

THE ANTIBIOTIC CONUNDRUM AND ANTIMICROBIAL STEWARDSHIP: AN OBSERVATIONAL STUDY ON PRESCRIBING PATTERN OF ANTIBIOTICS IN A TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

Background: In contemporary medicine, antimicrobial drugs are the cornerstone of treatment. Antibiotic resistance results from the inappropriate prescription of antibiotics. The World Health Organization (WHO) created the WHO AWaRe categorization of antibiotics and core prescribing indicators. It is necessary to comprehend antibiotic stewardship and prescription practices. The current study audits prescriptions in a teaching hospital for tertiary care to evaluate the pattern of antibiotic prescribing. **Methods:** A hospital-based study was carried out over 6 months among inpatients in the General Medicine ward. The WHO AWaRe categorization tool, WHO core prescribing indicators, and Standard Treatment Guidelines (STGS) compliance were used to assess prescriptions. **Results:** 577 of the 2373 medications that were prescribed in 307 prescriptions were antibiotics. There were 7.73 medications per prescription. 93.5% of antibiotics were from the Essential

Medicines List (EML), whereas 26.51% of antibiotics were prescribed in generic names. The most often used antibiotic was ceftriaxone, while the most widely used antibiotic medication class is penicillins with beta-lactamase inhibitors. The proportion of antibiotics prescribed from the watch and access groups was 63.93 % and 35.88 %, respectively. More than half of

the antibiotic prescriptions were concordant with STGs. **Conclusion:** This study offers proof of the need for and a method to establish an antimicrobial stewardship at the hospital, which may facilitate the implementation of Culture-guided antibiotic prescribing, as well as the development of institutional standards.

KEYWORDS: Antimicrobial resistance (AMR), Access Watch Reserve (AWaRe), Essential medicine list (EML), Standard treatment guidelines (STG), WHO Core prescribing indicators.

INTRODUCTION

Antibiotics are natural, synthetic, or semisynthetic antimicrobial agents that, at extremely low doses, selectively inhibit the growth of or kill other microbes.^[1] When Alexander Fleming discovered Penicillin in 1928, the era of antibiotics began.^[2] They are one of the few classes of drugs that can cure, and not just palliate disease. The antibiotic utility is increased in developing nations where infectious illnesses are more common. They are among the most often used and abused medications as a class.^[1] Nevertheless, improper antibiotic usage leads to bacterial resistance, which hastens the appearance and dissemination of resistant microbes.^[3]

Antimicrobial resistance: The resistant microbes' genetic ability to exhibit inhibitory action by resistance genes on antibiotics is known as antimicrobial resistance.^[4] Or when potentially dangerous bacteria alter their behaviour to lessen or completely eradicate the antibiotic's potency, antibiotic resistance (ABR) occurs. Ineffective therapy, recurring infections, delayed recovery, or even death are more likely to occur in patients with antibiotic-resistant infections.^[3] AMR is thought to be the cause of about 700,000 deaths each year, and if nothing is done, it might increase to 10 million fatalities by 2050.^[5] It is commonly known that one of the main causes of antibiotic resistance is antibiotic misuse; hence, it is imperative to optimize antibiotic use.^[6]

In India, antibiotics are inappropriately prescribed by doctors and sold over the counter without a prescription. Infectious diseases that are self-limiting do not require antibiotic treatment; therefore, dispensing antibiotics for self-limiting infections without a prescription is a very common practice in community pharmacies.^[4] Hence, an effort at all levels is required to prevent antimicrobial resistance. The CDC currently advises the establishment of an Antibiotic

Stewardship Program (ASP) and advises medical professionals to improve the usage and prescription of antibiotics in human health care.^[3]

Antibiotic stewardship program: It is defined as a set of coordinated interventions meant to evaluate and improve the appropriate use of antibiotics by promoting the choice, dose, duration, and route of the optimal antibiotic, all of which improve patient outcomes and lessen adverse effects.^[6] Stewardship is defined as "the careful and responsible management of something entrusted to one's care". The term "antimicrobial stewardship" (AMS) was applied in the healthcare sector to describe a strategy for maximizing the use of antibiotics.

An AMS programme aims to limit the adverse economic impact of AMR, optimize antibiotic use, promote behavioural changes in antibiotic prescribing and dispensing practices, improve patient outcomes and quality of care, reduce unnecessary health care costs, prolong the life of currently available antibiotics, and enhance health care professional's ability to use best practices when it comes to the prudent use of antibiotics.^[7]

WHO core drug prescribing indicators: According to the World Health Organization, rational use of drugs is when patients receive their prescriptions accurately, for an adequate period of time, at the lowest feasible cost, and in compliance with their clinical and individual needs. Irrational drug use can lead to polypharmacy, increased use of branded drugs, higher prescription costs per person, drug interactions, adverse effects, irrational antibiotic prescriptions, and antibiotic resistance. Using antibiotics irrationally and continuously may lead to a post-antibiotic era when even simple infections might kill people.^[8] Practitioners should be educated on the importance of combination therapy in the management of certain diseases in order to minimize the possibility of resistance development.^[9] The World Health Organization (WHO) and the International Network for the Rational Use of Medications (INRUD) developed indicators in 1993 to monitor the rational use of medications. The standard of prescription in health care systems is commonly assessed using these indicators.^[2] Understanding the pattern of antibiotic prescriptions is the initial step in putting antimicrobial stewardship programs into place in low-resource countries. Therefore, the purpose of this study was to assess the antibiotic prescribing pattern in the institution's inpatient department. The goal of prescribing pattern research is to monitor, evaluate, and suggest modifications to practitioners' prescription habits to ensure that patients receive effective and appropriate care. The various prescription indicators are meant to provide light on certain prescribing

characteristics.^[10] Although none of the indicators have been empirically proven, the WHO has recommended reference levels for each of them.

Application of prescribing indicators: When looking at possible areas of medication usage issues, prescribing indicators might be helpful. To determine whether polypharmacy is a problem, it's critical to look at the average number of medications prescribed in every session. A higher proportion of interactions that lead to antibiotic usage (beyond recommended reference values) may indicate indiscriminate antibiotic use. The percentage of encounters with an injection prescribed highlights whether there is an inappropriate use of injectable medications. The proportion of prescription drugs that are given both generically and from EML highlights the need to establish and follow the prescribing guidelines. For instance, a low prescription rate for generic medications might mean that no reasonably priced generic substitutes are available.

AWaRe Classification: The World Health Organization (WHO) developed the Access, Watch, and Reserve (AWaRe) antibiotic classification system in 2017 as part of AMS.^[6] The 2019 WHO AWaRe Classification Database was developed based on recommendations from the WHO Expert Committee on Selection and Use of Essential Medicines. In addition to their pharmacological classifications, the WHO Essential Medicines List status, and Anatomical Therapeutic Chemical (ATC) codes, it includes information on 180 antibiotics that are classified as Access, Watch, or Reserve. It is intended to be an interactive tool that aids countries in better promoting the appropriate use and surveillance of antibiotics.^[11]

The main issues with modern medicine include over- or underuse of medication, high drug costs, increased use of injectables and antibiotics, polypharmacy, non-compliance with approved clinical guidelines, and the use of brand names rather than generic ones.^[12] This study aims to assess the prescribing patterns of antibiotics in a Tertiary Care Teaching Hospital, with the objectives to analyze the prescription pattern of antibiotics using the WHO Core Indicators and the WHO AWaRe classification of antibiotics, and identify commonly prescribed antibiotics and drug Interactions.

MATERIALS AND METHODS

1. **Study Design:** A prospective observational study.
2. **Study Location:** The study was carried out in the General Medicine Department of a tertiary care teaching hospital, Osmania General Hospital (OGH).

3. **Study Population:** All patients admitted to the General Medicine ward.

4. **Duration of study:** Six months

5. **Size of the sample:** 307 patient prescriptions.

6. Study criteria

Inclusion Criteria: a) Patients who are 18 years of age or older.

b) Patients of either gender.

c) Patients admitted to the general medicine ward with antibiotics prescribed.

Exclusion criteria: a) Women who are lactating or pregnant, because many antibiotics pose Potential risks, including teratogenicity and transmission to infants through breast milk.

b) Terminally ill & cancer patients are excluded: Patients with advanced Metastatic cancer or those in hospice care have a complex condition, Comorbidities and increased risk of secondary infections.

c) Patients with Tuberculosis.

d) Subjects who declined to take part in the research.

The study was done for a period of 6 months to find the prescribing pattern of antibiotics. Data was collected from patient charts using a self-designed data collection form, patients' demographic data, disease, antibiotics prescribed, route of administration, dosage, duration, reason of antibiotic use (prophylactic, empirical, therapeutic), drug interactions, and culture sensitivity test results until the patient was discharged were recorded in the form. After obtaining complete data, prescriptions were analysed in accordance with the WHO AWaRe assessment tool, essential prescribing metrics, hospital indicators, antibiotics listed in NLEM, and concordance with STGs.

Data analysis: The data was analyzed using descriptive statistics. These data were analyzed using Microsoft Excel, and the results were represented in tables and graphs. Inferential statistics (Chi-Square test) was applied for the WHO AWaRe classification parameter, and the T-Test was applied on the WHO Core prescribing indicators using SPSS software, the latest version.

Formulae to determine the WHO core prescribing indicators and antibiotic-specific indicators

1. Average number of medicines/encounters =

$$\frac{\text{Total number of medicines in prescriptions (y)}}{\text{Total number of prescriptions collected (x)}}$$

2. Percentage of medicines prescribed by generic name =

$$\frac{\text{Number of medicines prescribed in generic} \times 100\%}{\text{Total number of medicines (y)}}$$

3. Percentage of encounters with an antibiotic prescribed =

$$\frac{\text{Number of prescriptions with one or more antibiotics} \times 100\%}{\text{Total number of prescriptions}}$$

4. Percentage of encounters with an injection prescribed =

$$\frac{\text{Number of encounters with injection} \times 100\%}{\text{Total number of prescriptions (x)}}$$

5. Percentage of medicines prescribed from the EML list =

$$\frac{\text{Number of medicines from EML} \times 100\%}{\text{Total number of medicines (y)}}$$

6. Average number of antibiotics per prescription =

$$\frac{\text{Number of total antibiotics}}{\text{Total number of prescriptions with antibiotics}}$$

7. Percentage of antibiotics in FDC =

$$\frac{\text{Number of antibiotics with FDC} \times 100}{\text{Total number of antibiotics}}$$

8. Percentage of antibiotics in the generic name =

$$\frac{\text{Total number of antibiotics in generic} \times 100}{\text{Total number of antibiotics}}$$

9. Percentage of antibiotics in brand name =

$$\frac{\text{Total number of antibiotics in brand} \times 100}{\text{Total number of antibiotics}}$$

10. Percentage of antibiotics from EML=

$$\frac{\text{Number of antibiotics from EML} \times 100}{\text{Total number of antibiotics}}$$

11. Percentage of antibiotics with injections =

$$\frac{\text{Number of antibiotics in injections} \times 100}{\text{Total number of antibiotics}}$$

12. Average duration of antibiotic therapy =

$$\frac{\text{Total number of days on antibiotic therapy}}{\text{Total number of antibiotics prescribed}}$$

13. Percentage of antibiotics for prophylaxis =

$$\frac{\text{Total number of prophylactic antibiotic prescriptions}}{\text{Total number of antibiotic prescriptions}}$$

Ethical Statement - The study was approved by the institutional ethics committee (Reno-MCP/IEC/PD/PR/86) and informed consent was obtained from all participants.

RESULTS

A total of 307 inpatient prescriptions were examined in this prospective analysis. Of the 2373 medications administered, 577 were antibiotics. These medications' prescription patterns were gathered for additional analysis.

Demographics of patients

Male patients made up 49.49 % of the 307 prescriptions examined, while female patients made up 50.46%. The age group of 36–45 years had the greatest number of patients (20.84%, n = 64), followed by the age group of >65 years (17.91%, n = 55), as shown in Table 1

Table 1: Demographic data.

| Age | Male | | Female | | Total | Percentage |
|--------------|------|--------|--------|--------|-------|------------|
| | (n) | % | (n) | % | | |
| 16-25 | 14 | 4.56% | 22 | 7.16% | 36 | 11.72% |
| 26-35 | 24 | 7.81% | 28 | 9.12% | 52 | 16.93% |
| 36-45 | 28 | 9.12% | 36 | 11.72% | 64 | 20.84% |
| 46-55 | 29 | 9.44% | 22 | 7.16% | 51 | 16.61% |
| 56-65 | 29 | 9.44% | 20 | 6.51% | 49 | 15.96% |
| >65 | 28 | 9.12% | 27 | 8.79% | 55 | 17.91% |
| Total | 152 | 49.49% | 155 | 50.46% | 307 | 100 % |

The number of antibiotics per prescription

From the collected prescriptions, about 44.29% (n=136) of them had two antibiotics prescribed per prescription, followed by 36.48% (n =112) with one antibiotic and 16.28% (n =50) with three antibiotics prescribed per prescription. Only 2.93% (n = 9) of prescriptions had more than 3 antibiotics prescribed, as shown in Table 2 and Figure 1

Table 2: The number of antibiotics per prescription.

| Quantity Of Antibiotics | Frequency | Percentage |
|-------------------------|-----------|------------|
| 1 | 112 | 36.48% |
| 2 | 136 | 44.29% |
| 3 | 50 | 16.28% |
| More than 3 | 9 | 2.93% |
| TOTAL | 307 | 100 % |

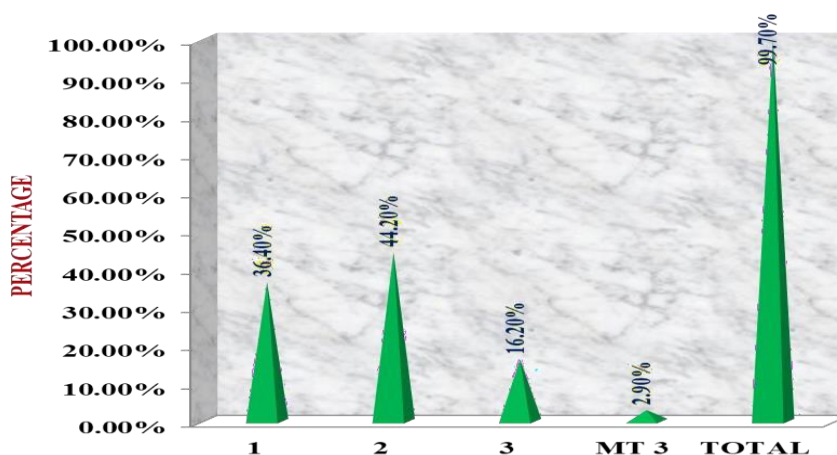


Fig 1: The number of antibiotics per prescription.

Route of antibiotic administration

About 26.68% (n = 154) of the antibiotics recommended were taken orally, whereas 73.31% (n = 423) of the antibiotics were provided intravenously. This high use of the IV route could be justified, i.e., that the study was conducted among inpatients. As shown in Figure 2.



Fig. 2: Route of antibiotic administration.

Commonly prescribed antibiotics

From the total prescriptions evaluated, it was observed that Penicillin and Beta-lactamase Inhibitors were the most commonly prescribed drug class with a percentage of 28.24% (n=163), and among them, Amoxicillin and Clavulanate 13.34% (n=77) was the most common. The second most commonly prescribed drug class was cephalosporins, 27.01% (n=156). Ceftriaxone was the most commonly given antibiotic medication, accounting for 25.47% of prescriptions (n=147). It was followed by metronidazole (18.71%), piperacillin and tazobactam (14.90%), amoxicillin and clavulanate (13.34%), and azithromycin (9.70%) as described in Table 3.

Table 3: Commonly Prescribed Antibiotics.

| Sr. NO. | THERAPEUTIC CLASS OF ANTIBIOTICS | NAME OF THE DRUG | FREQUENCY | PERCENTAGE | DRUG CLASS PERCENTAGE |
|---------|---------------------------------------|-------------------------------|-----------|------------|-----------------------|
| 1. | CEPHALOSPORINS | Ceftriaxone | 147 | 25.47% | 27.01% |
| | | Cefixime | 6 | 1.03% | |
| | | Cefotaxime | 3 | 0.51% | |
| 2. | MACROLIDES | Azithromycin | 56 | 9.70% | 10.04% |
| | | Clarithromycin | 1 | 0.17% | |
| | | Erythromycin | 1 | 0.17 % | |
| 3. | PENICILLIINS | Ampicillin | 1 | 0.17 % | 0.17% |
| 4. | PENICILLIN + BETA LACTAMASE INHIBITOR | Amoxicillin +clavulanate | 77 | 13.34 % | 28.24% |
| | | Piperacillin +Tazobactam | 86 | 14.90% | |
| 5. | ANTIPROTOZOAL | Metronidazole | 108 | 18.71 % | 18.71 % |
| 6. | TETRACYCLINES | Doxycycline | 2 | 0.34% | 0.34 % |
| 7. | AMINOGLYCOSIDES | Amikacin | 4 | 0.69% | 0.86% |
| | | streptomycin | 1 | 0.17 % | |
| 8. | FLOROQUINOLONES | Ciprofloxacin | 28 | 4.85% | 5.71% |
| | | Levofloxacin | 5 | 0.86% | |
| 9. | NITROFURAN DERIVATIVE | Nitrofurantoin | 2 | 0.34% | 0.34% |
| 10. | LINCOSAMIDES | Clindamycin | 2 | 0.34 % | 0.34 % |
| 11. | CARBAPENEMS | Meropenem | 2 | 0.34 % | 0.34 % |
| 12. | OXAZOLIDINONES | linezolid | 1 | 0.17% | 0.17 % |
| 13. | CO TRIMOXAZOLE | Sulfamethoxazole trimethoprim | 11 | 1.90% | 1.90% |
| 14. | RIFAMYCINS | Rifaximin | 29 | 5.02% | 5.02% |
| 15. | GLYCOPEPTIDE | Vancomycin | 4 | 0.69% | 0.69% |

Drug class percentage of β -lactamase inhibitor (28.24 %) includes the values of Piperacillin +Tazobactam (14.90 %) and Amoxicillin + Clavulanate (13.34 %)

Aware classification of antibiotics

This study had 35.88 % (95% CI: 32.0% - 39.8%) antibiotics prescribed from the ACCESS group, 63.93 % (95% CI: 60.04% - 67.86%) from the WATCH category, and 0.17% from the RESERVE category, as shown in Table 4 and Figure 3. According to WHO estimates, more than 60 % of all antibiotics should be prescribed by the access group. Chi-square test was done to compare whether the observed frequencies significantly differ from expected frequencies as recommended by the WHO AWaRe classification. A chi-square value of 221.25 and a chi-square critical value of 5.99 were obtained. Since $221.25 > 5.99$, there is a highly significant difference between the observed results and the WHO recommendation.

Table 4: WHO AWaRe classification of antibiotics.

| Sr. NO. | AWaRe CATEGORY | DRUG | (n) | % | AWaRe CATEGORY PERCENTAGE | 95 % CI | IF LISTED IN EML | ATC CODE |
|--------------|----------------|---------------------------|-----|---------|---------------------------|----------------|------------------|----------|
| 1. | ACCESS | Metronidazole | 108 | 18.72 % | 35.88 % | 32.0-39.8% | YES | J01XD01 |
| | | Ampicillin | 1 | 0.17 % | | | YES | J01CA01 |
| | | Amoxicillin + clavulanate | 77 | 13.34 % | | | YES | J01CR02 |
| | | Co-trimoxazole | 11 | 1.91% | | | YES | J01EE01 |
| | | Doxycycline | 2 | 0.35% | | | YES | J01AA02 |
| | | Nitrofurantoin | 2 | 0.35% | | | YES | J01XE01 |
| | | Amikacin | 4 | 0.69 % | | | YES | J01GB06 |
| | | Clindamycin | 2 | 0.35% | | | YES | J01F01 |
| 2. | WATCH | Ceftriaxone | 147 | 25.48% | 63.93% | 60.04 - 67.86% | YES | J01DD04 |
| | | Cefixime | 6 | 1.04% | | | YES | J01DDO8 |
| | | Cefotaxime | 3 | 0.52% | | | YES | J01DD01 |
| | | Piperacillin + Tazobactam | 86 | 14.90% | | | YES | J01CR05 |
| | | Azithromycin | 56 | 9.70% | | | YES | J01FA10 |
| | | Clarithromycin | 1 | 0.17% | | | YES | J01FA09 |
| | | Ciprofloxacin | 28 | 4.85 % | | | YES | J01MA02 |
| | | Levofloxacin | 5 | 0.87 % | | | YES | J01MA12 |
| | | Vancomycin | 4 | 0.69 % | | | YES | J01XA01 |
| | | Rifaximin | 29 | 5.02% | | | NO | A07AA11 |
| | | Meropenem | 2 | 0.345% | | | YES | J01DH02 |
| | | Streptomycin | 1 | 0.17% | | | YES | J01GA01 |
| Erythromycin | 1 | 0.17% | YES | J01FA01 | | | | |
| 3. | RESERVE | Linezolid | 1 | 0.17 % | 0.17% | - | YES | J01XX08 |

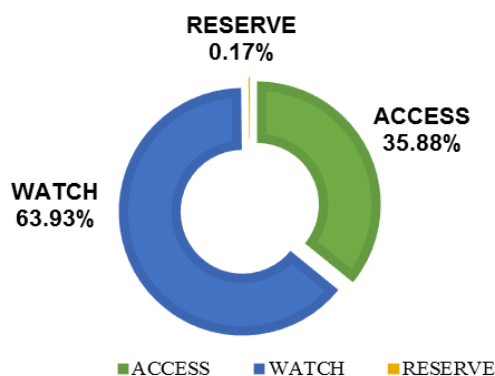


Fig. 3: A WaRe Classification of Antibiotics.

WHO prescribing indicators

Table 5: WHO prescribing indicators.

| INDICATORS | OBSERVED VALUES | STANDARD VALUES | **SD | *P value |
|--|-----------------|-----------------|--------|----------|
| 1. Average number of drugs per encounter | 7.73 | 1.6 - 1.8 | 4.2638 | < 0.001 |
| 2. The proportion of encounters with antibiotics prescribed | 100% | 20.0 - 26.8 | 49.497 | < 0.0001 |
| 3. The proportion of encounters with an injection prescribed | 91.5% | 13.4 - 24.1 | 50.558 | < 0.001 |
| 4. The proportion of medications prescribed using generic names | 30.13% | 100 | 49.405 | < 0.0001 |
| 5. Percentage of drugs prescribed from the essential medicine list | 83.81 % | 100 | 11.448 | < 0.001 |

***P-value shows a statistically significant difference between observed values and standard values.**

**** SD indicates standard deviation.**

The objective of the study was to analyse prescriptions according to the WHO core prescribing indicators. The outcomes were:

1. It was found that the average number of drugs/encounters was 7.73, much more than the typical range of 1.6-1.8.
2. The percentage of encounters with an antibiotic was found to be 100%. Since only prescriptions with antibiotics were included in the study.
3. Around 91.5% of prescriptions had injections prescribed, which is higher than the WHO recommendation of (13.4-24.1).
4. The generic prescription was found to be 30.13% which was way lower than the WHO-recommended standard value of 100%. The total value encompasses all prescribed medications, including but not limited to antibiotics.

5. Approximately 83.81% of prescription medications, according to our data, were from the national list of essential medicines. This study has shown significant deviation from the WHO recommendations, as shown in Table 5. The p-value of < 0.001 was found for each core prescribing indicator.

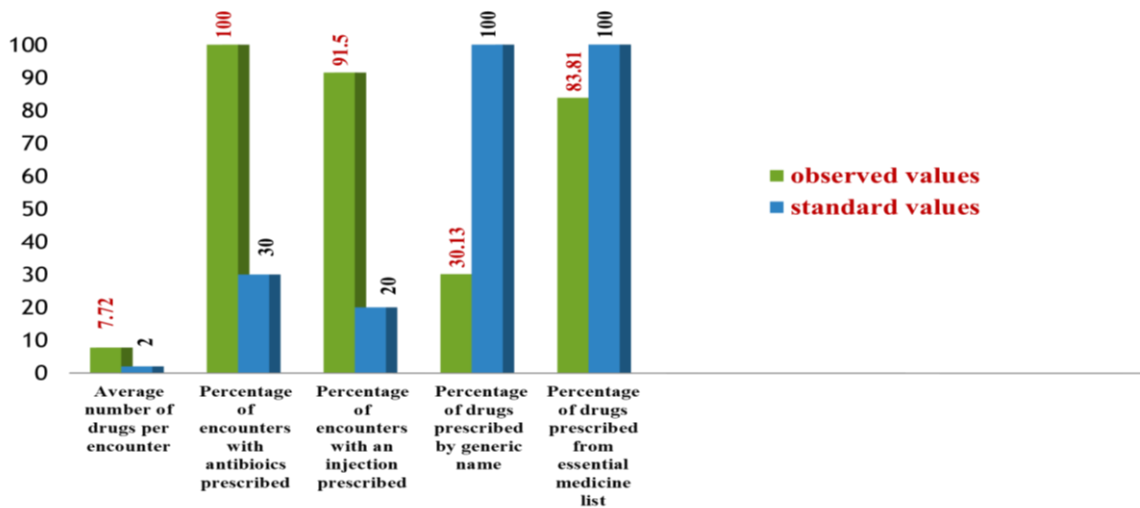


Fig 4: WHO core drug prescribing Indicators.

Specific antibiotic indicators

Analyzing antibiotic prescription patterns was the study's primary goal. It was found that just 29.46 % of the antibiotics administered were generic, while the majority, 70.53%, were prescribed under brand names. The total value includes only the prescribed antibiotics. Around 93.5% of antibiotics were prescribed from the EML. The average duration of antibiotic therapy was found to be 4.03 days, and most of the antibiotics were prescribed empirically 64.82% and about 35.17% of antibiotics were used for prophylactic purposes, as described in Table 6.

Table 6: Antibiotic-specific indicators.

| Sr. NO. | INDICATORS | RESULTS |
|---------|--|---------|
| 1. | The average number of antibiotics per prescription | 1.87 |
| 2. | Percentage of Antibiotics in fixed dose combinations (FDC) | 27.90% |
| 3. | % of Antibiotics in generic name | 29.46% |
| 4. | % of Antibiotics in brand names | 70.53 % |
| 5. | % of Antibiotics from EML | 93.5% |
| 6. | % of Antibiotics with Injections | 73.65 % |
| 7. | Average duration of Antibiotic therapy | 4.03 |
| 8. | % of antibiotics for prophylaxis | 35.17% |
| 9. | % of Antibiotics for empiric therapy | 64.82% |

Hospital indicators**Table 7: Hospital Indicators.**

| Sr. NO. | HOSPITAL INDICATORS | RESULTS | RECOMMENDED |
|---------|---|----------|-------------|
| 1. | Existence of Drugs and Therapeutics Committee. | Not sure | 1 |
| 2. | Existence of a copy of the National STG for a tertiary hospital. | Yes | 1 |
| 3. | Existence of Institutional STG/clinical guidelines for infectious diseases | Yes | 1 |
| 4. | Existence of a national EML copy. | Yes | 1 |
| 5. | Institutional FL/ML's existence. | Yes | 1 |
| 6. | List of key antibiotics that were available in the hospital during the research period. | Exist | 100% |
| 7. | Number of sensitivity tests performed for the prescribed antibiotics. | Exist | Exist |

Duration of antibiotic therapy**Table 8: Duration of Antibiotic Therapy.**

| Sr.NO. | DURATION | FREQUENCY | PERCENTAGE |
|--------|------------------|-----------|------------|
| 1. | Less Than 3 days | 170 | 29.46% |
| 2. | 4 – 5 days | 239 | 41.42 % |
| 3. | 6 – 7 days | 125 | 21.66 % |
| 4. | More than 7 days | 43 | 7.45 % |
| | TOTAL | 577 | 100% |

Diseases commonly observed with antibiotic prescription

The disease conditions commonly observed with antibiotic prescriptions were assessed. The most commonly observed disease condition was gastrointestinal disorders, 29.3 % (n=90), followed by respiratory tract conditions 24.1% (n=74), renal disorders 11.07 % (n=43), and cardiovascular disorders 10.4 % (n=32), as shown in Table 9.

Table 9: Commonly observed disease conditions with antibiotic prescription.

| Sr. No. | DISORDERS | FREQUENCY | PERCENTAGE |
|---------|-------------------------------|------------|-------------|
| 1 | Respiratory Tract Infections | 74 | 24.10% |
| 2 | GIT Disorders | 90 | 29.31% |
| 3 | Renal Disorders | 34 | 11.07% |
| 4 | Endocrine Disorders | 8 | 2.60% |
| 5 | Cardiovascular Disorders | 32 | 10.42% |
| 6 | Neurological Disorders | 25 | 8.14% |
| 7 | UTIs | 10 | 3.25% |
| 8 | Gynaecological Disorders | 2 | 0.65% |
| 9 | Inflammatory Breast Condition | 1 | 0.32% |
| 10 | Dermatological Disorders | 6 | 1.95% |
| 11 | Haematological Disorders | 6 | 1.95% |
| 12 | Others | 19 | 6.18% |
| | Total | 307 | 100% |

Concordance with Standard Treatment Guidelines (STGs)

The prescribed antibiotics were also analyzed for concordance with the STGs. This study used the AIIMS (2018) and ICMR (2019) guidelines to check for the appropriateness. As shown in Figure 4, about 50.35 % of antibiotic prescriptions were found to be concordant with the STGs, and 16.54 % of antibiotic prescriptions were found to be inappropriate as per guidelines. In about 33.09 % of prescriptions, antibiotics were prescribed although no antibiotics were recommended for the disease condition mentioned in them.

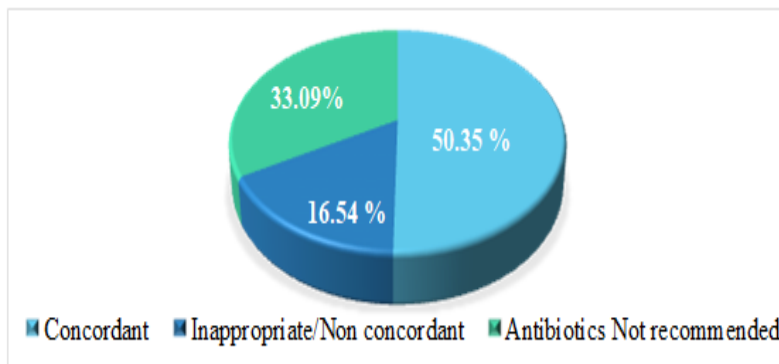


Fig 5: Concordance of Antibiotic Prescription with STGs.

The level of appropriateness for the prescribed antibiotics for respective disease conditions was also determined using the standard treatment guidelines. The results obtained are depicted in the following graph in Figure 5.

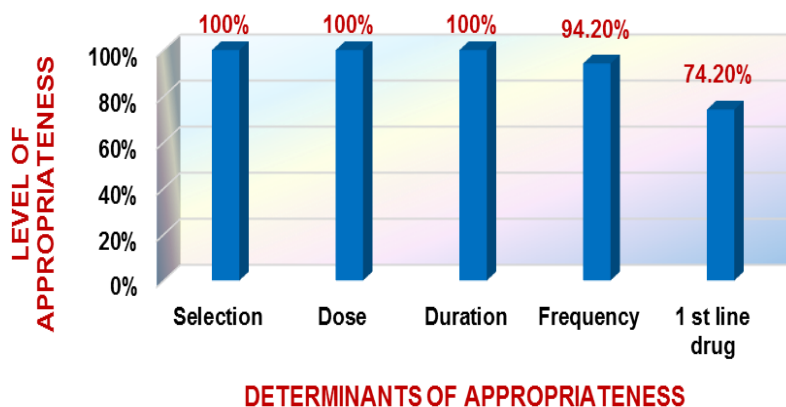


Fig. 6: Level of Appropriateness of Antibiotic Prescription.

DISCUSSION

In this study, a tertiary care teaching hospital's antibiotic prescribing pattern was assessed using WHO prescribing indicators and the WHO AWaRe categorization tool. The hospital

has its own EML of medications and its own institutional STG. Additionally, culture and sensitivity tests were conducted, but only in a small number of patients. A total of 307 patients' prescriptions with antibiotics prescribed were collected for a period of 6 months and included in this study. The majority of prescriptions, i.e., 50.46% (n=155), were of female patients, and 49.49% (n=152) were of male patients (Table 1). This is comparable to the study by Vinod Kumar Mugada *et al.* 2020.^[13] They found that females were administered more antibiotics than males (53.37% vs. 46.3%).

In this study, the antibiotics prescriptions were more in the age group 36-45 years (20.84%), followed by the age group > 65 years (17.91%), and less in the age group 16-25 years (11.72%). This contrasts with research by Abdul Aslam Parathoduvil *et al.* 2022.^[2] They found that prescriptions for antibiotics were lower in the age group over 60 (19.3%) and higher in the age range 21–40 (37.9%). The number of antibiotics administered for each of the 307 prescriptions in our research was examined. Antibiotic prescriptions for 1, 2, 3, and more than three were found to be 36.48 %, 44.29 %, 16.28 %, and 2.93%, respectively (Table 2 and Fig. 1). This contrasted with the Maryam *et al.* 2020.^[15] research, which found that 68.0 %, 26.5%, 4.0 %, and 1.5% of antibiotic prescriptions were for 1, 2, 3, and more than three medications, respectively. The indication for prescribing more than one antibiotic depends on the patient's response to the antibiotic and the recommended antibiotic prescribing guidelines. This study found that 73.31% (n=423) of antibiotics were administered parenterally, followed by 26.68% (n=154) administered orally (Fig. 2). In a study by Vineel B.J *et al.* 2023,^[12] 50.9% of injections were predominantly prescribed over oral tablets, i.e., 49.1%. In our study, likely, injectable antibiotics were commonly prescribed because they are reserved for hospitalized patients, and in the context of this study, such patients would be managed inwards, whereas outpatients were not included in our study. Overprescribing injectable antibiotics is considered a case of inappropriate antibiotic use. Therefore, prescribers need to emphasize replacing injectable antibiotics with the oral route to reduce injection-related infections, shorten hospital stay, and decrease healthcare costs.^[3]

Ceftriaxone (25.47%) was the highest prescribed antibiotic, followed by metronidazole (18.71%), Piperacillin with Tazobactam (14.90%), Amoxicillin with Clavulanate (13.34%), and Azithromycin (9.70%) (Table 3). This is similar to a study conducted by Vineel B.J *et al.* 2023.^[12] which showed that ceftriaxone was the most commonly prescribed antibiotic, with a rate of 30.32%. This deviates from the study conducted by Thomas Opoku *et al.* 2021,^[5]

where the most often given antibiotic was metronidazole. Ceftriaxone has a high prescription rate, although it should not be taken frequently due to significant potential for resistance. Penicillin with beta-lactamase inhibitors and cephalosporins were the most commonly prescribed drug classes with percentages of 28.24% and 27.01%, respectively. This is similar to the findings of a study by Maryam *et al.* 2020.^[15] that found the combination of penicillin and beta-lactamase inhibitors to be the most frequently prescribed drug class. In another study by Vineel B.J *et al.* 2023,^[12] cephalosporins were frequently prescribed as a class of antibiotics with 44.51%. Additionally, in research by Anu Chandran in 2023,^[14] the most often given fixed-dose combination (FDC) of antibiotics was beta-lactamase inhibitors and penicillin. The most often prescribed antibiotics among the fixed-dose combination (FDC) of Penicillin and β -lactamase inhibitors were Amoxicillin and clavulanate, as well as Piperacillin and Tazobactam. Only 0.17% and 0.34% of prescriptions were written for the reserve antibiotics, which are linezolid and Meropenem, respectively. This was comparable to research by Abdul Aslam *et al.* 2022,^[2] which found that relatively few prescriptions were written for reserve antibiotics as they have the highest potential for resistance.

WHO core prescribing indicators were examined and contrasted with related research. The first parameter, the average number of drugs per encounter, was found to be 7.73, which is higher than the WHO standard value of 1.6 – 1.8 (Table 5). Similarly, it was found to be 6 in another study conducted by Sidra Mushtaq *et.al.*, 2021.^[16] In contrast, a higher average of 8.2 drugs per prescription was obtained in a study by Vineel B.J. *et al.*, 2023.^[12] A t-test was applied, and a P-value of < 0.001 was obtained, which indicates that there is a statistically significant difference between the observed values and the standard value. It is a crucial metric for evaluating polypharmacy and identifies measures that should be performed for proper prescription practices to lower the risk of medication interactions, bacterial resistance, and hospital expenses. The drugs prescribed per prescription must be fewer.^[17] There are several possible explanations for the higher number of medications prescribed, such as lack of evidence-based guidelines, polypharmacy, and clinician incompetence.

The proportion of antibiotics prescribed in our study is 100%, which is greater than the WHO-recommended reference value of less than 30%. This high number can be explained by the fact that our analysis only included prescriptions that contained antibiotics. The percentage of injections encountered is 91.5% which is higher than the standard WHO value of < 20%. Research by Maryam *et al.* 2020,^[15] Abdul Aslam *et al.* 2022,^[2] and Vineel B.J *et*

al. 2023.^[12] revealed similar findings, with 96%, 66.7%, 96% respectively. It was found that 29.7% of medications were prescribed in generic names. The total value encompasses all prescribed medications, including but not limited to antibiotics. This is less than the 100% WHO guideline threshold. Abdul Aslam *et al.*'s research from 2022.^[2] showed a comparable figure of 29%. This demonstrates the need for improvement as the percentage of medications prescribed under generic names is still low. According to research by Anu Chandran *et al.* 2024,^[14] 17% of prescriptions were generic. In order to rationalize medicine use and save healthcare costs, generic prescriptions should be promoted.

According to our research, 83.81% of patients had medications (including antibiotics) recommended from EML, which is less than the WHO guideline threshold of 100%. This was comparable to the 84.8% found in a research by Janki Patel *et al.* in 2021.^[18] In our analysis, 93.5% of the antibiotics administered were from the EML list, which is less than the WHO guideline value of 100%. Additionally, our findings contradict those of a research published by Gebre Teklemariam *et al.* 2020.^[3] that found that all (100%) of the antibiotics administered came from Ethiopia's EML. Hence, it should be ensured by the organizations that all antibiotics listed under the EML are available to avoid inflicting pressure on prescribers.

The WHO created the AWaRE classification database as a tool to ensure that antibiotics are used appropriately and optimally. 180 antibiotics were divided into access, watch, and reserve groups.^[19] Our study had 35.88 % (95% CI: 32.0% - 39.8%) antibiotics from ACCESS, 63.93 % (95% CI: 60.04% - 67.86%) from WATCH, and 0.17% from the RESERVE category (Table 4 and Fig. 3). This is contrary to the findings of Thomas Opoku *et al.* 2021,^[5] where 74% of the antibiotics administered were from the "Access" group, followed by 24% from the watch group. Antibiotics in the WATCH category have a significant potential for resistance and therefore require appropriate management. Chi-square statistics were applied. A chi-square value of 221.25 and a chi-square critical value of 5.99 were obtained. Since $221.25 > 5.99$, there is a highly significant difference between the observed results and the WHO recommendation. According to WHO estimates, Prescriptions of over 60% of all antibiotics from the Access group would provide simple access to essential medicines, lower the risk of antibiotic resistance, and encourage responsible antibiotic use. Access group antibiotics are more readily available than watch group antibiotics at the primary care level, and because watch group medications need monitoring, access group

antibiotics may be preferable. In addition to tracking antibiotic prescriptions, the AWaRe program helps policymakers classify EML and revise national treatment guidelines.

Furthermore, the average no of antibiotics per patient, i.e., 1.87 in our research, was higher than the WHO-recommended limit of 1.6–1.8. Similar result of 2.01 were reported by Gebre Teklemariam *et.al*, 2020.^[3] Another finding from our study was that patients used antibiotics for an average duration of 4.03 days (Table 8), which is less time than is typically required. Similar results of 4.2±2.3 days during their hospital stay were reported by Gebre Teklemariam *et.al*, 2020.^[3] However, in our study, the majority, 29.46% of patients, were on antibiotics for a duration of less than 3 days, while nearly 41.42 % of patients were taking them for 4-5days, 21.66% for less than 6-7 days, and 7.45% for more than 7days.

In our study, the common diseases that utilized antibiotics were GIT (29.31%), followed by LRTI (24.10%) (Table 9). This was contrary to the results found by Thomas Opoku *et.al*, 2021,^[5] where antibiotics were used frequently for LRTI followed by UTI. The prescriptions were assessed using the ICMR (2019).^[6] and AIIMS (2018).^[20] guidelines to determine the appropriateness of the antibiotics prescribed. The following factors were taken into consideration: dosage, frequency, duration of therapy, and the choice (selection) of an antibiotic for the identified illness condition that is included in STGs. Antibiotics used for the treatment of LRTI were found to be concordant with the STGs. The second most frequently observed disease condition was gastritis. Metronidazole 500mg and ciprofloxacin 500 mg were prescribed to most of the patients with gastritis, although no antibiotics are recommended for the treatment of the above condition according to STGs. Similarly, no antibiotics are recommended for the treatment of acute pancreatitis. Treatment of UTIs with nitrofurantoin 100mg BD for 5 days, ciprofloxacin 50mg BD for 3-5 days, being first-line agents for the condition, was found to be concordant with the STGs. The treatment of Diarrhea with ciprofloxacin 500 mg BD and metronidazole 500 mg TID for 3-5 days was also found to be appropriate according to the guidelines. The cases with sepsis and cellulitis were non concordant with the recommendation of Imipenem-cilastatin +/-Amikacin for sepsis and cefazolin /cephalexin /amoxicillin + clavulanate +/- clindamycin for cellulitis. Last resort antibiotic linezolid 600 mg was prescribed only to a case of Necrotizing fasciitis, which was concordant with the guidelines. It can be concluded that around 50.35% of the cases were found to be concordant with the guidelines with respect to the determination criteria. In 16.54% of cases, the antibiotics other than recommended were prescribed. And in 33.09% of

cases, antibiotics are prescribed although no antibiotics are recommended for the condition (Fig. 4 and Fig. 5). Rost LM et al reported that 30-50% of antibiotics are prescribed inappropriately without adherence to prescription guidelines, Abdul Aslam et.al, 2022.^[2] Similar results were reported by Steward Mudenda et al, 2022.^[21] Culture and sensitivity testing were done for only a few cases. Differences from previous studies may reflect local antimicrobial resistance trends, hospital formulary restrictions, or prescriber preferences. To promote rational use of medicines, the foremost step required is to quantify the extent of irrational use. This is where prescription pattern monitoring plays an important role. Prescription patterns explain the quality and quantity of drugs, give insight into recent trends among physicians/surgeons, quantify the extent of adherence to WHO indicators like standard treatment regimen, overuse/underuse of recommended antibiotics, and usage of drugs from EML, etc.^[8]

LIMITATIONS

Our study has certain limitations. Since the prescribing antibiotics pattern was investigated in a single hospital, the results of the study cannot be generalized to all hospitals, and as this study was conducted among inpatients, it does not represent outpatients. The present institution was a government hospital, and the prescription pattern depends on the government supply of drugs. In this study, all the clinical departments of the institution were not included, especially super-specialty departments.

CONCLUSION

Prescribing pattern studies have become a potential tool for evaluating health care systems. Our study evaluated the prescribing pattern of antibiotics among inpatients. In this study, out of the prescriptions analyzed, most of them had two antibiotics prescribed. The IV route of antibiotic administration was more common among the patients. This could be explained by the fact that the study included only the inpatients. Cephalosporin (ceftriaxone) was the most commonly prescribed antibiotic. In this study, prescriptions were analyzed using the WHO core prescribing indicators. We observed polypharmacy and high use of injections in the hospital. Generic prescriptions were very low, although generic products were used in the hospital. Hence, generic drug prescribing should be encouraged among the prescribers. In this study, more than half of the patients were on at least 1 antibiotic. 93.5 % of antibiotics were prescribed from the EML. Education and training of physicians regarding prescribing practice according to WHO parameters can ensure appropriate prescribing. However, most of the

antibiotics were prescribed without culture and sensitivity (C & S) testing. It is recommended that the (C & S) testing be done for specific treatment. Hospitals should also consider local microbial susceptibility patterns and follow STGs to facilitate appropriate prescribing. A considerable variations in antibiotic prescribing with respect to AWaRe classification of antibiotics were observed. The watch group of antibiotics was most frequently prescribed, followed by the access group. The AWaRe tool is used not only to monitor the antibiotic prescribing but also to guide policymakers to ensure easy access to basic antibiotics, reduce the risk of antibiotic resistance, and promote responsible use of antibiotics. At a primary care level, access group antibiotics are easily accessible, whereas watch group antibiotics need supervision, and hence, access antibiotics may be preferred over watch antibiotics. Therefore, prescribers must be made aware and familiar with the WHO AWaRe classification tool. This could be done by developing an Antibiotic stewardship program (ASP), introducing the practice of antibiotics with the aid of (C & S) testing, and developing appropriate institutional guidelines. It was found that more than half of the antibiotic prescriptions were concordant with STGs, and a few deviated from the STGs. The data from this study can be utilized for measuring and designing the steps to be taken to promote the appropriate use of antibiotics. Therefore, this study provides evidence for the necessity and a way forward for the establishment of an ASP in the hospital. Every hospital should monitor drug utilization based on the WHO prescribing indicators. Generic name prescribing and essential drug prescribing are highly recommended among primary-care physicians. Prescription of antibiotics should be avoided for viral infections. When prescribed, the antibiotic should be prescribed based on the AWaRe assessment tool, and access to antibiotics is highly recommended at the primary care level.

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AUTHORS CONTRIBUTIONS

All the authors in the study have contributed their equal parts. Dr.Syeda Rana Nikhat, Mubashira Mahveen, Zoya Simran, Nadira Arjuman, and Syeda Nikhat Mehwish designed and framed the study. Data acquisition, analysis, and interpretation were done by all the authors. Writing and editing of the manuscript were done by Mubashira Mahveen, Zoya simran, and Nadira Arjuman, and revised by Mubashira Mahveen and Zoya Simran. The work was supervised by Dr.Syeda Rana Nikhat.

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