

DRUG PRESCRIBING PRACTICES IN PAEDIATRIC DEPARTMENT OF A NORTH INDIAN UNIVERSITY TEACHING HOSPITAL

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Received: 14 November 2011, Revised and Accepted: 11 January 2011

ABSTRACT

Background: Drug utilization studies have become a useful tool to facilitate rational use of drugs. A very few studies provides information on drug use patterns in children. Objectives: To evaluate drug utilization and associated cost of treatment in the paediatric outpatient and inpatient department of a university teaching hospital in north India. Methods: A prospective observational study approved by Institutional Review Board was carried out on 302 subjects executed for 4 months. Data were collected from clinical notes and analyzed for the various WHO/ INRUD indicators. Results: Average number of drugs per prescription was 5.6, whereas most common individual drug was found to be paracetamol (90.72%). The drugs prescribed by generic name were only 2.6 %. Overall, 81.13% of patients indicated good compliance and none of the drugs were prescribed from non registered/banned drug list given by CDSCO, Government of India. The average consultation time was found to be 7 minutes. The copy of essential medicine list and clinical guidelines with internet facility was available. 89.36 % medicine was available from the list of essential drugs. The average cost of drugs per prescription was INR 215.33. Average prescribed dose of paracetamol (PCM) and Ibuprofen was found to be 9.5 mg/kg and 9.5 mg/kg of body weight. Conclusions: Our study highlighted some rational prescribing practices including very low rate of prescription of injections, negligible use of 'off-label' drugs, a higher consultation time resulting in knowledge of correct doses and hence of improved compliance. Some areas of concern were high polypharmacy, higher rate of antibiotics prescribing and prescribing by brand names.

Keywords: Prescribing patterns, Rationale, Paediatrics, North India

INTRODUCTION

Inappropriate prescribing is a recognised worldwide problem of the health care delivery system¹. In recent years, drug utilization studies are found to be useful tool to facilitate rational use of drugs in health care delivery systems. It truly reflects the status of health care system. In order to be rational, use of a drug must be effective, safe, prescribed for the proper therapeutic indication and the correct dosage in an appropriate formulation, easily available and of a reasonable cost. The general public needs information and education on medicines and appropriate treatment seeking strategies so that individuals and communities can take responsibility for their health. Various indicators were developed by International Network for the Rational Use of Drugs (INRUD) in collaboration with WHO that provide objective indices to allow for assessment of drug use practices and suggesting remedial measures.² Many studies point to major misconceptions and misuse of medicines. The design of a drug use indicator study, however, varies from settings to settings. While a large number of drug utilization studies are available for adults all over the World,^{3,4} a very few studies provides information on drug use patterns in Paediatrics. Paediatrics is among the most vulnerable population group of infectious diseases. Since pharmacodynamic and pharmacokinetics are different in children, which often make them more susceptible to various adverse drug reactions.^{5,6} Additionally, the impact of maternal drug intake on neonates is also relevant in this context. Such issues therefore call for close monitoring of drug prescribing trends in neonates and infants as previously described.^{7,8} Besides, due to economic and ethical issues, children do not often participate in clinical trials and specific knowledge about effect of drugs in children is often inadequate.^{4,9} Another common problem encountered in children is failure to comply with therapeutic regimen due to either inconvenient dosing schedule and/ or large number of medicines prescribed.⁷ It is well documented that safe and effective drug therapy is possible only when patients are well informed about the medication and their use.¹⁰

The present study was designed with the aim to assess prevailing prescription patterns, patient non-compliance and to provide proper counseling in the pediatric department. The information is expected to aid in interventions that would improve the prescribing patterns and rational drug use in children.

STUDY DESIGN AND METHODOLOGY

The drug utilization pattern was carried out in the Paediatric OPD and IPD of a 350 bedded university teaching hospital at north India.

A prospective observational study was designed and medication utilization form was designed for in-depth interview based on WHO format,¹¹ during a period of 4 months from January to April in 2008. Patients below 12 years of age having fever were included in the study. The study protocol was approved by the Jamia Hamdard Institutional Review Board. A written consent was obtained from parents before the participation of subjects in the study. The following drug utilization indicators were assessed: **1. Prescribing Indicators:** a. Average number of medicines prescribed per patient encounter; b. Percentage of drugs prescribed by generic name c. Percentage of encounters with an antibiotic prescribed; d. Percentage of encounters with an antipyretic prescribed; e. Percentage of encounters with an injection prescribed; f. Percentage of medicines prescribed from essential medicine list or formulary; g. Percentage of drugs prescribed from banned drugs/non registered drug list given by CDSCO **2. Patient care indicators:** a. Average consultation time; b. Average dispensing time; c. Percentage of medicines actually dispensed; d. Percentage of patients with knowledge of correct doses; **3. Facility indicators:** a. Availability of essential medicine list or formulary to practitioners; b. Availability of clinical guidelines; c. Percentage key medicines available; **4. Complementary drug use indicators:** a. Average medicine cost per encounter; b. Average antibiotic cost per encounter **5. Other indicators:** a. Most common diagnosis b. Residence environment of parents. Besides these, age and sex distribution of the child, most common pharmacological group, most commonly individual drugs prescribed and average prescribed dose of antipyretics were also being taken into consideration.

RESULTS

A total 302 respondents suffering from fever were participated in the study during the four months period. A gender distribution of the subjects indicated 65.89% of males and 34.11% of females. Majority of subjects belongs to OPD (292, 96.68%) in compare to IPD (10, 3.32%) respectively (Table 1). It was observed that maximum number of patients (29.80%) comes under the age group of > 1month-1 year (Table 2). The most commonly prescribed pharmacological group was Antipyretics (100%) followed by anti-infectives (81.12%) while the most common individual drug was

found to be paracetamol then chlorpheniramine (Table 3). Analysis of the WHO Core drug-prescribing indicators is summarized in Table 5. Average number of drugs per prescription was found to be 5.61. The drugs prescribed by generic name were only 2.63 %. The percentage of antibiotics prescribed to the patient was 81.12 % whereas all the patients received antipyretic drugs. The percentage encounter with injections was also low (0.68%) in OPD against IPD (100%). 90.23 % of medicines prescribed from essential medicines list whereas none of drugs prescribed from banned drugs/non registered drug list given by CDSCO, Government of India. The average consultation and dispensing time was 7 and 4 minutes respectively. At the time of patient counseling it was observed that the medicines actually dispensed was 96.07 %. During follow-up, only 46 patients re-visited OPD and interviewed. Among them 41(89.93%) patients had taken the drug properly indicates good compliance. The copy of essential medicine list and clinical guidelines with internet facility was available. 89.36 % medicine was available from the list of essential drugs. Average cost of drugs per prescription was INR 215.33. Whereas, the average cost of antibiotic per encounter contributed to be INR 113. A large proportion of children (80.13%) were suffering from upper respiratory tract infections followed by acute gastroenteritis (9.27%). Most of the patients enrolled were from nearby localities belonging to low socioeconomic region.

The average prescribed dose of PCM and Ibuprofen was found to be 9.52 (3.77 to 15.28) mg/kg and 9.4 (6.25 to 12.5) mg/kg of body weight.

Table 1: Distribution of patients and drugs used.

Outpatient & Inpatient Distribution	No. Of patients	Percentage
OPD	292	96.68
IPD	10	3.32
Sex Distribution	No. Of Patients	Percentage
Male	199	65.89
Female	103	34.11

Table 2: Age distribution of patients.

Age Distribution	Male		Female		Total	
	No.	Percentage	No.	Percentage	No.	Percentage
0-1 month	06	03	02	02.96	08	2.460
>1 month-1 year	64	32	26	25.49	90	29.80
>1 year-2 year	42	21	17	16.66	59	19.53
>2 year-4 year	42	21	29	28.43	71	23.50
>4 year-6 year	21	10.5	12	11.76	33	10.92
>6 year-8 year	12	06	09	08.82	21	06.95
>8 year-10 year	08	04	05	04.91	13	04.30
>10 year-12 year	05	02.5	02	1.96	07	02.31
Total	200	100	102	100	302	100

DISCUSSION

Irrational use of drugs is common in developing countries with a high rate of polypharmacy, overuse of antibiotics and injections, use of 'off-label' drugs and drugs with improper efficacy. Several studies have documented prescribing practices in different countries.¹²⁻¹⁵ But there is still dearth of information on the prescribing practices in paediatrics. In the present study, we have used the WHO/INRUD indicators in addition to the other indicators such as most commonly prescribed antipyretic drugs and their dosage used in children etc attending the paediatric OPD and IPD of a 350-bedded university teaching hospital of Jamia Hamdard, New Delhi, India.

We found a predominance of male patients (65.89%) as compared to females (34.11% Female) and the ratio was more than expected from the sex ratio of South Delhi (India). It reflects a deep rooted

gender bias in Indian culture where girls are treated as lesser over boys and are therefore less often brought to the hospital for medical attention.¹⁶ With regard to age, maximum (29.80%) patients were in the age group of 1 month to 12 months.¹⁷⁻¹⁸ This may be due to a higher susceptibility of infections at a younger age and needs a greater concern for infant's health relatively.

Table 3: Most common pharmacological group.

Drug Category	No. of patients	Percentage
NSAIDs (Antipyretics)	302	100
Anti-infectives	245	81.12
Cough and cold preparations	235	88.81
Vitamins	88	29.13
Anti-diarrhoeals	39	12.91
Anti-emetics	29	09.60
Anti-asthmatics	21	06.95
Anti-helmentics	18	05.96
Anti-malarials	11	03.64
Anti-epileptics	05	01.65

A total of 74 medicines were prescribed with the average of 5.6 medicines per patient. This finding was in contrast to previous studies.¹⁹⁻²⁰ Prevalence of polypharmacy was high and it gradually results when there is a possible diagnostic uncertainty. This leads to increased risk of adverse effects, drug-interactions, increased cost and reduced patient compliance. Only 3.32% patients were hospitalized that is much lesser as compared to outpatients. The drugs most commonly used among them were paracetamol followed by chlorpheniramine (Table 4) whereas the most common pharmacological group was antipyretics followed by anti-infectives and cold and cough preparation as related to prevalence of disease (Table 5).²¹

Table 4. Most commonly individual drugs prescribed.

Drug	No. of patients	Percentage
Paracetamol (Ibuprofen+ Paracetamol)	273	21.66
Chlorpheniramine	162	11.62
Ambroxal	113	08.1
Co-amoxiclav	93	06.67
Phenyl propanolamine	66	04.73
L. sporogenes	63	04.51
Cefaclor	50	03.58
Pseudoephedrine	38	02.72
Cefpodoxime	28	02

In our study, only 2.63 % drugs were prescribed by generic name that is inconsistent to previously reported studies.^{4,19} Prescribing by brand name may be an evidence of vigorous promotional strategies by pharmaceutical companies that may undermine some of the goals of essential drug list concept. On the other hand, prescribing by generic name may reduce overall expenditure on drugs especially on newer antibiotics etc. The practice of brand name prescribing thus should be discouraged as use of generics is a cheaper alternative. The drugs especially antibiotics is also thought to be administered only when needed. The antibiotic usage practices in the hospital were 81.12 % that increases direct cost of treatment. However, Evidence indicates that overuse of anti-infectives is scientifically unjustified, uneconomical and gluttonous. Since the most common diagnosis was upper respiratory infections which could also be a viral origin. Antibiotic use in most of the cases may not be required and this can potentially lead to antimicrobial resistance.

Similar to studies reported, antipyretics, anti-infectives, cough & cold preparations and vitamins were the commonest category of drugs prescribed.¹⁰ Further, the use of vitamins and cough & cold preparations was relatively high increasing the cost of prescription.¹⁰

Similar to previous studies, we found that out of 292 prescriptions, only 2 (0.68%) patients have received injection in paediatric OPD indicating a rational practice as previously reported.^{4,20} In IPD; however 100% patients received injections (I.V. / I.M.).¹³

Antipyretic use plays an important role in daily paediatric practice to reduce fever and maintain homeostasis. Average number of antipyretic drugs was found to be 1.086 per prescription as reported earlier.²² The prescribing rate of antipyretic is justified since we selected only those children who were suffering from fever. Among the antipyretic drugs prescribed, PCM was found to be most commonly prescribed drug (90.72%) followed by combination of PCM and Ibuprofen (8.60%). In different studies, the efficacy and tolerability of Ibuprofen and PCM have controversial reports.²³⁻²⁶ It was also reported that alternating PCM and Ibuprofen is more effective as compared to treatment with single drug. In our study, alternating PCM and Ibuprofen were not prescribed because instructing parents to alternate drugs may create confusion and dosing errors. Combination of PCM and Ibuprofen was, however, prescribed in children with high grade fever but this is inconsistent.²⁷ The safe recommended dose range of PCM and Ibuprofen is 12-15mg/kg and 5-10 mg/kg of body weight. Similarly, in our study the average prescribed dose of PCM and Ibuprofen was found to be 9.5 mg/kg and 9.5 mg/kg of body weight. In this range of the dose, none of the adverse drug reactions were reported.^{24,27}

Table 5: Assessment of WHO core prescribing indicators.

Parameters accessed	Result
Prescribing Indicators	
a. Average number of medicines prescribed per patient encounter	5.61
b. % medicines prescribed by generic name	2.63
c. % encounters with an antibiotic prescribe	81.12
d. % encounters with an antipyretic prescribed	100
e. % encounters with an injection prescribed	0.68
f. % medicines prescribed from essential medicines list or formulary	90.23
g. % of drugs prescribed from banned drugs/non registered drug	Nil
Patient Care Indicators	
a. Average consultation time (Minute)	7
b. Average dispensing time (Minute)	4
c. % medicines actually dispensed	96.07
d. % patients with knowledge of correct doses	89.93
Facility Indicators	
a. Availability of essential medicines list or formulary to practitioners	Yes
b. Availability of clinical guidelines	Yes
c. % key medicines available	89.36
Complementary Drug Use Indicators	
a. Average medicine cost per encounter (INR)	215.33
b. Average antibiotic cost per encounter (INR)	113.72
Other indicators:	
a. Most common diagnosis (Percentage)	
Upper Respiratory Tract Infection	80.13
Acute gastroenteritis	9.27
Typhoid	5.29
Malaria	2.98
Lower respiratory tract infection	1.32
b. Residence environment of parents.	Insanitation

Most new compounds proceed through the approval process without any paediatric studies. Knowledge about efficacy and safety of drugs in infants and children is therefore often sparse. In our study none of drugs used belonged to 'off-label' drugs. Some antipyretic drugs like Nimesulide has been banned in Canada, USA, UK etc. due to possible hepatotoxicity in children but it is not banned by CDSCO, Govt. of India. In our study, Nimesulide was prescribed to only one child.

In OPD, Acute upper respiratory tract infections (including rhinitis and nasopharyngitis) were the commonest disease in 242 (80.13%) of patients and it is followed by acute gastroenteritis and typhoid (Table 5). Similar experiences have been reported from other developing country due to localities with poor sanitation and unhygienic conditions.^{16, 19-20}

Furthermore, several studies have acknowledged the improvement in patient knowledge about medications following counseling by

pharmacist.¹⁰ In our study 41 (89.13%) patients had taken drugs properly indicates of good compliance in children due to verbal clarification from the pharmacist. One of the reasons for increased percentage of patients with knowledge of correct doses could be due to increased consultation time (7 minutes) and dispensing time (4 minutes) given by pediatricians and pharmacist respectively in contrast to different previous studies.^{3,13}

Pharmacoeconomics are now extremely important key factor in health management from last decades. The cost of medications is one of the key barriers for accessing medications in developing country. Average cost per prescription was found to be 215.33 INR. In our study antibiotics contributed maximum of total drug cost. The high cost of medications especially antibiotics and anti-retroviral drugs directly affect poorest and most vulnerable population such as children that leads to non compliance, morbidity and mortality.^{3,10}

Our study had many limitations. The study was carried out over a four-month period, and seasonal variations in disease pattern and drug utilization were not considered. Further, the number of patients in our study was low and the study was restricted to only one hospital. In addition, our study did not evaluate the effect of antipyretic drugs on biochemical parameters such as liver function test etc. In spite of all these limitations, our study highlighted some rational prescribing practices including negligible rate of injectable prescribing, 'off-label' drugs and use of controversial drugs like Nimesulide. A higher consultation time resulting in improved knowledge of correct doses and reflects good compliance & lesser use of controversial. We also found some areas of concerns regarding drug use. These were high polypharmacy, higher rate of antibiotics prescribing and prescribing by brand names suggesting interventions. Continuing education on rational drug use and development of easy to use treatment guidelines for common diseases in children is suggested.

ACKNOWLEDGEMENT

The authors would like to acknowledge the assistance rendered for data collection by all nursing personnel, medical officers of the paediatric unit in the conduct of the study.

REFERENCES

- Report of a conference of experts, Nairobi, November 24-29, 1985. The rational use of drugs. World Health Organization: Geneva, 1987.
- Laporte JR, Porta M, Capella D., *Drug utilization studies: a tool for determining the effectiveness of drug use*, Brit J Clin Pharmacol, 1983; 16: 301-304.
- Guyon AB, Barman A, Ahmed AU, Alam MS., *A baseline survey on use of drugs at the primary health care level in Bangladesh*, Bull WHO 1994; 72: 265-271.
- Vallano A, Montane E, Arnau JM, Vidal X, et al., *Medical speciality and pattern of medicines prescription*, Eur j Clin Pharmacol 2004; 60: 725-730.
- Ginsberg G, Hattis D, Sonawane B, Russ A, et al., *Evaluation of Child/Adult Pharmacokinetic Differences from a Database Derived from the Therapeutic Drug Literature*, Toxicol Sci 2002; 66: 185-200.
- Takahashi H, Ishikawa S, Nomoto S, et al., *Developmental changes in pharmacokinetics and pharmacodynamics of warfarin enantiomers in Japanese children*, Clin Pharmacol Ther 2000; 68: 541-555.
- Hanne M, Morten A, Jesper H, *Drug prescribing in Danish children: a population based study: Pharmacoepidemiology and Prescription*, Eur J Clin Pharmacol 2001; 57: 159-165.
- Strand J, Rokstad K, Heggedal U, *Drug prescribing for children in general practice: A report from the More & Romsdal Prescription Study*, Acta Paediatr 1998; 87: 218-224.
- Karande S, Sankhe P, Kulkarni M. *Patterns of prescription and drug dispensing*, Ind J Pediatr 2005; 72: 117-121.
- Tzimis L, Kafatos A, *Drug utilization and nutrition patterns among children from indigent and emigrant families in Crete, Greece*, Public Health 2000; 114: 393-397.

11. World Health Organization. How to investigate drug use in health facilities: Selected drug use indicators. Geneva, World Health Organization 1993. WHO/DAP 1993; 1: 1-87.
12. Chatterjee S, Mandal A, Lyle N, Mukherjee S, Singh AK, *Drug utilization study in a neonatology unit of a tertiary care hospital in eastern India*, Pharmacoepidemiol Drug Saf 2007; 16: 1141-1145.
13. Jeevangi SR, patil RB, Awanti SM, Manjunath S, patil B, Devi K, *Drug utilization study in a burn care unit of a tertiary care hospital*, Asian Pac J Trop Dis 2011; 41-46.
14. Cazzato T, Pandolfini C, Campi R, Bonati M, *The ACP Puglia-Basilicata Working Group. Drug prescribing in out-patient children in Southern Italy*, Eur J Clin Pharmacol 2001; 57: 611-616.
15. Straand J, Rokstad K, Heggedal U, *Drug prescribing for children in general practice. A report from the More & Romsdal Study*, Acta Paediatr 1998; 87:218-24.
16. Jhaj R, Bhargava VK, Uppal R, Reeta KH, Saha L, Kaur N, Kumar L, *Drug Prescribing in Children in a North Indian Referral Hospital*, Pharmacoepidemiol Drug Saf 2000; 9: 423-427.
17. Bocian AB, Wasserman RC, Slora EJ, Kessel D, Miller RS, *Size and age-sex distribution of pediatric practice: A study from pediatric research in office settings*, Arch Paediatr Adolesc Med 1999; 153:9-14.
18. Richard J, Osmond MH, Nesbitt L, Stiell IG, *Management and outcomes of pediatric patients transported by emergency medical services in a Canadian prehospital system*, Can J Emerg Med 2006; 8(1):6-12.
19. Isah AO, Ohaju-Obodo J, Isah EC, Ozemoya O, *Drug Use Profile in a Nigerian city Hospital*, Pharmacoepidemiol & Drug Saf 1997; 6: 319-324.
20. Karande, S., Punam, S., Madhuri, K, *Patterns of prescription and drug dispensing*, Ind J Paediatr 2005; 72(2):117-121.
21. Shankar PR, Upadhyay DK, Subish P, Dubey AK, Mishra P, *Prescribing pattern among paediatric inpatients in a teaching hospital in western Nepal*. Singapore Med J 2006; 47(4): 261-265.
22. Issacs SN, Axelrod PI, Lorber B, *Antipyretic orders in a university hospital*, Am J Med 1990; 88(1): 31-35.
23. Sheth UK, Gupta K, Paul T, Pispati PK, *Measurement of antipyretic activity of ibuprofen and paracetamol in children*, J Clin Pharmacol 1980; 20(11-12): 672-675.
24. Ulukol B, Koksall Y, Cin S, *Assessment of the efficacy and safety of paracetamol, ibuprofen and nimesulide in children with upper respiratory tract infections*, Eur J Clin Pharmacol 1999; 55(9): 615-8.
25. Autret E, Reboul-Marty J, Henry-Launois B, Laborde C, Courcier S, Goehrs J M, et al., *Evaluation of ibuprofen versus aspirin and paracetamol on efficacy and comfort in children with fever*, Eur J Clin Pharmacol 1997; 51: 65-71.
26. Sarrell EM, Eliahu A, Herman AC. *Antipyretic treatment in Young children with fever*. Arch Pediatr & Adolescent Med 2006; 160:197-202.
27. Lal A, Gomber S, Talukdar B. *Antipyretic effects of Nimesulide, Paracetamol and Ibuprofen-Paracetamol*. Ind J Pediatr 2000; 67(12): 865-870.