

# Antibiotic Utilization Pattern Based On WHO AWaRe Classification in General Medicine Department: A Prospective Observational Study

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## abstract

**Background:** The Access, Watch, and Reserve (AWaRe) antibiotic classification was developed by the World Health Organisation (WHO) to enhance clinical outcomes and accessibility, minimize the likelihood of antimicrobial resistance, and conserve the efficacy of antibiotics used as a last resort.

**Purpose:** To study the antibiotic utilization pattern in a tertiary care hospital using WHO AWaRe classification.

**Methods:** A prospective observational study was conducted for 6 months among the in-patients of the tertiary care hospital. In-patients prescribed with antibiotics were enrolled in the study while the patients discharged within 24 hours of hospital admission were excluded.

**Results:** The study sample included 217 patients, among which 65% were males. 36.8% of the patients belonged to the 61-80 age group. It was observed that the Watch class of antibiotics (85%) were prescribed at a higher rate compared to the Access class (14.11%). Overall, the consumption of watch class antibiotics in terms of Days of therapy (DOT) was 875.31 DOT /1000 PD with cephalosporins being the most consumed class (619.07 DOT/1000 PD). Ceftriaxone was the most highly consumed antibiotic accounting for 566.35 DOT/1000 PD. There were no drug-drug interactions associated with ceftriaxone. The incidence of ADR was negligible, occurring in 0.9% of patients.

**Conclusion:** High prescription rate and usage of Watch group antibiotics, particularly cephalosporins, exceeding the WHO-recommended threshold was observed emphasizing the need for antimicrobial stewardship programs.

**Keywords:** Antimicrobial Resistance, Antimicrobial stewardship, AWaRe, WHO, Antibiotic utilisation

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## INTRODUCTION:

Antibiotic resistance is a healthcare hazard that poses a major threat to global health, economic growth, and public well-being[1]. The inappropriate use of antibiotics is a major driver of Anti-microbial resistance (AMR), and irrational prescribing practices has exacerbated this issue [1]. In India, the extensive misuse of antibiotics has been identified as a major factor contributing to antibiotic resistance [2]. AMR has further led to the rise of multidrug-resistant bacteria and making treatments of many infections more costly and, in some cases, untreatable [2].

Antibiotic stewardship programs (ASPs) and surveillance are essential to preserving antibiotic effectiveness and limiting the spread of antimicrobial resistance (AMR)[2]. Some of the ASP interventions include enhancing the diagnostic precision of culture reports, treatment duration optimization aligning with the appropriate guidelines, minimizing prolonged antibiotic prophylaxis to reduce the risk of surgical site infections, and promoting a switch to oral antibiotic therapy [3]. A highly valuable tool for monitoring ASPs is the Access, Watch and Reserve (AWaRe) classification system, created by the WHO expert

committee in 2017, based on the Essential Medicines List (EML) [4,5]. Access includes first- and second-choice antibiotics intended for widespread infections, Watch covers broad-spectrum antibiotics that pose a higher risk of resistance and need monitoring, and Reserve consists of antibiotics used only as a last resort for very specific cases [6,7].

Hospitals also require trustworthy methods of monitoring the quantity of antibiotics; yet the most effective way to measure consumption of antibiotics is still up for debate[6]. To measure inpatient antibiotic utilization, ASPs employ metrics that indicate the volumes of antibiotics used (numerators) divided by person-time (denominators), such as Defined daily doses (DDDs) or days of therapy (DOT) per 100 patient-days (PDs)[8,9]. Using Defined Daily Dose (DDD) to measure antimicrobial consumption in hospitals is problematic because it often overestimates actual prescription practices, especially in ICU settings where patients' altered pharmacokinetics require adjusted dosages [6]. In Comparison, the Days of Therapy (DOT) method is easier to apply in settings with individual-level prescriptions but faces challenges when calculating consumption for patients on multiple antibiotics[6]. Given the high burden of AMR and lack of region-specific prescribing data, this study aimed to assess antibiotic prescribing patterns using the WHO AWaRe classification and estimate antibiotic consumption.

### METHODS AND MATERIALS:

A six-month prospective observational study was carried out at a tertiary care teaching hospital. The study was approved by the Institutional Ethics Committee (CDSIMER/MR/0107/IEC/2024). The study followed STROBE guidelines and was conducted in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. All adult in-patients of both genders admitted to the general medicine wards with antibiotic prescriptions who provided informed consent were included. Patients discharged within 24 hours of admission and those who did not provide consent were excluded. Antibiotic consumption was calculated using the Days of Therapy (DOT) estimate. The patient case sheets were screened to identify prescriptions containing antibiotics. Patient information was recorded on a pre-designed data collection form which included patient demographics, socio-demographics, culture reports, diagnosis, and treatment chart sections. The stratification of antibiotics was done using the WHO AWaRe classification. The prescriptions were screened for the incidence of adverse drug reactions and drug interactions. The causality assessment for adverse drug reactions was done using the WHO UMC scale while for the severity assessment, Hartwig scale was employed. Microsoft Excel was used to collect and compile the data. Statistical analysis was carried out using SPSS version 27 and R.

### RESULTS:

#### Socio-demographic data

The study sample consisted of 217 patients amongst which 65% (n=141) were males and 35% (n=76) were females. The median age of the patients included in the study was 58 (IQR 45.8 - 76) years among which the mean age of males was 56.35±18.10 years and the mean age of females was 57.59±17.67 years. The age group of 61-80 (36.8%; n=80) were the most commonly prescribed with antibiotics while patients above 80 (7.8%; n=17) were least commonly prescribed with antibiotics. Among the 217 in-patients most had a Length of stay (LOS) between 5-10 days (46.5%; n=101) and the least had a LOS above 20 days (1.4%; n=3).

Characteristic	n (%)/ Median (IQR)
<b>Gender</b>	
Male	141 (65)
<b>Age (in years)</b>	58 (45.8 - 76)
<b>Length of hospital stay (in days)</b>	7 (5 - 9)
<b>Co-Morbidities</b>	
Pulmonary Tuberculosis	7 (3.23)
Asthma	5 (2.30)

Hypertension	50 (23.04)
Type 2 Diabetes mellitus	56 (25.81)
Ischemic heart disease	9 (4.15)
Chronic Obstructive Pulmonary Disease	15 (6.91)
Hypothyroidism	6 (2.76)
<b>Habits</b>	
Smoking	13 (5.99)
Alcoholism	15 (6.91)

**Table 1: Characteristics of the study samples**

### Descriptive data

The patients between the ages of 61 and 80 (36.4%; n = 124) and those between the ages of 45 and 60 (29.4%; n = 100) had the highest rate of antibiotic prescriptions compared to the other age groups, while patients above 80 (8.5%; n = 29) had the lowest rate of antibiotic prescription. Males were prescribed more antibiotics than females (67.7%; n=231 vs. 32.2%; n=110, respectively). The association of demographic and clinical variables with WHO AWaRe antibiotic classification was assessed using Chi-square test. No statistically significant association was observed between age groups and AWaRe categories or between gender and AWaRe categories. However, length of hospital stay demonstrated a statistically significant association with AWaRe classification across different hospital stay durations (Table 2).

Variable	Access	Access+Watch	Watch	Reserve	p-value
<b>Age</b>					0.2356 ( $\chi^2$ - 11.62)
18-44	2	14	34	1	
45-60	0	17	47	0	
61-80	1	13	70	0	
>80	1	3	13	0	
<b>Gender</b>					0.4381 ( $\chi^2$ - 2.712)
Male	4	34	102	1	
Female	1	13	62	0	
<b>Length of stay</b>					0.0002 ( $\chi^2$ - 26.86)*
1 to 7 days	1	31	103	0	
8 to 14 days	4	13	55	0	
>14 days	0	3	6	1	

\*p value <0.05 – statistically significant

**Table 2: Association between patient variables and AWaRe antibiotic categorisation**

Ceftriaxone was the most commonly prescribed antibiotic, comprising 52.04% (n=178) followed by Azithromycin (16.95%; n=52), Piperacillin/Tazobactam (7.60%; n=26) and Metronidazole (4.67%; n=16). The DOT for Ceftriaxone was high relative to that of other antibiotics (566.355 DDD/1000/day, Table 3). Among the AWaRe class of drugs, watch antibiotics (85%; n=283) were the most prescribed followed by Access antibiotics (14.1%; n=48) and Reserve antibiotics (0.8%; n=3) (Table 4). Of the total antibiotics prescribed, ten antibiotics belonged to the Access category and twelve belonged to the Watch category of the AWaRe classification (Table 4).

Antibiotic	ATC codes	DOT /1000 PD
Amikacin	J01GB06	8.72
Amoxicillin/Clavulanic acid	J01CR02	46.10
Ampicillin	J01CA01	1.86
Azithromycin	J01FA10	155.14
Cefixime	J01DD08	12.46
Cefoperazone/Sulbactam	J01DD62	33.64
Cefotaxime	J01DD01	6.23

Ceftriaxone	J01DD04	566.355
Ciprofloxacin	J01MA02	17.44
Clarithromycin	J01FA09	1.86
Clindamycin	J01FF01	8.72
Colistin	J01XB01	9.34
Doxycycline	J01AA02	31.15
Fosfomycin	J01XX01	1.86
Gentamicin	J01GB03	9.96
Meropenem	J01DH02	8.09
Metronidazole	J01XD01	56.07
Nitrofurantoin	J01XE01	21.80
Ornidazole	J01XD03	4.36
Piperacillin/Tazobactam	J01CR05	92.21
Rifaximin	A07AA11	9.96
Tinidazole	J01XD02	2.49
Vancomycin	J01XA01	1.86

**Table 3: Days of therapy of each antibiotic with ATC codes**

AWaRe class	Antibiotic	Frequency(N)	Percentage (%)	Listed in EML
<b>Access</b>	Amikacin	48	14.11	YES
	Amoxicillin/Clavulanic acid			YES
	Ampicillin			YES
	Clindamycin			YES
	Doxycycline			YES
	Gentamicin			YES
	Metronidazole			YES
	Nitrofurantoin			YES
	Tinidazole			YES
	Ornidazole			NO
<b>Watch</b>	Azithromycin	283	85	YES
	Cefixime			YES
	Cefoperazone/Sulbactam			NO
	Cefotaxime			YES
	Ceftriaxone			YES
	Ciprofloxacin			YES
	Clarithromycin			YES
	Meropenem			YES
	Piperacillin/Tazobactam			YES
	Fosfomycin			YES
	Rifaximin			NO
	Vancomycin			YES
<b>Reserve</b>	Colistin	3	0.8	YES

**Table 4: Antibiotic categorisation based on WHO AwaRe classification**

All the antimicrobials prescribed were consistent with the hospital formulary list and prescribed by their generic names. The average duration of antimicrobial therapy was  $8.2 \pm 3.35$  days. 44.4% of antimicrobials for pneumonia patients were prescribed in accordance with standard treatment guidelines (Table 5).

WHO Prescribing Indicators	Result
The percentage of the antimicrobials prescribed consistent with the hospital formulary list	100%
Average duration (in days) of prescribed antimicrobial treatment	8.2 ± 3.35
Percentage of antimicrobials prescribed by generic name	100%
The average number of antibiotics prescribed per hospitalization	1.608
Percentage of patients with pneumonia who are prescribed antimicrobials in accordance with standard treatment guidelines	44.4%

**Table 5. WHO Prescribing indicators for antimicrobial use in the hospital**

Antimicrobial culture and sensitivity tests were done for 39.4% (n=86) of the patients' isolates, amongst which only 50% (n=43) of the cultures showed microbial growth. Two organisms were isolated from among 9.83% (n=4) of the positive cultures. A total of 47 microbial specimens were isolated from the tested patients. *Klebsiella* (34.04%; n=16) was the most common organism isolated followed by *Escherichia coli* (21.2%; n=10) and *Pseudomonas aeruginosa* (12.7%; n=6). (Table 6)

Organism (n; %)	Antibiotic	No. Resistant/No. Tested (%)
<i>E. coli</i> (10; 21.2%)	Piperacillin/Tazobactam	2/9 (22.2)
	Amoxicillin/Clavulanic acid	4/8 (50)
	Co-trimoxazole	4/9 (44.4)
	Cefotaxime	5/9 (55.5)
	Ceftazidime	2/5 (40)
	Ciprofloxacin	6/10 (60)
	Gentamicin	2/10 (20)
	Meropenem	3/8 (37.5)
<i>Klebsiella spp.</i> (16; 34.04%)	Piperacillin/Tazobactam	3/13 (23)
	Amoxicillin/Clavulanic acid	10/14 (71.4)
	Co-trimoxazole	3/11 (27.2)
	Cefotaxime	8/13 (61.5)
	Ceftazidime	7/11 (63.6)
	Ciprofloxacin	6/15 (40)
	Gentamicin	6/13 (46.1)
	Meropenem	4/12 (33.3)
<i>Enterococcus spp.</i> (5; 10.6%)	Penicillin G	2/4 (50)
	Ampicillin	2/5 (40)
	Nitrofurantoin	1/3 (33.3)
	Ciprofloxacin	3/4 (75)
	Levofloxacin	5/5 (100)
	Norfloxacin	4/5 (80)
	Fosfomycin	4/4 (100)
	Gentamicin	2/4 (50)
<i>Pseudomonas aeruginosa</i> (6; 12.7%)	Piperacillin/Tazobactam	2/6 (33.3)
	Ceftazidime	3/6 (50)
	Cefepime	2/6 (33.3)
	Ciprofloxacin	2/6 (33.3)
	Gentamicin	2/4 (50)
	Tobramycin	2/5 (40)
	Meropenem	1/5 (20)
	Imipenem	1/3 (33.3)

Moraxella spp. (3; 6.38%)	Amoxicillin/Clavulanic acid	0/3 (0)
	Azithromycin	1/3 (33.3)
	Ciprofloxacin	2/3 (66.6)
	Levofloxacin	1/3 (33.3)
	Doxycycline	0/3 (0)

**Table 6. Common micro-organisms isolated from the microbial cultures of the study samples and their resistance pattern**

### DISCUSSION:

In this prospective observational study, an average of 1.6 antibiotics were prescribed per patient, which aligns with WHO-recommended standards for rational antibiotic use. The majority of patients (52.5%) received monotherapy, while a significant proportion were prescribed two (35.9%) or more antibiotics, consistent with the findings reported by Jokandan et al. and Khare et al., who observed a predominance of single-antibiotic prescriptions in similar settings [10,11]. The most common clinical indications for antibiotic therapy were acute infectious exacerbation of COPD (26%), lower respiratory tract infections (16.14%), pneumonia (6.2%), and acute infectious exacerbation of bronchial asthma (1.6%), then followed by urinary tract infections (10.7%) and acute gastroenteritis (8.5%). This trend reflects high burden of respiratory and gastrointestinal infections. Out of the 342 antibiotics prescribed, Ceftriaxone (52.04%), azithromycin (16.95%), and piperacillin/tazobactam (7.60%) were the most frequently used agents. In contrast, a study by Mugada et al., found that the most commonly given antibiotics were amoxicillin + clavulanic acid (n=322), Cefixime (n=236), and azithromycin (n=231) [12]. In another study by Priyadarshini R et al., Phenoxy penicillin, Amoxicillin, Cloxacillin, Doxycycline, and Ciprofloxacin were among the most prescribed antibiotics [13]. The median duration of therapy for commonly prescribed antibiotics in our study was 5 days with ceftriaxone (Quartile range [IQR] 3-6), azithromycin with 5 days (IQR 3-5) and piperacillin /tazobactam with 5 days (IQR 4-7). Compared to studies such as Bansal et al., where durations were shorter, our findings suggest a tendency toward prolonged antibiotic use, which may reflect delayed de-escalation practices [14]. In terms of consumption, ceftriaxone had the highest DOT (566.355 DOT /1000 PD) followed by azithromycin (155.14 DOT /1000 PD), piperacillin/tazobactam (92.21 DOT /1000 PD) and metronidazole (56.07 DOT /1000 PD). These findings contrast with Bansal et al., who observed higher metronidazole use [14]. Notably both drugs fall under the Watch category of the WHO AWaRe classification, which emphasizes their restricted use due to their higher potential for driving antimicrobial resistance. A critical finding of this study is the disproportionate reliance on Watch category antibiotics. While WHO recommends that at least 60% of antibiotics used should be from Access group to ensure lower resistance potential, our data revealed that only 18% of prescriptions belonged to Access antibiotics, whereas 85% were from the Watch group. Broad spectrum agents such as ceftriaxone and azithromycin were frequently used empirically.

Adverse drug reactions were rare, reported in only 0.9% of the patients, and included mild cutaneous manifestations such as rash and pruritic. Both the ADRs were classified as “probable/likely” based on the WHO-UMC scale. No significant drug-drug interactions were reported, due to the relatively short duration of antimicrobial exposure and the careful monitoring in the inpatient setting.

Despite its strengths, the study has some limitations. It was confined to the general medicine department of a single tertiary care institution, which may limit the generalizability of findings to other departments or health care settings. The six-month data collection period might not capture seasonal variations or long term trends in antibiotic prescribing. Additionally, potential confounding variables were not fully accounted for. Future research should explore interventional strategies to improve adherence to stewardship guidelines and evaluate their impact on prescribing patterns and resistance trends over time.

### CONCLUSION:

Watch class of antibiotics were highly prescribed exceeding the WHO recommended range. The study also identified a significant association between duration of hospital stay and WHO AWaRe antibiotic classification, with longer stays linked to increased use of broad-spectrum agents. These results emphasize

the need for strengthened antimicrobial stewardship programs to optimise antibiotic selection, promote adherence to WHO AWaRe guidelines, and limit the inappropriate use of broad-spectrum antibiotics, thereby contributing to the containment of antimicrobial resistance.