

A retrospective study of drug utilization pattern in the outpatient department of pediatrics in a tertiary care teaching hospital of Rajasthan, India

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ABSTRACT

Background: Though irrational prescribing is known throughout the world, but in developing countries because of small amount of funds available in the overall health budget for drugs, it has become more meaningful to prescribe drug rationally for optimum use of the allocated funds. The objective of this study was to study drug utilization pattern in paediatric patients attending paediatrics outpatient department, J. L. N. Hospital, Ajmer, Rajasthan.

Methods: Study was carried out retrospectively, for a period of one year, by analysing a total 2100 carbon copies of prescriptions of patients who had visited the O.P.D. of Pediatric of J. L. N. Hospital Ajmer.

Results: Among the total of 2100 patients, 67.71% patients were in age group of 1 to 14 years. 56.76% of total prescriptions accounted for the respiratory system followed by gastrointestinal system (26.62%). The most frequent classes of drugs prescribed were: antimicrobials (77.42%) followed by analgesic-antipyretics (69.28%). Cephalosporins were the most common among the antimicrobials prescribed. Total 7531 drugs were prescribed. The average number of drugs per prescription was 3.59. Of total medicine formulations prescribed, only 13.09% were prescribed by generic names and 38.03% were matching with those listed in model list of essential medicines. 50.68% medicine formulations were in the form of fixed dose combinations (FDCs) of which 26.96% were form the essential medicine list.

Conclusions: There is a lot of scope in prescribing pattern regarding poly-pharmacy, medicines prescribed by generic name and from Essential Drug List and usage of fixed dose combinations.

Keywords: Drug utilization, Poly-pharmacy, Generic name, Antimicrobials

INTRODUCTION

Though irrational prescribing is known throughout the world, but in developing countries because of small amount of funds available in the overall health budget for drugs, it has become more meaningful to prescribe drug rationally for optimum use of the allocated funds.¹

The principal aim of drug utilization research is to facilitate rational use of drugs in populations. Rational drug prescribing can be defined as “appropriate drugs taken in the right dose, at correct time intervals and for sufficient duration”.

Poly-pharmacy, use of non-essential based on WHO criteria, indiscriminate use of analgesics, antibiotics, and vitamins, use of brand names of the medicines more commonly while prescribing than generic preparations and even some time prescribing banned drug because of ignorance are few important irrationalities.

Infants and children constitute a large proportion of the population in developing countries.

The study of drug use in paediatric out patients have always been associated with difficulties resulting from the limited number of drug utilization studies investigating therapeutic patterns in relation to clinical

diagnosis in paediatrics.² Several drug utilization studies in children previously published are based only on the availability of drug-sale data or focused on antibiotics prescription in general for a group of infectious conditions or are reviews of a concrete diagnosis specifically.³

Considering these facts, this study was planned to find the prescribing pattern and drug use in children taking outpatient treatment in the Paediatric Department of J L N Hospital, Ajmer, Rajasthan, India.

The objective of this study was to evaluate the prescribing and drug utilization pattern in paediatric outpatient department of J. L. N. Hospital Ajmer (Rajasthan) with an objective of studying the;

- Total number of prescriptions and their percentage wise distribution in each system (respiratory system, GIT system etc.)
- Total number of prescriptions and their percentage wise distribution in different age groups
- Prescribing prevalence of drugs in each system
- Poly-pharmacy and average number of drugs per prescription
- Prescribing frequency of most commonly prescribed drugs in whole study
- Prescribing frequency of commonly prescribed agents in different systems
- Prescribing frequency of different dosage forms
- Prescribing prevalence of antimicrobials given in whole study
- Prescribing frequency of fixed - dose combinations
- Prescribing by trade/generic name
- Percentage of drugs prescribed from WHO EDL (essential drug list)/national list of essential medicines/current RSEML (Rajasthan state essential medical list).

METHODS

The study was carried out retrospectively by analysing the copies of prescriptions of patients who had visited the O.P.D. of the paediatric department of J.L.N. Hospital Ajmer.

Before starting study a written approval for the protocol from Principal, Head of Department paediatrics was obtained. Then carbon copies of the prescriptions were collected from paediatrics OPD monthly from January 2010 to December 2010. From the collected carbon copies we randomly selected 175 copies for each month, a total of 2100 carbon copies were selected for study.

To avoid undue bias of the physicians during prescribing to a patient, the prescription copies were obtained from the office of Paediatric department.

Information on demographic profile, diagnosis and treatment were spread over different age groups (i.e. neonates: up to one month of age, Infants: 1 month to 1 year, children: 1-14 years). Each prescription then was analysed as per objectives of study.

RESULTS

Among the total of 2100 patients, 61.24 % were males where as 38.76% were females.

Table 1 shows age wise distribution of prescriptions. Most of the patients (67.71 %) were in more than twelve months of age group.

Table 1: Number of prescriptions- age group wise.

Age group	Total no. of prescriptions	Percentage (%)
(Neonates) up to 1 Month	122	5.81
(Infants) 1-12 months	556	26.48
(Children) > 12 months	1422	67.71
Total	2100	100

Table 2 Shows system wise distribution of prescription. More than half of the total prescriptions (56.76%) accounted for the respiratory system. Prescriptions for Gastrointestinal System constitute 2nd largest group, (26.62%).

Table 2: Number of prescriptions system wise (total no. of prescriptions-2100).

System	No. of prescriptions	Percentage (%)
Respiratory	1192	56.76
Gastrointestinal (GIT)	559	26.62
Pyrexia of unknown origin (PUO)	255	12.14
Central nervous system (CNS)	25	1.19
Cardiovascular system (CVS)	16	0.76
*Others	53	2.52
Total	2100	100

*Others -Include prescriptions having diagnosis of skin diseases, anaemia, urinary tract infections and diagnosis not written.

Total 7531 drugs were prescribed. Among the various dosage forms used syrups were prescribed most commonly (53.56%), followed by tablets (29.09%). Injections were used least (0.29%). Other dosage forms used were drops, powders, nebulization/inhalation, capsules and topically cream/lotion/ointment.

Table-3: Shows frequency of prescribing agents. Antimicrobials were the most frequent class of drugs prescribed, as 77.42% of total prescriptions contained

these agents followed by analgesic-antipyretics (NSAIDs).

Table 3: Frequency of prescribing agents (total no. of prescriptions-2100 and total no. of drugs- 7531).

Agents	Total no. of prescriptions-2100		Total no. of drugs-7531	
	Number of prescriptions	Percentage (%)	Number of drugs	Percentage (%)
Antimicrobials	1626	77.42	1931	25.64
Analgesic and antipyretics (NSAIDs)	1455	69.28	1455	19.32
Respiratory drugs	1192	56.76	1997	26.52
GIT Drugs	559	26.62	902	11.98
Haematinics, minerals and vitamins	585	27.85	921	12.22
CNS and CVS drugs	41	1.95	203	2.70
Other drugs	53	2.52	122	1.62

Table 4 shows prescribing prevalence of antimicrobials. Total 1931 antimicrobial agents were prescribed, with an average of 1.19 per prescription. Cephalosporin group of antibiotics was the leading antibiotic prescribed (28.79%). Penicillins were the next commonest antibiotics prescribed (23.82%).

Table 4: Prescribing prevalence of antimicrobials (total no. of medicine formulations-7531).

Antimicrobial	Total no.	Prescribing frequency %	
		Among AMs	As a whole
Penicillins	460	23.82	6.11
Cephalosporins	556	28.79	7.38
Macrolides	231	11.96	3.07
Quinolones	46	2.39	0.61
Metronidazole	122	6.32	1.62
Antimalarial	153	7.92	2.03
Anthelmintics	108	5.59	1.43
*Other combinations	230	11.91	3.05
**Others	25	1.29	0.33
Total	1931	100	25.64

*Other combinations - Metronidazole + Norfloxacin, Cotrimoxazole, Ofloxacin + Ornidazole, Norfloxacin + Tinidazole, Ofloxacin + Tinidazole, Ofloxacin + Metronidazole. **Others - Linezolid, Colistin Sulphate.

Table 5 shows number of drugs per prescription. On an average 3.59 drugs were prescribed per prescription. Around half (48%) of the patients were given four or more medicines.

Table 5: Number of drugs per prescription.

Number of drug (s) per prescription	Prescription		Total number of drugs
	Number	%	
1	34	1.62	34
2	252	12.00	504
3	795	37.85	2385
4	701	33.38	2804
5	177	8.43	885
6	86	4.10	516
7 and above	55	2.62	403
Total	2100	100	7531

Average no. of drugs per prescription= 3.59.

Table 6 shows rationality of prescriptions. Of total 7531 medicine formulations prescribed, 86.91%, (6545) were prescribed by brand names.

Table 6: For the rationality of prescriptions (total no. of medicine formulations-7531).

Drug Prescribed	Number (%)
By generic name	986 (13.09%)
By brand name	6545 (86.91%)
Banned drug formulations	0

Table 7 shows the essential status of medicines. 38.03% (2864) of total medicine formulations prescribed were matching, with those listed in model list of essential medicines (EML). Of total FDCs prescribed only 26.96% (1029) were from the EML.

Table 7: Essential status of medicines and fixed dose combinations (FDCs.).

Parameter	Essential	Non-essential	Total	FDCs as % of total non-essential medicines
Medicines formulations	2864 (38.12%)	4667 (61.97%)	7531	59.73%
FDCs	1029 (26.95%)	2788 (73.04%)	3817	

DISCUSSION

Upper respiratory tract infections (URI) is the most common infectious pathology in children, often reported in a frequency of 5 to 8 episodes per year in urban areas.⁴ In India, again, the most common disease affecting children is acute respiratory infection (ARI), which is responsible for about 30-50% of visits to health facilities and for about 20-40% hospital admissions.⁵ In our study we also found this fact, as more than half of the total prescriptions (56.76%) accounted for the respiratory system. Prescriptions with diagnosis of common cold, pharyngitis, laryngitis (URI), pneumonia, bronchitis, bronchiolitis (LRTI), and bronchial asthma were included within this system. Similar results were found in a study conducted in Kathmandu Valley, and by Ashraf et al while studying prescribing pattern of drugs, where Pneumonia was found to be the most common diagnosis.^{6,7}

Prescriptions for Gastrointestinal System constitute 2nd largest group, (26.62%). Rests of the prescriptions belong to other systems. In our study we saw that prescriptions for the CNS and CVS systems were very few, which shows that these patients are mostly treated as indoor patients, where treatment is given after thorough examination and investigations and under supervision. Prescriptions included in others were those having the diagnosis of skin diseases, anaemia, urinary tract infections and the prescriptions where no diagnosis was mentioned. In few prescriptions diagnosis was missing, which may have medicolegal consequences in cases, some adverse reaction happens with the prescribed drugs. But such prescriptions were found very few.

Among the various dosage forms used, syrups (53.56%) were the dosage form of choice by prescribers, followed by tablets (29.09%). This may be because of the reason they are most convenient for the paediatric population. Similar results were found by different studies by Vijay S et al and Dimri et al where syrups were found to be most commonly prescribed followed by tablets.^{8,9}

The prescription trend suggested (Table 3) the antimicrobials to be the most frequent class of drugs prescribed, (77.42%) followed by analgesic-antipyretics, accounted for second most common class of drugs prescribed (69.28%). Palikhe N et al in his study also, found antibiotics the most frequently prescribed class of drugs (93%).⁶ In a study by Ashraf H et al, 72% patients were prescribed at least one antibiotic whereas the NSAIDs were only 14.28%.⁷

Among the drugs prescribed in respiratory system, cough remedies prescribed were 12.72% and anti-cold preparations were 13.80% of total medicine formulations prescribed. Cough remedies included both containing single drug like salbutamol, Montelukast, as well as combinations of bronchodilators and antitussives. Similarly anti-cold preparations included antihistaminic, nasal decongestants and their combinations. Among the GIT cases most of the cases were of acute diarrhoea/dysentery. Other cases included were of pain abdomen, nausea vomiting, gastritis, mouth ulcer, decrease appetite etc. Trend towards the prescription of oral rehydration salt (ORS) were noticed in present study, as ORS were prescribed more frequently among the GIT drugs (24.72%) as compared with a previous Indian study, where ORS were prescribed to 22% of the children, and a study conducted in Sri Lanka where ORS was prescribed for only 3.4% of children.^{10,11} This is a welcome sign. The prescribing frequency is, however, lower as seen by Deepali et al (58%).¹² Prescriptions for diarrhoeal disease also contained other drugs like antibiotics, probiotics, anti-emetics or racecadotril, which are not recommended in the guideline.¹³ Broad spectrum antibiotics were used and often in illogical combinations for diarrhoeal disease like ofloxacin with ornidazole, norfloxacin with metronidazole etc. Antiemetics (19.62%) probiotics (16.08%) antispasmodics (15.41%) and appetizers (10.20%) were the next groups prescribed frequently after ORS among the GIT drugs.

Paracetamol was the choice among the non-steroidal anti-inflammatory drugs (NSAIDs) as it was accounted for 48.38% of all NSAIDs prescribed during study. In other studies by Vijay S et al, and by S Dimri, also, paracetamol was found to be the most frequently prescribed among the analgesic-antipyretic drugs.^{8,9} If antipyretic therapy is needed, for a symptomatic child with high fever, Paracetamol is the preferred pharmacotherapy.¹⁴ In our study we also found that paracetamol was prescribed mostly by the prescribers.

In our study we also saw that a significant number of prescriptions contained Nimesulide and its combination with Paracetamol. Around 17% of total NSAIDs prescribed, were nimesulide and its combination with paracetamol.

Numerous studies have established the life threatening hepatotoxic effects of nimesulide.¹⁵ Nimesulide is not used in the United States, and many European countries have also banned the drug because of its unacceptable rate of serious adverse reactions. No rationale exists for

selecting nimesulide as the first drug of choice for fever or pain. A plethora of scientific data shows that nimesulide should not be used as the primary mode of treatment as an antipyretic or analgesic, especially in children, for whom much better and safer choices are available. Fortunately, soon nimesulide suspension for paediatric use would be banned in India. The Drug Controller General of India has forwarded a proposal to the health ministry recommending imposition of ban on the sale of this drug in the Indian market.

Antibiotic resistance

Excessive and in appropriate use of antibiotics has been a major contributor to this ever-growing problem. Acute respiratory infection (ARI), acute watery diarrhoea (ADD) and viral fever are the common childhood illnesses accounting for the major proportion of paediatric outpatient visits. Only a small proportion of these patients (<20%) require antibiotic therapy.¹⁶ Studies have shown that there is an inappropriate use of antibiotics, especially the broad-spectrum antibiotics, for these common childhood illnesses, which has contributed largely to the development of antibiotic resistance. Arch G Mainous et al showed that the use of broad-spectrum antibiotics has increased from 10.6% to 40.6% for bronchitis in a span of 6 years from 1993 to 1999.¹⁷

The proportion of antibiotic prescription was 77.42% in the present study as against the WHO recommendation of 20% antibiotic use for these common childhood illnesses.¹⁶ Antimicrobials constituted 25.64% of the total drugs prescribed during study. The number of encounters containing antimicrobials found in our study were less than found in the study by Palikhe N (93%) but comparatively more than the study done by S Dimri et al (29.1%).^{6,9}

Antibiotics were prescribed without investigation mainly based on clinical judgment with an average of 1.19 per prescription. Cephalosporin group of antibiotics was the leading antibiotic prescribed (28.79%). Cefpodoxime was the leading antibiotic prescribed within the group as well as a whole among the antibiotics prescribed. Penicillins were the next commonest antibiotics prescribed (23.82%), among which fixed dose combination of Amoxicillin+Clavulanic acid was the most frequently prescribed of all. Among the macrolides, azithromycin was prescribed mainly. These drugs were prescribed mainly for upper/lower respiratory infections. Quinolones were used least (2.38%) as a single drug. Uses of antibiotics of this group were also included use as eye drops. In the Imidazole group Metronidazole was used most commonly as a single drug. In some cases of GIT and respiratory system uses of colistin sulphate and linezolid were also found. Antimalarial constituted 7.92% of total antimicrobial prescribed. Chloroquine was used most frequently. 5.6% of all antimicrobial used were antihelmintics in which albendazole alone and along with ivermectine were used mostly. Among the all prescribed

antimicrobials 11.91% were prescribed as a fixed dose combination (excluding combinations of antihelmintics and penicillins). Combinations of imidazoles with quinolones, and co-trimoxazole were commonly prescribed for gastrointestinal infections.

Poly-pharmacy

It is expressed as number of drugs per prescription. It is an important index of the scope for review and educational intervention in prescribing practices. In the present study on an average 3.59 drugs were prescribed per prescription, (Table 5) which is higher than the recommended value of 2.¹⁸ values under 1.4 have been reported from Sweden, and Italy.^{19,20} Indian studies by Prakash et al and by Ansari et al found this number to be 5.86 and 5.05 medicines per prescription respectively in their studies.^{21,22}

Thus it is evident that the poly-pharmacy and over prescribing are common in India, an economically developing country, as compared to economically developed western countries. Various reasons can account for this situation like unrealistic expectations and demand for quick relief from the patients; availability of non-essential and irrational drug combinations; and aggressive medicine promotion and unethical marketing practices of pharmaceutical companies.²²

In our study prescribing by brand name dominated (Table 6) as, of total 7531 medicine formulations prescribed, 86.91%, (6545) were prescribed by brand names whereas only 13.09% (986) were prescribed by official/ generic names. Similar results, were also found by Vijay S et al, and by S Dimri et al, in their study where they found 83% and 94.2% drugs were prescribed by brand names respectively.^{8,9} Prescribing medicines by official names avoids the confusion and makes the drug therapy rational and cheaper. Moreover in the teaching institutions world over, in textbooks, in scientific journals and in the research publications, medicines are always mentioned by official names. Despite this, most doctors prescribe the medicines by their brand names. The reasons for this could be (i) tradition, (ii) aggressive medicine promotion by brand name, (iii) availability of multi-ingredient fixed-dose drug combinations, (iv) faulty medicine policy and lack of "political will" etc. Essential medicines and rational use of medicines are two sides of a coin - inseparable from each other and mutually dependent. Increase in the use of essential medicines makes the medicine therapy more rational.²³ In our study (Table 7), 38.03% (2864) of total medicine formulations, were matching, with the those listed in model list of essential medicines (EML), whereas remaining 61.97% (4667) medicine formulations could be constructed as non-essential.²⁴⁻²⁶ Of total non-essential medicine formulations, 59.73% (2788) were in the form of fixed dose combinations. Biswas et al found 96%, 94% and 74% of essential medicines prescribed in three Delhi based hospitals.²⁷ This is certainly higher than in our

study. One reason for this could be an effective and successful implementation of EML in government hospitals of Delhi. This clearly shows how “political will” can bring about a desirable change.

A fixed dose combination (FDC) refers to the combination of two or more drugs in a single pharmaceutical formulation. The rationality of FDCs should be based on certain aspects such as.²⁸

- The drugs in the combination should act by different mechanisms
- The pharmacokinetics must not be widely different
- The combination should not have supra-additive toxicity of the ingredients.

Unfortunately, many FDCs being introduced in India are usually irrational. The most pressing concern with irrational FDCs is that they expose patients to unnecessary risk of adverse drug reactions. In our study of total medicine formulations prescribed, 50.68% (3817) were in the form of fixed dose combinations (FDCs). Vijay S et al found, 6.75% of the drug prescribed was in the form of FDCs, in their study and 25.92% among them were outside the WHO recommended list.⁸ In our study most of the fixed dose combinations were of cough syrup/ anti-cold preparations and analgesic-antipyretic preparations.⁸

Among the respiratory drugs 82.42% of the medicine formulations were in the form of FDCs and none of them is included in either of EML, WHO or National. Combinations found were mostly of antihistamines with decongestants. Similarly combinations of antitussive with expectorants were also found, both of these drugs act in opposite direction and their combination in a preparation is highly unjustified. However there are certain combinations which are rational yet not included in essential drug list, like combination of β_2 -agonist with inhaled corticosteroid. β_2 -agonist cause bronchodilatation and inhaled corticosteroid acts because of its anti-inflammatory and immunosuppressant action. This combination provides good synergism in bronchial asthma. Similarly among the analgesic-antipyretics 44.81% medicine formulations were in the form of FDCs and none of them is present in EML. The combinations used were of paracetamol with Ibuprofen and with nimesulide. In India, a variety of NSAID combinations are available, often as over the counter products. Combining two NSAIDs does not and cannot improve the efficacy of treatment. It only adds to the cost of therapy and more importantly, to the adverse effects.²⁹

In the group of GIT drugs, maximum numbers of FDCs (91.02%) were from EML, and it is mainly due the fact that ORS was the most frequently prescribed agent among the GIT drugs, and is included in essential medicine list. Non-essential combinations were of proton pump inhibitors with anti-emetics. There is no justification of combining these drugs with antiemetic drug domperidone

or ondansetron as hyperacidity is not always associated with vomiting.

Among the AMAs 65.98% and among the vitamins and minerals 60.17% FDCs were from the EML. Among the AMAs rational drug combinations used were amoxicillin with clavulanic acid and co-trimoxazole which were included in essential drug list. Other combinations used were FDCs of quinolones and nitroimidazoles (e.g. Norfloxacin + Metronidazole, Ciprofloxacin + Tinidazole, Ofloxacin + Ornidazole etc.). These combinations have not been recommended in any standard books and not included in EDL, but continue to be heavily prescribed drugs in gastrointestinal infections to cover up for diagnostic imprecision and the lack of access to laboratory facilities. Such injudicious use of antibiotic FDCs can rapidly give rise to resistant strains of organisms, which is a matter of serious concern to the health care situation in our resource poor country. A glaring example is the emergence of ciprofloxacin-resistant *salmonella typhi* strains which have made treatment of typhoid fever a difficult and expensive proposition in India today.²⁸

CONCLUSION

Most of the prescriptions were in accordance to an ideal prescription in many regards. Age, weight, sex, date and diagnosis were written in most of the prescriptions which is the satisfactory fact in the present study. Average number of drugs per prescription found to be more than the recommended. This should be decreased. There is a lot of scope for improvement in case of medicines prescribed by generic name. Percentage of medicines prescribed from EDL should be encouraged. Prescribing of fixed dose combinations that are not included in essential drug list and are of doubtful rationality, should be stopped. The proportion of prescription containing antibiotic was quite high in the present study as against the WHO recommendation of antibiotic use for the common childhood illnesses. This should be decreased.

Thus, the study of drug utilization and prescribing pattern is an essential part of medical audit which seeks to monitor, evaluate and, if necessary suggest modification in prescribing practices of medical practitioners so as to make medical care rational and cost effective.

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