

Prospective Cross Sectional Observational Study On Evaluation Of Drug Use Pattern Using WHO Core Indicators In Paediatric Department Of Tertiary Care Teaching Hospital

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ABSTRACT:

Context: The study delivers a thorough evaluation of the use of World Health Organization (WHO) prescribing indicators in the pediatric patient population at a tertiary care hospital, offering comprehensive insights into their implementation, adherence, and potential impact on prescription practices.

Aim: The aim is to evaluate the drug use pattern and assess the rational use of drugs in pediatrics using the WHO core drug indicators.

Settings and Design: The study was a prospective, cross-sectional observational study conducted over a period of 6 months at the pediatric outpatient department (OPD) and inpatient department (IPD) of a tertiary care teaching hospital.

Materials and Methods: This included consent form and Data collection form.

Statistical Analysis: Statistical measures, including frequency, average, percentage, and variable measures such as mean, median, mode, and standard deviation, were calculated using SAS 9.4 and Microsoft Excel.

Results: A total of 750 prescriptions were included in the study, with the majority of patients being male (391, 50.20%). The mean age of the patients was 4.92 years (SD±3.79.), ranging from 2 days to 17 years. The average number of drugs per prescription was 4.38 (SD±2.72). A high 85.60% of medications were prescribed by their generic names. Antibiotics were prescribed in 26.95% of prescriptions, while injections were prescribed in 47.15%. Medications included in the essential drug list (EDL) accounted for 87.40% of prescriptions. Additionally, 100% of the drugs were appropriately labelled and dispensed. The average consultation time was 9.99 minutes, and the dispensing time was 68.8 seconds.

Conclusion: The study highlighted areas of pediatric prescribing that require improvement, including excessive medications, antibiotic, and injection prescriptions. However, it found high rates of generic prescribing, adequate labelling, and optimal dispensing. Recommendations include regular audits, evidence-based guidelines, and training programs to enhance pediatric prescribing practices and ensure patient safety.

Keywords – Paediatrics , WHO core indicators , Drug Use Pattern.

INTRODUCTION:

The 1985 WHO conference in Nairobi developed key indicators for rational drug use, sparking increased global efforts and objective assessments of drug use and prescribing in healthcare⁽¹⁾. Rational drug use, according to WHO, means patients get the right medication, at the right dose, for the right time, and at the lowest cost⁽²⁾. Irrational drug prescribing is a worldwide problem driven by doctor experience, patient requests, complex illnesses, and Drug Company marketing⁽³⁾. Medicines are vital for health, and prescriptions are a key way doctors communicate with patients⁽⁴⁾. Prescription audit is vital in medical auditing, which reviews healthcare worker actions to improve patient care and resource use. A prescription is a doctor's written order for patient health management, with pharmacists/nurses playing a key role in medication use⁽⁵⁾. A drug prescription, usually the last step in a consultation, is a formal, medico-legal instruction from a prescriber to a dispenser that needs to be clear, accurate, and complete. While formats differ slightly, core components are generally agreed upon⁽⁶⁾. Misinterpreting a prescription can lead to wrong treatment, worsened health, complications, financial loss for the patient, and wasted resources. Medications mainly aim to prevent, treat, or manage illnesses⁽⁴⁾. Irrational medicine use, encompassing practices like unnecessary polypharmacy, antibiotic overuse, inadequate dosing, and excessive reliance on injections over oral medications, undermines patient safety and treatment success. Furthermore, deviating from evidence-based guidelines, preferring expensive brand-name drugs over equally effective generics, and inappropriate self-medication contribute to escalating healthcare costs and the alarming rise of antimicrobial resistance⁽⁷⁾. A recent study found that junior doctors and interns, who write most hospital prescriptions, make a wide range of errors (2-510 per 1,000 prescriptions), affecting 5.2% to 72% of patients⁽⁵⁾. Paediatric prescriptions are more complex than adult ones because dosages often depend on weight, and some drugs are unsuitable or need extra care for children⁽⁸⁾. Best treatment results for children require accurate diagnosis and then evidence-based medication tailored to each child's needs for effective outcomes⁽⁹⁾. For many years, children's medications were often prescribed using information from adult studies because there wasn't enough research specifically on the safety and effectiveness of drugs in children⁽¹⁰⁾. Limited child participation in drug trials due to cost and ethics means we lack full understanding of how drugs work in them. Also, children often don't stick to treatment plans because of complicated dosing and taking many medicines⁽¹¹⁾. A systematic review conducted in the UK found that paediatric prescriptions experience roughly 500,000 dosing errors each year⁽¹²⁾. Irrational medicine use is especially harmful to children, with infants and pre-schoolers receiving the most prescriptions, according to studies⁽¹³⁾. Irrational medication use is more common in developing countries due to weaker healthcare systems and less robust monitoring of how medicines are used⁽¹²⁾. Despite much research on adult drug use, there's little data on how children use drugs. This is worrying because children are more prone to infections and react to drugs differently than adults, making them more likely to have side effects. Also, what mothers take during pregnancy can affect new-borns⁽⁹⁾. Ensuring children use medications safely and correctly is vital. Healthcare providers can give effective, evidence-based treatment when they have reliable access to necessary medicines⁽⁸⁾. Regular audits by trained pharmacists and prescribing based on evidence are key to making children's treatments consistent, safer, and more effective, leading to better health⁽¹⁰⁾. Irrational medicine use causes

unsafe/ineffective treatment, longer illnesses, patient harm, higher costs, worsening chronic diseases (like diabetes, hypertension, epilepsy), and antibiotic resistance (a major public health risk). Addressing this requires identifying the types and extent of irrational use and its causes. Understanding these factors allows healthcare systems to create focused strategies to promote rational medicine use, improving patient outcomes and lowering risks and costs ⁽¹⁴⁾. INRUD and WHO jointly developed a range of indicators offering objective ways to measure drug use and guide necessary changes ⁽¹⁰⁾. Encouraging rational medicine use is vital for successful National Medicine Policies (NMPs), and WHO has set up key measures to assess drug usage, including: Prescribing Indicators, Patient Care Indicators and Facility Indicators.

I. Prescribing Indicators:

1. Average number of drugs per encounter: To measure the degree of polypharmacy.

Calculation: Average, calculated by dividing the total number of different drug products prescribed, by the number of encounters surveyed.

2. Percentage of drugs prescribed by generic name: To measure the tendency to prescribe by generic name.

Calculation: Percentage, calculated by dividing the number of drugs prescribed by generic name by the total number of drugs prescribed, multiplied by 100

3. Percentage of encounters with an antibiotic prescribed: To measure the overall level of uses of two important, but commonly overused and costly forms of drug therapy.

Calculation: Percentage, calculated by dividing the number of patient encounters during which antibiotics are prescribed, by the total number of encounters surveyed, multiplied by 100.

4. Percentage of encounters with an injection prescribed: To measure the overall level of use of two important, but commonly overused and costly forms of drug therapy.

Calculation: Percentage, calculated by dividing the number of patient encounters during which injections are prescribed, by the total number of encounters surveyed, multiplied by 100.

5. Percentage of drugs prescribed from essential drugs list or formulary: To measure the degree to which practices conform to a national drug policy, as indicated by prescribing from the national essential drugs list or formulary for the type of facility surveyed.

Calculation: Percentage, calculated by dividing the number of products prescribed which are listed on the essential drugs list or local formulary (or which are equivalent to drugs on the list) by the total number of products prescribed, multiplied by 100.

II. Patient Care Indicators:

5 Average consultation time: To measure the time that medical personnel spend with patients in the process of consultation and prescribing.

Calculation: Average, calculated by dividing the total time for a series of consultations, by the number of consultations.

6 Average dispensing time: To measure the average time that personnel dispensing drugs spend with patients.

Calculation: Average, calculated by dividing the total time for dispensing drugs to a series of patients, by the number of encounters.

7 Percentage of drugs actually dispensed: To measure the degree to which health facilities can provide the drugs which were prescribed.

Calculation: Percentage, calculated by dividing the number of drugs actually dispensed at the health facility by the total number of drugs prescribed, multiplied by 100.

8 Percentage of drugs adequately labelled: To measure the degree to which dispensers record essential information on the drug packages they dispense.

Calculation: Percentage, calculated by dividing the number of drug packages containing at least patient name, drug name and when the drug should be taken, by the total number of drug packages dispensed, multiplied by 100.

9 Patients' knowledge of correct dosage: To measure the effectiveness of the information given to patients on the dosage schedule of the drugs they receive.

Calculation: Percentage, calculated by dividing the number of patients who can adequately report the dosage schedule for all drugs, by the total number of patients interviewed, multiplied by 100.

III. Facility Indicators:

10 Availability of copy of essential drugs list or formulary: To indicate the extent to which copies of the national essential drugs list or local formulary are available at health facilities

Calculation: Yes or no, per facility ⁽¹⁵⁾.

These quantitative metrics have been adopted as universal benchmarks for identifying prescribing issues and have been widely applied in over 30 developing countries ⁽²⁾.

TABLE-1: Core Drug Use Indicators and their Optimal Values

Indicator	Optimal Values
Prescribing Indicators	
Average Number Of Drugs Prescribed Per Patient Encounter	1.6-1.8
Percent Generics	100
Percent Antibiotics	20.0-26.8
Percent Injections	13.4-24.1
Percent Drugs On EDL	100
Patient Care Indicators	
Average Consultation Time(Min)	≥ 10
Average Dispensing Time (Sec)	≥ 90
% Drugs Dispensed	100
% Medicines Adequately Labeled	100
% Adequate Knowledge	100
Facility Indicators	
% Drugs In Stock	100
Availability Of EDL/Formulary	Yes

(NOTE: Data is obtained from WHO source) ^(16, 17)

MATERIALS AND METHODS:

Study population:-

The study population includes children attending pediatric OPD and IPD of the hospital.

Study design:-

This study is a prospective cross-sectional observational study.

Study duration:-

This study was conducted for 6 months (August 2024–January 2025).

Study criteria:-

The inclusion criterion is patient's ≤ 18 years from OPD & IPD of any medical illness, and the exclusion criteria are medico-legal cases and who are not willing to participate.

Sampling method:-

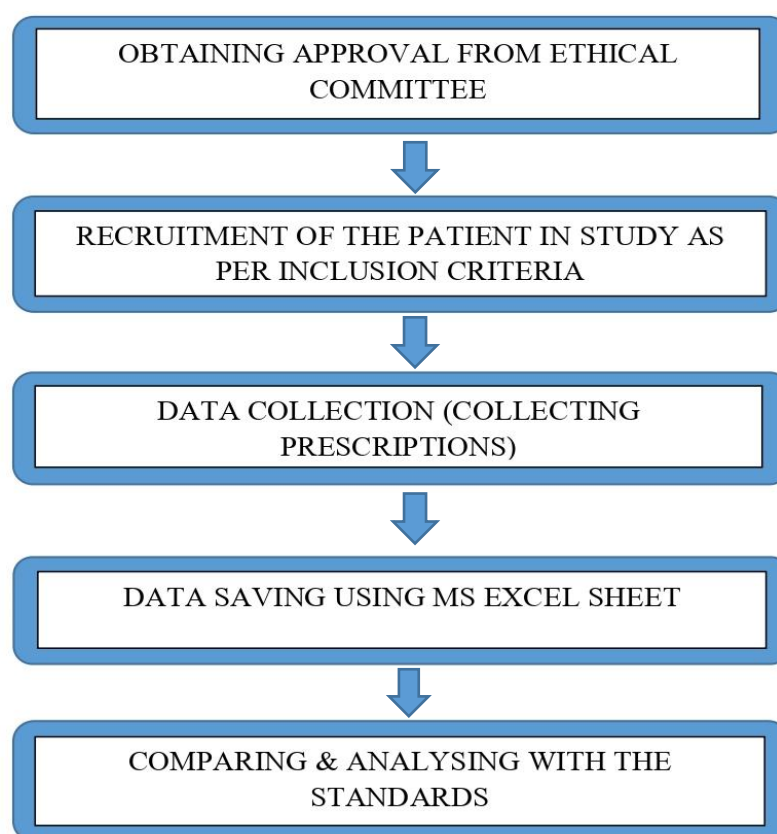
The sampling method used was convenience sampling.

Statistical analysis:-

Statistical measures, including frequency, average, percentage, and variable measures such as mean, median, mode, and standard deviation, were calculated using SAS 9.4 and Microsoft Excel.

Ethical approval:-

The protocol proposed for the conduction of this study was approved by Institutional Ethics Committee of Anil Neerukonda Hospital (ANH) located in Visakhapatnam; a multi-specialty hospital covering maximum number of cases in north coastal Andhra Pradesh.

PROCEDURE:**RESULTS:**

A total of 750 prescriptions were collected. Age, gender, locality status, socio-economic status and patient Education were actually, the five primary

parameters targeted for evaluating prescriptions. The weight & height were considered as secondary parameters for evaluation.

Among 750 patients, 391 (52.20%) were male and 359 (47.80%) were female (Figure 1). The mean age of the patients was 4.92(SD±3.79) years, with a range of 2 days to 17 years (Figure 2). The highest number of patients, 436 (58.13%), were from urban areas, with the majority falling into the lower middle (III) socioeconomic category, 328 (43.73%). A significant portion of these patients were infants (no education), as well as those with primary education, comprising 303 (40.40%) and 252 (33.60%), respectively [Table 2]. The average weight and height of the patients were 15.38 ± 8.50 kg and 160.94 ± 29.32 cm, respectively.

TABLE -2: CHARACTERISTICS OF STUDY PARTICIPANTS (n=750)

Characteristics		N	Percentage (%)	Mean	Standard Deviation
Gender	Male	391	52.20%	375	±22.63
	Female	359	47.80%		
Age	<29 Days	13	1.73%	4.29	±3.79
	1M-1yr	169	22.53%		
	1.1-5 yrs	236	31.46%		
	5.1-12 yrs	321	42.80%		
	12.1-18 yrs	11	1.46%		
Locality Status	Metro	30	4%	187.5	±173.88
	Urban	436	58.13%		
	Sub Urban	142	18.93%		
	Rural	142	18.93%		
Socio-Economic Status	Upper(I)	0	0%	150	±122.76
	Upper Middle (II)	194	25.80%		
	Lower Middle (III)	328	43.73%		

Patient Education	Upper Lower (IV)	86	11.46%	150	±134.08
	Lower (V)	142	18.93%		
	No Education	303	40.40%		
	Pre-School	169	22.53%		
	Primary School	252	33.60%		
	Middle School	23	3.06%		
	High School	3	0.40%		

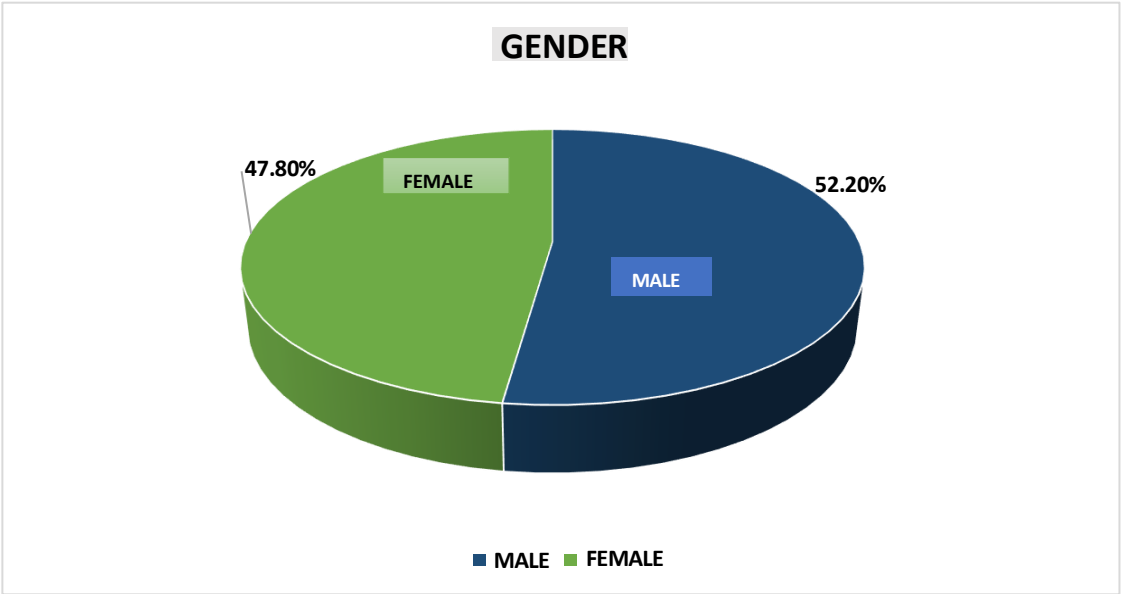


Figure: 1 Gender wise distribution.

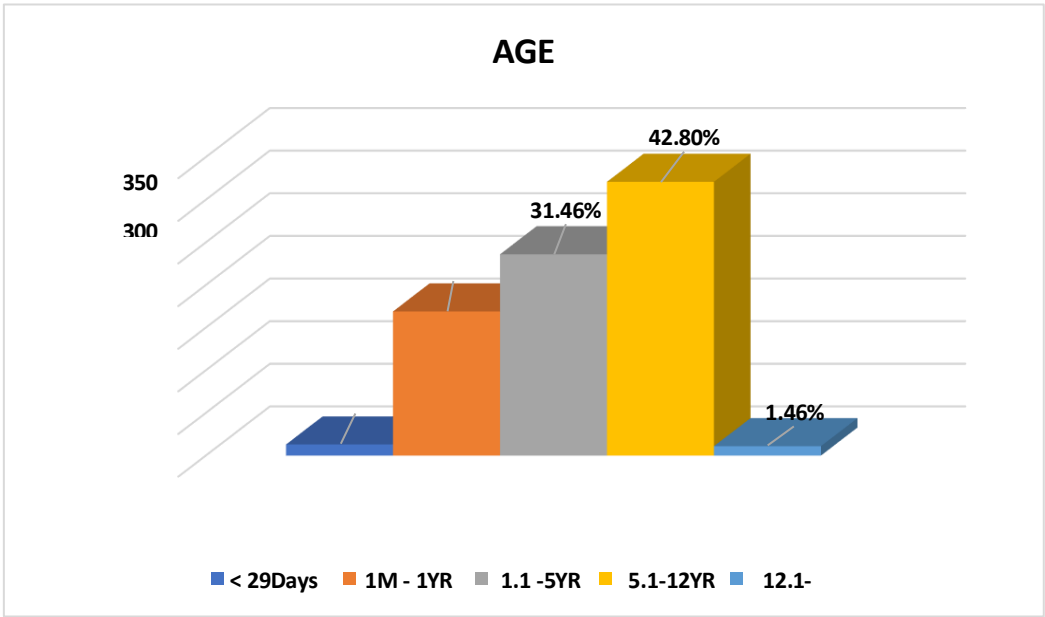


Figure: 2 Age wise distribution.

A total of 3272 drugs were prescribed in 750 prescriptions. The number of drugs per encounter ranged from one to thirteen [Figure 3].

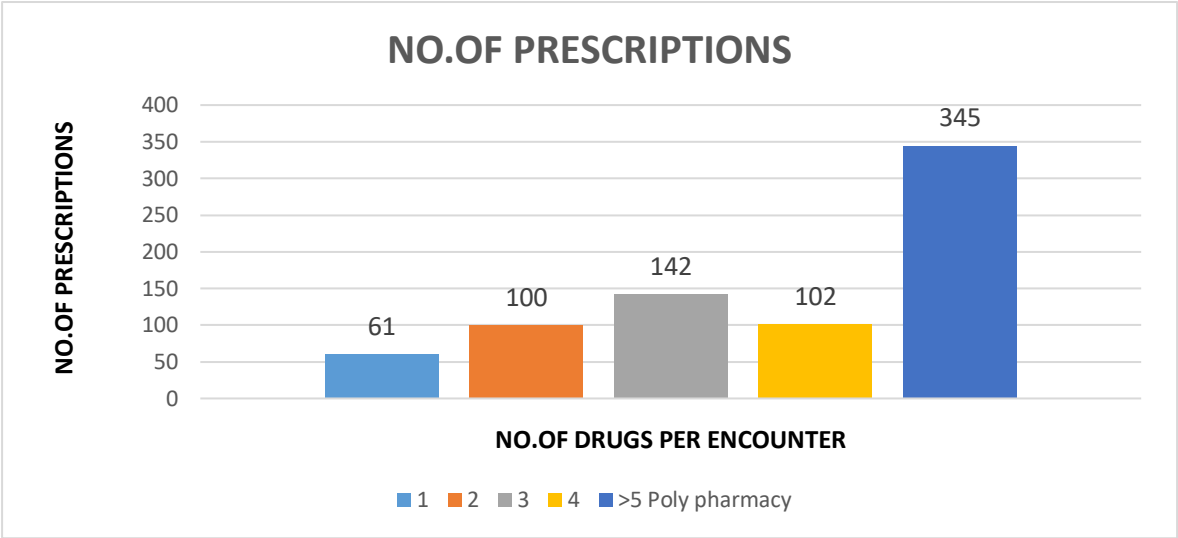


Figure-3 Number of the per drug prescriptions.

Among the prescribing indicators, we found that the average number of drugs per prescription was 4.36(±2.72). Only 2801 (85.60%) drugs were prescribed by generic name. Antibiotics and Injections were prescribed in 882 (26.95%) and 1543 (47.15%) prescriptions, respectively. Drugs that were prescribed from the EDL were only 2860 (87.40%) drugs (Table 3] [Figure 4].

TABLE - 3:

PRESCRIBING INDICATORS ASSESSED	TOTAL DRUGS/ ENCOUNTER	AVERAGE/ PERCENTAGES (%)
AVERAGE NO. OF DRUGS PER ENCOUNTER	3272	100%
GENERIC	2801	85.60%
ANTIBIOTICS	882	26.95%

INJETIONS	1543	47.15%
EML	2860	87.40%
PATIENT CARE ASSESSED	TOTAL DRUGS/ ENCOUNTER	AVERAGE/ PERCENTAGES (%)
DISPENSED DRUGS	3272	100%
LABELLED DRUGS	3272	100%

SUMMARY OF RESULTS OF AN OUTPATIENT/INPATIENT STUDY AT ANH:

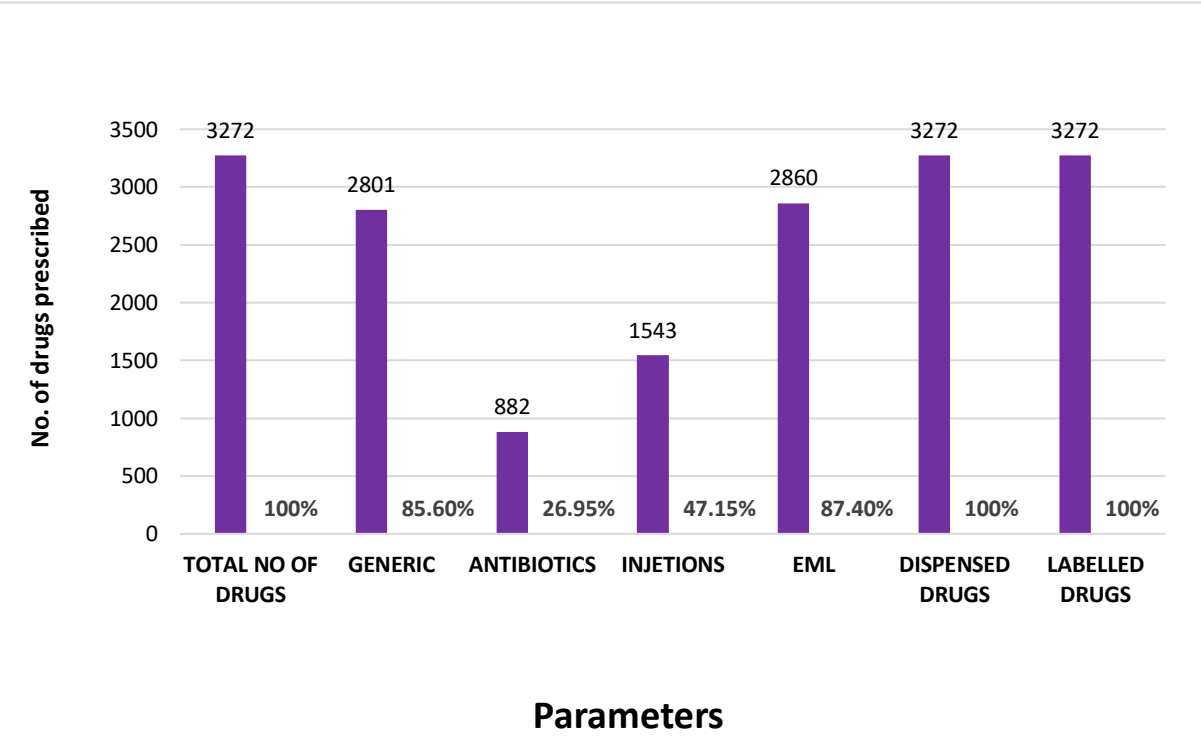


Figure -4 Represents the proportion the drugs prescribe WHO CDI metrics

Out of 750 prescriptions, drug dispensing and labelling were performed with 100% accuracy. The average consultation time was 9.99 minutes, and the dispensing time was 68.8 seconds per prescription. Additionally, the percentage of patient or guardian knowledge was 75.18% [Table 4].

**TABLE-4: COMPARISON WITH THE OPTIMAL VALUES OF WHO
CORE DRUG INDICATORS:**

INDICATOR	Results	Optimal Values
Prescribing Indicators		
Average Number of Drugs Prescribed Per Patient Encounter	4.35	1.6-1.8
Percent Generics	85.60%	100%
Percent Antibiotics	26.95%	20.0-26.8%
Percent Injections	47.15%	13.4-24.1%
Percent Drugs On EML	87.40%	100%
Patient Care Indicators		
Average Consultation Time (Min)	9.99	≥ 10
Average Dispensing Time (Sec)	68.8	≥ 90
% Drugs Dispensed	100%	100%
% Medicines Adequately Labeled	100%	100%
% Adequate Knowledge	75.18%	100%
Facility Indicators		
Availability Of EDL/Formulary	Yes	Yes

DISCUSSION:

Core Drug Indicators (CDIs) in Pediatric Pharmaceutical Use: An Updated Assessment Core Drug Indicators (CDIs) are vital metrics for monitoring and assessing drug use patterns and prescribing behaviour, particularly in pediatric populations. These indicators are crucial for addressing issues such as dosing inaccuracies and irrational drug use, which are common in children. Our study provides an updated evaluation of WHO prescribing indicators within a pediatric population at a tertiary care teaching hospital. The study included 750 patients aged ≤ 18 years and was a prospective, cross-sectional observational analysis.

Patient Demographics and Age Distribution

The majority of prescriptions in our study were for children under 5 years old (31.46%), with infants accounting for 24.53%. The mean age ranged 4.92 years ($SD \pm 3.79$). These findings are consistent with those of Lawal Waisu Umar et al. ⁽¹⁸⁾, who reported 31.8% prescriptions for children up to 5 years, including 28.1% for infants, with a mean age of 3.2 years. Similarly, Suwitha S et al. ⁽¹³⁾ reported that the largest group of prescriptions (45%) were for children aged 1-5 years, while Rahul et al. ⁽¹⁹⁾ found 51.6% of prescriptions in this age group. In contrast, Alitta Prasad et al. ⁽²⁰⁾ had a mean patient age of 5.87 years, while other studies, like Jose and Devassykutty's ⁽⁸⁾, reported a mean age of 6.1 years.

Gender Distribution and Socio demographic Factors

The gender distribution in our study showed a slight male predominance, with 52.20% male patients and 47.80% female patients, aligning with other studies by Suwitha et al. ⁽¹³⁾, Sharma and Shweta ⁽¹⁰⁾, and others, which reported higher male proportions. However, some studies, such as those by Alitta Prasad et al. ⁽¹⁶⁾ and Harshal N Pise et al. ⁽²¹⁾, found a female predominance. Additionally, 58.13% of prescriptions in our study were from urban areas, and 43.73% of subjects belonged to the lower middle-class population, as determined by the Kuppuswamy scale.

Medication Use and Polypharmacy

The average number of medications per prescription was found to be 4.36 ($SD \pm 2.72$), which exceeds the WHO's recommended threshold of fewer than 2 medications per prescription. Studies by Sharma and Shweta ⁽¹⁰⁾ and Desalegn ⁽²²⁾ adhered to this guideline, with an average of 1.9 medications per prescription. However, several other studies, such as those by Pise et al. ⁽²¹⁾ and Thiruthopu et al. ⁽²³⁾, reported higher averages (3.4 and 4.56 medications, respectively). Polypharmacy, or the prescription of multiple medications, increases the risk of drug-drug interactions and adverse drug reactions, especially in pediatric populations. The high number of prescribed drugs is associated with higher healthcare costs and a greater likelihood of non-compliance, as complex regimens are harder for pediatric patients to follow.

Drug Prescribing Practices

Our study found that 85.60% of drugs were prescribed by their generic names, which is consistent with the practices of Jinish Jose et al. ⁽⁸⁾ and other studies that reported high rates of generic drug prescribing. However, some studies, like those by Dr. D. Sharad Gedam et al. ⁽⁹⁾ and Alitta Prasad et al. ⁽²⁰⁾, found much lower rates of generic prescribing (2.69% and 4.21%, respectively). Prescribing generic drugs ensures cost-effectiveness and patient safety, and higher rates of generic prescribing are encouraged by WHO.

Antibiotic Prescriptions and Resistance

In our study, 26.95% (882) of encounters involved the prescription of antimicrobials, which is close to the WHO's recommended target of below 30%. However, this rate still presents concerns regarding antibiotic overuse, which can lead to antibiotic resistance. Similar studies, like those by Berha and Seyoum ⁽²⁴⁾ and Bansal et al. ⁽²⁵⁾, reported lower antibiotic prescription rates, while studies like those by Akhtar et al. ⁽¹¹⁾ and Pandey et al. ⁽²¹⁾ found much higher rates (81.12% and 79%, respectively). Reducing the use of antibiotics in pediatric populations is crucial to mitigate resistance and minimize healthcare costs.

Injectable Medications and WHO Standards

Injectable medications were prescribed in 47.15% (1543) of the 750 encounters in our study, which exceeds the WHO recommended upper limit of 20%. This rate is much higher than those found in studies by Faris El-Dahiyat et al. ⁽²⁶⁾ and Atif M et al. ⁽²⁷⁾, who reported lower rates of injectable prescriptions (16.9% and 27%, respectively). Overuse of injectable drugs increases the risk of complications and healthcare costs, so adherence to WHO standards is necessary.

Essential Drugs List (EDL) Prescribing

In our study, only 87.40% of drugs were prescribed from the WHO Model List of Essential Medicines for Children (EDL). This is lower than the optimal rate, which is ideal for ensuring safety, effectiveness, and cost-effectiveness in treatment. Other studies, such as those by Berha and Seyoum ⁽²⁴⁾ and Irunde et al. ⁽²⁸⁾, also reported lower rates of EDL prescribing (96.5% and 96.7%, respectively). Ensuring that drugs prescribed are on the essential medicines list can improve the quality of care and lower treatment costs.

Drug Dispensing and Labelling

Drug dispensing was 100% in our study, which meets the WHO standard. This is similar to findings by Jinish Jose and Denny Devassykutty ⁽⁸⁾, who also reported 100% drug dispensing, while Haiqa Hafeez et al. ⁽²⁾ found lower rates in their studies (89.3% and 98%). Adequate drug labelling is critical, and our study met the WHO standard with 100% compliance, ensuring that essential details such as dosage and patient information were clearly provided.

Knowledge and Awareness

The percentage of patients or patient guardians with adequate knowledge about medications in our study was 75.18%, which is lower than the WHO standard of 100%. Similar findings were observed in other studies, such as Sissay et al. ⁽²⁹⁾, which reported 75.7% in eastern Ethiopia. Ensuring that caregivers and patients have adequate knowledge about the medications they are taking is crucial to prevent misuse and improve adherence to prescribed treatments.

Drug Dispensing Time and Consultation Time

The average dispensing time observed in our study was 68.8 seconds, which is below the WHO-recommended threshold of over 90 seconds. Short dispensing times could indicate rushed or inadequate interactions between healthcare providers and patients, potentially compromising the quality of care. In contrast, other studies, like those by Haiqa Hafeez et al.⁽²⁾, reported dispensing times of 13.5 seconds and 29 seconds in different facilities, which were much lower than the WHO recommendation. However, the study by Faris El-Dahiyat et al.⁽²⁶⁾ reported a substantially higher average dispensing time of 9.6 minutes, which may indicate a more thorough dispensing process.

The average consultation time in our study was 9.99 minutes, which is just below the WHO standard of over 10 minutes. However, it remains within an acceptable range. In contrast, some studies like those by Haiqa Hafeez et al.⁽²⁾ and Mohammad Atif et al.⁽²⁷⁾ reported much shorter consultation times (1.5 minutes and 1.2 minutes, respectively), which may compromise patient care.

Availability of Essential Drugs List

The availability of the essential drugs list (EDL) in our study was 100%, meeting the WHO standard of 100%. This indicates effective utilization of the essential medicines list by healthcare providers. However, some studies, like those by Haiqa Hafeez et al.⁽²⁾, reported availability rates of 90% and 95% in different facilities.

CONCLUSION:

The study revealed that while some aspects of pediatrics prescribing practices were satisfactory other requires improvement. Specifically the average no. of medications per prescription exceeds the optimal recommendations and the percentage of antibiotics prescription was higher than recommended and the percentage of injections prescribed exceeded the recommended. However, the study also found high rates of generic prescribing, adequate drug labelling, and optimal dispensing practices. The average consultation time was slightly below than the recommended standards, while the average dispensing time was lower than optimal. Patient knowledge about medication was adequate, but not optimal. The availability essential drugs and the essential drugs list (EDL) or formulary was satisfactory. Overall, the study highlights the need for ongoing monitoring and evaluation of pediatrics prescribing practices to ensure optimal patient care and safety. Recommendation like regular audits, development and implementation of evidence based guidelines, education and training programs for health care professionals on rational pediatrics prescribing practices.

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