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EVALUATION OF ANTIBACTERIAL UTILIZATION USING WHO-PRESCRIBING INDICATORS AT A RURAL TERTIARY CARE TEACHING HOSPITAL IN NORTHERN INDIA

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ABSTRACT: Introduction: Due to the appropriate use of antibacterials, management of infectious diseases has undergone a revolutionary change. However, inappropriate use leads to several problems, including increased antibacterial resistance, adverse drug reactions, infection severity, increased treatment cost, and health care burden. Antibacterials drug utilization studies are valuable in overcoming the inappropriate and promoting the appropriate use of antibacterials. Therefore, the current study aims to estimate the pattern of antibacterial drug utilization by using WHO prescribing indicators. **Material & Methods:** A Non-interventional, Cross-sectional study was conducted among 800 OPD patients of SHKM, GMC, Nuh, and Haryana over a period of 12 months. A simple random sampling technique was employed to select prescriptions during data collection. Data processing and analysis were done using SPSS version 20. **Results:** 2105 patients were screened, and 800 patients were included in the study based on inclusion criteria. It was found that the maximum number of patients were in the adult age group (43%), followed by 29.8% in the paediatric age group. There were 4.56 drugs prescribed per patient, of which 1.36 were antibacterials. The percentage of encounters with at least one antibacterial was 38%, and the percentage of antibacterials prescribed by generic name was 45%. A total of 0.50% of antibacterials were prescribed in injectable form, and 87.3% were prescribed from the essential drugs list. **Conclusion:** The use of antibacterials weren't high, but more efforts are needed to enhance the rational use of antibacterial drugs.

INTRODUCTION: One of the ten great public health achievements of the twentieth century was the discovery of antimicrobial agents ¹. Antibacterials are a very important group in antimicrobial drugs.

Antibacterial refers to any substance or product that kills bacteria, inhibits their growth, or prevents them from reproducing ². Antibacterials are generally produced de novo or derived from bacteria or molds.

Precisely, "antibiotic" denotes only antimicrobials produced from bacteria but is often used synonymously with "antibacterial" ³. In 1909, Paul Ehrlich discovered the very first antibacterial, Salvarsan (synthetic arsenic-based drug which showed significant promise for treating patients

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with syphilis). Since, then, antibacterials have saved millions of lives. As a result of the appropriate use of antibacterials, the management of infectious diseases has undergone a revolutionary change. According to WHO appropriate use of antibacterial drugs is defined as “patients receive antibacterials that are appropriate for their clinical needs, in doses that fulfill their requirements, for a sufficient time interval and at the least possible cost to them and their community”⁴.

As mentioned above, the appropriate use of antibacterials in managing infectious diseases has brought a revolutionary change but also resulted in inappropriate use (underuse, overuse, or misuse). Nowadays, inappropriate use leads to several issues, including increased antibacterial resistance, adverse drug reactions (increases patient morbidity & mortality), infection severity, increased cost of treatment and re-hospitalization (increases health care burden)⁵.

In recent years, to overcome the inappropriate (irrational) and promote the appropriate (rational) use of antibacterials, drug utilization studies have become an important tool to be used in evaluating drug use in health systems.

Drug use was defined by the World Health Organization (WHO) in 1977 as “The marketing, distribution, prescription and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences”⁶. Rational drug use is the supreme goal of drug utilization studies.

In order to evaluate drug use in healthcare settings, the WHO and the International Network of Rational Use of Drugs (INRUD) developed a list of core and complementary drug use indicators in 1993⁷. The WHO has validated the core drug use indicators as the most valuable indicators for assessing drug use. Compared to the complementary indicators, the core drug use indicators are more revealing, feasible, and less likely to alter over time and place. They are also simpler to measure. Therefore, to improve the quantitative assessment of appropriate drug usage, the core drug use indicators have been selected as a main indicators.

Among core drug use indicators main group is Prescribing Indicators. Presently, there is a paucity of drug utilization studies on antibacterials in the Mewat Region; thus, the utilization status is not readily available. Therefore, the current study aims to estimate the pattern of antibacterial drug utilization by using WHO prescribing indicators.

MATERIALS AND METHODS:

Study Area: The study was carried out in OPD patients of Shaheed Hasan Khan Mewati, Government medical college, Nalhar, Nuh, Haryana.

Study Design: A Non-Interventional, Cross-Sectional study was conducted. Data were collected using a structured pre-designed validated proforma⁸.

Sample Size: As per WHO, at least 600 prescriptions should be included to study prescribing indicators⁸. Accordingly, 800 prescriptions of outpatients for prescribing indicators were included in our study. A simple random sampling technique was employed to select prescriptions during data collection.

Sources of Data: All Outpatients with their prescriptions presented to the SHKM, GMC Hospital pharmacy outlet.

Inclusion Criteria: All prescriptions (with at least one antibacterial) written for the new outpatients attending the pharmacy outlet of the SHKM GMC during the study period, of all ages and gender were included in the study. OPD patients/attendants who were willing to give written informed consent to share their prescription data.

Exclusion Criteria:

1. Prescriptions with inadequate information or not clear.
2. Prescriptions not containing any antibacterial.
3. Prescriptions of the HIV, TB, immunocompromised, cancer patients and those patients who were attending the OPD to receive preventive services such as vaccinations, prenatal or postnatal care, or child health services.

4. OPD patients/attendants who were not willing to give written informed consent to share their prescription data.

Study Period: The study was carried for a period of 12 months from August 2021 – July 2022.

Data Collection: Data were collected from prescriptions/interview of the patients. A structured pre-designed validated proforma⁸ adopted from WHO indicators guidelines and similar literatures was used.

Data Management and Statistical Analysis: During the data collection process, periodic quality checks of collected data were done. All the collected data were checked and coded for computer entries; then it was entered in excel sheet. The data were analyzed using SPSS 20.0 version. The results were expressed using descriptive statistics (mean, numbers and percentages).

Prescription Assessment was done by using WHO Prescribing Indicators Like⁸:

Percentage of encounter with at least one antibacterial.

Number of encounters in which an antibacterial was prescribed / Total number of encounters surveyed $\times 100$

Average number of drugs per prescription.

Total number of drugs prescribed / Total number of encounters included

Average number of antibacterials per prescription.

Total number of antibacterials prescribed / Total number of encounters included

Percentage of antibacterial prescribed by generic name.

Number of antibacterials prescribed by generic name / Total number of antibacterials prescribed $\times 100$

Percentage of antibacterial prescribed in injection form.

Number of antibacterials prescribed in injection form / Total number of antibacterials prescribed $\times 100$

Percentage of antibacterials prescribed from essential drugs list.

Number of antibacterials prescribed which are in essential drug list / Total number of antibacterials prescribed $\times 100$

*For this Prescribing Indicator Essential Drug List of Haryana-2013 was used.

Ethical Consideration: Ethical clearance for the study was obtained from the institutional ethics committee of SHKM, GMC, Nuh (IEC Study Approval No. –EC/OA-08/2021). The study was started after obtaining ethical clearance from the institutional ethics committee of SHKM GMC, Nuh. Written informed consent was taken from all the study participants.

RESULTS: The study was conducted among OPD patients of SHKM, GMC, Nuh, Haryana. A total of 2105 patients were screened for prescribing indicators, and based on inclusion criteria 800 patients were included in the study.

Sociodemographic Characteristics: Age-wise distribution of the patients was analyzed, and it was found that the maximum patients were in the adult age group (43%), followed by 29.8% in the paediatric age group and only 9.5% were in the elderly group **Table 1**.

TABLE 1: AGE-WISE DISTRIBUTION OF PATIENTS

S. no.	Age	Frequency	Percentage %
1	Paediatric group 0-18 years	238*	29.8*
2	Adult Group 19-44 years	344*	43*
3	Middle Aged Group 45-63 years	142	17.8
4	Elderly Group ≥ 64 years	76	9.5
	Total	800	100

WHO Prescribing Indicators: Out of 2105 patients who were screened, a total number of 800 patients were included in the study. In these 800 patients; total 3650 drugs were prescribed. Average number of drugs per prescription were 4.56 (3650), of which 1.36 (1090) were antibacterials.

The percentage of encounters with at least one antibacterial were 38% (800) and the percentage of antibacterials prescribed by generic name was 45% (489). A total of 0.5% (5) of antibacterials were prescribed in injection form, and 87.3% (952) were prescribed from the essential drugs list. The percentage of antibacterials in FDCs was 31% (335) **Table 2 & 3, Fig. 1, 2, 3 & 4**.

TABLE 2: VALUES FOR WHO PRESCRIBING INDICATORS

S. no.	Prescribing Indicators	Total
1	No. of drugs prescribed	3650
2	Number of antibacterials prescribed	1090
3	Number of antibacterials prescribed from EDL-Haryana	952
4	Number of antibacterials prescribed by generic name	489
5	Number of antibacterials prescribed in injections form	5
6	Number of antibacterials in FDCs (fixed dose combinations)	335

TABLE 3: WHO PRESCRIBING INDICATORS

S. no.	Prescribing Indicators	Average/ Percentage	WHO Standards
1	Percentage of encounter with at least one antibacterial	38%	20.0%-26.8%
2	Average number of drugs per prescription	4.56	<5
3	Average number of antibacterials per prescription	1.36	1.6-1.8
4	Percentage of antibacterial prescribed by generic name	45%	100%
5	Percentage of antibacterial prescribed in injection form.	0.5%	13.4%-24.1%
6	Percentage of antibacterials prescribed from essential drugs list	87.3%	100%
7	Number of antibacterials in FDCs (fixed dose combinations)	31%

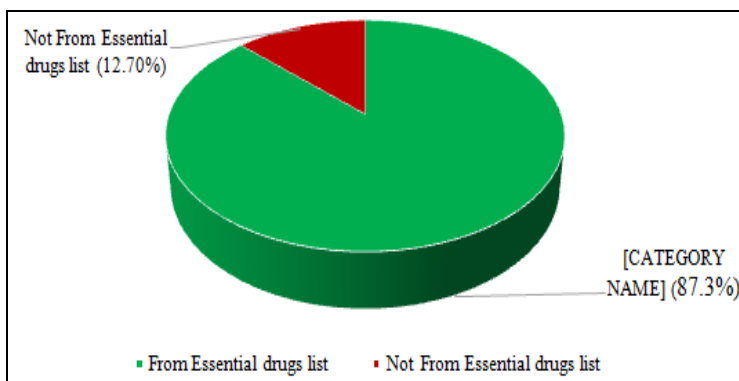


FIG. 1: ANTIBACTERIALS PRESCRIBED FROM ESSENTIAL DRUG LIST

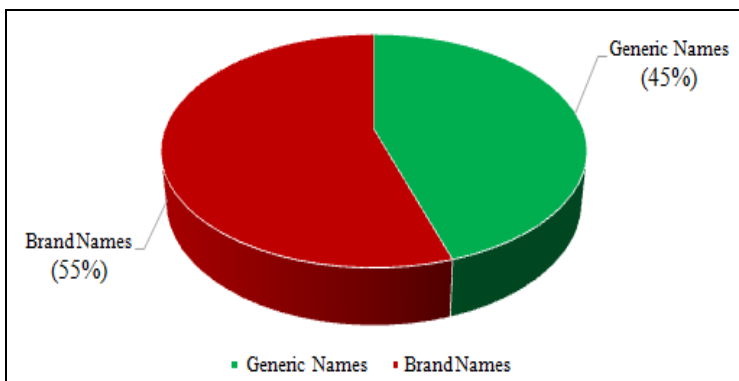


FIG. 2: ANTIBACTERIALS DISTRIBUTION WITH RESPECT TO GENERIC NAMES

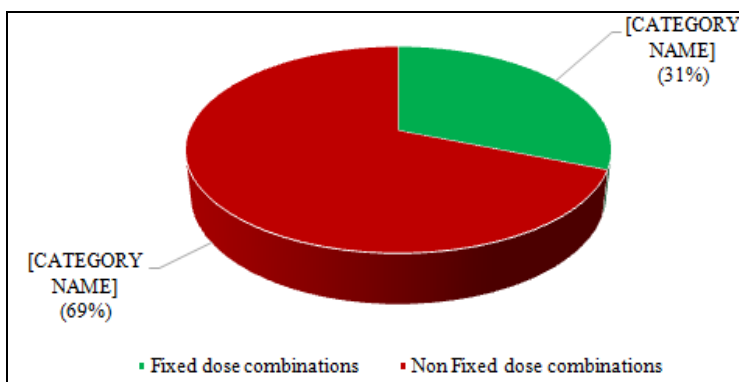


FIG. 3: ANTIBACTERIALS DISTRIBUTION WITH RESPECT TO FIXED DOSE COMBINATIONS

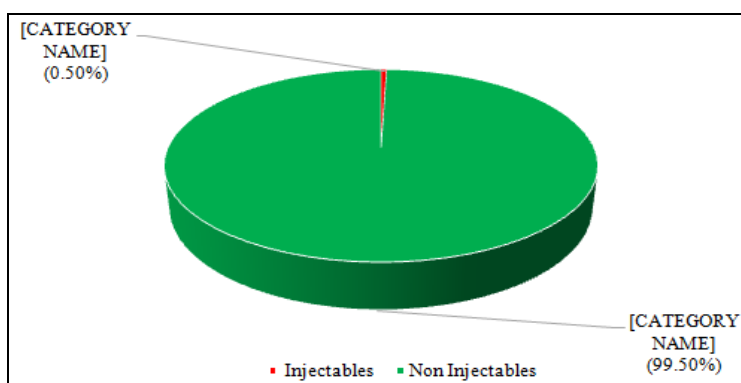


FIG. 4: ANTIBACTERIALS DISTRIBUTION WITH RESPECT TO DOSAGE FORMS

DISCUSSION:

Sociodemographic Characteristics: Age-wise distribution of the patients was analyzed, and it was found that the maximum patients were in the adult age group (19-44 years) followed by in the paediatric age group (0-18 years). A similar study conducted by Mayank *et al.*⁹ also noted that the maximum number of patients were 20 – 40 years old. The data in our study based on age-wise distribution is also comparable to the results of study done by Kanishk Kala *et al.*¹⁰ but a study conducted by Prachi Tayal *et al.*¹¹ showed that maximum number of the patients were in the age group 51-60 years.

WHO Prescribing Indicators: A total of 3650 drugs were prescribed in 800 patients. In our study, average number of drugs per prescription were 4.56 (3650) and this is within the normal range of WHO Ideal Value (≤ 5).¹² On average, 1.36 (1090) per prescription were antibacterials (lower than the range recommended by WHO, with a limit of 1.6–1.8). These results are nearly similar to 4.1 & 4.7 reported in previous studies conducted by Roland Nnaemeka Okoro *et al.*¹³ and Nirav N Patel *et al.*¹⁴. A study conducted in South India by Mamatha V *et al.*¹⁵ found an average of 6.73 drugs/prescription and 1.24 antibacterials/ prescription. A higher average of antibacterials per prescription (2.21) were reported by Nirav N Patel *et al.*¹⁴. The lower the number of drugs prescribed per patient, the more appropriate is the prescription practice. It declines polypharmacy, which reduces disease complications caused by drug interactions and adverse drug reactions. However, symptomatic treatment of cases increases the number of drugs per prescription. The percentage of encounters with at least one antibacterial was 38% (800), which is higher than WHO reference value of 20.0-26.8%.

However, it is lower than other studies conducted by Kanishk Kala *et al.*¹⁰ and Mamatha V *et al.*¹⁵. A higher percentage of encounters with at least one antibacterial is possibly suggesting an indiscriminate use of antibacterials. Although, high antibacterial use can be associated with an increased rate of local infections.

In the current study, 87.3% (952) of all prescribed antibacterials were from the essential drugs list of Haryana. A lower percentage of antibacterials from the essential drugs list (82.9%) were reported in previous studies conducted by Roland Nnaemeka Okoro *et al.*¹³ and Kanishk Kala *et al.*¹⁰ Similarly, high rates (over 85%) have been obtained from a study carried out by Mamatha V *et al.*¹⁵. These findings indicate that there is still enough room for improvement to attain the 100% benchmark in our study setting. A low percentage of drugs prescribed from an EDL may highlight prescriber's lack of awareness of the role of EDL in cost-effectiveness augmentation or general nonadherence to prescribing guidelines.

However, in an interesting twist, the percentage of antibacterials prescribed by generic name were 45% (489), which is considerably lower than the standard of 100%. This finding denotes an underuse of generic antibacterials in the study setting. This finding of our study is consistent with the results reported by previous studies conducted by Roland Nnaemeka Okoro *et al.*¹³ and Mamatha V *et al.*¹⁵. A less percentage of generic antibacterials (33% and 26.7%) were reported by a study conducted by Kanishk Kala *et al.*¹⁰ and Nirav N Patel *et al.*¹⁴. Generics are generally less expensive than their branded counterparts and reduce the patients' economic burden. Generic prescribing also has the added benefit of decreasing

dispensing errors due to misidentification of the prescribed drug. A low percentage of antibacterials prescribed by generic name can indicate unavailability of cost-effective generic antibacterials because of patency concerns, prescriber's lack of confidence in generic antibacterials and patients choice of branded products.

In our study, 0.5% (5) of antibacterials were prescribed in injectable form. Overusing injectables increases economic costs and health hazards as non-sterile injection contributes to transmitting hepatitis, HIV, AIDS and other blood-borne diseases. In this study, the percentage of encounters with injectables were lower than the recommended range of WHO (13.4%-24.1%) because it is an OPD-based study and instead of including all drugs, only the encounters with antibacterials were included. A higher percentage of antibacterials prescribing in injectable form highlights issues like prescriber's skill, emergency issues and biased understanding on the potency of various antibacterial formulations (oral versus injectable forms). In the present study, the percentage of antibacterials in FDCs was 31% (335).

Strength & Limitations: The sample size and duration of our study were appropriate as per recommendations of WHO, study design was also prospective and patients of all age groups were included in the study. This study has generated baseline data for comparison with similar studies at state, national, and international level and similar type of studies in the future at this institution. Obviously, this study will help establish antimicrobial prescribing guidelines in our tertiary care setup and augment rational prescribing. Possible limitations of the present study were the lack of inclusion of patients from the inpatient department.

CONCLUSIONS: In our study, the percentage of encounters with at least one antibacterial was higher than WHO reference value, although the average drug per prescription was within the normal range. As per WHO recommendations, More generic prescriptions are needed in our hospital setting. Prescribing from the essential drug list is near the WHO target value, but there is still enough room for improvement to attain the 100%

benchmark in our study setting. By conducting drug utilization studies, we can sensitize the prescribers to develop rational prescribing habits by WHO prescribing indicators.

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