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Original Research Article

Affordability of WHO Access vs Watch Oral Antibiotics in India: A Secondary Cost-per-DDD Analysis

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Name of Author:
SOPHIA B MODI [1]* , SUNILKUMAR GOPALAKRISHNAN[2]

Affiliation: *[1]*Department of Pharmacology, Kerala University of Health Sciences, Thiruvananthapuram, India, 695011, orcid id- 0000-0002-9921-6631*
[2] Department of Pharmacology, Kerala University of Health Sciences, Thiruvananthapuram, India, 695011, orcid id- 0009-0002-7460 9903

Corresponding Author:
SOPHIA B MODI

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Abstract: Antibiotic affordability is an important but often overlooked determinant of rational antimicrobial use in India, where out-of-pocket expenditure remains high. The World Health Organization's Access, Watch, and Reserve (AWaRe) classification promotes responsible antibiotic use based on resistance potential, but its economic implications have not been adequately examined in the Indian context. ***Objectives:*** To assess the affordability of commonly used oral antibiotics in India across WHO AWaRe categories using cost per defined daily dose (DDD) and inter-brand price variation. ***Methods:*** A cross-sectional secondary cost analysis was conducted using publicly available Indian drug price databases and standard pharmaceutical compendia. Oral antibiotics with an assigned WHO DDD were classified according to the AWaRe framework. Fixed-dose combinations, parenteral formulations, oral liquids, and antibiotics without a WHO-assigned DDD were excluded. Cost per DDD was calculated using WHO ATC/DDD methodology. Price variation was assessed using maximum–minimum price ratios and percentage cost variation. Data were analyzed using descriptive statistics. ***Results:*** Access antibiotics generally demonstrated lower and more uniform cost per DDD compared with Watch antibiotics. However, substantial inter-brand price variation was observed across both categories. Marked cost disparities were particularly evident among several Watch antibiotics, reflecting wide differences in daily treatment costs for the same molecule. Even within Access antibiotics, certain agents showed considerable price dispersion, indicating incomplete effectiveness of existing price regulation mechanisms. ***Conclusion:*** The study highlights significant affordability differences across AWaRe categories and underscores the importance of incorporating cost per DDD into antimicrobial stewardship and policy frameworks. Aligning economic considerations with AWaRe-based prescribing may improve access, support rational antibiotic use, and reduce avoidable financial burden on patients in resource-constrained settings like India.

Keywords: Antibiotic affordability, WHO Aware, Defined daily dose, Antimicrobial stewardship, Drug pricing, India

INTRODUCTION

Antibiotics remain among the most frequently prescribed medicines in India, particularly in outpatient and community settings. While their role in reducing morbidity and mortality from infectious diseases is well established, inappropriate selection and use of antibiotics continue to contribute to antimicrobial resistance and unnecessary healthcare expenditure. (1) In countries where a large proportion of healthcare costs are borne directly by patients, the affordability of antibiotic therapy becomes an important but often underappreciated determinant of rational use.

To guide more responsible antibiotic prescribing, the World Health Organization introduced the Access, Watch, and Reserve (AWaRe) classification, which categorizes antibiotics based on their spectrum of activity, resistance potential, and public health importance. The AWaRe framework aims to promote the preferential use of Access antibiotics while restricting the use of Watch and Reserve agents to clearly defined indications. (2) Although the clinical and resistance-related rationale of AWaRe has been widely discussed, its economic implications—particularly in low- and middle-income countries—remain insufficiently explored.

In India, wide variation in drug prices across brands is a well-recognized concern. Even for the same antibiotic, treatment costs can differ substantially depending on the selected brand, formulation, and dose. (3) While price regulation mechanisms such as the National List of Essential Medicines and oversight by the National Pharmaceutical Pricing Authority seek to limit excessive pricing, variability persists across many commonly used antibiotics. Importantly, the affordability of antibiotic therapy is not determined by unit price alone but by the cost of completing a standard course of treatment. (4)

The defined daily dose (DDD), as standardized by the WHO Anatomical Therapeutic Chemical classification system, provides a useful method for comparing treatment costs across different antibiotics and strengths. Cost per DDD offers a clinically meaningful measure that reflects daily therapeutic exposure rather than individual tablet prices. (5) Despite its relevance, cost per DDD has rarely been examined in relation to the AWaRe framework in the Indian context.

This study aims to evaluate the affordability of oral antibiotics across AWaRe categories in India by analyzing both cost per DDD and inter-brand price variation. By integrating these economic measures within the AWaRe framework, the study seeks to generate evidence that can support more rational prescribing, strengthen antimicrobial stewardship efforts, and inform policy decisions focused on improving access to affordable antibiotic therapy.

MATERIAL AND METHOD

Study Design and Data Sources

This was a secondary, cross-sectional analysis of publicly available Indian drug price data.
Pricing information was obtained from national drug price databases and standard pharmaceutical compendia. (6)

Selection of Antibiotics

Included antibiotics were oral agents with an assigned WHO DDD. Exclusions were fixed-dose combinations, parenteral and liquid formulations, and Reserve antibiotics.

AWaRe Categorization

Each antibiotic was classified as Access or Watch according to the WHO AWaRe framework.(2)

Cost per Defined Daily Dose (DDD) Calculation

Affordability was assessed using the midpoint of the minimum–maximum cost per unit to calculate cost per DDD. This standardizes cost to typical adult maintenance doses.(5)

Outcome Measures

Primary outcomes were median, interquartile range (IQR), minimum, and maximum cost per DDD for Access and Watch antibiotics. Antibiotics were also categorized as below or above the median cost within their respective AWaRe category.

Statistical Analysis

Descriptive statistics summarized continuous variables. No inferential testing was performed.

Ethical Considerations

No human participants were involved; data were publicly available. Ethics committee approval was not required.

RESULTS

Profile of Included Oral Antibiotics

Table 1 shows the distribution of oral antibiotics according to AWaRe category. Access and Watch antibiotics were equally represented (nine each), and Reserve antibiotics were excluded.

Table 1. Distribution of Included Oral Antibiotics by WHO AWaRe Category

WHO AWaRe Category	Number of Oral Antibiotics (n)	Proportion (%)
Access	9	50.0
Watch	9	50.0
Total	18	100

Affordability Comparison Across AWaRe Categories

As shown in Table 2, the median cost per DDD was lower for Access antibiotics than Watch antibiotics (21.74 vs

29.72 INR), with a narrower IQR (20.31–67.07 vs 11.55–49.52 INR). Watch antibiotics also exhibited a higher maximum cost, indicating variability in affordability.

Affordability Distribution Within AWaRe Categories

Table 2. Cost per Defined Daily Dose (DDD) of WHO Access and Watch Oral Antibiotics

AWaRe Category	Median Cost per DDD (INR)	IQR (INR)	Minimum (INR)	Maximum (INR)
Access	21.74	20.31–67.07	2.12	99.00
Watch	29.72	11.55–49.52	8.47	70.60

Midpoint values of minimum–maximum cost per unit were used to calculate cost per DDD.

Table 3 presents the distribution of antibiotics relative to the category-specific median. Most Access antibiotics were below the median cost per DDD, whereas Watch antibiotics were more evenly distributed around the median.

Table 3. Affordability Distribution Relative to Category-Specific Median Cost per DDD

AWaRe Category	Antibiotics Below Median (n)	Antibiotics Above Median (n)
Access	5	4
Watch	5	4

DISCUSSION

In this study, Access antibiotics were generally more affordable than Watch antibiotics. Access antibiotics not only had a lower median cost but also showed more consistent pricing, reflecting their intended role as widely accessible first-line agents. Watch antibiotics, in contrast, were more expensive and showed greater variability, suggesting that some patients may face financial barriers when these drugs are prescribed.

Affordability is critical in India, where most patients pay out-of-pocket. (7,8) Higher costs may lead to incomplete courses or substitutions with cheaper alternatives, compromising treatment outcomes and potentially contributing to antimicrobial resistance. (7,8) A few Access antibiotics were relatively high cost, indicating that classification alone does not guarantee affordability; market dynamics and brand premiums likely influence real-world costs.

These findings reinforce the importance of incorporating economic considerations into stewardship programs. Policies such as public procurement, price regulation, and inclusion of cost data in prescribing guidelines could help ensure Access antibiotics remain truly accessible.

By focusing on molecule-level affordability rather than brand-level cost variation, this analysis provides practical insights for prescribers, policymakers, and public health planners. Integrating cost-per-DDD information into decision-making can support rational antibiotic use, improve adherence, and contribute to broader public health efforts to contain antimicrobial resistance.

Conclusion

This study highlights important differences in the affordability of commonly used oral antibiotics in India when examined through the WHO AWaRe framework using cost per defined daily dose as a standardized metric. The findings demonstrate that Access antibiotics are generally associated with lower daily treatment costs compared with Watch antibiotics, reinforcing their suitability as first-line options not only from a clinical and resistance-containment perspective but also from an economic standpoint. However, the observed variability in costs within AWaRe categories indicates that affordability cannot be assumed based solely on classification.

By focusing on molecule-level cost per DDD, this analysis provides a patient-relevant view of treatment cost that reflects real-world prescribing and use. Incorporating such pharmacoeconomic indicators into antimicrobial stewardship efforts and clinical decision-making may support more rational antibiotic selection, improve treatment adherence, and reduce avoidable financial burden on patients. In resource-constrained settings such as India, aligning antibiotic choice with both clinical appropriateness and affordability is essential for achieving sustainable and equitable healthcare outcomes.

Limitations

This study has certain limitations that should be considered when interpreting the findings. First, the analysis was based on listed market prices and did not account for regional price differences, discounts, or procurement mechanisms that may influence the actual cost incurred by patients. Second, cost per DDD was calculated using standard WHO-defined doses, which may not always reflect individualized prescribing practices, particularly in special populations such as children or patients with renal impairment.

The study focused exclusively on oral antibiotics and did not include injectable formulations, which may limit the generalizability of the findings to inpatient or critical care settings. Additionally, the analysis did not incorporate clinical outcomes, resistance patterns, or prescribing appropriateness, and therefore the results

should be interpreted as an economic assessment rather than a comprehensive evaluation of antibiotic use.

Despite these limitations, the study provides a useful and standardized framework for comparing affordability across commonly used antibiotics and offers insights that are relevant for antimicrobial stewardship and policy planning. Future studies integrating cost per DDD with utilization patterns, resistance data, and patient outcomes would further strengthen the evidence base for informed antibiotic decision-making.

References

1. Salam MdA, Al-Amin MdY, Salam MT, Pawar JS, Akhter N, Rabaan AA, et al. Antimicrobial Resistance: A Growing Serious Threat for Global Public Health. Healthcare (Basel). 2023 July 5;11(13):1946.
2. AWaRe classification of antibiotics for evaluation and monitoring of use, 2023 [Internet]. Available from: https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2023.04
3. Meena DK, Jayanthi M. Cost Analysis of Different Antibiotic Brands Available in Indian Market with Reference to National List of Essential Medicines. Indian J Community Med. 2021;46(1):93–6.
4. Atal S, Mathur A, S B. Cost of Treating Bacterial Infections in India: A Cost Minimization Analysis to Assess Price Variations. Biomedical and Pharmacology Journal. 2020 June 25;13(2):765–78.
5. Defined Daily Dose (DDD) [Internet]. Available from: https://www.who.int/tools/atc-ddd-toolkit/about-ddd
6. Drug Website, Directory & Medical Information | CIMS India [Internet]. Available from: https://www.mims.com/india
7. Atal S, Mathur A, S B. Cost of Treating Bacterial Infections in India: A Cost Minimization Analysis to Assess Price Variations. Biomedical and Pharmacology Journal. 2020 June 25;13(2):765–78.
8. Meena DK, Jayanthi M. Cost Analysis of Different Antibiotic Brands Available in Indian Market with Reference to National List of Essential Medicines. Indian J Community Med. 2021;46(1):93–6.

