INTRODUCTION

The World Health Organization (WHO) defines drug utilization study as “the marketing, distribution, prescription and use of the drug in a society, with special emphasis on the resulting medical, social and economic consequences.” Prescription monitoring and drug utilization studies (DUS) may help to identify the problems involved in therapeutic decision and promote the rational drug prescribing.1,2

Infants and children constitute a large proportion of the population in developing countries. They are especially vulnerable to contact illnesses and to the harmful effect of drugs due to differences in pharmacodynamics and pharmacokinetics. Children constitute 40% of India’s population. They suffer from frequent but usually non serious illnesses. Most of these are self-limiting and often treated not only inappropriately but also resorting to poly-pharmacy.3

Paediatrics is the branch of medicine dealing with the development, diseases and disorders of children. Drug therapy is considered to be major component of paediatric management in health care setting like hospital. Effective medical treatment of a paediatric patient is based upon an accurate diagnosis and optimum course of therapy, which usually involves a medication regimen. At the same time Infancy and childhood is a period of rapid growth and development. The use of antimicrobial agents, especially antibiotics has become a routine practice for the treatment of paediatric illnesses.
However, there are also reports of an irrational use of antibiotics which may even lead to infections that are worse than the originally diagnosed ones. The assessment of drug utilisation is important for clinical, educational and economic reasons. There is enough evidence to demonstrate that prescribing of drugs has shifted from generics to branded and prescribing out of National List of Essential Medicine (NLEM). The rational prescribing can be assessed with the help of conducting prescription audit on continuous basis.

Prescribing practices are a reflection of health professional’s abilities to determinate among the various choices of drugs and determine the ones that will most benefit the patients. The study of prescribing pattern is a part of the medical audit and seeks to monitor, evaluate and if necessary, suggest modification in prescribing practices to make medical care rational and cost effective. Appropriate drug utilization it terms of efficacy, safety, convenience and economic aspects at all levels in the chain of drug use. Epidemiological evaluation of medicine use in the elderly is now a highly visible topic, but drug utilization studies in paediatric population have been limited. The assessment of medicine utilization is important for clinical, educational and economic purpose. Infants and children represent a large part of the population in developing countries. Pediatric population is prone to suffer from recurrent infections of the respiratory tract and gastrointestinal system. Lower respiratory tract infections (LRTI) are the leading cause of death in children below 5 (five) years of age. Acute respiratory infection, acute watery diarrhoea and viral fever are the common childhood illnesses accounting for the major proportion of paediatric visits.  

**METHODS**

The present study was a prospective, cross sectional conducted by department of pharmacology in association with department of paediatrics of a tertiary care hospital. The study was performed over a period of 12 months from 1st October 2014 to 30th September 2015 after approval from Institutional Ethics Committee.

- Protocol development

An appropriate study protocol and Performa were developed and discussed with teaching staff members of the pharmacology department and head of paediatrics department.

**Selection criteria of patients**

**Inclusion criteria**

- Patient admitted in pediatric wards
- Whose parents or child willing to participate in study.

**Exclusion criteria**

- Parents or child unwilling to participate in study
- Patient admitted in NICU.

**Sample size**

WHO recommendation on sample size is that there should be at least 600 encounters in a cross-sectional survey describing current treatment practices. 2

- Type of study was prospective, observational, cross sectional study conducted in the department of pediatrics at tertiary teaching care hospital
- Study duration was 12 month from 1st October 2014 to 30th September 2015
- Source of data case record of inpatient in the pediatric ward was used as a source of data
- Informed consent written consent was taken in the child accent form.

Pediatric prescriptions dealing with antibiotic and other drug usage were analysed and Investigator had visited paediatric ward regularly. Total 610 cases were collected and analysed.

Data like age, sex, weight, socio-economical status, duration of hospitalization, diagnosis and detailed drug prescription pattern were collected from paediatric wards.

Finally, all the data was compiled and subjected to descriptive statistical analysis.

**RESULTS**

**Data analysis**

The present prospective and observational study was done to analyse the prescription pattern in paediatric patients admitted in paediatric wards of a tertiary care hospital. We had collected data of 610 patients and following parameters were analysed

**A. Demographic profile**

**Sex wise distribution**

Out of total 610 patients majority 404 (66.23%) were male patients while 206 (33.77%) were female patients (Table 1).

![Table 1: Sex wise distribution.](image_url)
Age wise distribution

In age wise distribution, out of total 610 majority of patients 266 (43.61%) were 1-5 year of age followed by 204 (33.44%) were of < 1 year and 140 (22.95%) were > 5 years of age (Table 2).

| Age (years) | No. of cases (%) |
|-------------|------------------|
| <1          | 204 (33.44)      |
| 1-5         | 266 (43.61)      |
| >5          | 140 (22.95)      |
| Total       | 610 (100)        |

B. WHO drug prescribing indicator

Average number of drugs per encounter

In our study total 3156 drugs prescribed in total 610 patients. So, average number of drugs per encounter is 5.17±2.41 (Table 3).

| Total no. of drugs prescribed | Total no. of encounters | Average number of drugs per encounter (± SD) |
|-------------------------------|-------------------------|---------------------------------------------|
| 3156                          | 610                     | 5.17±2.41                                   |

Total number of drugs per encounter

In our study from 610 patients, total 1 drug prescribed in 12 (1.96%) patients, 2 drugs in 39 (6.39%) patients, 3 drugs in 91 (14.91%) patients, 4 drugs in 132 (21.64%) patients, 5 drugs in 109 (17.87%) patients, 6 drugs in 106 (17.38%) patients, 8 drugs in 30 (4.92%) patients, 9 drugs in 14 (2.29%) patients and >9 drugs in 39 (6.39%) patients (Table 4).

| No. of drugs | No. of encounter | Percentage (%) |
|--------------|------------------|----------------|
| 1            | 12               | 1.96           |
| 2            | 39               | 6.39           |
| 3            | 91               | 14.91          |
| 4            | 132              | 21.64          |
| 5            | 109              | 17.87          |
| 6            | 106              | 17.38          |
| 7            | 38               | 6.23           |
| 8            | 30               | 4.92           |
| 9            | 14               | 2.29           |
| >9           | 39               | 6.39           |
| Total        | 610              | 100.00         |

Drugs prescribed from essential medicines list (EML)

In this study, from total 3156 drugs, 57% drugs are prescribed from WHO model list of essential medicine for children, 4th list (April 2013) while 43% drugs are not in EML (Figure 2).
Route of drug administration

From total 610 prescriptions, 1605 drugs given by oral route, 1485 drugs given by parenteral route (IM/IV), 210 drugs by inhalation route and 10 drugs by topical route. (Figure 3).

Duration of hospital stay in pediatric patients

Out of 610 patients, 44.26% patients stay for 2-4 days in hospital, 34.59% patient hospitalized for 5-7 days and 21.15% patient for >7 days (Table 5). Average number of duration of hospitalization was 5.85±4.

Table 5: Duration of hospital stay in pediatric patients.

| Duration of hospital stay (days) | Number of patient (%) |
|---------------------------------|-----------------------|
| 2-4                             | 270 (44.26)           |
| 5-7                             | 211 (34.59)           |
| >7                              | 129 (21.15)           |
| Total                           | 610 (100)             |

C. Morbidity pattern in pediatric patients

Out of total 610 cases, in 208 (34.09%) patients respiratory system (RS) diseases were seen, in 110 (18.03%) patients gastro-intestinal tract (GIT) involved, in 70 (11.47%) patients infectious diseases like malaria, dengue etc., in 62 (10.16%) patients central nervous system (CNS) diseases were seen, while 26 (4.26%) patient blood involvement, 18 (2.95%) patients had renal, acute febrile illness and viral fever, 8 (1.31%) cases had cardiovascular (CVS) and endocrine system involved, and 64 (10.49%) patients had other diseases (Figure 4).

While in GIT acute gastroenteritis (AGE) cases 56 (50.91%, n = 110) were most common followed by dysentery 27 (24.54%, n = 110).

D. Drugs prescribed in pediatric patients

In our study from total 3156 drugs, majority of drug prescribed 740 (23.44%) were anti-infective drugs, followed by 461 (14.61%) drugs acting on respiratory system, 456 (14.45%) non-steroidal anti-inflammatory drugs (NSAIDs), 373 (11.82%) intra-venous fluids, 372 (11.79%) nutritional supplements, 370 (11.73%) drugs acting on GIT, 111 (3.52%) drugs acting on CNS, 104 (3.29) corticosteroids and 169 (5.53%) others (Figure 5).

In anti-microbial agents (AMA) most commonly prescribed drug were B-lactam 411 (55.54%, n = 740), followed by aminoglycosides 139 (18.78%, n = 740), antimalarial 69 (9.32%, n = 740), vancomycin 34 (4.59%, n = 740), anthelmintic drugs 28 (3.78%, n = 740), sulphonamides 22 (2.97%, n = 740), linezolid 11 (1.46%, n = 740), macrolides 8 (1.08%, n = 740), antifungal and anti-amoebic 6 (0.81%, n = 740), and doxycycline 2 (0.27%, n = 740) and acyclovir 4 (0.54%, n = 740) (Figure 6).

Figure 4: Morbidity pattern in pediatric patients.

Among the respiratory diseases majority of patients had pneumonia 77 (37.02%, n = 208) followed by 45 (21.63%, n = 208) patients had Wheezing associated lower respiratory tract Infection (WALRI).

Figure 5: Drugs prescribed in pediatric patients.

Figure 6: Anti-microbial agents prescribed in pediatric patients.
E. Fixed dose combinations (FDCs) prescribed in paediatric wards

Commonly used FDCs in total 610 patients were amoxycillin + clavulanic acid, multivitamins, sulfadoxin + pyrimethamine and NSAIDs combinations like paracetamol with ibuprofen or diclofenac sodium (Table 6).

| Fixed dose combination (FDC) | No. of paediatric patients (%) |
|-----------------------------|-------------------------------|
| Amoxycillin+Clavulanic acid | 143 (48.15)                   |
| Multivitamins               | 122 (41.08)                   |
| Sulfadoxin+Pyrimethamine    | 22 (7.41)                     |
| Ibuprofen+Paracetamol       | 8 (2.69)                      |
| Diclofenac sodium+Paracetamol| 2 (0.67)                      |
| Total                       | 297 (100)                     |

DISCUSSION

Children are not simply small adults but they differ in anatomical as well as physiological aspect. Anatomically they differ in body size, body proportions and constituents. Physiologically their body function shows some difference as compared to adults and so pharmacokinetic processes show variation and thus, the drug response which may be of clinical significance. These differences are of important for therapeutic point of view. So, we had collected data of 610 patients and parameters like age, sex, duration of hospital stay, drug prescription pattern and morbidity pattern in paediatric indoor patients were analysed.

A. Demographic profile

Sex wise distribution

In our study from total 610 patients, 404 (66.23%) were male and 206 (33.77%) were female (Table 1). Similar finding also found in Study conducted by Vishwanath M. et al and Murali et al in which 53.33% and 54.6% males respectively.3,6 This study reported a similar sex distribution of patients as seen in other studies.

The reason of male predominance might be due to female child ignorance in the developing countries like in India.

Age wise distribution

Most commonly affected age group between 1-5 year of age 43.66% (n = 610) during present study (Table 2) which is similar to study conducted by Viswanand et al.5

It may be due to low immunity in the children <5 year of age which are more prone to infections.

B. WHO drug prescribing indicator

Average no. of drugs per encounter

The main purpose is to measure the polypharmacy.

Average number of drugs per prescription is an important index of scope for review and educational intervention in prescribing practices. One must remember that benefit: risk ratio for each drug prescription. It decreases when multiple drugs are given. Extreme and empirical treatment is an important cause of irrational antimicrobial use. It is preferable to keep the mean number of drug per prescription as low as possible.

In present study, average number of drugs per encounters was 5.17±2.41 (Table 3).

It is higher in Vishwanath M et al study 5.69 (±1.4) while lower 4.8 (±2.4) in Murali et al study as compared to our study.3,7

Poly-pharmacy is highly prevalent in paediatric patients, exposing them not only to adverse effects but also to the drug interactions, increased cost of therapy and non-compliance.3

Drug prescribed by generic name

Prescribing medicines by official names avoids the confusion and makes the medicine 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

- Tradition
- Aggressive medicine promotion
- Availability of multi-ingredient fixed dose drug combinations
- Faulty medicine policy and lack of “political will” etc.

Out of total 3156 drugs, 71% drug prescribed by generic name, while 29% drugs prescribed by the trade name in our study (Figure 1).

While 62.30% drugs prescribed by generic name in Vishwanath M et al study,3 In Shankar PR et al conducted retrospective study in which drugs prescribed by generic name were only 58.1% which is very less as compared to our study.4

Drugs prescribed by generic name should be promoted as it decreases the cost of therapy and increase the rationality of prescription.
Drugs prescribed from essential medicines list

The purpose of drugs prescribed from EML is to measure degree to which practices confirm to a national drug policy, as indicated by prescribing from national essential drug list or formulary for the type of facility surveyed. In this study, 57% drugs are prescribed from WHO Model list of essential medicine for children, 4th list (April 2013) 9 while 43% drugs are not in EML (Figure 2).

In Vishwanath M et al 86.42% drugs prescribed from EML, while in Shankar PR et al 45.7% drugs prescribed from EML. 3,4

Route of drug administration

In our study, one particular drug given by the more than one route or route of drug administration changed from parenteral to oral due to patient well-being. So, it had considered as a single drug only. For example in case of artesinin given in malaria and amoxycillin+clavulanic for respiratory tract infections.

Our study shows 1605 drugs given by oral route, 1485 drugs given by IM or IV route, 210 drugs by inhalation route and 10 drugs by topical route (Figure 3).

In Murali et al 43% drugs given by parenteral route, 42% drugs given orally, 12% by inhalational route, 1% drugs topically and 2% drugs given by other route. 6

Parenteral route of drug administration increases the length of the hospital stay which in turn exposes the children to nosocomial and multidrug resistant infection. The parenteral route may be necessary in paediatric patients but is more expensive in terms of nursing resources. Disposable syringes are used to administer drugs, thus reducing the risk of infection but adding to the cost of treatment. 5

More number of parenteral drugs prescriptions in our study may be due to study conducted in indoor patients.

Duration of hospital stay in paediatric patients

Out of 610 patients, 44.26% patients stay for 2-4 days in hospital, 34.59% patient hospitalized for 5-7 days and 21.15% patient for > 7 days. Average number of duration of hospitalization was 5.85±4 (Table 5).

In Murali et al, majority 55.2% patient admitted for 3 days in hospital, followed by 20.6% for 2 days, 14.3% for 4 days, 4.6% for 5 days, 3.9% for 6 days and 0.7% for 7 days. 6

Long duration of hospitalization, increases the chances of hospital acquired infection in paediatric patients.

C. Morbidity pattern in paediatric patients

In our study respiratory system disease 208 (34.09%) most commonly seen followed by gastro-intestinal tract involvement in 110 (18.03%) patients which is similar to Vishwanath M et al study in which 33.33% paediatric patients shows respiratory tract involvement and 19.33% patients were had gastrointestinal tract diseases. 9

In study done by Murali et al most common disease was fever (34.6%) followed by respiratory disease (21.7%), gastrointestinal disorder (16.8%). 5

Acute gastroenteritis (16.6%) was the most common reason for hospitalization in Shankar PR study. 5

The burden of respiratory diseases in India is relatively great and expected to increase further which could be due to multiple factors like high level of pollution, use of indoor fuels, inadequate ventilation, overcrowding and infections. 1

D. Drugs prescribed in paediatric patients

Out of 3156 drugs prescribed, majority of drug prescribed 740 (23.44%) were anti-microbial agents, followed by 461 (14.61%) drugs acting on respiratory system (Figure 5). In study done by Murali et al, Shankar PR and Vishwanath M et al also anti-microbial agents were the main class of drugs prescribed 24.8%, 23% and 28.10% respectively. 3,5,6,8

In anti-microbial agents (AMA) most commonly prescribed drug were B-lactam 411 (55.54%), followed by aminoglycosides 139 (18.78%) which is similar to the Vishwanath M et al study in which penicillin used most commonly 28.75% followed by aminoglycosides 23.33%. 9 While in In Murali et al study 6 beta-lactam were prescribed in 51.9% patients followed by quinolones in 17.1% patients (Figure 6).

Type of AMA used at each centre depend on many factor like the patient profile, type of infection, availability of antimicrobial, susceptibility pattern, the prescriber’s awareness on rational antimicrobial use etc. 10

The reason for most commonly prescribed AMA like beta-lactam and aminoglycosides are might be due to more number of respiratory diseases in our study. It also depends on local availability of drugs in hospital area.

E. Fixed dose combinations (FDCs) prescribed in paediatric wards

Amoxycillin+clavulanic acid, multivitamins, sulfadoxin+pyrimethamine and NSAIDs combinations like paracetamol with ibuprofen or diclofenac sodium were FDCs prescribed in our study (Table 6).
Irrational and haphazard use of combinations like NSAIDs and multivitamins should be minimized to decreases un-necessary cost and side-effect chances.

Limitations of this study were single centre study, relatively small sample size.

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