ABSTRACT

Introduction: Paediatric population is prone to suffer from recurrent infections of the respiratory tract. The present study is done to assess the prescribing pattern of drugs in Lower Respiratory Tract Infection (LRTI) in children aged 1 month to 14 years old using WHO core drug prescribing indicators. Materials and methods: A non-interventional, prospective, observational study was done in paediatric inpatient department of Rajarajeswari Medical College and Hospital, Bangalore from September 2014 to December 2014. A total of 150 case records of paediatric patients were analysed. Results: 1034 drugs (6.9 drugs per prescription) were prescribed. Males were 94 (62.7%) and Females 56 (37.3%). The prevalence of LRTI was more pronounced in age group of 1 year to 5 years (42.7%) followed by less than 1 year age group (29.3%). Bronchopneumonia (37.3%) was the most common diagnosis followed by Bronchiolitis (30%). The most commonly prescribed drugs were antibiotics (97.3%) followed by bronchodilators (90%). Most commonly prescribed antibiotic was Amoxicillin + Clavulanic acid (57.33%) followed by Amikacin (40%). 45.3% patients received one antibiotic and 33.3% patients received two antibiotics. Most commonly prescribed bronchodilator was salbutamol (88.67%) followed by budesonide (70%). Steroids were prescribed in 18% patients. Only 13% drugs were prescribed by generic name.
(28%) FDC’s were prescribed and one rational FDC observed was amoxicillin+clavulanic acid. **Conclusions:** Most patients received only one antibiotic. Prescribing by generic name was less and polypharmacy was observed. Irrational use of antibiotics for bronchiolitis was also observed in our study.

**KEYWORDS:** Children, LRTI, Inpatients, Drug utilisation.

**INTRODUCTION**

Worldwide, infants and children represent a higher proportion of the population. 28% of the world’s total population is accounted by children younger than 15 years of age. Pediatric population is prone to suffer from recurrent infections of the respiratory tract.

Respiratory tract infection (RTI) is considered as one of the major public health problems in developing countries. It is recognized as the leading cause of morbidity and mortality in many developing countries. In developing countries 25% of all paediatric admissions are due to acute respiratory tract infections and which ultimately causes death of 3.5 million children each year. Most infections are limited to the upper respiratory tract and only 5% involve the lower respiratory tract. Viruses are the most common cause of lower respiratory tract disease in infants and young children and are a major public health problem in this age group. Worldwide, respiratory syncytial virus is by far the most common cause of viral lower respiratory tract infection in infants and young children.

Paediatric population is a spectrum of different physiologies and comprises subgroups differing by age as preterm neonates, full term neonates, infants and toddlers, and older children and adolescents. Significant changes in the pharmacokinetics and pharmacodynamics occur as preterm infants mature towards term, as infants mature during the first few years of life, and as children reach puberty and adolescence. The bioavailability, pharmacodynamics, pharmacokinetics, efficacy and adverse effects can differ markedly between paediatrics and adult patients as well as among paediatric patients because of difference in age, organ function and disease state.

The quality of medical care requires prescribing to be judicious, appropriate, safe, effective and economic. “Good” prescribing is a complex balance between various conflicting factors. The aim is to achieve clinical benefit with minimum risk at cost effective price while respecting the patient’s choice. Essential drugs offer a cost-effective solution to many
health problems in a developing country.\textsuperscript{[7]} They should be selected with due regard to disease prevalence, be affordable, with assured quality and be available in the appropriate dosage forms.\textsuperscript{[7]} Prescribers can only treat patients in a rational way if they have access to an essential drugs list and essential drugs are available on a regular basis.\textsuperscript{[8]}

The use of antimicrobial agents, especially antibiotics has become a routine practice for the treatment of paediatric illnesses.\textsuperscript{[9]} It is driven largely by patient demand, time pressure on clinicians and diagnostic uncertainty.\textsuperscript{[6]} An overall rise in health care costs, lack of uniformity in drug prescribing and the emergence of antibiotic resistance, monitoring and control of antibiotic use is of growing concern.\textsuperscript{[9]}

If the gains in the treatment of infectious diseases are to be preserved, clinicians must be wiser and more selective in the use of antimicrobial agents. Optimal and judicious selection of AMAs for the therapy of infectious diseases requires clinical judgment and detailed knowledge of pharmacological and microbiological factors. The first consideration in selecting an AMA is whether it is even indicated. The reflex action to associate fever with treatable infections and prescribe antimicrobial therapy without further evaluation is irrational and potentially dangerous. Definitive identification of a bacterial infection, before treatment is initiated, often is not possible. Initiation of optimal empirical antibiotic therapy requires knowledge of the most likely infecting microorganism and their susceptibilities to antimicrobial drugs.\textsuperscript{[6]}

Therefore Paediatric patients require more attention while prescribing medications in order to avoid the resistance, adverse drug reactions and drug-drug interactions. The study of prescribing pattern is a part of the medical audit and seeks to monitor, evaluate, and if necessary, suggest modifications in prescribing practices to make medical care rational and cost-effective.\textsuperscript{[10]}

**OBJECTIVE**

1) To assess the prescribing pattern of drugs in Lower Respiratory Tract Infection (LRTI) at a tertiary care teaching hospital using WHO core drug prescribing indicators.
MATERIALS AND METHODS

Study design, study site and duration
A non-interventional, prospective, observational study was done in paediatric in patient department of Rajarajeswari Medical College and Hospital, a tertiary care hospital, Bangalore from September 2014 to December 2014. The study was approved by Institutional Ethics Committee (IEC). Children were enrolled based on following criteria:

Inclusion criteria
- Children aged 1 month to 14 years with LRTI admitted to paediatric wards.

Exclusion criteria
- Outpatients with LRTI.
- Patients with hepatic and renal diseases.
- Children with gastrointestinal infections, CNS infections.
- Children with congenital anomalies.
- Children with major illness/admitted to ICU.
- Patients with pulmonary tuberculosis.

Study procedure
Patient case records were analysed for demographic characteristics, date of admission, duration of hospitalization, diagnosis, date of discharge, different drugs used and dosage regimen (form, route, frequency and duration) using WHO core drug prescribing indicators. Data was recorded in a separate data collection form.

Statistical analysis
The data obtained was analysed by descriptive statistics using Microsoft Excel. Utilization of different classes of drugs was analysed and presented in the form of tables and graphs.

RESULTS
Out of the 150 case records of paediatric patients aged 1 month to 14 years old included in the study, 94 (62.7%) were males and 56 (37.3%) were females (Figure 1). All the case records of patients contained the patient and drug information data – patient’s name, age, Inpatient number, strength, dose, dosage form, frequency and duration of treatment. The age group 1 to 5 years accounted for the highest number 64 (42.7%) of patients followed by less than 1
yearage group 44 (29.3%)(Table 1). The average duration of stay in the hospital was 6.36 days.

![Gender Distribution](image)

**Figure: 1 Gender distribution**

**Table 1: Age distribution**

<table>
<thead>
<tr>
<th>Age</th>
<th>&lt;1y</th>
<th>1y-5y</th>
<th>5y-10y</th>
<th>&gt;10y</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>44</td>
<td>64</td>
<td>26</td>
<td>16</td>
</tr>
<tr>
<td>% of patients</td>
<td>29.3</td>
<td>42.7</td>
<td>17.3</td>
<td>10.7</td>
</tr>
</tbody>
</table>

The total number of drugs prescribed was 1034 in 150 prescriptions (Table 2) and the mean number of drugs per prescription was 6.9. The most common diagnosis was Bronchopneumonia (37.3%) followed by Bronchiolitis (30%) (Figure 2).

**Table 2: Analysis of Drug Prescribing Patterns**

<table>
<thead>
<tr>
<th>WHO Core Drug Prescribing Indicators Among Inpatients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PARAMETER</strong></td>
</tr>
<tr>
<td><strong>NUMBER / PERCENTAGE</strong></td>
</tr>
<tr>
<td>Total number of patient case records analysed</td>
</tr>
<tr>
<td>Total number of drugs prescribed</td>
</tr>
<tr>
<td>Average number of drugs prescribed</td>
</tr>
<tr>
<td>Number of drugs prescribed by generic name</td>
</tr>
<tr>
<td>Percentage of prescriptions with an antibiotic prescribed</td>
</tr>
<tr>
<td>Percentage of prescriptions with an injection prescribed</td>
</tr>
<tr>
<td>Number of drugs prescribed from WHO essential drug list</td>
</tr>
<tr>
<td>Percentage of FDC prescribed</td>
</tr>
</tbody>
</table>
Figure 2: Disease distribution

Antibiotics were prescribed for 146 (97.3%) patients followed by bronchodilators 135 (90%), antipyretics 113 (75.3%), cough medications 96 (64%) intravenous fluids 79(52.7%), nasal decongestants 36 (24%), others which includes multivitamins in 34 (22.7%) and steroids in 27(18%) prescriptions.(Figure 3).

Figure 3: Percentage of prescription of major drugclasses

Beta lactam (78.67%) group of antibiotics were most frequently prescribed antibiotics followed by aminoglycoside group (40%), cephalosporins (28%), macrolides 11.34%), glycopeptides (4%), fluoroquinolones (2.67%) and carbapenem group (1.34%) (Figure 4). Most commonly prescribed antibiotic was Amoxicillin + Clavulanic acid (57.33%) followed by Amikacin (40%) (Figure 5). In our study, 68 (45.3%) patients received one antibiotic, two
antibiotics in 50 (33.3%), three antibiotics in 22 (14.6%), four antibiotics in 6(4%) and no antibiotics were prescribed to 4 (2.6%) patients (Table-3).

![Figure 4: Different groups of antibiotics prescribed](image)

![Figure 5: Distribution of individual AMA's](image)

**Table 3: Number of antibiotics per prescription**

<table>
<thead>
<tr>
<th>Number of antibiotics</th>
<th>No. of prescriptions</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single drug</td>
<td>68</td>
<td>45.3</td>
</tr>
<tr>
<td>Two drugs</td>
<td>50</td>
<td>33.3</td>
</tr>
<tr>
<td>Three drugs</td>
<td>22</td>
<td>14.6</td>
</tr>
<tr>
<td>Four drugs</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Nil</td>
<td>4</td>
<td>2.6</td>
</tr>
</tbody>
</table>
Most commonly prescribed bronchodilator was salbutamol (88.67%) followed by budesonide (70%). (Figure 6). Intravenous route (96.7%) was the most common route of administration followed by oral (92.7%) and inhalational (92.7%) (Figure 7). Figure 8 shows that only 13% (134) of medicines were prescribed by generic name. There was poor tendency of prescribing by generic name and paracetamol, ceftriaxone and amikacin constituted the major proportion of medicines prescribed by generic name. In our study only 19 drugs were prescribed from the WHO list of essential medicine, 2015.

![Figure 6: Distribution of individual bronchodilators](image)

![Figure 7: Routes of drug administration](image)
The total number of FDC formulations prescribed was 290 (28%) (Figure 9). Out of 13 FDC approved by WHO EML 2015, only one was prescribed in 150 prescriptions. The rational combination observed was amoxicillin+clavulanic acid.

DISCUSSION
The present study was done to evaluate drug utilization pattern among paediatric in-patients. Infancy and childhood is a period of rapid growth and development. Infants and children represent a large part of the population in developing countries.\textsuperscript{[2]} Audit studies can and should become a method of increasing job satisfaction and means of education for health professionals, rather than being perceived as a threat or another bureaucratic burden.\textsuperscript{[6]}
The present study shows that out of 150 case records of children with LRTI analysed, male children constituted 62.7% and 1-5 years age group (42.7%) was the most common age group observed followed by less than 1 year (29.3%). This shows that children under 5 years of age are more vulnerable to infections.

Antibiotics were prescribed for 97.3% of patients and Bronchopneumonia (37.3%) was most common diagnosis observed followed by Bronchiolitis (30%) and out of 45 patients of bronchiolitis 32 children received antibiotics. As Bronchiolitis is caused mainly by Respiratory Syncytial Virus,[11] the treatment is mainly supportive and antibiotics do not influence the course of viral LRTI.[3] However viral LRTI predispose to secondary bacterial infections and hence children at risk can be put on prophylactic antibiotic treatment[3] and in our study most commonly prescribed antibiotic was Amoxicillin + Clavulanic acid (57.33%) followed by Amikacin (40%). The antibiotics used in the hospital were of older generation antibiotics (amoxicillin + clavulanic acid) and this has to be welcomed.

Most patients were put on only one antibiotic (45.3%) and 33.3% of patients were put on two antibiotics which is a very good clinical practice observed. Most preferred route of drug administration was intravenous route (96.7%) followed by oral and inhalational route (92.7%). Parenteral route is expensive and associated with other problems.[12] WHO recommends lesser use of injection as it helps in reducing the cost of treatment and its disadvantages.[9] But some factors facilitate the use of this route. In oral dosage forms the most commonly used dosage form was syrup. Children are comfortable with the dosage form like syrup and drops compared to tablets and capsules. It increases compliance and helps in completing the treatment regimen.

Bronchodilators were observed in 90% of case records and Salbutamol (88.67%) was most commonly prescribed followed by Budesonide (70%). The American Academy of Pediatrics recommends that inhaled bronchodilators should not be used routinely for the management of bronchiolitis.[13] One possible exception is for LRTI with underlying reactive-airway disease and where wheeze is the hallmark symptom of LRTI, short acting beta 2 agonists may be effective for individual patients.[14] A recent Cochrane review also concluded that bronchodilator treatment can improve clinical symptom scores in the short term in viral LRTI cases but that it does not reduce the duration of hospitalization and increases treatment cost.[15]
Intravenous Hydrocortisone was prescribed for 18% of patients in our study in addition to inhalational budesonide but a meta-analysis of studies comparing systemic glucocorticoid treatment to placebo did not find any difference in the length of hospital stay or clinical score for infants and young children with LRTI from either group.\textsuperscript{[16]} Hence routine use of corticosteroids is not recommended according to standard treatment guidelines.

The average number of drugs per prescription was 6.9. This could be because the study setting was inpatient department. Shivalleela et al study\textsuperscript{[17]} and Triruthopu NS et al study\textsuperscript{[18]} showed that average number of drugs per prescription was 4.26 and 4.56 respectively which is less than the present study. The WHO recommends that the average number of drugs per prescription should be less than two.\textsuperscript{[19]} In present study this number is more than two, which indicates polypharmacy.\textsuperscript{[19]} The average number of drugs per prescription value should be low as possible to prevent the unfavorable outcomes of polypharmacy such as increased risk of drug interactions, increased cost of therapy, non-compliance and emergence of resistance in case of use of antimicrobials.

Most of the drugs were prescribed by brand name. Clinicians often prefer to prescribe by trade names, with which they are familiar and the patients find it easier to procure. Prescribing by generic name is known to reduce the cost of drug treatment and to rationalize drug therapy. This varies from 13.3-93\% across the globe.\textsuperscript{[20]} In our study it was found to be 13\% which is very less.

Only 19 drugs were prescribed from essential medicine list. The low rate of prescribing of essential drugs is a matter of concern but it must be noted that though essential drugs are primarily meant for primary health care system while this study was done in a tertiary care hospital. Drug prescription from essential list of medicine is beneficial in terms of cost effectiveness and safety of the drugs.\textsuperscript{[9]} Recording adverse drug reaction is very important to evaluate the safety of drugs. In no case sheets adverse drug reactions were reported and no proper documentation is done.

It is evident from the present study that only one FDC was in accordance with the WHO list of recommended FDCs. Potential advantages of FDC’s include reduced side effects, increased patient compliance, synergy and increased efficacy and reduced cost. Potential disadvantages include inflexible fixed dose ratio, incompatible pharmacokinetics, increased toxicity, physician and pharmacist’s ignorance of contents.\textsuperscript{[6]}
Irrational prescribing is a habit that is difficult to cure. However, prevention is possible by interventions such as short problem based training course in pharmacotherapy and rational use focused workshops. Doctors should be educated on more appropriate and cost effective prescribing. There have been many forum of intervention aimed at changing physician’s prescribing behaviour. These include audit studies, group discussions and feedback, introduction of hospital formulary, guidelines for antibiotics and NSAID’s. Rational prescribing messages should be promoted at national and local medical meetings.

CONCLUSION
In present study, the number of drugs prescribed by generic name was low, and efforts must be made to encourage prescribing by generic names. Polypharmacy was observed. Usage of antibiotics for viral infections should be reduced. Beta-lactam antibiotics were the highly prescribed antibiotics among which Amoxicillin+Clavulanic acid was most commonly prescribed. Most of the patients were put on single or two antibiotics which is a good sign and only one rational FDC was observed. Limitations of present study were small sample size. The study was carried out over a four-month period during winter and seasonal variations in disease pattern and drug utilisation were not considered. Seasonal variations should be explored further in future studies. A study of one-year duration can nullify the effect of seasonal variations. Cost analysis was not done in this study. Further studies for a longer time period and with a larger sample size should be carried out. Rational use of drugs is largely influenced by knowledge and attitude and its importance has to be emphasized at the earliest. This should be included in medical education to have long term beneficial effects. Strict antibiotic prescribing policy may significantly overcome the overuse of antibiotics and reduce the development of resistance to antibiotics.

REFERENCES

