Research Article

Assessment of drug prescription pattern in children: A descriptive study

Ajitha Sharma, Oommen Shweta

Department of Pharmacology, Pondicherry Institute of Medical Sciences, Puducherry, India.

Correspondence to: Ajitha Sharma, E-mail: drajithasharma@gmail.com

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Abstract

Background: Irrational drug prescription leads to ineffective treatment, occurrence of adverse effects, prolonged duration of illness and suffering to patient, and an increased economic burden to society. Since children are more vulnerable than adults, it is crucial that principles of rational prescription are strictly adhered to **Aims and Objective:** To assess drug prescription pattern in children in a tertiary care hospital in India. **Materials and Methods:** Prescriptions were collected from hospital pharmacy and copied using a digital camera and analyzed using seven-point criteria for rationality of fixed dose combinations (FDCs) and the World Health Organization (WHO) core prescribing indicators for rationality of prescriptions. **Result:** Among 1008 prescriptions collected, majority was for male patients (571, 56.7%) and those aged 1–5 years (372, 36.9%). Prescriptions for immunization alone constituted 24.7% (249), of which injectable polio vaccine was the most common (143, 57.4%). The most commonly prescribed drugs were paracetamol (279/759, 36.8%) and antimicrobials (267/759, 35.2%). Out of 285 FDCs noted, 81 (28.4%) were found to be rational and 70 (24.6%) were from Essential Medicines List. Average number of drugs per encounter was 1.9. Most of the drugs were prescribed using generic name (60.2%) while 75.1% of drugs were from the WHO Model List of Essential Medicines for Children. Percentage of encounters with antibiotics and injections were 25.7% and 4.1%, respectively. **Conclusion:** Although usage of antibiotics and parenteral drugs was conforming to WHO recommended standards, there is a need to improve prescription pattern by generic name and drugs from Essential Drug List.

KEY WORDS: Drug Prescription Pattern; Pediatrics; WHO Drug Prescribing Indicators; Fixed dose combinations

Introduction

For decades, medicines have been prescribed to children, based on reports from adult clinical studies due to paucity in data from relevant pediatric safety and efficacy studies. However, these practices are often fraught with complications due to differences in pharmacokinetic (PK) and pharmacodynamic profiles in children when compared to adults.[1,2] Rational prescription is well-reflected by the World Health Organization (WHO) definition stating, "Rational use of medicines requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at lowest cost to them and their community."[3] Consequently, continuous monitoring of treatment effects, re-evaluating risk–benefit ratio, and, if indicated, withdrawing the drug or changing the dose, become indispensable.[4]

Fixed dose combinations (FDCs) are combination of two or more active drugs present in a dosage form. Use of FDCs offers many advantages such as synergistic action, reduced pill burden, and better patient compliance. Conversely, some disadvantages are to be borne with, such as inability to adjust doses of individual drugs and additional adverse effects.[5] An alarming trend of greater prescription of FDCs has been observed.[6] Unfortunately,

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most of them are irrational and harmful. It is crucial that principles of rational prescription are adhered to and an important step toward this is by prescribing drugs only published in Essential Medicines List (EML). WHO Model list of Essential Medicines for children (WHO EMLc) contains only 12 FDCs.[7]

Promoting safe and judicious use of drugs in children is fundamental. Regular audit by trained pharmacists with rational and judicious prescribing practices will help toward standardizing pediatric therapeutic interventions and promote better and safe futures for children.[8] This study was aimed at assessing drug prescription pattern in a tertiary care hospital with following objectives: (1) to evaluate adherence to prescription format; (2) to determine commonly prescribed FDCs for children and analyze whether they are rational; and (3) to assess drug prescription pattern in children using the WHO prescribing indicators.

Materials and Methods

This descriptive, quantitative, cross-sectional study aimed to analyze prescriptions for children aged 0–18 years, attending various outpatient departments (OPDs) of the institute, from June to October 2014. The WHO recommends that at least 600 encounters should be included in a cross-sectional survey to describe current prescribing practices, with a greater number, if possible.[9] In this study, over 1000 pediatric prescriptions were scrutinized and only outpatient prescriptions for children were included, based on their legibility. Prescriptions that had no drugs (prescriptions for syringes, surgical gloves, etc.), illegible, and inpatient prescriptions were excluded. Ethical approval was obtained from Institutional Ethics Committee prior to commencement of study and a waiver of consent was obtained, since there was no patient encounter. All prescriptions were collected by researchers from hospital pharmacy and copied using a digital camera.

Prescriptions were checked for adherence to prescription format with specific prescription indicators namely, patient's name; age; sex; hospital outpatient number; body weight; diagnosis; doctor's name and signature; complete prescription of drugs that includes drug name, dose, route, strength, frequency, and dosage form; instructions regarding medication use; follow-up advice; total number of drugs prescribed; and duration of treatment. Any FDCs prescribed were duly noted and checked for rationality.

Seven-point criterion developed by Panda et al.[10] was used for assessing rationality of FDCs. These criteria include all magnitudes of defining a rational FDC and each criterion has been assigned an appropriate score. Total score thus obtained by an FDC reflects its rating on the scale. The criteria are as follows:

i. Each active pharmaceutical ingredient (API) of combination should preferably be in EML of WHO or in National List of Essential Medicines of India.
ii. Dose of each API should meet requirements for a defined population group and be appropriate for intended use.
iii. Combination should have established evidence of efficacy and safety.
iv. Cost of combination should be less than cost of individual components.
v. FDC should facilitate either reduction of dose of individual drugs or reduction of their adverse effects.
vi. PK parameters of each API should not be affected or there should be a favorable PK interaction between APIs.
vii. Individual drugs should have different mechanisms of action.

The WHO EMLc was used for assessment of first criteria. Dose of individual APIs and detailed information about PK parameters were verified from standard textbooks of pharmacology and therapeutics.[11,12] Published data regarding clinical evidence of safety and efficacy were collected from databases such as Pubmed, Medscape, and Cochrane Library. Cost data of individual components, as well as FDCs, was obtained from Current Index of Medical Specialities.[13] Maximum scoring of seven-point criteria is 14 with each criterion carrying a score of 2. FDC with score of $\geqslant 8$ was considered rational for purpose of this study.

The WHO core prescribing indicators[9] were used for evaluating rationality of prescriptions, which are as follows:

1. Average number of drugs prescribed per encounter was calculated by dividing total number of drug products prescribed by number of encounters surveyed.
2. Percentage of drugs prescribed by generic name was calculated by dividing number of drugs prescribed by generic name by total number of drugs prescribed, multiplied by 100.
3. Percentage of encounters with an antibiotic prescribed was calculated by dividing number of patient encounters in which an antibiotic was prescribed by total number of encounters surveyed, multiplied by 100.
4. Percentage of encounters with an injection prescribed was calculated by dividing number of patient encounters in which an injection was prescribed by total number of encounters surveyed, multiplied by 100. Vaccines are to be excluded from the calculation.
5. Percentage of drugs prescribed from an essential drug list (EDL) was calculated by dividing number of products prescribed from EDL by total number of drugs prescribed, multiplied by 100.

Statistical Analysis

The values were expressed as actual numbers and the corresponding percentages. Frequency analysis was carried out using Statistical Package for the Social Sciences (SPSS), version 20.0 (IBM, Corp., Armonk, NY).

Results

In 5 months, a total of 1123 prescriptions for children were collected, of which 115 were excluded as they were illegible or did not have drugs. Among 1008 prescriptions analyzed, 571 were for male patients (56.7%) and 372 for children aged 1–5 years (36.9%). The most common diagnoses for which drugs were prescribed were respiratory tract infections (20.7%) and

Table 1: Characteristics of study participants (n = 1008)

Characteristics		*N*	%
Gender	Male	571	56.7
	Female	437	43.3
Age group	<1 month	93	9.2
	1 month–1 year	294	29.2
	1–5 years	372	36.9
	5–12 years	178	17.7
	12–18 years	71	7.0
Clinical diagnosis	Immunization	249	24.7
	Respiratory tract infections	209	20.7
	Fever	165	16.4
	Dermatological complaints	66	6.5
	Otitis media	39	3.9
	Acute gastroenteritis	29	2.9
	Urinary tract infections	25	2.5
	Worm infestations	21	2.1
	Asthma	16	1.6
	Seizure disorders	8	0.8
	Headache	4	0.4
	Iron deficiency anemia	3	0.3
	Rheumatic heart disease	3	0.3
	Undernutrition	3	0.3
	Conjunctivitis	3	0.3

fever (16.4%) (Table 1). A total of 840 (83.3%) prescriptions were made by pediatric OPD, 64 (6.4%) by pediatric surgery, 39 (3.9%) by dermatology department, and remaining from various departments such as otorhinolaryngology (27, 2.7%), pulmonary medicine (10, 1.0%), cardiology (8, 0.8%), ophthalmology (7, 0.7%), orthopedics (5, 0.5%), neurology (3, 0.3%), plastic surgery (3, 0.3%), and urology (2, 0.2%).

Most prescriptions (971, 96.3%) had complete basic patient information, such as name, age, gender, and hospital outpatient number. The assessment of various prescription indicators like prescribing doctor's name and signature, body weight of child, and diagnosis, complete prescription is depicted in Figure 1. Prescriptions for drugs (other than vaccines) were 759. Antipyretics like paracetamol were most commonly prescribed drugs (279/759, 36.8%), followed by antimicrobials (267/759, 35.2%) (Table 2).

Considerable number of prescriptions was for immunization alone (249, 24.7%), of which injectable polio vaccine was the most common prescribed (143, 57.4%) (Figure 2). As one prescription can have more than one vaccine, total percentage is more than 100%. Various drug formulations were prescribed in the study, highest being syrups (351, 34.8%), followed by injections (280, 27.8%), nasal drops (195, 19.3%), tablets/capsules (134, 13.3%), oral rehydration salts (ORS) (22, 2.2%), creams/ointments (15, 1.5%), and inhalers (11, 1.2%). Most commonly prescribed antibiotics were cephalosporins (95/267, 35.6%) and penicillins (94/267, 35.2%) (Figure 3).

FDCs prescribed in this study belonged to various drug classes, the most common among them being cough and cold

Table 2: Various groups of drugs prescribed in the study (n = 759)

Classes of drugs prescribed	*N*	%
Antipyretics	279	36.8
Antimicrobials	267	35.2
Saline nasal drops	194	25.6
Nasal decongestants	163	21.5
Zinc	57	7.5
Analgesics	30	4.0
Oral rehydration salts	22	2.9
Steroids	15	2.0

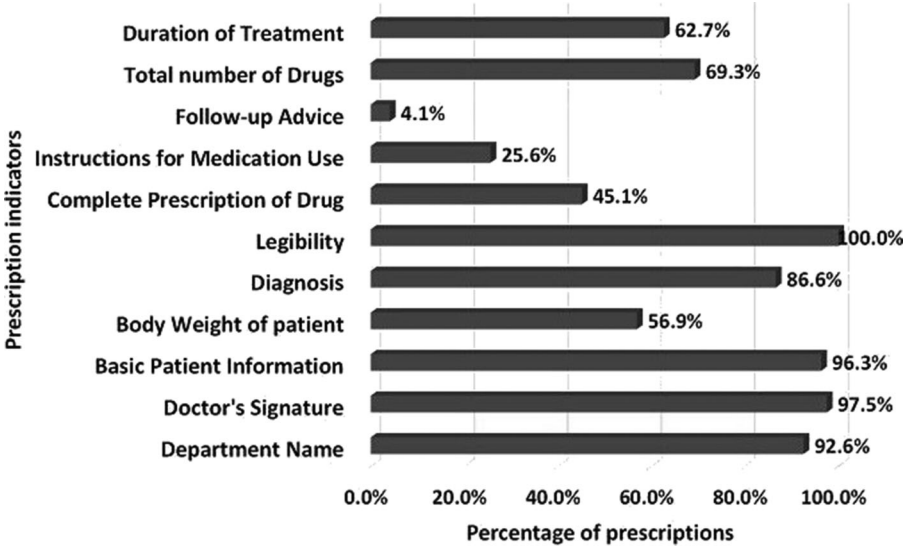

Figure 1: Assessment of prescription indicators.

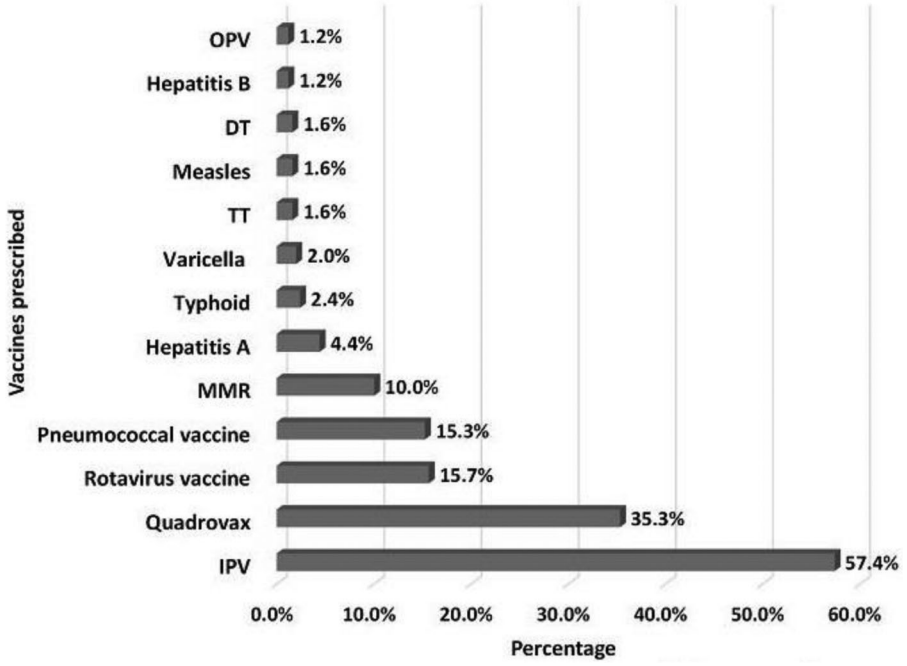

Figure 2: Various vaccines prescribed in the study population. OPV, oral polio vaccine; DT, diphtheria; TT, tetanus toxoid; MMR, measles, mumps, rubella; quadrovax, diphtheria, pertussis, tetanus and hemophilus type b conjugate; IPV, injectable polio vaccine.

medications (134/285, 47%) and antibiotics (72/285, 25.3%). Among 285 FDCs prescribed, number of rational FDCs and those included in WHO EMLc are shown in Table 3. Based on seven-point criteria, scoring was done for each FDC, which is illustrated in Figure 4. Rationality of prescriptions was assessed using WHO core prescribing indicators, values of which are presented in Table 4.

Discussion

In this study, majority of prescriptions (56.7%) were for male children aged 1 month–5 years (66.1%). This may be due to the fact that these age groups are more vulnerable and morbidities are commoner than older children and hence attendance to OPD is more. Most prescriptions had documented patient information (96.3%) and had doctor's signature (97.5%) but only 45% of analyzed prescriptions had full prescription for a drug. Antipyretics (36.8%) and antimicrobials (35.2%) were most commonly prescribed drugs in this study. Most antimicrobials were age-appropriate, prescribed for 3–7 days, in appropriate strengths and frequencies. Cephalosporins were the most common prescribed (35.6%) followed closely by penicillins (35.2%). As per the WHO core prescribing indicators, average number of drugs per encounter was found to be 1.9, which was in accordance with the recommended standard of 1.6–1.8. Percentages of drugs prescribed by generic name and from EML were 60.2% and 75.1%, respectively, which was lower than

Table 3: Groups of FDCs prescribed in the study (n = 285)

Drug classes of prescribed FDCs	Number of FDCs *N* (%)	Rational FDCs *N* (%)	FDCs in EML *N* (%)
Cough and cold medications	134 (47)	0	0
Antibiotics	72 (25.3)	48 (66.7)	48 (66.7)
Oral rehydration salts	22 (7.7)	22 (100)	22 (100)
Vitamins	17 (6)	0	0
Analgesics	12 (4.2)	0	0
Ear wax solvents	13 (4.6)	0	0
Antiasthmatic medications	11 (3.9)	11 (100)	0
Antacids	4 (1.4)	0	0

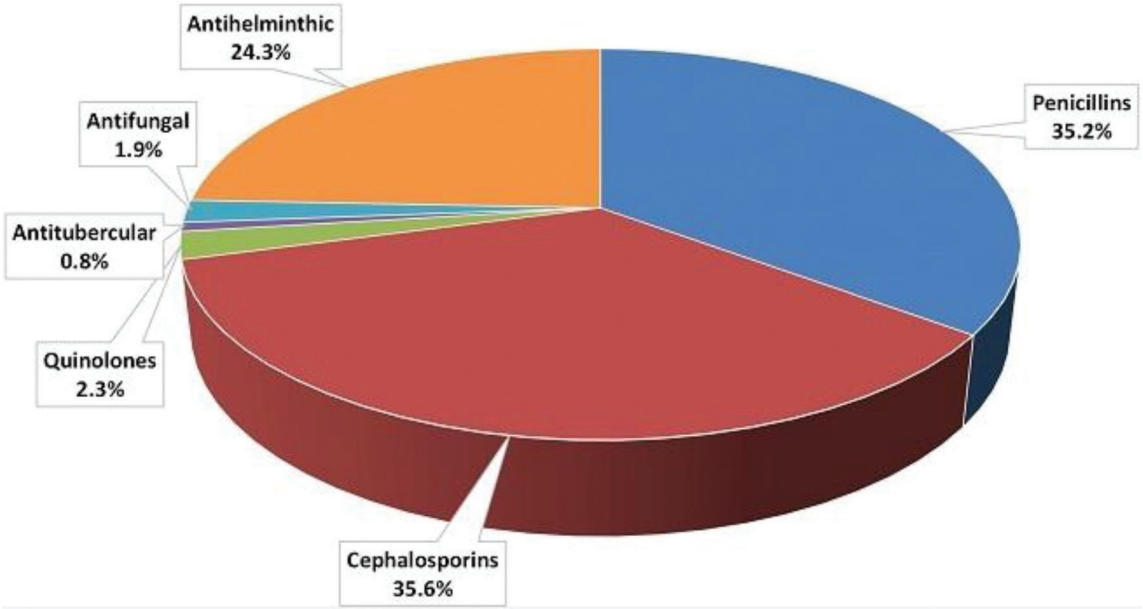

Figure 3: Various antibiotics prescribed in the study population.

recommended ideal of 100%. Percentage of encounters with antibiotics was 25.7% and was concurrent with derived standards of 20%–26.8%. Percentage of encounters with injections was 4.1%, which was found to be lower than derived standards of 13.4%–24.1%. Seven-point criteria determined rationality of the FDCs in this study, and it was found that ORS and most antibiotic combinations like amoxicillin + clavulanic acid were rational and included in WHO EMLc. However, cough and cold preparations, combinations of vitamins or analgesics, and antibiotic combinations like ampicillin/amoxicillin + cloxacillin were found to be irrational and not included in the WHO EMLc. Antiasthmatic combinations like budesonide + formoterol are commonly available as metered dose inhalers and account for rational FDCs as per seven-point criteria but are not included in the WHO EMLc.

Comparable findings as regards to age and gender of children were reported by Sachdeo et al.[14] and Shinde et al.[15] The drugs that were prescribed are comparable to studies done by Al Balushi et al.[16] and Kumar et al.[17] (13% and 17.9% paracetamol, respectively), and Gedam et al.[18] (44.2% antipyretics). However,

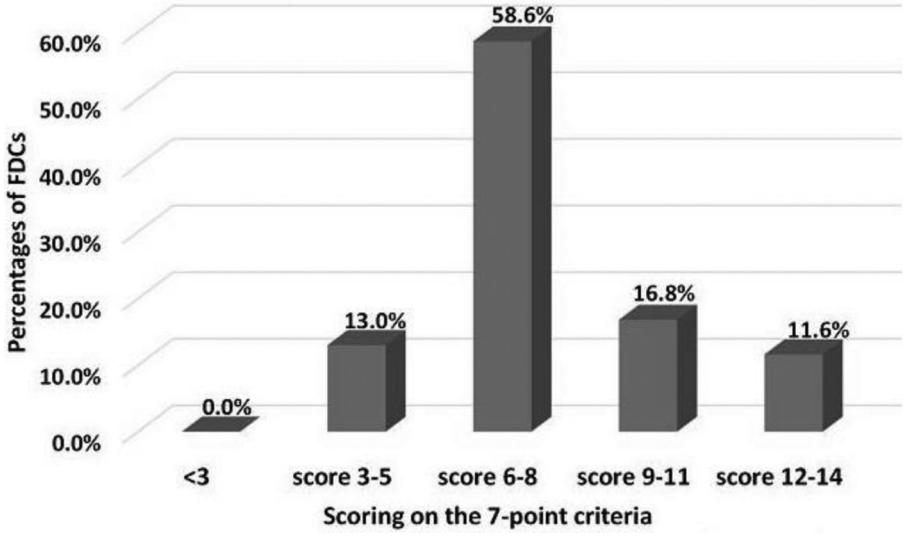

Figure 4: Scoring of various fixed drug combinations on the seven-point criteria scale.

Table 4: The WHO core prescribing indicators assessed for drug prescriptions (n = 759)

Prescribing indicators assessed	Total drugs/encounters	Average/percentage	Standard derived or ideal
Average number of drugs per encounter	1432	1.9	1.6–1.8
Percentage of drugs prescribed by generic name	862	60.2	100
Percentage of encounters with antibiotics	195	25.7	20.0–26.8
Percentage of encounters with injections	31	4.1	13.4–24.1
Percentage of drugs from essential drug list	1076	75.1	100

in some other studies, antibiotics were most prescribed drugs.[14,19] This observation may be because of differing profiles of presenting complaints in various hospitals. Prescriptions for children attending study center for immunization formed a significant portion. The study center follows guidelines of Indian Academy of Pediatrics Committee on Immunization. Hence, injectable form of polio vaccine is routinely administered here in contrast to oral polio vaccine that was earlier recommended.[20] Higher usage of cephalosporins were reported by Kumar et al.[17] (61%) and Thiruthopu et al.[21] (50.6%). In this study, it was found that most prescriptions conformed to WHO core drug prescribing indicators. The average number of drugs prescribed per encounter was less than other reported studies such as Thiruthopu et al.[21] (4.56), Oshikoya et al.[22] (3.7), Dimri et al.[23] (2.3), and Risk et al.[24] (2.2). Drugs prescribed by generic name and from EML were less than those reported by Risk et al.[24] (74.8% prescriptions by generic name) and Karande et al.[25] (73.4% and 90.3%, respectively). However, other studies reported a lower value.[18,21,23] Some similar studies reported higher values for antibiotics prescribed, such as Gedam et al.[18] (37.3%), Thiruthopu et al.[21] (33.3%), and Risk et al.[24] (63.4%), while prescriptions with injections were lesser than the values reported by Thiruthopu et al.[21] (21.8%) and Oshikoya et al.[22] (18%), but higher than Dimri et al.[23] (1.2%). The findings regarding FDC usage in our study concur with those reported by Sachdeo et al.[14] and Shinde et al.[15]

Limitations of the study could be that it was conducted in a single center and results may not be applicable to general population. Also, study evaluated drug use pattern in only patients attending OPDs and prescription pattern will definitely vary among inpatient population. Seven-point criteria used for assessing rationality of FDCs cannot be regarded as the sole measure of rationality. WHO core drug prescribing indicators only indicate quantity of drugs prescribed but cannot determine accuracy of diagnosis or adequacy of drug choices. Furthermore, patient care indicators and facility indicators were not included as this was a prescription-based study. However, it provides useful baseline data over which future studies can be built upon.

Conclusion

Findings of the study highlight need for reinforcing rational prescribing practices and increasing awareness among physicians and medical students. Irrational FDCs are being commonly prescribed and there is an urgent need to curb these harmful practices by stringent regulations and developing local guidelines for rational prescribing. Although usage of antibiotics and parenteral drugs were conforming to WHO recommended standards, there is a need to improve prescription pattern by generic name and drugs from EDL.

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