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Original Article

Identifying Prescription Gaps Using WHO Core Indicators: A Pediatric Audit from a Rural Setting

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ABSTRACT

Background and Aim: Infants and children are especially susceptible to medication errors due to their recurrent illnesses and unique physiological traits. This underscores the significance of rational and evidence-based prescribing in paediatric care. **Materials and Methods:** This study examined 730 paediatric prescriptions from outpatient and inpatient departments at the MM Institute of Medical Sciences and Research over a period of five months, utilising World Health Organisation (WHO) core drug usage indicators. Excluding seriously sick patients. **Results:** The study found a 60% male predominance, with 78% of patients living in rural areas. Notwithstanding this, 88.6% of carers possessed literacy skills and 40% were highly educated, resulting in a dosage comprehension rate of 99.3%, despite only 97.5% of given prescriptions being appropriately labelled. Each prescription averaged 3.16 medications, with generic prescriptions constituting 40.49% and Fixed-Dose Combinations (FDCs) comprising 60.68%. The mean durations for consultation and dispensing were 13.9 min and 7.8 min, respectively. **Conclusion:** The study recommends reducing polytherapy, using generics, minimizing fixed-dose combinations, improving dispensing times, and increasing education to enhance care quality and align with World Health Organization standards.

Keywords: Fixed Dose Combinations, National List of Essential Medicines, Pediatric, Prescription, World Health Organization.

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INTRODUCTION

According to the World Health Organisation (WHO), the responsible use of pharmaceuticals is an essential part of global health care, ensuring that every patient receives medications that are appropriate for their clinical needs, in the appropriate dosages, for an adequate period of time, and at the lowest possible cost to them and their community. The WHO has developed core prescribing indicators to assess prescribing practices methodically which enable comparisons across healthcare settings and offer a uniform standard for prudent prescribing. It encompasses selecting the appropriate medication, prescribing it accurately, administering it appropriately, and ensuring patient compliance.

Prescription analysis serves as a valuable method to systematically assess prescribing patterns, improve patient care, minimize medication error and boost therapeutic results. Irrational prescribing can result in unsafe treatments, worsening health, and higher costs, often due to patient pressure, peer influence, and aggressive marketing. Analyzing prescriptions helps ensure the right medication is prescribed at the correct dose and duration, enhancing safety and treatment effectiveness (Shrestha *et al.*, 2019; D'Errico *et al.*, 2022).

Writing a *prescription* is a vital part of healthcare, but common mistakes can occur, such as errors of omission and commission. Omission errors include omitting key details like the format, dosage, frequency, duration, special instructions, and warnings. Whereas the commission errors involve prescribing too many drugs, unnecessary antibiotics, injectable forms when not needed, or costly medications instead of cheaper alternatives. Additionally, prescribing drugs without indication or those that increase the risk of adverse drug reactions is problematic (Joshi *et al.*, 2022; Thiruthopu *et al.*, 2014; Sema *et al.*, 2021). Errors in medication administration may compromise patient safety and healthcare quality, resulting in extended hospital stays or even mortality (Joshi *et al.*, 2022).

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In developing nations, a significant portion of the population consists of infants and children. Research shows that children are more susceptible to the negative effects of drug errors and irrational prescribing than adults. The chances of treatment errors in children were shown to occur in a 1:6.4 proportion during hospital admissions, with around 31% of these errors resulting in pediatric mortality, compared to 13% in adult admissions (Viswanath *et al.*, 2019). This higher incidence of death may be due to children's limited ability to communicate effectively with healthcare practitioners and the fact that most pharmaceuticals are primarily designed for adults. Additionally, children are more vulnerable to adverse drug reactions due to their underdeveloped kidneys, immune systems, and livers, which affect pharmacokinetic and pharmacodynamic properties. Given these challenges, it is essential to practice evidence-based prescribing to ensure the efficient and safe administration of medications for pediatric patients (Joshi *et al.*, 2022).

A prescription analysis effort helps to make sure that drugs given to pediatrics are correct, safe, and suitable for their age, weight, and health. It is crucial to clearly define a prescription for pediatric patients because of the special needs and features that set children apart from adults (Sema *et al.*, 2021). Consequently, a doctor's prescription should align to the WHO recommendations promoting practices such as monotherapy, the use of generic medications, and medications from the essential list, while minimizing the use of FDC, antibiotics, and polytherapy with multivitamins, etc. (Viswanath *et al.*, 2019). The WHO's development of the "National List of Essential Medicine " (NLEM) brought significant attention to this issue. The list included a selection of drugs that must always be easily accessible and affordable in every basic healthcare institution (Sema *et al.*, 2021).

A prescription analysis involves reviewing prescriptions and comparing them to globally recognized standards provided by the WHO as a reference for effective prescription writing. It is also a part of medical analysis to quantify the quality of the prescription, which is described as "a quality improvement process aimed at enhancing patient care and outcomes by studying care against explicit criteria and implementing necessary changes." Additionally, Pediatric age groups need to be carefully considered while a prescription is issued for pediatric patients, as it classifies a diverse age range and various pharmacological conditions they may have (Mukhopadhyay *et al.*, 2020). The present analysis targets pediatric healthcare practices. Due to limited literature resources available on pediatric prescription analysis, this study focuses to examine trend and identify the area of improvement. Thus, analyzing pediatric prescriptions is crucial for ensuring safe and effective medication treatment for younger patients.

MATERIALS AND METHODS

Sample size and setting

A cross-sectional observational study of prescriptions was conducted between November 2023 and March 2024 after obtaining approval from the institutional ethics committee for conducting the study [IEC No-2743]. No patient was deprived of standard treatment during the duration of the study. The prescriptions were collected from Outpatient (OPD) and Inpatient (IPD) departments of pediatrics, Dermatology, ENT, and Psychiatry covering age group (≤16 years) of both genders, Patients who were willing to give informed consent and the prescription with at least a provisional diagnosis were included in the study. Critically ill patients, incomplete prescription with patient demographic details and prescription without any treatment (drugs) were excluded from the study.

Data collection

Study Procedure

Consent Procedure

The participant's consent was obtained before leaving the Pediatric Department (OPD/IPD). The signed agreement was considered certified for their willingness to take part in the study.

Sampling procedure

Patients who fulfilled the inclusion criteria and those who provided informed consent participated in the study. The prospective study participation was explained, along with the complete study objectives and procedures. The eligible prescriptions were captured (photographed) until the sample size for that day was obtained.

Participant's Details

After the consent, the information of the participant was directly taken from the prescription. Moreover, follow-up with the patient via phone calls was also used to gather the patient's specific information (if required).

Assessment

It was necessary to gather participants' data, which was directly taken from the prescription and augmented by questions to direct the patient. A structured Case Record Form was then created using the collected data, and the extensive dataset was entered into a form. The following prescribing indicators were assessed.

- Dosage frequency and duration.
- Adherence to the NLEM.
- Fixed-dose combination.
- Avoidance of polypharmacy.
- Follow-up Recommendations.

- Patient-Care Indicators.
- Average consultation time.
- Average dispensing time.
- Percentage of drugs actually dispensed.
- Percentage of drugs adequately labelled.
- Patients' knowledge of the correct dosage.
- Health Facility Indicators.
- Availability of a copy of NLEM in all OPDs.
- Availability of key drugs.

Statistical Analysis

IBM SPSS Statistics version 26 was used for analysis. After compilation, the information was displayed as percentage (%) and Mean±SD. The findings supported key observations in the study.

RESULTS

A total of 730 prescriptions were collected and evaluated from various departments, including Pediatric, Dermatology, ENT, Ophthalmology, Orthopedic, and Psychiatry. Mostly prescription was from outpatient departments, only 12% were from the pediatric Inpatient Department (IPD). Out of all the patients, the high-scoring participation came from the Pediatric OPD, covering about half of the total prescriptions; the other half was from the other mentioned departments. Within the remaining 50%, half came from dermatology, while the remainder was from the other departments (Figure 1).

Demographic Details

The proportion of male patients was 20% greater than that of female patients. Most of the patients came from rural regions, and only one-fifth came from urban areas (Figure 2). In the present study, while evaluating the responsibilities of parents, both fathers and mothers were equally engaged in bringing their children to the hospital, as no significant difference was observed between the two. The patient representative shows varied educational backgrounds: 11.4% had Illiterate, 21.8% had below the matric level, 17.3% had completed matric-level education, 20.4% had intermediate education, 18.1% were graduates, and 11.1% with post-graduate or higher education (Figure 3).

WHO Indicators

Prescription Indicators

The study examined prescription indicators among 2309 prescribed drugs, resulting in an average of 3.16±1.71 drugs per prescription. The majority of the patients received polydrug therapy, while a smaller portion (16%) of patients received mono-drug therapy. Only two-fifths of the medications were prescribed by their generic name, while the remaining ones were prescribed by brand names. The presence of Fixed Dose Combination (FDC) was at about 29%, which says a significant portion of drugs prescribed consist of combinations of active pharmaceutical ingredients in fixed doses. Almost an equal number of drugs were prescribed from both NLEM and Hospital Formulary, accounting for about 60% of the total drugs. About one-third of the prescriptions contained at least one antimicrobial medication and nutritional supplements, with injectables accounting for 10.68% of prescriptions, mostly for pediatric IPD (Table 1).

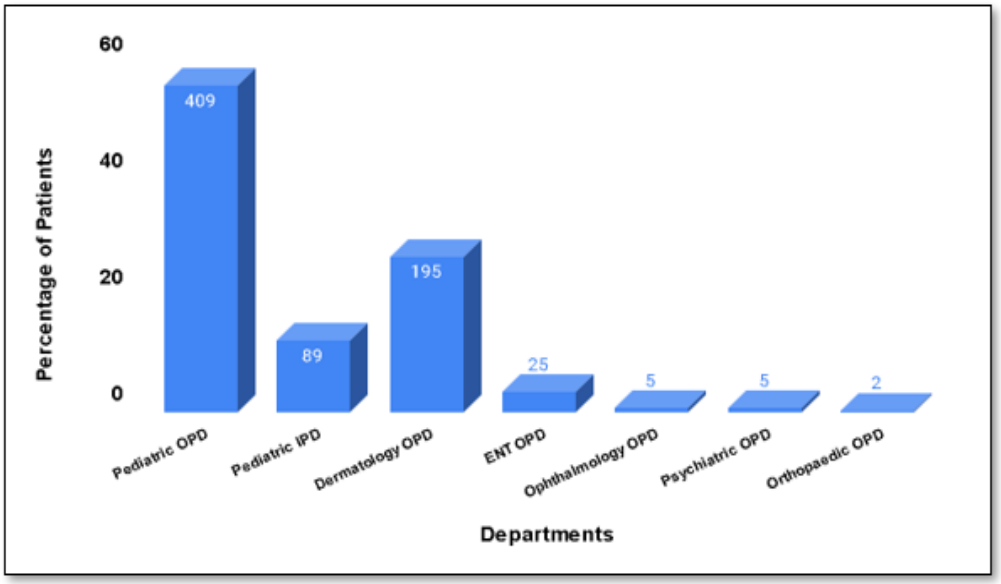

Figure 1: Distribution of Patients Based on Departments (IPD, OPD).

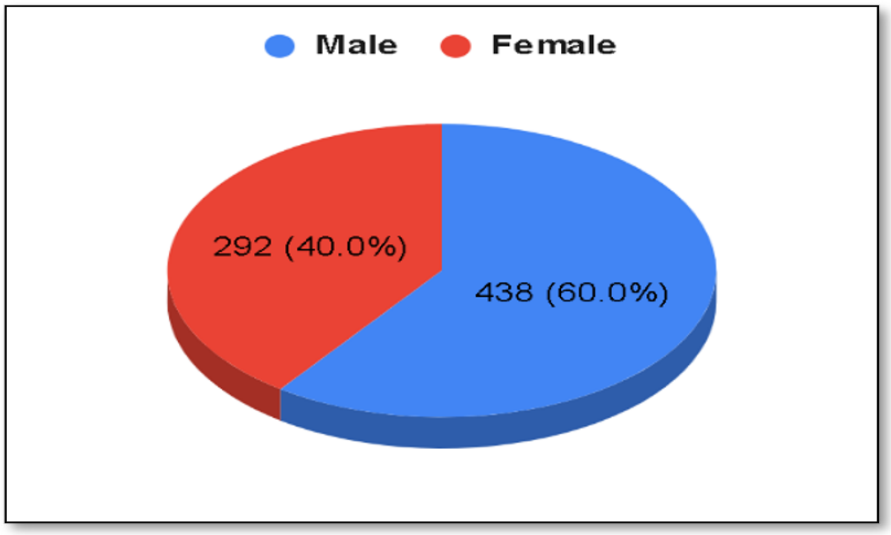

Figure 2: Distribution of Patients Based on Their Gender. (Data Presented as n; %) (*n*=730).

Table 1: Details of Prescribing Indicators as per World Health Organization Criteria.

WHO Indicators	
Parameters	Results (*n*=730)
Prescribing indicators	Percentage (%)
Percentage of prescriptions containing monotherapy	16.02
Percentage of prescriptions containing polytherapy	83.94
Percentage of drugs prescribed by generic name	40.49
Percentage of prescriptions containing Drugs from NLEM	87.39
Percentage of prescriptions containing Fixed dose combinations Drugs	60.68
Percentage of prescriptions containing antimicrobial agents (Antibiotics)	33.64
Percentage of prescriptions containing injectables	10.68
Percentage of prescriptions with Vitamin/ Minerals/Nutritional Preparation	32.60

Patient Care Indicators

In patient care indicators, the average consultation time was approximately twice the dispensing time per individual, whereas the percentage of medications dispensed and adequately labelled drugs was almost at full compliance. Most patients show an understanding of proper dosing, which probably indicates successful counselling from physicians and pharmacists (Table 2).

Health Facility Indicators

The quality of hospital support for promoting appropriate drug use was also assessed (Table 3).

Evaluation of Different Prescribing Indicators

All the prescribing indicators were evaluated in detail shows the following prescribing practices: On average, number of drugs, number of drugs dispensed, number of prescriptions contains generic drugs, number of drugs prescribed from NLEM, hospital formulary, number of FDCs, number of antimicrobials and number of prescriptions contains nutritional preparations, including vitamins and minerals (Table 4).

DISCUSSION

This study used a prospective observational design to analyze pediatric prescription patterns, focusing on WHO indicators, identifying errors of omission, evaluating prescription completeness, and quantifying antimicrobial usage as per WHO guidelines (Shrestha *et al.*, 2019; D'Errico *et al.*, 2022). In this study, out of 730 patients, males were dominant compared to females contrary to findings by (Biradar *et al.*, 2018) where females were predominant. However, this result aligns with studies by (Thiruthopu *et al.*, 2014). Most patients (78.01%) were from rural areas. Because the hospital organization is located in a rural area. In contrast, studies by James *et al.* (2013) and Abula *et al.* (1999) disclose higher proportions of urban patients (58.5% and 76.1%, respectively) and fewer from rural areas (41.06% and 23.8%, respectively). The higher illness rate among rural patients in the current study may be attributed to limited healthcare access, lower socio-economic conditions, and poorer living environments compared to urban populations (Abula *et al.*, 1999).

Prescribing Indicators

The average number of medications prescribed per prescription was 3.16, which is equivalent to the 3.07 observed in Iran (Karimi *et al.*, 2014; Bilal *et al.*, 2016). This exceeds the WHO-recommended range of 1.6 to 1.8 (Joshi *et al.*, 2022), but aligns with findings

from Ethiopia and Saudi Arabia (1.9 to 2.3) (Bilal *et al.*, 2016). In contrast, a study from Karnataka reported an average of 6.9 (Biradar *et al.*, 2018). All the studies showed less adherence to the WHO-recommended range for "drug prescribed per prescription rate".

Although there isn't a single, identical criterion for prescription quality, more medications prescribed per prescription are associated with higher risks of polypharmacy, including resistance, interactions, and adverse drug events (Karimi *et al.*, 2014). High polypharmacy, often due to multiple comorbidities, can lead to side effects and higher costs (Chedi *et al.*, 2015). For instance, a child with asthma might require several medications, including vitamin D supplements, to manage their condition effectively, as breast milk doesn't contain vitamin D. Monitoring drug interactions is essential to ensure safety and efficacy.

Prescription quality is often identified by the proportion of medicines prescribed by their generic names, as recommended by the WHO (Joshi *et al.*, 2022). This study found that only 40.49% of medicines were prescribed generically, lower than in Pakistan (71.6%), Iraq (68.33%), and Nepal (59.02%) (Karimi *et al.*, 2014; Atif *et al.*, 2016; Dahal *et al.*, 2012). Some regions, like Jordan, reported 100% generic prescriptions, (El-Dahiyat *et al.*, 2022) while India shows variability, with Puducherry at 79% (Kumar *et al.*, 2021) and UP at 3.79% (Abidi *et al.*, 2012). These differences may reflect brand preferences, pharmaceutical promotions, or weak regulations (Mathew *et al.*, 2021). The low percentage of generic prescriptions alongside high polypharmacy raises concerns about prescription quality (Joshi *et al.*, 2022).

The utilization rate of injections was found to be 10.68%, which aligned well with the threshold of <20% as specified by WHO. This pattern was observed more likely in pediatric IPD than OPD. In a similar vein, many studies conducted in Saudi Arabia (3.90%), North India (7.54%), Ethiopia (9.50%), and other nations revealed findings that were within or even below the WHO value range (Viswanath *et al.*, 2019; Jain *et al.*, 2015).

It was discovered that at least one vitamin supplement was included in almost one-third of the prescriptions. The majority of them FDCs with a large number of active ingredients, and they are typically recommended as part of nutritional supplements for a variety of medical ailments. A study conducted in Southern India also demonstrated slightly more results than the present, i.e., 40.4% (Biradar *et al.*, 2018).

Drugs from the NLEM accounted for 87.29% of prescriptions, higher than in Puducherry (76%) and Uttar Pradesh (53.2%) (Kumar *et al.*, 2021; Abidi *et al.*, 2012), but lower than the 100% observed in Ethiopia and the UAE (Viswanath *et al.*, 2019). NLEM ensures standardized, cost-effective, and safe care for pediatric

Table 2: Details of Patient Care Indicators as per World Health Organization Criteria.

Patient care indications	Average±SD/ Percentage
Average consultation time (Minutes)	13.9±5.58
Average dispensing time (Minutes)	7.8±4.28
Percentage of drugs actually dispensed	95.7
Percentage of drugs adequately labelled	97.53
Patients' knowledge of the dosage	99.31

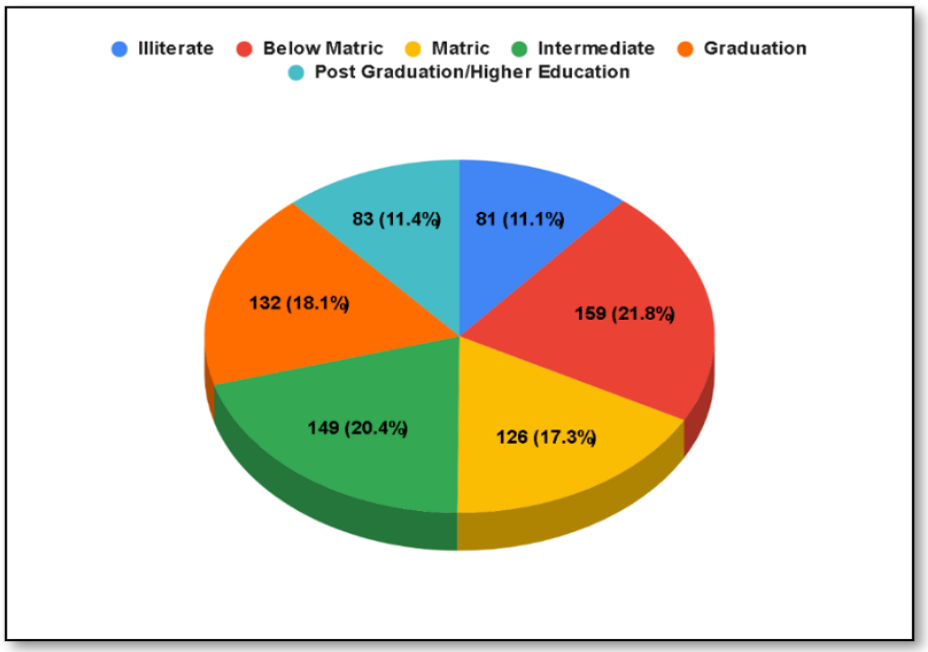

Figure 3: Distribution of Parents based on their Literary Rate. (Data Presented as n; %) (*n*=730).

Table 3: Details of Health Facility Indicators as per World Health Organization Criteria.

Health facility indicators	Results
Availability of a copy of NLEM in all OPDs	Yes
Availability of key drugs	Yes

Table 4: Details of the average number of drugs per prescription for each parameter as per the World Health Organization Drug Use Indicators.

Parameters	Average ± SD (*n*=730)
Average Number of Prescribed Drugs Per Prescription	3.163 ± 1.71
Average Number of Dispensed Drugs Per Prescription	3.032 ± 1.68
Average Number of Drugs Prescribed by Generic Name Per Prescription	1.28 ± 1.31
Average Number of Drugs from NLEM Prescribed Per Prescription	1.938 ± 1.41
Average Number of Drugs from Hospital Formulary Prescribed Per Prescription	1.83 ± 1.4
Average Number of FDC Drugs Prescribed Per Prescription	0.923 ± 1.71
Average Number of Antimicrobials Prescribed Per Prescription	0.58 ± 0.79
Average Number of Vitamins/Minerals/ Nutritional Preparation Prescribed Per Prescription	0.51 ± 0.91
Average Number of Injectables Prescribed per Prescription	0.26 ± 0.98

patients. FDCs were used in 60.68% of prescriptions, higher than in some studies but lower than in others from India (76% and 75%) (Sema *et al*., 2021; Biradar *et al*., 2018). While FDCs reduce pill burden and improve compliance, they can complicate dose adjustments and increase costs, making flexibility and monitoring crucial. On the other hand, the FDC drugs have drawbacks worth considering. They can be complex because they combine different medicines into one pill, making it tricky to adjust doses for children who need specific amounts. This complexity can also affect their cost, potentially making them more expensive than single-drug formulations, which may burden families or the healthcare system. Hence, prescribing FDCs should adhere to the essential medicines list to balance benefits and drawbacks (Kumar *et al*., 2021).

Patient Care Indicators

The typical consultation duration was found to be about 14 min, considered as per the WHO standards (>10 min), and aligns with a similar study from Abu Dhabi (17 min). This prolonged consultation time enhances patient satisfaction and communication. The average dispensing time was 7.3 min, considered appropriate for ensuring proper labelling and patient knowledge. Caregiver educational level and their region of residence may further explain the gap between labeling and patient comprehension. Most of the pediatric patients were from rural backgrounds. In spite of this, 88.6% of the parents who accompanied them were literate, and 40% were well educated. The high level of dosage comprehension (99.3%) in this population indicates that even in rural areas, literacy, along with verbal counseling, aids in overcoming the imbalance of inadequate drug labeling (97.5%). This observation corresponds with WHO recommendations advocating for the incorporation of medicine-use education into literacy and adult education programs to foster rational medicine use: "Education about the use of medicines may be integrated into the health-education segment of school curricula or into adult education programs, such as literacy courses." (World Health Organisation, 2002.) The findings of this study align with previous research indicating average dispensing times of 9.6 min, 6-8 min, and 10 min (Sema *et al*., 2021; El-Dahiyat *et al*., 2022; World Health Organization (assessed on 22.05.2024)). However, they contrast with other studies reporting an average dispensing time of only 1 min (Karande *et al*., 2005), which falls below the WHO standard of over 90 sec.

Medicine dispensing was 95.72%, below the WHO's ideal of 100%, likely due to the unavailability of some drugs. Similar issues were noted in studies from Andhra Pradesh (84.74%) and Ethiopia (77.17%, 75.77%) (Sema *et al*., 2021; Viswanath *et al*., 2019). This could be due to the unavailability of certain prescribed drugs in the dispensary of the institution; Therefore, the authorities should make as many medications available as they can. The proportion of medications with suitable labels was 97.53%, slightly below the WHO recommendation of 100%, though this is better than some previous studies. In the study performed by (Sema *et al*., 2021) the percentage of medicine adequately labelled was lower than in the present study, as well as the WHO-recommended value (100%). The adequate labelling will increase the awareness about the regimen that is taken by the patient and also increase treatment adherence and a better outcome (Viswanath *et al*., 2019).

Patient knowledge of correct dosing was 99.3%, close to the WHO-recommended value of (100%) and better than in studies from Egypt (94%), Saudi Arabia (79.3%), Southwest Ethiopia (69%), and Pakistan (62.1%) (Jain *et al*., 2015; Chedi *et al*., 2015; Biradar *et al*., 2018). Henceforth, the present study signifies that knowledge supports adherence and improves healthcare outcomes.

Health Facility Indicators

In this present study, key drug attainability was 79.45%, below the 100% seen in similar studies from Kenya and Sudan (Akl *et al*., 2014; Rabie *et al*., 2020). Factors contributing to this shortfall may include supply issues, budget constraints, or the lack of a procurement policy. Addressing these issues could help achieve

higher availability. The NLEM and Formulary were present in all hospital departments, which is consistent with best practices that enhance patient care. The hospital should continue to maintain these resources to ensure effective healthcare delivery (Nyabuti *et al.*, 2020).

CONCLUSION

The purpose of this study was to evaluate paediatric prescribing practices at a tertiary care hospital using WHO core medication use indicators and patient-care metrics. Although many indicators, such as the utilisation of necessary medicines and the average consultation time, exceeded WHO recommendations, other highly problematic findings were discovered. The evaluation of WHO core indicators helped make things better in the prescribing of drugs in monotherapy with generic names, reduced the use of FDCs, and encouraged the prescription of a higher proportion of drugs from the NLEM. Additionally, the study discovered that the average number of antibiotics administered was greater than suggested per guidelines and that the proportion of medications prescribed under generic names was lower than recommended. Therefore, increasing awareness, continuing education, and motivating prescribers to use drugs in generic names is crucial. The study helps dermatologists to reduce common prescribing errors, especially in the context of polypharmacy, and improves therapeutic outcomes by promoting more accurate and appropriate medication choices.

RECOMMENDATIONS

- Considering the results and the benchmarks set by WHO, the following strategies have been designed to improve rational prescribing:
- Encourage the use of generic medications at the policy level and through educational programs directed at the prescribing community.
- Limit irrational prescribing of FDCs, particularly in children and in rural areas, unless there is a strong clinical justification.
- Integrate prescription writing for drugs from the NLEM through e-prescription interfaces and up-to-date hospital formularies.
- Take advantage of caregivers' literacy skills by providing supplementary educational materials, translated instructions, and organized counselling regarding dosage and administration.
- Audit prescriptions regularly for prescription patterns by department to identify and record deviations from accepted standards and give feedback to prescribers.

ACKNOWLEDGEMENT

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ABBREVIATIONS

WHO: World Health Organization; **NLEM:** National List of Essential Medicines; **FDC:** Fixed-Dose Combination; **OPD:** Outpatient Department; **IPD:** Inpatient Department.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHOR CONTRIBUTOR STATEMENT

A Khandelwal, TG, A Kumar, SB, and RJ conceived the study. A Khandelwal, TG, A Kumar, RJ, SB, RC, KK and SG and AKS were involved in protocol writing, database search, screening of articles, and preparation of the final draft. SB, RJ, SG and AKS were responsible for article screening till the writing of the final draft. SB, RJ, and AKS were consulted for the critical revision of the manuscript to resolve any discrepancies. Finally, all the authors read and approved the final manuscript.

ETHICAL APPROVAL

A cross-sectional observational study of prescriptions was conducted between November 2023 and March 2024 after obtaining approval from the Institutional Ethics Committee of Maharishi Markandeshwar Institute of Medical Science and Research Hospital, Mullana, Ambala, Haryana. Protocol number: IEC No-2743 dated 18.12.2023.

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