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Pharmacology Section

Assessment of Antibiotic Prescribing Pattern Using WHO Access, Watch, and Reserve Classification (AWaRe) at a Tertiary Care Centre of Northern India: A Cross-sectional Study

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ABSTRACT

Introduction: Rapid emergence of antibiotic resistance has rendered the treatment of bacterial infections challenging. This is mainly attributed to irrational use of antibiotics. To address this, the World Health Organisation (WHO) has developed Access, Watch and Reserve (AWaRe) classification of antibiotics as a tool for surveillance.

Aim: To evaluate the prescribing pattern of antibiotics at a tertiary care hospital and classify the antibiotic usage as per AWaRe classification.

Materials and Methods: This was a cross-sectional study conducted for one year (August 2021 - July 2022) across various outpatient departments. The prescriptions containing at least one antibiotic were analysed for the antibiotic prescribing pattern. Antibiotics were categorised into 'Access', 'Watch', 'Reserve', 'Not recommended' groups, in the whole population and in three age groups: children, adults and elderly. Access: Watch index was calculated. Descriptive analysis was performed to assess the pattern of antibiotic prescriptions.

Results: Of 800 prescriptions, 402 (50.2%) belonged to women and the mean age of the patients was found to be 32.03±8.45 years. A total of 1,090 antibiotics were prescribed, of which 48.34% were 'Watch' drugs, 40.64% were 'Access' drugs and 0.82% were from 'Reserve' group. 3.7% of antibiotics were not recommended by the WHO. Cefixime (J01DD08) was the most commonly prescribed antibiotic, accounting for 294 (27%) prescriptions, followed by amoxicillin-clavulanic acid (J01CR02) with 258 (23.7%) prescribed and ciprofloxacin (S02AA15) with 95 (8.7%) prescriptions. On average, 1.36 antibiotics were prescribed per patient. Access: Watch index was found to be 0.84.

Conclusion: The study found high use of 'Watch' antibiotics in general and across different age groups of children, adults and elderly. A lower Access: Watch index suggests the need for rational antibiotic prescribing to tackle the problem of resistance.

Keywords: Antibiotic resistance, Antimicrobial agents, Antimicrobial stewardship, Bacterial infections, Irrational prescribing

INTRODUCTION

The discovery of antibiotics has been one of the most remarkable milestones achieved in the medical practice. It dates back to the serendipitous discovery of penicillin in 1920s. Since then, a large number of antibiotics have been in use, significantly altered the course of infections and the resulting morbidity and mortality [1]. However, over the last couple of decades, injudicious use of antibiotics has been the cause for concern. They are being overwhelmingly used in an empirical manner, without proper justification for the need for antibiotics. It is estimated that 55-70% of the patients who visit a healthcare setting are prescribed at least one antibiotic [2]. The incidence is found to be more in outpatients, patients admitted to intensive care units and the paediatric population [3]. The inappropriate use of antibiotics has rendered them ineffective upon several populations of microorganisms despite the availability of newer, more efficient and lifesaving antibiotics. Not only has it become nearly impossible to treat an infection, but it is also posing difficulties in prophylaxis of various diseases and surgical procedures as well. Antimicrobial resistance has led to 1.27 million global deaths directly and contributed to 4.95 million deaths in 2019—more than HIV/AIDS and malaria [4]. This issue also impacts the nation's economy.

To address this problem, several joint initiatives are being taken worldwide. One of these is development of the AWaRe classification of antibiotics by the WHO [5]. It provides a stewardship framework to support antibiotic monitoring. It classifies antibiotics into different groups to emphasise the importance of their appropriate use.

Access group includes antibiotics with lower resistance potential that are used for commonly encountered susceptible pathogens. Watch group includes antibiotics with higher resistance potential, which are only indicated for specific, limited infective syndromes. Reserve group includes antibiotics used to tackle multi-drug-resistant organisms and are considered as "last resort" options. There is another category of "Not recommended," which includes Fixed-Dose Combinations (FDCs) of multiple broad-spectrum antibiotics, use of which is not evidence-based nor recommended in high-quality international guidelines. A country-specific target has been proposed by the WHO to achieve 60% of antibiotic consumption from access groups of antibiotics. This would limit the use of the 'Watch' group antibiotics and hence save the microorganisms from being rendered resistant [5].

Injudicious and irrational use of antibiotics, along with not adhering by the WHO target of antibiotic consumption, is leading to antibiotic resistance, as is seen by a number of studies conducted worldwide [6-8]. However, the studies were conducted in different healthcare settings [6-8]. The present study aimed to assess the antibiotic prescribing pattern in the various outpatient departments at a tertiary care centre in Northern India and classify the antibiotic usage as per the WHO AWaRe classification. Additionally, the study evaluates the access: watch ratio, which tells about the overall consumption of

antibiotics and in three separate age groups: children (≤18 years), adults (>18-65 years) and elderly (>65 years).

MATERIALS AND METHODS

This was a cross-sectional observational study conducted in the patients presenting to the various clinical outpatient departments at a government-based tertiary care centre of Haryana (Shaheed Hasan Khan Mewati, Government Medical College, Nalhar, Nuh, Haryana) for a period of one year (August 2021 - July 2022). The study was conducted after the approval from the Institutional Ethics Committee (IEC) (SHKM/IEC/2021/11 dated 04/03/2021).

Inclusion criteria: The data source of the study is secondary and includes all the prescriptions of the new outpatients of all ages and either gender that contain at least one antibiotic.

Exclusion criteria: Illegible prescriptions, prescriptions for HIV, Tuberculosis (TB), immunocompromised patients, cancer patients and those patients attending the OPD to receive preventive services such as vaccinations, prenatal or postnatal care, or child health services were excluded from the study.

Sample size calculation: Sample size was calculated based on the WHO recommendation, which states that a minimum of 600 prescriptions is needed for prescription pattern analysis in an outpatient department setting. Considering the prevalence of antibiotic prescription as 52.3% in the study "Prescribing Pattern of Antibiotics using WHO Prescribing Indicators among Inpatients in Ethiopia: A Need for Antibiotic Stewardship Program" by Demoz GT et al., with a 99% confidence interval and an acceptable difference of 5%, the calculated sample size was 662 [9]. However, taking overprescription of antibiotics in India into consideration, we conducted the study on 800 patients. The software used for this calculation was OpenEpi.

Study Procedure

A consecutive non random sampling method was used to collect data. The images of the prescriptions were captured at the pharmacy outlet of the tertiary care centre using a handheld device or a mobile camera after obtaining written informed consent. The data was then anonymously transcribed into structured predesigned proforma, which included socio-demographic details, clinical information and details of medicines prescribed with focus on antibiotics. The antibiotics were coded according to the WHO ATC (Anatomic, Therapeutic, Chemical) classification. The use of antibiotics was categorised as per the WHO AWaRe classification into access, watch, reserve and 'not recommended' groups for the entire population and in three age groups: children (≤18 years), adults (>18-65 years) and elderly (>65 years) [5]. Access: Watch index was calculated as a tool to assess the rational antibiotic prescribing (recommended value is 1.5) [6].

STATISTICAL ANALYSIS

Data entry and analysis were done using IBM Statistical Package for the Social Sciences (SPSS) Statistics for Windows, Version 20.0 (released in 2011; IBM Corp., Armonk, New York, United States). The results were expressed in terms of descriptive statistics, including frequencies, percentages, ranges, means and standard deviations.

RESULTS

A total of 800 patients were included in the study, of which 402 (50.2%) were women. The mean age of the patients was 32.03±8.45 [Table/Fig-1].

The most common indication for which antibacterials were prescribed was respiratory infection, with 191 (23.9%) cases, followed by infections of ear, nose and throat (189, 23.6%) and genitourinary tract infections (85, 10.6%). In 39 (4.9%) patients, details of infection were not clearly stated and in 17 (2.1%) patients, there was no mention of diagnosis.

Parameter	Subgroups	Result
Gender n (%)	Female	402 (50.2)
	Male	398 (49.8)
Age group (years)	Paediatric group (0-18)	238 (29.8)
	Adult Group (>18-44)	344 (43)
	Middle Aged Group (>44-63)	142 (17.8)
	Elderly Group (≥64)	76 (9.5)

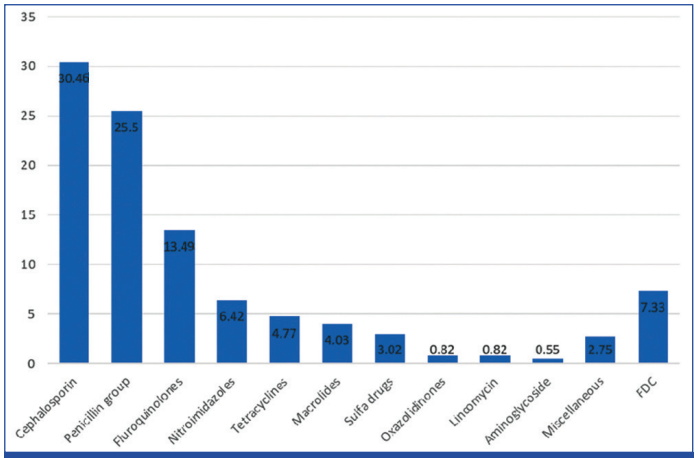
[Table/Fig-1]: Demographic details.

A total of 3,650 medicines were prescribed to 800 patients, of which 1,090 were antibiotics. Majority of the patients, 542 (67.75%), were prescribed one antibiotic [Table/Fig-2]. The study shows prescription of up to four antibiotics were prescribed per patient. The mean number of antibiotics prescribed per prescription was 1.36±1.9.

No. of antibiotics prescribed per patient	n (%)
1	542 (67.75)
2	230 (28.75)
3	27 (3.37)
4	1 (0.12)

[Table/Fig-2]: Number of antibiotics prescribed per patient.

Cephalosporins (332, 30.46%) were the most commonly prescribed antibiotic group, followed by broad-spectrum penicillins (278, 25.50%) and fluoroquinolones (147, 13.49%). A total of 80 (7.33%) combinations of antibiotics were prescribed as FDCs [Table/Fig-3].



[Table/Fig-3]: Distribution of antibiotics as per drug class in percentage.

The most common antibacterial prescribed was cefixime (J01DD08) with 294 (27%), followed by amoxicillin-clavulanic acid (258, 23.7%) and ciprofloxacin (S02AA15) with 95 (8.7%) [Table/Fig-4]. An FDC of antibiotics (ofloxacin and tinidazole) that was prescribed to a patient is not classified by the WHO in ATC classification. As per the WHO, its use is not considered evidence-based and it is not recommended in high-quality international guidelines.

The study shows that 92.3% of antibiotics were prescribed from National List of Essential Medicines (NLEM) 2022. Only 7.7% of drugs were not prescribed from the list, which mainly includes FDCs of antibiotics that are not recommended by the WHO.

[Table/Fig-4] also depicts the distribution of prescribed antibacterials according to the AWaRe classification. It was observed that cefixime from the Watch group (294, 27%) was most frequently prescribed, followed by amoxicillin/clavulanic acid (258, 23.7%) from Access group.

Overall, maximum number of the antibiotics prescribed was from the 'Watch' group (527, 48.34%) [Table/Fig-5]. 443 (40.64%) antibiotics belonged to 'Access' group and only 9 (0.82%) were from 'Reserve' group. Linezolid was the only antibiotic prescribed from the 'Reserve' group. Additionally, 38 (3.7%) of antibiotics were prescribed from the 'Not recommended' group of AWaRe classification, which included

S. No	Antibacterials	ATC Code	NLEM 2022	AWaRe Category	n (%)
1	Neomycin and Polymyxin B	A07AA51	No	Not classified	1 (0.1)
2	Mupirocin	D06AX09	Yes	Not classified	23 (2.1)
3	Framycetin	D09AA01	Yes	Not classified	1 (0.1)
4	Benzoyl peroxide	D10AE01	Yes	Not classified	7 (0.6)
5	Clindamycin	D10AF01	Yes	Access	9 (0.8)
6	Clindamycin, combinations	D10AF51	No	Not classified	3 (0.3)
7	Doxycycline	J01AA02	Yes	Access	52 (4.8)
8	Amoxicillin	J01CA04	Yes	Access	20 (1.8)
9	Amoxicillin/ clavulanic acid	J01CR02	Yes	Access	258 (23.7)
10	Cefuroxime	J01DC02	Yes	Watch	33 (3)
11	Ceftriaxone	J01DD04	Yes	Watch	2 (0.2)
12	Cefixime	J01DD08	Yes	Watch	294 (27)
13	Cefpodoxime	J01DD13	No	Watch	2 (0.2)
14	Azithromycin	J01FA10	Yes	Watch	44 (4)
15	Clindamycin	J01FF01	Yes	Access	1 (0.1)
16	Ofloxacin	J01MA01	Yes	Watch	4 (0.4)
17	Ciprofloxacin	J01MA02	Yes	Watch	12 (1.1)
18	Levofloxacin	J01MA12	Yes	Watch	17 (1.6)
19	Moxifloxacin	J01MA14	Yes	Watch	1 (0.1)
20	Ofloxacin and Ornidazole	J01RA09	No	Not recommended	40 (3.7)
21	Metronidazole	J01XD01	Yes	Access	70 (6.4)
22	Nitrofurantoin	J01XE01	Yes	Access	33 (3)
23	Linezolid	J01XX08	Yes	Reserve	9 (0.8)
24	Tobramycin	S01AA12	Yes	Watch	5 (0.5)
25	Fusidic acid and Beclomethasone	S01AA20	No	Not classified	3 (0.3)
26	Polymyxin B and Chloramphenicol	S01AA30	No	Not classified	1 (0.1)
27	Ciprofloxacin*	S01AE03	Yes	Watch	5 (0.5)
28	Moxifloxacin	S01AE07	Yes	Watch	12 (1.1)
29	Prednisolone and antiinfectives*	S01CA02	No	Not classified	10 (0.9)
30	Ciprofloxacin†	S02AA15	Yes	Watch	95 (8.7)
31	Ofloxacin	S02AA16	No	Watch	1 (0.1)
32	Prednisolone and antiinfectives†	S02CA01	No	Not classified	1 (0.1)
33	Dexamethasone and antiinfectives	S02CA06	No	Not classified	20 (1.8)
34	Ofloxacin and Tinidazole	-	No	Not classified	1 (0.1)
	Total				**1090 (100)**

[Table/Fig-4]: Distribution of antibiotics prescribed in the study.
*- Topical Eye Preparations, † Topical Ear Preparations

S. No.	AWaRe categories	n (%)
1	Access	443 (40.64)
2	Watch	527 (48.34)
3	Reserve	9 (0.82)
4	Not recommended	40 (3.7)
5	Unclassified (UN)	71 (6.50)
	Total	**1090 (100)**

[Table/Fig-5]: Categorisation of antibiotics into different AWaRe groups.

FDC of ofloxacin and ornidazole. 71 (6.50%) antibiotics prescribed in the study were not classified by the WHO, mainly the FDCs and drugs like mupirocin, framycetin and benzoyl peroxide [Table/Fig-4]. Access: Watch index was found to be 0.84.

[Table/Fig-6] shows the number of antibiotics prescribed according to AWaRe classification in three age groups: children (≤18 years), adults (>18-65 years) and elderly (>65 years). It was found that in all the three population groups, majority of the antibiotics that were prescribed belonged to 'Watch' group, with the number and percentages being 155 (45.45%), 330 (49.03%) and 42 (55.26%), respectively.

AWaRe groups	Children	Adults	Elderly
Access	145 (42.52%)	276 (41.10%)	18 (23.68%)
Watch	155 (45.45%)	330 (49.03%)	42 (55.26%)
Reserve	1 (0.29%)	8 (1.18%)	0
Not recommended	5 (1.4%)	27 (4.01%)	6 (7.89%)
Unclassified	35 (1.01%)	32 (4.75%)	10 (13.15%)
Total no. of antibiotics prescribed	**341**	**673**	**76**

[Table/Fig-6]: Number of antibiotics prescribed according to AWaRe classification.

DISCUSSION

The study assessed the prescribing pattern of antibiotics at a tertiary care centre in Northern India. The most common indication for which the antibiotics were prescribed was respiratory tract infections, followed by infections of ear, nose and throat, which mainly included acute pharyngitis and nasopharyngitis. The respiratory tract infections, mostly involving the upper respiratory tract, are generally of viral origin and usually self-limiting. Routine use of antibiotics in these conditions is considered inappropriate and may lead to antibiotic resistance. The overuse of antibiotics for respiratory infections has been highlighted in many researches conducted in various parts of the country as well as abroad [10,11]. In 7% of the prescriptions, the diagnosis was not clearly mentioned. Prescribing antibiotics when the diagnosis is not made at all indicates injudicious use of antibiotics and deviates from the rational use of drugs. This also indicates carelessness on the part of prescribers. In fact, the Union Health Ministry of India has issued a notice to all the prescribers to clearly state the indication or reason before starting antibiotics [12].

The study shows that, on average, 1.36 antibiotics were prescribed per patient. This falls below the ideal value proposed by the WHO (1.6-1.8) [13]. Similar values have been found in other studies, ranging from 1.4 to 2.2 [10,14,15]. A 67.75% of the patients were prescribed one antibiotic; however, combination of antibiotics were also prescribed, ranging from two to four. Treating patients with three or four antibiotics on an outpatient basis, where non compliance may be an issue, is risky in terms of both cure as well as development of antibiotic resistance. However, the overall antibiotic prescribing rate was found to be 38% (WHO reference range 20.0-26.8%) [13]. According to the latest survey by National Centre for Disease Control (NCDC) India, involving 20 different sites, the prevalence of antibiotics use was found to be 72%, ranging from 37 to 100% [2]. Although the antibiotics usage in present study lies towards the lower limit of the range observed in the nationwide survey, it still exceeds the ideal value set by the WHO. This indicates the overuse of antibiotics in patients, even though the number of antibiotics prescribed per patient was lower in present study.

A 92.3% of antibiotics were prescribed from NLEM 2022 in the study population. Though this still falls to reach the 100% benchmark set by the WHO and provides scope for improvisation, it is quite higher than the values observed in other studies [16,17]. Adherence to NLEM promotes rational use of drugs, guides safe and effective treatment of priority disease conditions and optimising the available health resources.

The beta-lactams, like cefixime (J01DD08) and amoxicillin/clavulanic acid (J01CR02), were the most frequently prescribed antibiotics in present study, followed by ciprofloxacin. This was in concordance with other studies, where use of cephalosporins (cefixime,

ceftriaxone) and amoxicillin/clavulanic acid has been found to be greater in comparison to other drug classes [10,16,17]. However, cefixime (27%), the most prescribed antibiotic in the current study, belongs to 'Watch' group of the WHO AWaRe classification. This may be worrisome as it has higher propensity for acquiring resistance. Its overwhelming use may lead to development of Extended-Spectrum Beta-Lactamase (ESBL)-producing microbes.

Amoxicillin/clavulanic acid (23.7%), the next most prescribed antibiotic, belongs to 'Access' group, followed by ciprofloxacin (10.3%) from 'Watch' group. It has also been found in a study that the use of beta-lactams predominated in the public sector, while fluoroquinolones were prescribed more frequently in private sector. It may be attributed to the economic reasons, as beta-lactams being more affordable for patients and hence preferred in government settings. Furthermore, there could be a profit motive in the private sector for using the newer and more expensive antibiotics [18]. However, extensive and inappropriate use of fluoroquinolones is a cause for concern, as it may worsen the problem of antibiotic resistance.

Overall, majority of antibiotics prescribed in the current study belonged to the 'Watch' group (48.34%). Cefixime, ciprofloxacin and azithromycin were the most commonly prescribed antibiotics from this class, respectively. The higher use of 'Watch' antibiotics was consistent among all the population groups (children, adults and elderly). This is worrisome especially in the vulnerable population of children and elderly. A comprehensive study conducted in six districts of Tamil Nadu also shows a proportionately high use of 'Watch' group antibiotics [6]. Such a pattern is also observed in the nationwide survey, where 57% of the antibiotics fall into 'Watch' group [2].

The antibiotics prescribed from 'Access' group (40.64%), which falls far below the proposed target of 60% set by the WHO. The high use of 'Watch' group antibiotics may be attributed to the risk of treatment failure when using 'Access' group antibiotics, lack of proper regulation, the need to meet patient's expectations and pressure from seniors and colleagues [19].

Only 0.82% of antibiotics were prescribed from 'Reserve' group. This included the use of linezolid in serious skin infections, non-healing ulcer and traumatic amputation of limb. Since the study was conducted at a tertiary care centre where seriously ill patients in deteriorating conditions are referred for better care, the use of 'Reserve' group antibiotics seems justified. However, 3.7% of the drugs were prescribed from the 'not recommended' group of AWaRe classification, which included FDC of ofloxacin and ornidazole. Its use is not evidence-based.

There were a few drugs and some FDCs (6.50%) that were prescribed which were not included in the AWaRe classification, like, mupirocin, framycetin, benzoyl peroxide, the neomycin and polymyxin B combination, ofloxacin and tinidazole, fusidic Acid and beclomethasone and polymyxin B and chloramphenicol. Although these may not be listed in the 'not recommended' group, the list surely have a few combinations that seem irrational.

Access: Watch index was found to be 0.84, which was much below the WHO preferred value of 1.5. This could be attributed to the higher use of cephalosporins and fluoroquinolones, which belong to the Watch group. Good safety profile and broad-spectrum action of these drugs make them a preferred choice for clinicians, although this may not always be rational. Globally, there is also an increasing trend in prescribing of Watch group antibiotics. A study conducted in Kazakhstan showed a significant rise in use of Watch antibiotics, increasing from 61% to 68% between 2017 and 2019 [20]. Similarly, in Bangladesh, 64% of drugs belonged to 'Watch' group [21]. However, a few countries, like Australia and Vietnam, have achieved the WHO target by prescribing 60-70% of medicines from the Access group. Furthermore, they emphasised the role of tools like AWaRe classification in reducing the use of Watch antibiotics [22,23].

Limitation(s)

As this was a single-site study conducted at a government-based tertiary care centre involving only the outpatient departments, the results cannot be generalised. However, it provides the necessary information about the pattern of antibiotics prescribed at the given setting, thereby promoting its rational use. There is need to include private sector and pharmacies, as they form an integral part of drug dispensing. This demands a centralised and robust surveillance system to monitor antibiotics usage. If the AWaRe classification is taken into account sincerely, it can help in taking the first step in the fight against antibiotic resistance.

CONCLUSION(S)

The study showed high use of 'Watch' antibiotics in the entire population, as well as across the three age groups of children, adults and elderly. Moreover, some of the antibiotics prescribed were not recommended by the WHO and are considered irrational. Multiple antibiotics prescription was also observed. Some of the patients were prescribed antibiotic therapy without clear mention of diagnosis in the prescription. These factors may contribute to the development of antibiotic resistance and hence, the need of robust measures to tackle it.

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