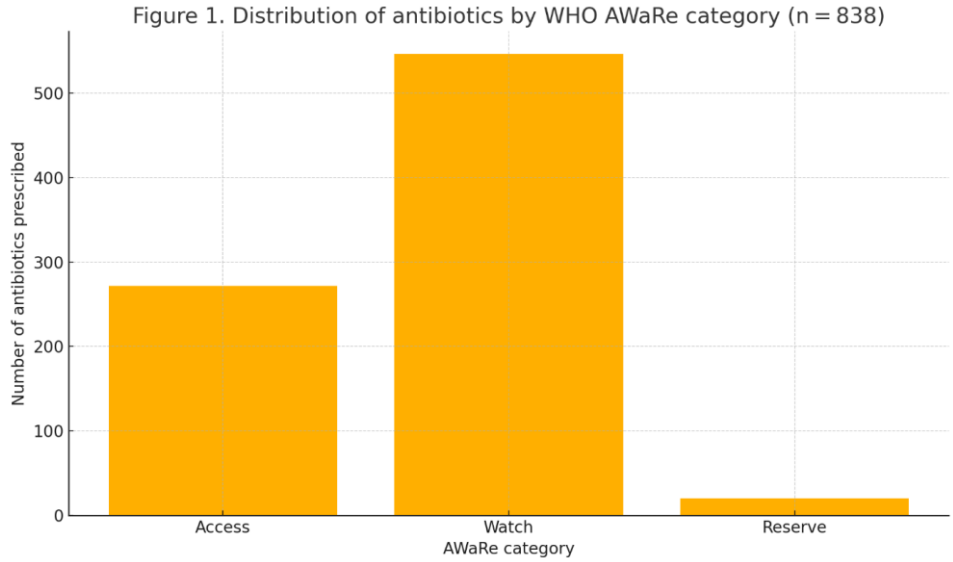
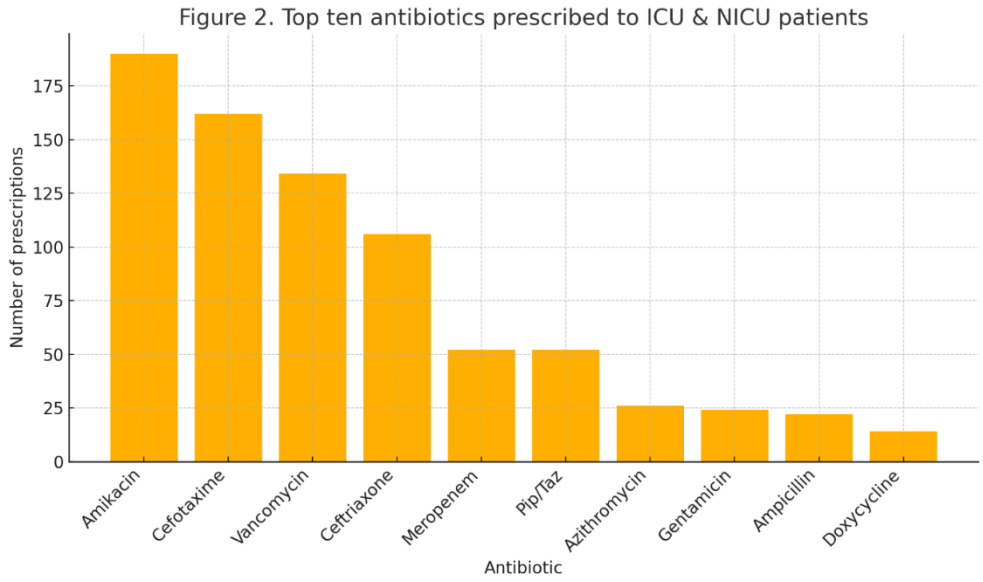


Figure 2. Top Ten Antibiotics Prescribed To Icu & Nicu Patient



DISCUSSION

This study represents one of the few Indian paediatric ICU/NICU audits applying the 2021 WHO AWaRe taxonomy. The predominance of Watch antibiotics (65 %) mirrors recent Indian multicentre PICU data (Watch 72 %) [6] and exceeds the global median of 49 % reported in a 42-country point-prevalence survey [10]. Although empiric broad-spectrum cover is defensible in critically ill infants, sustained over-reliance accelerates selection of extended-spectrum β-lactamase-producing *Enterobacterales* and MRSA [11].

Encouragingly, Access agents—principally amikacin, ampicillin and gentamicin—accounted for one-third of prescriptions, surpassing the 21 % reported from a northern-India NICU stewardship project [12]. The figure nonetheless remains far below the ≥60 % WHO benchmark, underscoring room for optimisation. High use of vancomycin (16 %) echoes concerns of indiscriminate glycopeptide initiation without Gram-positive confirmation [13]. Only 2.4 % of Reserve use aligns with stewardship standards, suggesting clinicians reserve last-line agents for culture-proven resistant infections.

A striking finding was the paucity of microbiological guidance—culture reports were available in <5 % of cases, consistent with

resource-limited settings where blood-culture yield is hampered by prior antibiotics and infrastructural constraints [14]. Absence of rapid diagnostics perpetuates empirical escalation and limits de-escalation, a recognised driver of Watch-class overuse [8]. Investment in automated blood-culture systems and point-of-care molecular diagnostics could transform prescribing precision.

Adherence to national STG was high overall (>87 %), reflecting effective dissemination and prescriber familiarity. Deviations centred on azithromycin and linezolid, possibly prescribed for atypical pneumonia or suspected resistant Gram-positives without microbiological confirmation. Periodic audit-and-feedback, a core antimicrobial stewardship programme (ASP) strategy, could address such variance [15].

Importantly, our ADR rate (5 %) aligns with paediatric meta-analytic estimates (4–6 %), but the dominance of nephrotoxic events highlights the need for therapeutic drug monitoring, particularly with aminoglycosides and vancomycin [16].

The study's strengths include prospective data capture, AWaRe mapping and evaluation against STG. Limitations are its single-centre design, absence of DOT/100 patient-days, and limited culture data precluding resistance trend analysis. Future work should incorporate longitudinal DOT metrics and explore ASP interventions (e.g., AWaRe-based formulary restrictions, rapid diagnostic testing) on antibiotic utilisation and resistance.

CONCLUSION

In this study, two-thirds of antibiotic prescriptions belonged to the WHO Watch category, contravening Access-preferential stewardship goals. Restricted culture testing and modest STG deviations further highlight optimisation gaps. Implementing an AWaRe-oriented ASP—combining real-time microbiology, regular prescription audits and targeted clinician education—could pivot prescribing towards narrow-spectrum agents, safeguarding paediatric patients from escalating AMR.

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