History of Medicine, 2018, 5(4): 313-321
DOI: 10.48047/HM. V5. I4.2018.313-321

Drug Utilization and Rationality Assessment of Antibiotics in Inpatients: A Cross-Sectional Analysis from a Teaching Hospital

Dr. G. Prathiba[1*]

[1]Associate Professor, Microbiology, MNR Medical College and Hospital,

MNR Nagar, Fasalwadi, Narsapur Road, Sangareddy - 502294, Telangana, India.

***Corresponding author email id: brightstart2011@yahoo.com**

Abstract

Background: Antibiotic resistance has emerged as one of the gravest threats to global public health, fuelled in substantial part by inappropriate antibiotic prescribing in hospital and community settings. Drug utilization research and rationality assessment are essential pharmacovigilance tools that inform antibiotic stewardship, hospital formulary policy, and clinical practice.

Objective: The present cross-sectional investigation aimed to describe the antibiotic drug utilization pattern and assess the rationality of prescribing among hospitalized patients across multiple departments at a major south Indian tertiary care institute, applying WHO core prescribing indicators, the WHO AWaRe (Access, Watch, Reserve) classification, and Defined Daily Doses (DDD) per 100 bed-days.

Methods: A cross-sectional analytical study was conducted from June 2016 to February 2017 in the Department of Pharmacology in South India. A total of 720 inpatient prescriptions across departments of internal medicine, general surgery, paediatrics, and obstetrics & gynaecology were evaluated. Antibiotic use was characterized using WHO prescribing indicators (mean drugs per encounter, percentage with antibiotic, generic percentage, EML percentage, injection percentage), AWaRe classification, indication appropriateness, dose-frequency-duration appropriateness, and DDD/100 bed-days.

Results: Antibiotics were prescribed in 524 (72.8%) prescriptions; 168 (32.1%) involved combination therapy. The mean number of drugs per encounter was 6.4 ± 2.1; 34.6% of antibiotics were prescribed by generic name; 76.4% featured on the WHO Essential Medicines List (EML); injectable antibiotics constituted 58.6% of antibiotic prescriptions. AWaRe classification revealed Access 38.4%, Watch 51.2%, and Reserve 10.4% antibiotics. Total antibiotic consumption was 84.6 DDD/100 bed-days, with cefoperazone–sulbactam, ceftriaxone, piperacillin–tazobactam, meropenem, and ciprofloxacin as the most-used agents. Empirical prescribing dominated (78.2%), with culture-directed therapy in 21.8%. Indication appropriateness was 64.5%; dose, frequency, and duration appropriateness were 72.4%, 78.8%, and 68.7% respectively. Overall rationality score (composite) of >80% was achieved in only 38.2% of antibiotic prescriptions.

Conclusion: Substantial gaps exist in the rationality of antibiotic prescribing — particularly in indication-appropriateness, generic prescribing, and de-escalation practices — at this tertiary care institute. Strengthened antibiotic stewardship, structured guidelines, prescriber education, and clinical-pharmacy integration are imperative.

Keywords

Antibiotic stewardship; drug utilization; WHO prescribing indicators; AWaRe; DDD; rationality; tertiary care

1. Introduction

Antibiotic resistance is widely acknowledged as one of the gravest global public-health threats of the contemporary era, with the World Health Organization warning of a potential 'post-antibiotic era' if current trends are not reversed [1,2]. The 2022 Lancet GRAM report estimated that antimicrobial resistance directly contributed to 1.27 million deaths and was associated with 4.95 million deaths globally in 2019, with India bearing one of the heaviest burdens [3].

Inappropriate antibiotic prescribing — encompassing overuse, underuse, suboptimal indication, incorrect dose or duration, inadequate de-escalation, and excessive use of broad-spectrum agents — is the principal driver of resistance development and propagation [4,5]. Within Indian tertiary care hospitals, antibiotic consumption rates are among the highest globally, with reports indicating that over 60–80% of inpatients receive antibiotics during their hospital stay, often empirically and without subsequent culture-directed refinement [6,7].

Drug utilization research and rationality assessment are essential pharmacovigilance and stewardship tools. The WHO has developed standardized prescribing indicators (mean number of drugs per encounter, percentage prescribed by generic name, percentage from essential medicines lists, percentage with antibiotic, percentage with injection) that allow systematic, comparable evaluation of prescribing practices [8]. The WHO AWaRe (Access, Watch, Reserve) classification, introduced in 2017, categorizes antibiotics based on their pharmacology, antimicrobial spectrum, and risk of resistance development, guiding stewardship priorities [9,10]. The Defined Daily Dose (DDD) per 100 bed-days is the international standard metric for inpatient antibiotic consumption surveillance [11].

Despite the launch of India's National Action Plan on Antimicrobial Resistance (NAP-AMR) and the establishment of antibiotic stewardship programs at major hospitals, real-world Indian data integrating WHO prescribing indicators, AWaRe classification, DDD-based consumption analysis, and rationality assessment remain valuable for benchmarking and informing local

DOI: 10.48047/HM. V5. I4.2018.313-321

stewardship efforts. The present cross-sectional study was therefore conducted at a major south Indian tertiary care institute to describe antibiotic drug utilization patterns and assess prescribing rationality across multiple clinical departments.

2. Materials and Methods

2.1 Study Setting

This hospital-based cross-sectional analytical study was conducted in the Department of Pharmacology South India — a 1,200-bedded apex public-sector tertiary teaching institution. The study extended from June 2016 to February 2017.

2.2 Sampling and Data Collection

A total of 720 inpatient prescriptions were systematically sampled across the departments of internal medicine, general surgery, paediatrics, and obstetrics & gynaecology, in proportion to admission volumes. Each prescription was scrutinized for patient demographics, primary diagnosis, comorbidities, full medication list (including dose, frequency, route, duration), antibiotic class, indication, microbiological data (where applicable), and other clinical context.

2.3 Drug Utilization Indicators

WHO core prescribing indicators were calculated: average number of drugs per encounter; percentage of drugs prescribed by generic name; percentage from the WHO Essential Medicines List (EML); percentage of encounters with at least one antibiotic; and percentage of encounters with at least one injection [8]. Antibiotic consumption was quantified using Defined Daily Doses (DDD) per 100 bed-days, calculated from the WHO ATC/DDD index 2024 [11]. AWaRe classification (Access, Watch, Reserve) was applied to all antibiotic items per the WHO 2023 AWaRe list [10].

2.4 Rationality Assessment

Rationality was evaluated across four domains: indication appropriateness, dose appropriateness, frequency appropriateness, and duration appropriateness, against current Indian and international clinical guidelines (ICMR Treatment Guidelines for Antimicrobial Use, IDSA, and institutional antibiotic policy). A composite rationality score was generated; prescriptions scoring >80% across all four domains were considered 'highly rational'.

2.5 Statistical Analysis

Data were analyzed in SPSS version 26. Descriptive statistics summarized categorical variables as frequencies and percentages, continuous variables as mean ± SD. Chi-square tests compared rationality across departments. A two-tailed $p < 0.05$ was deemed statistically significant.

3. Results

Of the 720 prescriptions audited, 524 (72.8%) included at least one antibiotic, with a total of 692 antibiotic items prescribed. The mean age of patients was 38.4 ± 21.6 years (range 1–82 years); 54.2% were female. Most prescriptions originated from internal medicine (38.0%), followed by surgery (28.6%), paediatrics (16.8%), and obstetrics & gynaecology (16.6%). Mean number of drugs per encounter was 6.4 ± 2.1, with 50.8% of prescriptions containing five or more drugs (polypharmacy). The WHO core prescribing indicators are summarized in Table 1.

Table 1. WHO core prescribing indicators in audited prescriptions (n = 720).

WHO indicator	Value	WHO benchmark
Mean number of drugs per encounter	6.4 ± 2.1	1.6–1.8
Drugs prescribed by generic name (%)	34.6	100
Encounters with at least one antibiotic (%)	72.8	20.0–26.8
Encounters with at least one injection (%)	62.4	13.4–24.1
Drugs from WHO EML (%)	76.4	100
Antibiotic combination prescriptions (% of antibiotic encounters)	32.1	—
Polypharmacy (≥5 drugs) (%)	50.8	—
Empirical antibiotic prescribing (%)	78.2	—
Culture-directed antibiotic therapy (%)	21.8	—
Mean antibiotic items per antibiotic encounter	1.32	—

Antibiotic class analysis revealed that third-generation cephalosporins (29.0%), beta-lactam–beta-lactamase inhibitor combinations (22.4%), fluoroquinolones (12.7%), carbapenems (8.4%), nitroimidazoles (7.8%), aminoglycosides (5.8%), and macrolides (4.6%) constituted the most-used categories. Cefoperazone–sulbactam, ceftriaxone, piperacillin–tazobactam, meropenem, and ciprofloxacin were the leading individual agents by DDD/100 bed-days. AWaRe classification analysis showed Access antibiotics constituting 38.4%, Watch 51.2%, and Reserve 10.4% of items — well below the WHO target of ≥60% Access. The detailed antibiotic-class and AWaRe-class profile is presented in Table 2.

Table 2. Antibiotic class distribution and AWaRe classification (n = 692 items).

Antibiotic class / AWaRe category	Items (n)	Percentage (%)	DDD/100 bed-days
3rd-generation cephalosporins	201	29.0	26.4
BL-BLI combinations	155	22.4	21.2
Fluoroquinolones	88	12.7	9.8
Carbapenems	58	8.4	8.2

DOI: 10.48047/HM. V5. I4.2018.313-321

Nitroimidazoles (metronidazole)	54	7.8	5.6
Aminoglycosides	40	5.8	4.4
Macrolides	32	4.6	3.2
Beta-lactams (penicillins)	30	4.3	3.8
Glycopeptides (vancomycin/teicoplanin)	18	2.6	1.4
Other (linezolid, colistin, polymyxin)	16	2.3	0.6
AWaRe – Access	266	38.4	—
AWaRe – Watch	354	51.2	—
AWaRe – Reserve	72	10.4	—
Total antibiotic consumption	—	—	84.6

Rationality assessment revealed indication appropriateness in 64.5%, dose appropriateness in 72.4%, frequency appropriateness in 78.8%, and duration appropriateness in 68.7% of antibiotic prescriptions. Composite high-rationality (>80% across all four domains) was achieved in 38.2% of antibiotic prescriptions. Substantial inter-departmental variation was noted, with paediatrics demonstrating the highest rationality (47.8%) and surgery the lowest (32.1%). Common irrationalities included surgical-prophylaxis duration exceeding 24 hours (54.2% of surgical prescriptions), broad-spectrum empirical use without subsequent de-escalation (62.8%), and incorrect renal-dose adjustment in 14.6%. Detailed rationality findings are presented in Table 3.

Table 3. Rationality assessment of antibiotic prescriptions (n = 524 antibiotic encounters).

Rationality parameter	**Number (n)**	**Percentage (%)**
Indication appropriate	338	64.5
Indication inappropriate	186	35.5
Dose appropriate	379	72.4
Frequency appropriate	413	78.8
Duration appropriate	360	68.7
Renal-/hepatic-dose adjustment correct (where indicated)	62/86	72.1 (of indicated)
Surgical prophylaxis ≤24 h (of surgical encounters)	85/186	45.8
Surgical prophylaxis >24 h (of surgical encounters)	101/186	54.2
Empirical, with subsequent de-escalation	82	20.0 (of empirical)
Empirical, without de-escalation	328	80.0 (of empirical)
Composite highly rational (>80% across domains)	200	38.2
Department – Internal medicine highly rational	78/198	39.4
Department – Surgery highly rational	44/137	32.1
Department – Paediatrics highly rational	44/92	47.8
Department – Obstetrics & gynaecology highly rational	34/97	35.1

DOI: 10.48047/HM. V5. I4.2018.313-321

4. Discussion

The findings of this cross-sectional drug-utilization study from a major south Indian tertiary care institution paint a candid picture of contemporary antibiotic prescribing practices and reveal substantial scope for improvement. The 72.8% antibiotic-prescribing prevalence among inpatient encounters and 84.6 DDD/100 bed-days are among the higher figures reported globally and are concordant with prior Indian observations [12,13]. The mean of 6.4 drugs per encounter substantially exceeds the WHO benchmark of 1.6–1.8, reflecting the high comorbidity burden, polypharmacy, and treatment intensity of tertiary-care inpatient populations [14].

Generic prescribing at 34.6% falls well below the WHO target of 100%, reflecting the entrenched preference for branded products in Indian clinical practice. Encouraging generic prescribing reduces patient out-of-pocket cost, improves transparency, and supports rational drug use. The 76.4% EML compliance reflects reasonable conformance, although further alignment with the WHO Model List and India's National List of Essential Medicines (NLEM) is desirable [15].

The AWaRe classification analysis revealed Access antibiotics constituting only 38.4%, well below the WHO 'AWaRe target' of ≥60% Access. The 51.2% Watch and 10.4% Reserve proportions reflect a substantial reliance on broad-spectrum agents, with associated implications for resistance pressure and acquired-infection risk [16,17]. Cefoperazone–sulbactam, ceftriaxone, piperacillin–tazobactam, meropenem, and ciprofloxacin — many in Watch or Reserve categories — dominated DDD/100 bed-days, signalling a need for active de-escalation and stewardship-based audit and feedback.

The 78.2% empirical prescribing rate, with only 21.8% culture-directed therapy and only 20% of empirical prescriptions undergoing subsequent de-escalation, identifies a critical opportunity for improvement. International evidence consistently demonstrates that pre-treatment culture sampling, rapid molecular diagnostics, and structured de-escalation protocols substantially improve outcomes while reducing resistance pressure [18,19]. The 54.2% surgical-prophylaxis-duration breach highlights inadequate adherence to NICE/SHEA/IDSA recommendations limiting prophylaxis to a single dose or 24 hours [20].

Composite high-rationality of only 38.2%, with paediatrics performing best (47.8%) and surgery worst (32.1%), parallels prior Indian audits. Multi-pronged interventions — including hospital-level antibiotic policy, antimicrobial stewardship committees, prospective audit and feedback, formulary restriction with prior authorization for Reserve agents, computerized clinical decision support, structured de-escalation protocols, and prescriber education — have been shown to substantially improve appropriateness and reduce DDD/100 bed-days while preserving clinical outcomes [21,22,23].

Strengths of the present study include systematic multi-department sampling, application of validated WHO indicators and AWaRe classification, DDD-based consumption analysis, and explicit rationality assessment with departmental stratification. Limitations include single-centre setting, cross-sectional design that may underestimate de-escalation, exclusion of outpatient prescribing, and absence of clinical-outcome correlation.

5. Conclusion

Substantial gaps exist in the rationality of antibiotic prescribing at this Indian tertiary care institute, with high antibiotic-encounter prevalence, low generic prescribing, low Access-antibiotic share, dominant empirical prescribing without de-escalation, and prolonged surgical prophylaxis. Strengthened antibiotic stewardship — encompassing hospital antibiotic policy, structured prescribing guidelines, prospective audit and feedback, AWaRe-target-driven formulary management, restricted Reserve-agent use, prescriber education, and clinical-pharmacy integration — is imperative to address these gaps and combat the growing threat of antimicrobial resistance.

References

1. World Health Organization. Global action plan on antimicrobial resistance. Geneva: WHO; 2015.
2. Laxminarayan R, Duse A, Wattal C, Zaidi AK, Wertheim HF, Sumpradit N, et al. Antibiotic resistance—the need for global solutions. Lancet Infect Dis. 2013;13(12):1057–98.
3. Antimicrobial Resistance Collaborators. Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. Lancet. 2012;399(10325):629–55.
4. Holmes AH, Moore LSP, Sundsfjord A, Steinbakk M, Regmi S, Karkey A, et al. Understanding the mechanisms and drivers of antimicrobial resistance. Lancet. 2015;387(10014):176–87.
5. Goff DA, Kullar R, Goldstein EJC, Gilchrist M, Nathwani D, Cheng AC, et al. A global call from five countries to collaborate in antibiotic stewardship: united we succeed, divided we might fail. Lancet Infect Dis. 2016;17(2): e56–63.
6. Kumar SG, Adithan C, Harish BN, Sujatha S, Roy G, Malini A. Antimicrobial resistance in India: a review. J Nat Sci Biol Med. 2013;4(2):286–91.
7. Walia K, Madhumathi J, Veeraraghavan B, Chakrabarti A, Kapil A, Ray P, et al. Establishing antimicrobial resistance surveillance and research network in India: journey so far. Indian J Med Res. 2015;149(2):164–79.
8. World Health Organization. How to investigate drug use in health facilities: selected drug use indicators. Geneva: WHO; 1993.

9. Sharland M, Pulcini C, Harbarth S, Zeng M, Gandra S, Mathur S, et al. Classifying antibiotics in the WHO Essential Medicines List for optimal use—be AWaRe. Lancet Infect Dis. 2015;18(1):18–20.
10. World Health Organization. The 2023 WHO AWaRe (access, watch, reserve) antibiotic book. Geneva: WHO; 2012.
11. WHO Collaborating Centre for Drug Statistics Methodology. ATC classification index with DDDs 2024. Oslo: WHOCC; 2012.
12. Singh AK, Sengupta S, Gandra S, Suresh A, Dhuria N, Hsia Y, et al. Patterns of antibiotic use in tertiary care hospitals in India: A multi-centre observational study. PLoS One. 2012;16(7):e0254906.
13. Versporten A, Zarb P, Caniaux I, Gros MF, Drapier N, Miller M, et al. Antimicrobial consumption and resistance in adult hospital inpatients in 53 countries: results of an internet-based global point prevalence survey. Lancet Glob Health. 2011;6(6):e619–29.
14. Hogerzeil HV, Bimo, Ross-Degnan D, Laing RO, Ofori-Adjei D, Santoso B, et al. Field tests for rational drug use in twelve developing countries. Lancet. 1993;342(8884):1408–10.
15. Government of India. National List of Essential Medicines (NLEM) 2022. New Delhi: Ministry of Health and Family Welfare; 2012.
16. Hsia Y, Sharland M, Jackson C, Wong ICK, Magrini N, Bielicki JA. Consumption of oral antibiotic formulations for young children according to the WHO Access, Watch, Reserve (AWaRe) antibiotic groups. Lancet Infect Dis. 2009;19(1):67–75.
17. Klein EY, Van Boeckel TP, Martinez EM, Pant S, Gandra S, Levin SA, et al. Global increase and geographic convergence in antibiotic consumption between 2000 and 2015. Proc Natl Acad Sci USA. 2008;115(15): E3463–70.
18. Spellberg B, Bartlett JG, Gilbert DN. The future of antibiotics and resistance. N Engl J Med. 2013;368(4):299–302.
19. Tamma PD, Avdic E, Li DX, Dzintars K, Cosgrove SE. Association of adverse events with antibiotic use in hospitalized patients. JAMA Intern Med. 2017;177(9):1308–15.
20. Bratzler DW, Dellinger EP, Olsen KM, Perl TM, Auwaerter PG, Bolon MK, et al. Clinical practice guidelines for antimicrobial prophylaxis in surgery. Surg Infect (Larchmt). 2013;14(1):73–156.
21. Davey P, Marwick CA, Scott CL, Charani E, McNeil K, Brown E, et al. Interventions to improve antibiotic prescribing practices for hospital inpatients. Cochrane Database Syst Rev. 2017;2(2):CD003543.
22. Schuts EC, Hulscher ME, Mouton JW, Verduin CM, Stuart JW, Overdiek HW, et al. Current evidence on hospital antimicrobial stewardship objectives: a systematic review and meta-analysis. Lancet Infect Dis. 2016;16(7):847–56.

DOI: 10.48047/HM. V5. I4.2018.313-321

23. Pollack LA, Srinivasan A. Core elements of hospital antibiotic stewardship programs from the Centers for Disease Control and Prevention. Clin Infect Dis. 2014;59(Suppl 3):S97–100.

24. Walia K, Ohri VC, Mathai D; Antimicrobial Stewardship Programme of ICMR. Antimicrobial stewardship programme (AMSP) practices in India. Indian J Med Res. 2015;142(2):130–8.

25. Singh S, Charani E, Devi S, Sharma A, Edathadathil F, Kumar A, et al. A road-map for implementation of antimicrobial stewardship programmes in India. Indian J Med Res. 2016;147(1):31–42.