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A PROSPECTIVE OBSERVATIONAL STUDY TO ASSESS DRUG UTILIZATION EVALUATION OF RESPIRATORY TRACT INFECTIONS AMONG PEDIATRICS IN TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

Introduction: Respiratory tract infections (RTIs) are among the most common causes of childhood morbidity and mortality, particularly in developing countries. Rational prescribing and drug utilization evaluation (DUE) are essential for improving outcomes, minimizing antimicrobial resistance, and ensuring cost-effective therapy. **Objective:** To assess drug utilization patterns among paediatric inpatients with RTIs in a tertiary care teaching hospital. **Methodology:** A six-month prospective observational study was conducted in the Department of Paediatrics, BMCRC, Ballari. A total of 140 children (aged <15 years) admitted with RTIs were included based on predefined criteria. Data were extracted from case sheets and analysed. **Results:** In 140 patients, 72 (51%) were males and 68 (49%) females, with the majority aged 1–5 years (42%). The most frequent diagnoses were bronchopneumonia (29.3%) and pneumonia (25%). One-third of children presented with comorbidities, mainly respiratory distress (35.4%), protein-energy malnutrition (16.7%), and anaemia (12.5%). A total of 833 drugs were prescribed, averaging 5.95 per patient. Antibiotics constituted the largest share (34.93%), followed by vitamins/minerals (18%), proton pump inhibitors (16.8%), analgesics/antipyretics (14.4%), IV fluids (8.52%), and antiemetics (6%). Cephalosporins

(44.3%) were the most commonly prescribed antibiotics, mainly ceftriaxone. Polypharmacy was frequent, with two antibiotics prescribed in 41% of cases. Injections were given to all patients (100%). About 66% of prescriptions were by generic name, and most aligned with the National Essential List of Medicines. The average hospital stay was 5–7 days (69%). **Conclusion:** The study showed reasonable adherence to essential medicine use and generic prescribing, reflecting efforts toward rational prescribing. However, high usage of injectables, frequent polypharmacy, and broad-spectrum antibiotic reliance highlight the need for stronger antimicrobial stewardship and hospital-specific prescribing guidelines. Addressing comorbidities such as malnutrition and anaemia is equally vital for improving outcomes in paediatric RTIs.

KEYWORDS: Paediatrics, Respiratory tract infections, Drug utilization, Antibiotics, Rational prescribing.

INTRODUCTION

Drug utilization evaluation (DUE) study was developed in the middle of the 1960s in Northern Europe and the United Kingdom. Arthur Engel in Sweden and Peter Siderius in Holland was the first who conducted initial drug utilization study.[1]

According to WHO (1997) Drug Utilization Review is defined as — the marketing, distribution, prescription and use of drugs in the society, with special emphasis on the resulting medical, social and economic consequences.[2]

Drug utilization review mainly focuses on:

- Ensuring that the drug therapy meets current standards of care.
- Controlling drug cost.
- Preventing problems related to medicines.
- Evaluating the effectiveness of drug therapy.
- Identification of areas of practice that require further education of practitioners.
- Stimulating improvements in medication use.
- Creating guidelines for appropriate drug utilization.
- Promoting optimal medication therapy.
- Describing the current treatment practices.[2]

➢ **TYPES OF DUE**

1) PROSPECTIVE: - An evaluation of the patient's predicted pharmacological therapy is done in the future before the medicine is prescribed. This process enables any problems to be identified and resolved before the patient ever receives the prescription. Pharmacists regularly do a prospective assessment by examining the dosage and instructions for prescription medications.[1]

❖ Various drug use problems can be detected and prevented from occurring with prospective monitoring, such as

- Incorrect dosage.
- Inappropriate dosage form/route of administration.
- Incorrect duration of therapy.
- Drug-drug interactions.
- Therapeutic duplication.
- Drug-disease contraindications.
- Drug-allergy and other side effects.
- Incorrect laboratory/monitoring.[2]

2) CONCURRENT: - Concurrent review is done while the patient is receiving treatment and involves monitoring the medication as it is administered to help the patient. It provides pharmacists with the opportunity to alert physicians to potential problems and take appropriate action in situations like

- Drug - Drug interactions
- Double therapy
- Overuse or underuse
- Excessive or inadequate dose.[1]

3) RETROSPECTIVE: - A retrospective DUR evaluates the patient's medication schedule. Retrospective DUR involves reviewing prescribed drugs after they are dispensed to the patients. To stop drug addiction and misuse in the future, specialized therapies and suggestions might be established based on the existing prescription usage patterns. The findings of this analysis may assist prescribers in providing better healthcare to their patients, either individually or for certain demography (e.g., patients with diabetes, high blood pressure, or asthma).[1]

Its chief drawback is that interventions cannot be made to improve drug use for the patients whose records were reviewed. It can be used to monitor the same aspects of drug use listed for prospective DUR, as well as.

- Identifying prescribing frequency of a single drug or class of drugs.
- Comparing drug prescribing among physicians.
- Comparing prescribing to standard treatment guidelines.
- Monitoring the therapeutic use of high-cost drugs.[2]

➢ HOW DUE PROMOTES RATIONAL DRUG USE

Drug utilization study by facilitating rational drug use ensures that drugs are available to individual patient in an optimal dose on the right indication with correct information and at an affordable price. For facilitating rational drug use it is important to know how drugs are being prescribed and used, so that we can initiate discussion and suggest measures to change the prescribing habits. A drug utilization study does this by three different ways

1) Description of drug use patterns
2) Early signals of irrational drug use
3) Interventions to improve drug use.[2]

➢ DRUG USE INFORMATION

- Different types of drug use information are required depending on the problem being examined.
- These include information about the overall use of drugs, drug groups, individual generic compounds or specific products.
- In addition, data on drug costs will be important in ensuring that drugs are used efficiently and economically. These types of drug information can be used to promote the rational use of drugs.[2]

➢ CORE DRUG USE INDICATORS BY WHO

- The indicators developed by WHO help in assessing drug use pattern in particular setting.
- There are three core indicators in addition to complimentary indicators.
- The three main indicators deal with the three areas in rational drug use.

1) Prescribing practices by health care professionals.
2) patient care.
3) facility standards.

❖ **PRESCRIBING INDICATORS**

Table 01: Prescribing Indicators.

Indicators	Purpose
Average number of medicines per encounter.	To measure the degree of polypharmacy.
Percentage of medicines prescribed by generic name.	To measure the tendency to prescribe by generic names.
Percentage encounters with an injection prescribed.	To measure the overall use of an important but commonly overused and costly form of drug therapy.
Percentage of medicines prescribed from essential medicine list/ hospital formulary.	To measure the degree to which practice conforms to national drug policy.

RESPIRATORY TRACT INFECTIONS (RTIs)

➢ **DEFINITION**

Acute Respiratory tract infection is a serious infection which prevents the person to breathe properly. The infection usually starts as a viral infection in the nose, trachea (windpipe), or lungs. If the infection is not treated, it may spread to the entire respiratory system.

Children tend to get more upper RTIs than adults because they have not yet built-up immunity (resistance) to the many viruses that can cause these infections.

➢ **CLASSIFICATION**

An infection of the respiratory tract is classified into two types:

1) **Upper respiratory tract infection**: Constitute Common Cold, Influenza, Laryngitis, Otitis media, Pharyngitis, Sinusitis and Tonsillitis.
2) **Lower respiratory tract infection**: Constitute Asthma, Bronchitis, COPD, Emphysema, Pneumonia, and Tuberculosis.[3]

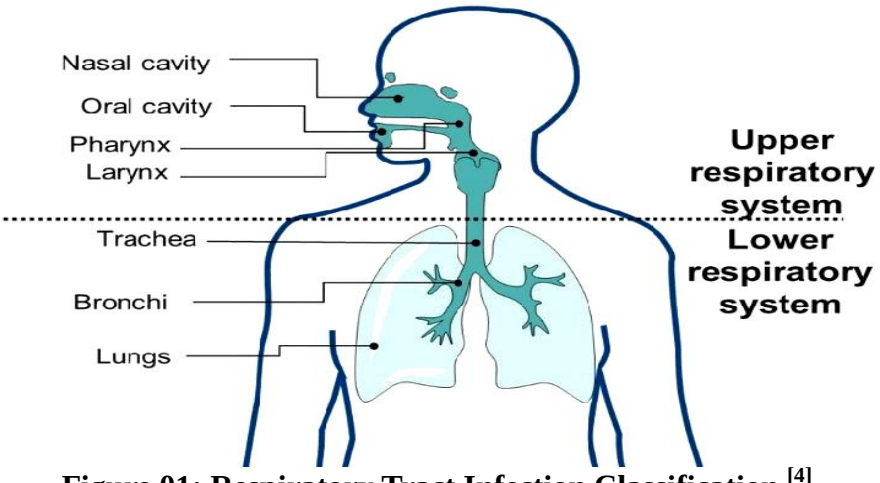


Figure 01: Respiratory Tract Infection Classification.[4]

- **Bronchitis:** Inflammation of the mucous membrane in the bronchial tubes, which carry air to and from lungs. People having bronchitis often cough up thickened mucous, which can be disclosed. It may be either acute or chronic.

- **Tonsillitis:** Inflammation of the tonsils, which are the two oval-shaped pads of tissue at the back of the throat, one tonsil on each side, most commonly caused by viral or bacterial infection. Tonsillitis is typically referred to as strep throat.

- **Otitis media:** Inflammation of the middle ear characterized by the accumulation of infected fluid in the middle ear, barging of the eardrum, pain in the ear and if the eardrum is perforated, drainage of purulent material (pus) into the ear canal is seen.

- **Pharyngitis:** Inflammation of the pharynx (the back side of the throat) which causes a sore throat, as well as scratchiness in the throat and difficulty in swallowing. In many cases, it is quite painful.

- **Pneumonia:** It is a lung inflammation caused by a bacterial or viral infection in which the air sacs fill with pus and may become solid, causing cough with phlegm or pus, fever, chills, and difficulty in breathing. It affects both the lungs (double pneumonia) and the single lung (single pneumonia).

- **Rhinitis:** It is the inflammation of the mucous membrane of the nose, caused by viral infection (common cold) or by an allergic reaction (hay fever). It is also defined as an allergic reaction that mimics the chronic cold.

- **Sinusitis:** Inflammation of the cavities around nasal passages (sinuses) air spaces within the bones of the face resulting in symptoms like thick nasal mucous, plugged nose and pain in the nose.[3]

➢ EPIDEMIOLOGY

- India is one of the 15 highest burdened countries in terms of total pneumonia episodes and related childhood mortality. In India, around 4,00,000 children aged below five years die every year from ARI related diseases.[5]

- ·WHO recognized respiratory diseases as the second important cause of death for children under five years in 2010. WHO states that pneumonia is one of the main three causes for newborn infant deaths.

- Pneumonia was diagnosed in approximately 156 million children in 2008 (151 million in developing countries and 5 million in developed countries).[6]

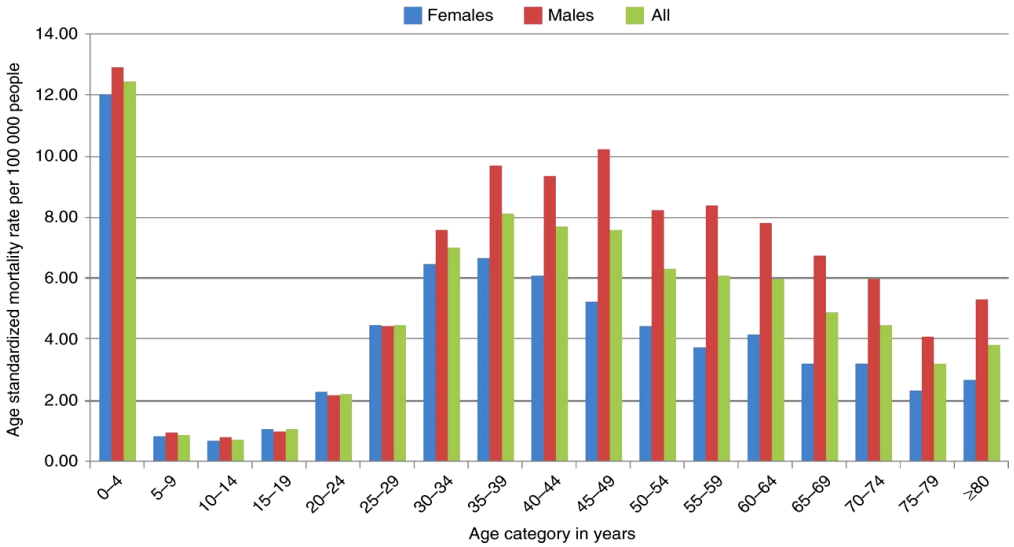


Figure 2: Epidemiological data of respiratory tract infections among different age groups.[7]

It is evident from the above data provided in the annual report of CIC that the number of RTI requests have been increasing. From a mere 24,436 in 2005-06 when RTI Act was first passed in the parliament to 12 lakh applications in 2017-18, the number of requests has increased.

- WHO reports in developing countries (e.g. Nigeria, Gambia, Senegal and Mali) demonstrate ARI incidence rate of 15-21% in children younger than five years old. In developing countries, respiratory tract infection accounts for more than 2 million deaths yearly.

- In developed countries, the yearly incidence of pneumonia is estimated to be 33 per 10000 in children < 5 years and 14 per 10000 in children 0 to 16 years old.

- Hospitalization rates of pneumonia (all causes) among children younger than two years in the United States have decreased (from 12 to 14 per 1000 population to 8 to 10 per 1000 population) after considering the pneumococcal conjugate vaccine as the routine childhood immunization plan for twelve years ago.[6]

- According to the World Health Organization (WHO), acute respiratory infections kill an estimated 2.6 million children annually every year worldwide.[3]

➢ PREVALENCE

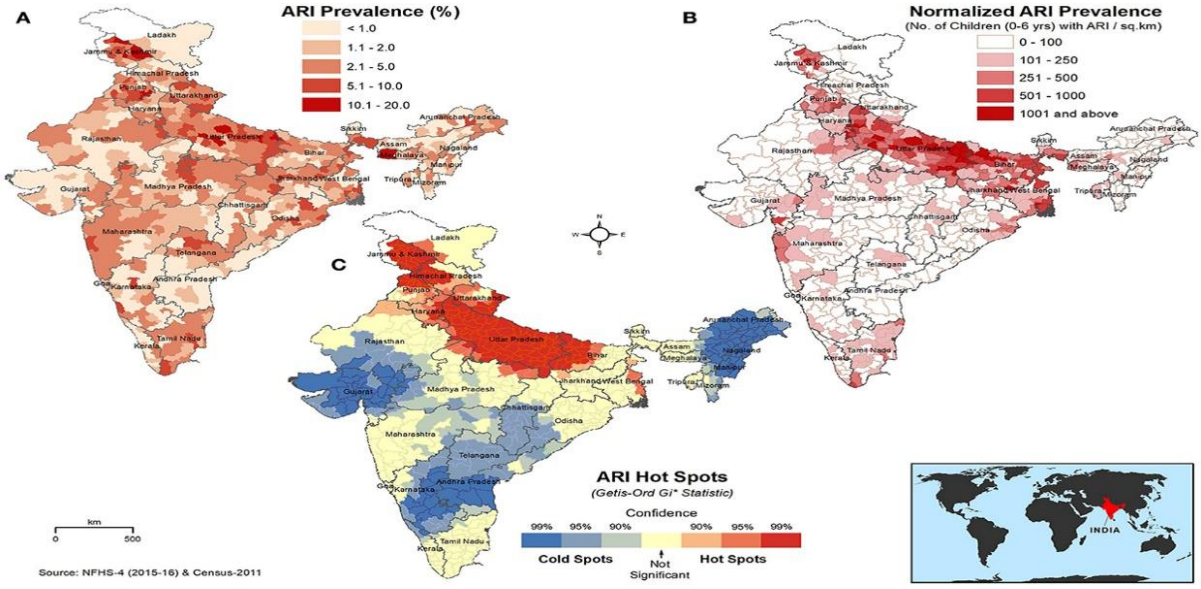


Figure 3 - Acute Respiratory Infection (ARI) prevalence in India among children aged 0-6 years, based on NFHS-4(2015-16) and census 2011 Data.

- Panel A: ARI prevalence (%) by district shows the percentage of children with ARI symptoms.

✓ Dark red areas (10.1-20%) indicate the highest prevalence, especially in Uttar Pradesh, Bihar, and parts of Jammu & Kashmir.

✓ Lighter areas like Kerala, Karnataka, and Tamil Nadu show lower prevalence (<1-2%).

✓ Panel B: Normalized ARI prevalence (Children per sq.km) displays the spatial density of ARI-affected children.

✓ Densely populated areas like eastern UP, Bihar, and West Bengal show high intensity (Deep red:>1000 children/sq.km).

✓ Panel C: ARI hot spots (Getis-Ord Gi statistic) identify statistically significant hot and cold spots:

✓ Hot spots(red): High prevalence with high spatial clustering (e.g.: Kerala, Karnataka, Maharashtra).

✓ Yellow areas are not statistically significant.[8]

RISK FACTORS

- Absence of breast feeding in infants.
- Aged younger than 12 weeks at presentation or born prematurely (i.e., before 37 weeks gestation).
- Chronic lung disease (e.g.: - premature baby or cystic fibrosis).
- Congenital heart disease.
- Immune deficiencies (congenital or acquired).
- Need for supplemental oxygen therapy at home (e.g.: - CLD of prematurity).
- Neuromuscular disorders (especially those with reduced consciousness or inability to clear secretion or protect airway).
- Older siblings in nursery or school (as they tend to bring respiratory tract infections home).
- Passive smoking, especially maternal smoking.
- Severe gastroesophageal reflux disease.[9]

➢ **CLINICAL MANIFESTATIONS**

1) Upper Respiratory Tract Infections (URTIs)

Includes: Common cold, pharyngitis, tonsillitis, sinusitis, otitis media, laryngitis, croup.

General Symptoms

- A runny nose
- Coughing
- A high temperature
- Sore throat, earache, or other aches and pains
- Noisy breathing (you may hear a Wheeze or whistle)
- Problems with feeding and drinking because of difficulty breathing
- Increased breathing through the mouth if they have a blocked nose.

2) Lower Respiratory Tract Infections (LRTIs)

Includes: Bronchiolitis, bronchitis, pneumonia, pertussis (whooping cough), tuberculosis.

General symptoms

- High temperature
- Coughing and vomiting with coughing
- Breathing difficulties

- Drowsiness
- A change in skin colour.[10]

➢ DIAGNOSIS

1. Clinical Examination

Observation of symptoms like fever, cough, nasal discharge, tachypnoea, retractions, and auscultatory findings like wheeze or crackles.[11]

2. Pulse Oximetry

Measures oxygen saturation (SpO_2) to detect hypoxemia, especially in lower respiratory infections like pneumonia.[12]

3. Chest X-ray

Used to confirm pneumonia, look for infiltrates, consolidation, pleural effusion. Not routinely required for uncomplicated upper RTIs.[13]

4. Nasopharyngeal Swab for Viral PCR or Rapid Antigen Test

Detects influenza, RSV, adenovirus, parainfluenza, SARS-CoV-2, etc. [14]

5. Complete Blood Count (CBC)

Leucocytosis or lymphocytosis can support bacterial or viral aetiology respectively.[15]

6. C-Reactive Protein (CRP) and Procalcitonin (PCT)

Helps differentiate bacterial vs viral ARTI.CRP > 40–60 mg/L and PCT > 0.5 ng/mL suggest bacterial infection.[16]

7. Blood Culture

Indicated in severe pneumonia or suspected sepsis. Helps identify causative bacteria.[17]

8. Sputum Gram Stain and Culture (in older children)

For a productive cough to identify bacterial pathogens.[18]

9. Tuberculin Skin Test (TST) / IGRA (Interferon-Gamma Release Assays)

Used when tuberculosis is suspected as a chronic ARTI cause.[19]

10. COVID-19 RT-PCR / Rapid Antigen:

Especially relevant post-2020 in paediatric patients with fever, cough, and upper respiratory symptoms.[20]

➢ PATHOPHYSIOLOGY

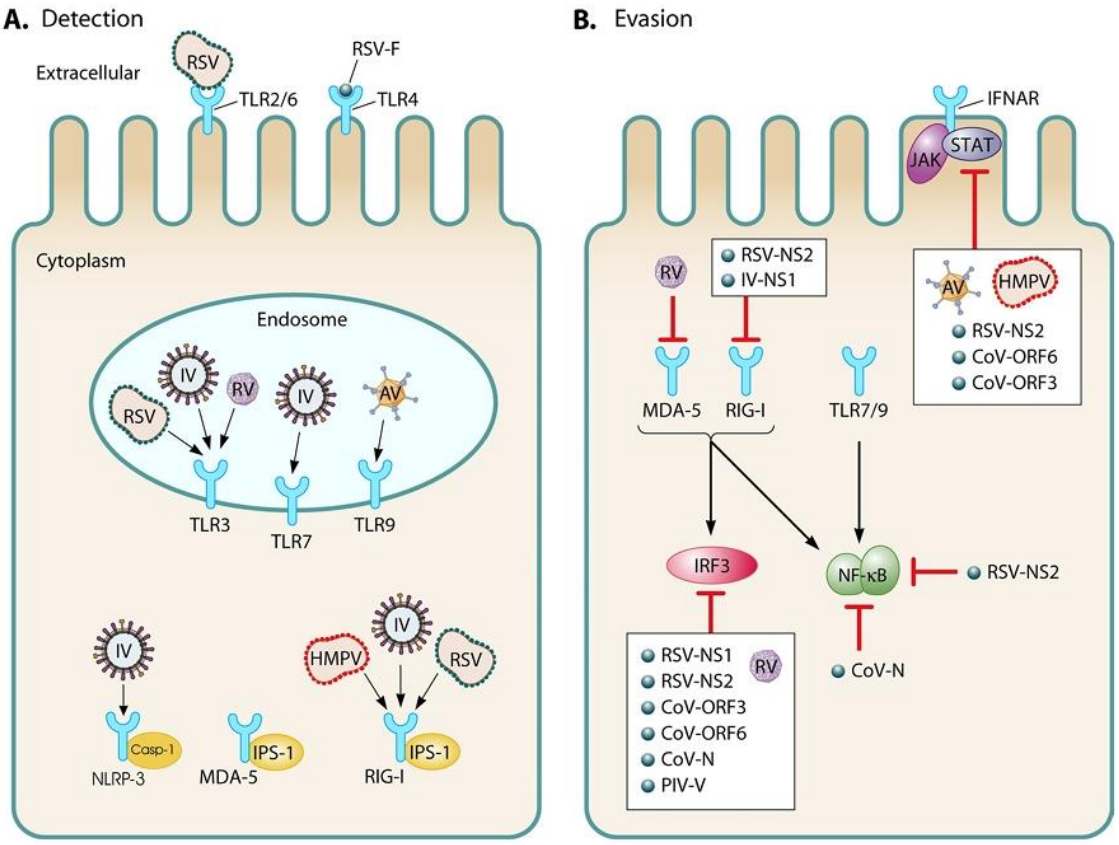


Figure 04 - Interplay of factors that cause disease following respiratory viral infection and impact of infancy.

The ultimate cause of illness/disease following respiratory viral infection is airway occlusion, which leads to a reduction in gaseous exchange, leading to respiratory distress. This airway occlusion can be either immune or virally mediated and most probably is a combination of both. Early life has an effect on both virus- and immune-mediated damage. The infant immune system is skewed to a hyporesponsive phenotype, with a reduced type I interferon response leading to a higher viral load. The adaptive immune response is also skewed and limited in its effect. These factors act in combination with small body size and small airways to further increase disease severity.[21]

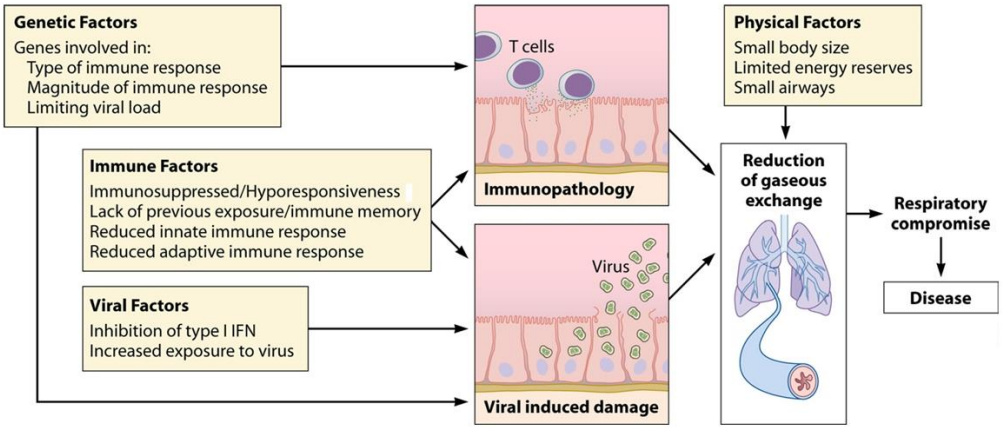


Figure 05 - Viral detection and viral evasion.

(A) Viral detection by the innate immune system. Respiratory viruses are detected extracellularly by TLR2, TLR4, and TLR6; in the endosome by TLR3, TLR7, and TLR9; and in the cytoplasm by RIG-I (retinoic acid-inducible gene I), MDA-5 (melanoma differentiation-associated gene 5), and NLRP3 (NLR family, pyrin domain-containing 3). (B) Viral evasion of the innate immune system. Viruses inhibit the pattern recognition receptors RIG-I and MDA-5 and the downstream molecules IRF3, NF-B, and JAK/STAT. In some cases, the viral protein that inhibits the response has been identified. Abbreviations: AV, adenovirus; CoV, SARS coronavirus; hMPV, human metapneumovirus; IV, influenza virus; PIV, parainfluenza virus, RSV, respiratory syncytial virus; RV, rhinovirus; TLR, Toll-like receptor; IFNAR, interferon alpha receptor; ORF, open reading frame; CASP-1, caspase 1; NS, non-structural.[21]

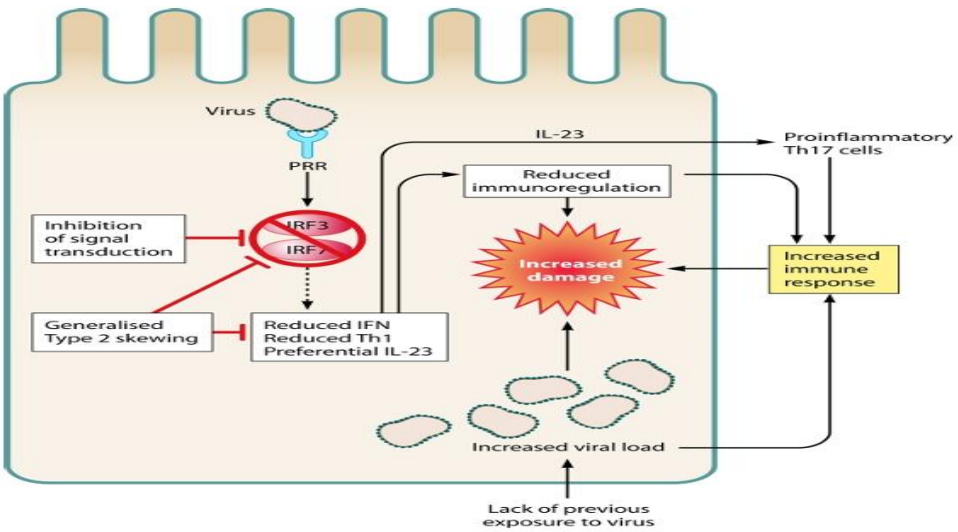


Figure 06 - The paradox of early-childhood immune hypo responsiveness and virally induced immunopathology.

Shown are possible mechanisms by which increased immunopathology may occur in the context of dampened responses to infection in infants. Similar levels of pattern recognition receptors are detectable for infant and adult leukocytes. However, the molecules that transduce the signal, e.g., IRF3 and IRF7, have reduced function. This leads to an altered immune response, with higher viral load, decreased immunoregulation (via IDO [indoleamine 2,3-dioxygenase]), and skewed cytokine production, all of which may increase damage caused by the immune response. Abbreviations: PRR, pattern recognition receptor; IRF, interferon response factor.[2]

- **Flowchart:** Pathophysiology of Respiratory Tract Infection.

1. Respiratory Viral Infection in Infants
Triggered by various predisposing factors.

↓

2. Predisposing Factors
Genetic: Weak immune genes, poor viral clearance.
Immune: Hyporesponsive system, reduced interferon response.
Viral: High exposure to virus, viral immune evasion.
Physical: Small airways, low energy reserves.

↓

3. Virus Entry & Detection
Detected by Toll-like receptors (TLRs): TLR2, TLR4, TLR7, TLR9
Detected by cytoplasmic PRRs: RIG-I, MDA-5

↓

4. Viral Evasion
Viral proteins inhibit PRRs
Block IRF3/IRF7, NF-κB, and JAK/STAT pathways
↓ Interferon production.

↓

5. Impaired Immune Response
↓ IFN, ↓ Th1, ↑ IL-23
Shift toward Type 2 immune response
Poor viral clearance → ↑ Viral load

↓

6. Immunopathology & Viral Damage
Direct virus-induced cell damage
Excessive immune response causes tissue injury

↓

7. Airway Occlusion
Mucus, swelling, and cell debris block airways
↓ Gaseous exchange

↓

8. Respiratory Compromise → Disease

➢ PHARMACOTHERAPY

➢ Goals of Therapy

1. Relieve Symptoms

- Reduce fever, nasal congestion, cough, and breathing difficulty.
- Improve feeding and sleep in infants and children.[22]

2. Prevent Complications

- Avoid progression from URTI (e.g., common cold) to LRTI (e.g., bronchiolitis or pneumonia).
- Monitor and manage risk of dehydration, respiratory distress, or secondary bacterial infections.[23]

3. Identify and Treat Underlying Cause

- Use diagnostic tools to distinguish between viral and bacterial infections.
- Initiate appropriate antimicrobial therapy **only if** bacterial infection is confirmed or strongly suspected.[22]

4. Minimize unnecessary antibiotic use

- Prevent development of **antimicrobial resistance (AMR)** by avoiding misuse of antibiotics in viral infections.[24]

5. Prevent Transmission

- Encourage hygiene measures: handwashing, cough etiquette, and isolation during contagious phases.
- Promote breastfeeding, immunization (e.g., for influenza, pneumococcus).[25]

6. Educate Caregivers

a. Advise parents on supportive care, warning signs for hospital visits, and importance of adherence to prescribed treatments.[26]

➢ Non-Pharmacological Therapy

1. Adequate Hydration & Nutrition

- Purpose: Prevent dehydration from fever/tachypnoea and support immunity.
- Practice: Continue breastfeeding in infants.
- Encourage small, frequent fluid intake. [11,27]

2. **Steam Inhalation / Humidification**
   - Purpose: Loosens mucus, relieves nasal blockage.
   - Practice: Use warm mist or saline nebulization under supervision.[22]

3. **Chest Physiotherapy**
   - Purpose: Aid mucus clearance in bronchiolitis or pneumonia.
   - Practice: Postural drainage, percussion, suctioning.[27]

4. **Caregiver Education**
   - Purpose: Empower families to manage symptoms and identify danger signs.
   - Practice: Continue feeding, monitor breathing rate, give paracetamol if fever.[26]

5. **Infection Control Measures**
   - Purpose: Prevent spread to others at home/school.
   - Practice: Handwashing, cough hygiene, avoiding crowded places, use of masks.[28]

DRUG CLASS	MEDICATION	PEDIATRIC DOSE	ROUTE AND FREQUENCY
Antipyretics / Analgesics	• Paracetamol (Acetaminophen)	10–15 mg/kg/dose	PO/PR every 4–6h; max 60 mg/kg/day
	• Ibuprofen	5–10 mg/kg/dose	PO every 6–8h; max 40 mg/kg/day
Antibiotics – Penicillin's	• Amoxicillin	40–90 mg/kg/day in 2–3 divided doses	PO
	• Amoxicillin-Clavulanate	40–90 mg/kg/day of amoxicillin component in 2 divided doses	PO
	• Penicillin V	250 mg BID (<27 kg); 500 mg BID (>27 kg)	PO x10 days
Antibiotics – Cephalosporins	• Cefdinir	14 mg/kg/day (single or divided doses)	PO
	• Ceftriaxone	50–75 mg/kg/day (max 2 g/day)	IM/IV once daily
Antibiotics – Macrolides	• Azithromycin	10 mg/kg on day 1, then 5 mg/kg/day (days 2–5)	PO once daily
	• Clarithromycin	15 mg/kg/day in 2 divided doses (max 1 g/day)	PO

PHARMACOLOGICAL THERAPY

Table 02 – Pharmacological therapy for respiratory tract infections.

DRUG CLASS	MEDICATION	PEDIATRIC DOSE	ROUTE AND FREQUENCY
Bronchodilators	• Salbutamol (Albuterol)	0.15 mg/kg/dose (min 1.25 mg, max 2.5 mg/dose)	Nebulized every 4–6h PRN
Corticosteroids	• Dexamethasone	0.6 mg/kg (max 10 mg) single dose	PO/IM/IV
	• Prednisolone	1–2 mg/kg/day (max 60 mg/day) for 3–5 days	PO
Antivirals	• Oseltamivir	<15 kg: 30 mg BID; 15–23 kg: 45 mg BID; 24–40 kg: 60 mg BID; > 40 kg: 75 mg BID	PO x5 days
Adjuncts	• Normal Saline Nasal Drops/Spray	0.9% saline, 1–2 drops per nostril	Intranasal PRN
	• Hypertonic Saline (3%)	2–4 mL via nebulization	Inhalation every 6–8h

➢ **NEED OF DUE IN RTI AMONG PEDIATRICS**

- DUE plays a crucial role in the health sector as it deals with the patterns of prescription, quality, determinants and outcomes of usage of drugs. Ultimately, it provides insight into the efficiency of drug use and results of such research can be used to help to set priorities for the rational allocation of health care budgets.

- Infections of the upper and lower respiratory tract are a major cause of morbidity and mortality particularly in patients at the extremes of age, and those with pre-existing lung disease or immune suppression.

- In India, we do not have adequate data on the lower respiratory tract pathogens, their resistance patterns and proper guidelines for rational use of antibiotics. At this juncture, Drug utilization studies provide good opportunity to generate data on the aforementioned issues.

- Most of the drugs prescribed for children have not been tested in the paediatric population due to the difficulties in carrying out clinical studies in children and ethical issues due to children not being able to make their own decisions to participate in a clinical trial. Epidemiological evaluation of medicine use in elderly is now a highly visible topic, but drug prescribing studies in paediatric patients have been limited.

- Various drug utilization reviews have been conducted all over the world but only limited studies are conducted addressing the drug use pattern in paediatric population especially in

India. 20 to 25% of total world population comprise paediatric, which are more prone to acute and chronic infectious disease. The incomplete development of paediatric physiological conditions and their rapid growth and development need some accurate diagnosis and evidence-based medical treatment.

- Moreover, rational drug therapy is important for all drug users, but it is of paramount importance for children. Dose recommendations for use in children vary according to age and body weight, in particular when considering newborns and young children.

- Hence, there is the need of DUE for the safe and effective drugs for use in sick neonates, infants, children and adolescents for the establishment of thoughtful drug therapy strategies.

NEED FOR THE STUDY

Respiratory Tract Infections (RTI's) continue to be one of the most frequent health problems affecting paediatrics, accounting for a significant proportion of hospital visits and admissions. In countries like India, the impact is even greater, where childhood pneumonia and other acute respiratory illnesses remain leading causes of death in children under five years of age. Children are especially vulnerable not only because of their developing immune system but also due to rapid growth and physiological changes, which make the safe & effective use of medicines more Complex.

Although antimicrobial agents and supportive drugs are widely used for treating RTIs, irrational prescribing is still common. Overuse of antibiotics, incorrect dosages and use of multiple drugs without clear indication are often seen in clinical practice. These practices can reduce treatment success, increase ADR, contribute to antimicrobial resistance - an issue of global concern.

DUE offers a systematic approach to assess current prescribing trends and identify areas for improvement.Unfortunately, studies focusing on paediatric prescribing in India are limited, and many regimens given to children are adult regimens without adequate paediatric trials.
This study, therefore aims to fill that gap by evaluating how drugs are being prescribed for RTIs in Pediatric patients. The findings are expected to highlight the extent of rational and irrational prescribing ultimately helping in developing strategies to promote safer and more.

METHODOLOGY

➢ STUDY SITE

❖ The study will be carried out in the department of Pediatrics, BMCRC, Ballari District, Karnataka.

➢ DURATION OF STUDY

❖ The study will be conducted for a period of 6 months.

➢ STUDY DESIGN

- A prospective observational study.

➢ PROPOSED SAMPLE SIZE

- Between 100-140 case sheets of patients admitted in the pediatric department of the hospital.

➢ STUDY CRITERIA

- The study will be carried out by considering the following inclusion and exclusion criteria.

Inclusion Criteria

- Children aged 1-15 years.
- Pediatric inpatients of both genders (male and female).
- Patients with or without comorbidities.
- Patients presenting to a tertiary care teaching hospital with a diagnosis of an RTI.
- Parenteral/guardian consent: Informed consent obtained from parenteral or legalguardians for participation in the study.

Exclusion Criteria

- Patients with severe neurological or developmental conditions that may impair communication.
- Patients with severe systemic diseases/conditions like congenital heart diseases, malignancies, etc.
- Patients with incomplete medical records or insufficient data for drug utilization evaluation.
- Patients or guardians who refuse consent.

- Patients admitted to Intensive Care Unit (ICUs) such as: Cystic fibrosis.

➢ **SOURCE OF DATA**

- Patient case sheet.
- Direct interaction with patient representative.

➢ **MATERIALS USED**

- Informed consent form.
- Patient profile data collection form.

➢ **METHOD**

❖ Data was collected from patient profile form.

❖ Data was recorded as patient demographic characteristics, clinical status, and duration of disease.

➢ **STUDY PROCEDURE**

- Regarding this project pilot study was done.
- Collection and review of literature pertaining to the project.
- Preparing of study protocol, including the study design and design of the Performa.
- Obtain ethical consent prior to study. • Enrollment of patients according to the inclusion and exclusion criteria.
- Taking parent consent.
- Collection of patient details from the patient case sheet.
- Therapeutic evaluation of various drug usage from the patient treatment chart.
- The obtained information will be represented in the form of graphs and tables. The data will be analyzed statistically.
- Submission of report.

➢ **PHASES OF THE STUDY**

➢ **PHASE 01**

- Review of literature.
- Obtained Institutional Ethical committee clearance.
- Obtained permission from the general department of the hospital.
- Designed the data collection form.

PHASE 02

- A data collection form was prepared which contains patient demographic details, chief complaints, diagnostic parameters, past medical and medication history, social history, treatment regimen.
- The data collected from the patient medical charts and medication charts was recorded in the data collection form.

PHASE 03

- Data was analyzed using Microsoft excel and results were analyzed statistically.

STATISTICAL METHOD

Data was represented graphically and analyzed using statistical method like MS Excel sheet.

RESULTS

A prospective observational study to assess drug utilization evaluation of respiratory tract infection among pediatric patients in a tertiary care teaching hospital was conducted in the department of pediatrics at BMCRC, Ballari. A total of 140 patients has participated in the study period of 6 months.

GENDER WISE DISTRIBUTION OF PATIENTS

A total of 140 samples were analyzed, among them 72 (51%) patients were male and 68 (49%) were female.

Here, males were more predominant than females.

Table 03 - Gender wise Distribution of Patients.

SL. NO	GENDER	NUMBER OF PATIENTS	PERCENTAGE
1.	Male	72	51%
2.	Female	68	49%
	Total	140	100%

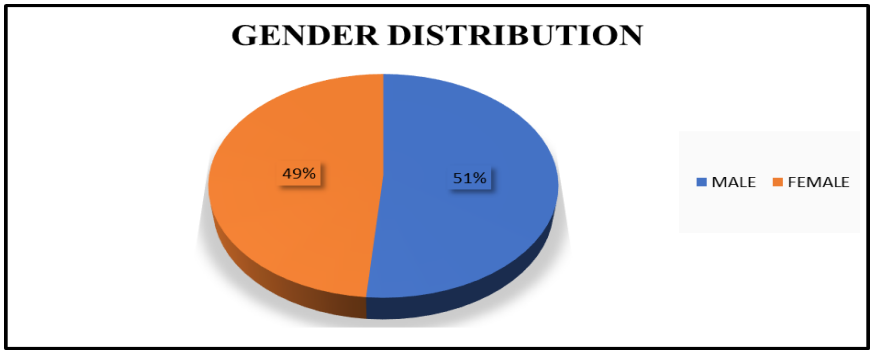


Figure 07 - Gender wise Distribution of Patients.

AGE WISE DISTRIBUTION OF PATIENTS

A total of 140 samples were analyzed, with 41 (29%) patients aged less than 1 year, 59 (42%) patients aged 1-5 years, 29 (21%) patients aged 6-10 years, and 11 (8%) patients aged 11-15 years.

Table 04: Age-wise Distribution of Patients.

SL.NO	AGE	NUMBER OF PATIENTS	PERCENTAGE
1.	Less than 1 year	41	29%
2.	1-5 years	59	42%
3.	6-10 years	29	21%
4.	11-15 years	11	8%
	Total	140	100%

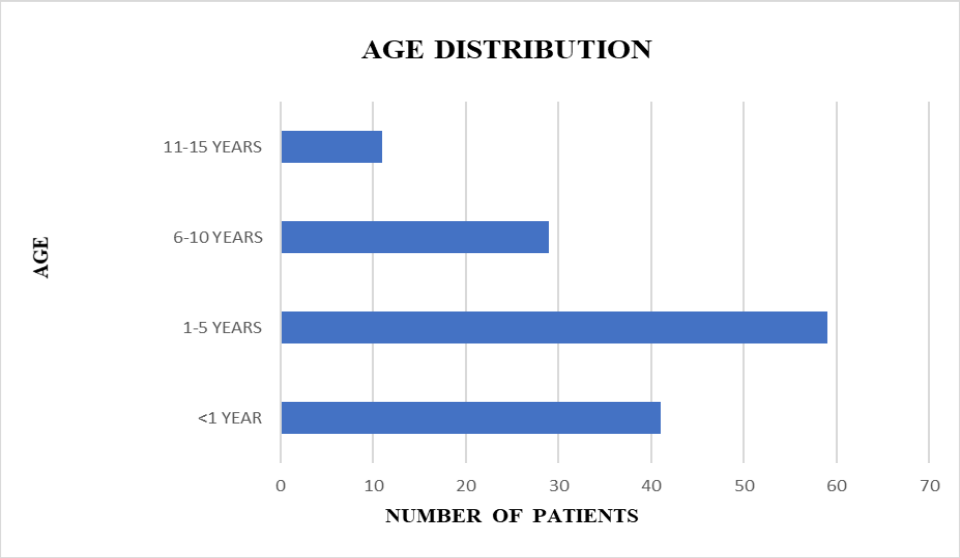


Figure 08 - Age-wise Distribution of Patients.

DISTRIBUTION OF PATIENTS WITH PRIMARY DIAGNOSIS

Out of 140 patients, 92 (65.7%) had a primary respiratory diagnosis. The most common conditions were bronchopneumonia (29.3%), pneumonia (25%), and wheeze associated with lower respiratory tract infection (19.6%), while other diagnoses, such as URTI, bronchiolitis, asthma, pharyngotonsillitis, bronchiectasis, and pneumothorax, were less frequent.

Table 05: Distribution of Patients with Primary Diagnosis.

SL.NO	PRIMARY DIAGNOSIS	NUMBER OF PATIENTS	PERCENTAGE
1.	Upper respiratory tract infection	9	9.8%
2.	Bronchopneumonia	27	29.3%
3.	Bronchiolitis	8	8.7%

4.	Pharyngotonsillitis	2	2.2%
5.	Pneumonia	23	25.0%
6.	Asthma	3	3.3%
7.	Bronchiectasis	1	1.1%
8.	Pneumothorax	1	1.1%
9.	Wheeze associated with lower respiratory tract infection	18	19.6%
	Total	92	100%

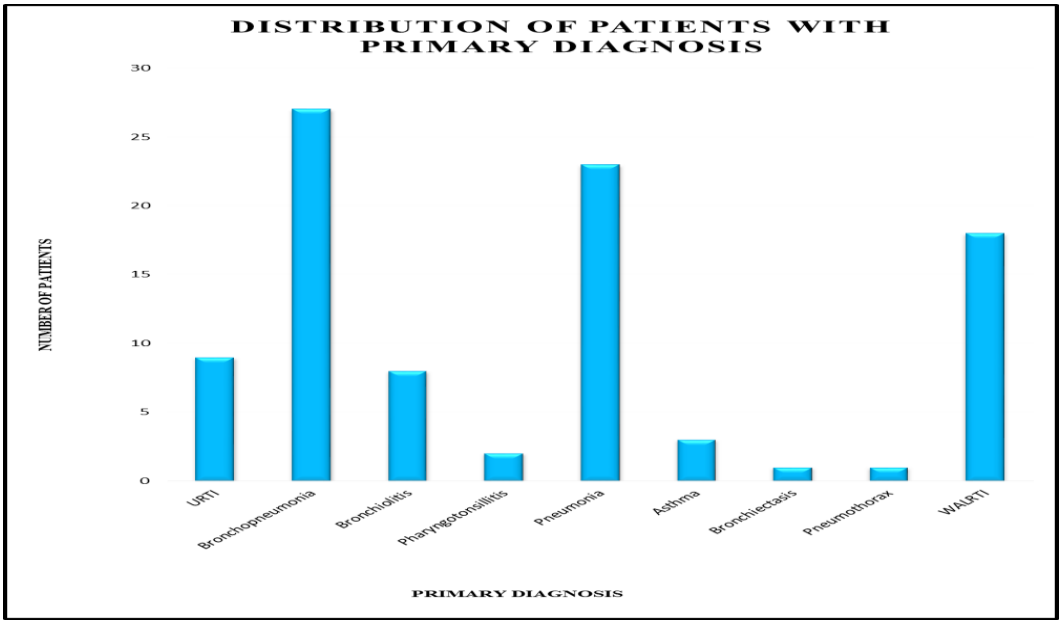


Figure 09: Distribution of Patients with Primary Diagnosis.

DISTRIBUTION OF PATIENTS WITH COMMON CO-MORBID CONDITIONS

Out of 140 patients, 48 (34.3%) had comorbidities. The most common were respiratory distress (35.4%), grade 2 protein-energy malnutrition (16.7%), and anemia, acute gastroenteritis (12.5% each), while other conditions were less frequent.

Table 06: Distribution of Patients with Common Co-Morbid Conditions.

SL.NO	CO-MORBIDITIES	NUMBER OF PATIENTS	PERCENTAGE
1.	Respiratory distress	17	35.4%
2.	Vitamin D deficiency	1	2.1%
3.	Anaemia	6	12.5%
4.	Otitis media	1	2.1%
5.	Urinary tract infection	1	2.1%
6.	Parenteral diarrhoea	4	8.3%
7.	Acute gastroenteritis	6	12.5%
8.	Sepsis	1	2.1%
9.	Minimal pleural effusion	2	4.2%
10.	Synpneumonic effusion	1	2.1%

11.	Grade 2 protein-energy malnutrition	8	16.7%
	Total	48	100%

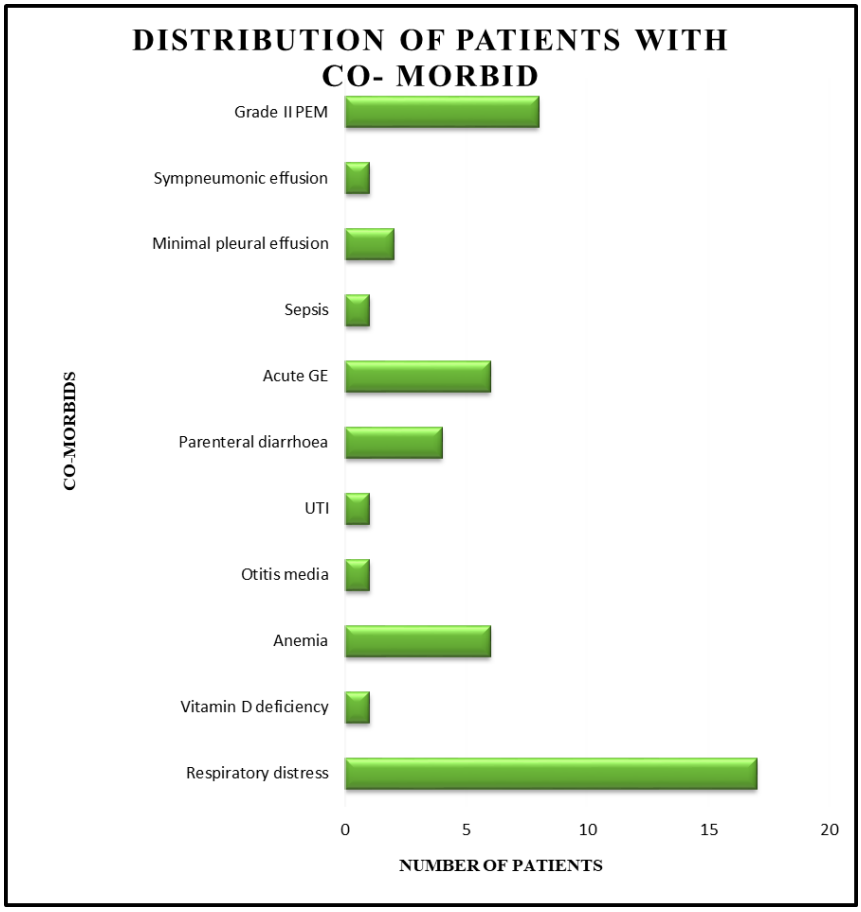


Figure 09: Distribution of Patients with Co-Morbid Conditions.

DISTRIBUTION OF PATIENTS WITH PRIMARY DIAGNOSIS VS CO-MORBIDITY

Out of 140 patients, 92 (65.7%) were diagnosed with a primary illness, while 48 (34.3%) presented with comorbidities. This indicates that more than one-third of the study population had additional health conditions along with their primary diagnosis.

Table 07: Distribution of Patients with Primary Diagnosis vs Co-Morbidity.

SL. NO.	PRIMARY DIAGNOSIS VS CO-MORBIDITY	NUMBER OF PATIENTS	PERCENTAGE
1.	Primary diagnosis	92	65.7%
2.	Primary diagnosis with Co-morbidity	48	34.3%
	Total	140	100%

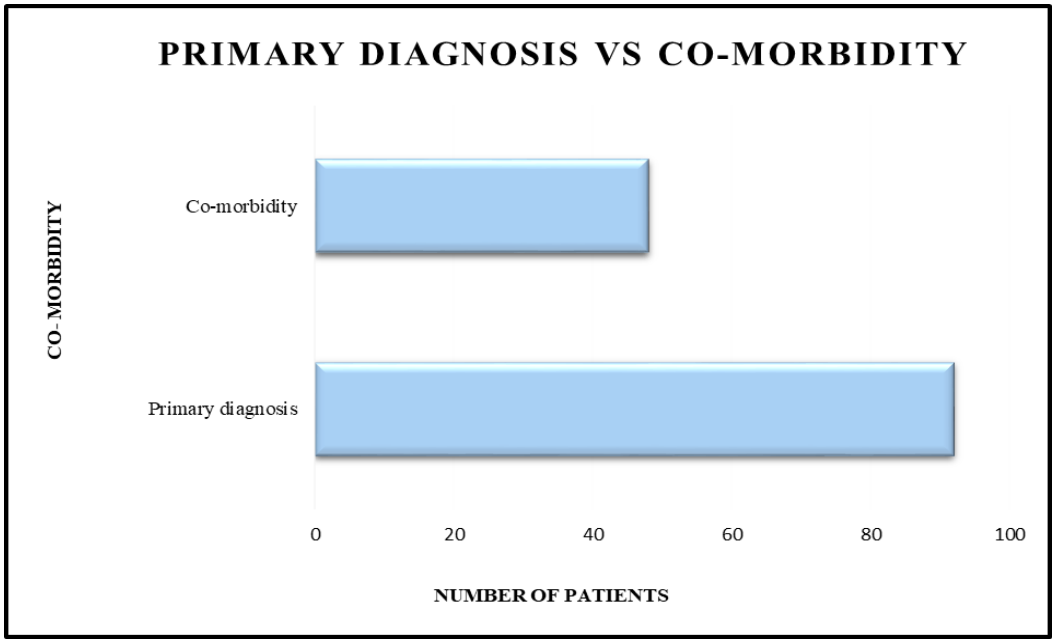


Figure 10: Distribution of patients with primary diagnosis vs co-morbidity

DISTRIBUTION OF MEDICATIONS AMONG THE SAMPLES

In the sample of 140 patients, a total of 833 drugs were prescribed. Antibiotics (34.93%) were the most frequently used, followed by vitamins/minerals (18.00%) and proton pump inhibitors (16.80%). Analgesics/antipyretics (14.40%), IV fluids (8.52%), and antiemetics (6.00%) were also commonly prescribed, while antacids and anthelmintics were rarely used. This indicates a predominance of antibiotics and supportive therapies in the treatment pattern.

Table 08: Distribution of Medications Among the Samples.

CLASS OF MEDICATIONS	NUMBER OF DRUGS PRESCRIBED	PERCENTAGE
Antibiotics	291	34.93%
Vitamin + Minerals	150	18.00%
Proton pump inhibitors	140	16.80%
Analgesics and Antipyretics	120	14.40%
IV Fluids	71	8.52%
Anti-emetics	50	6.00%
Antacids	6	0.72%
Anthelmintics	5	0.60%
Total	833	100%

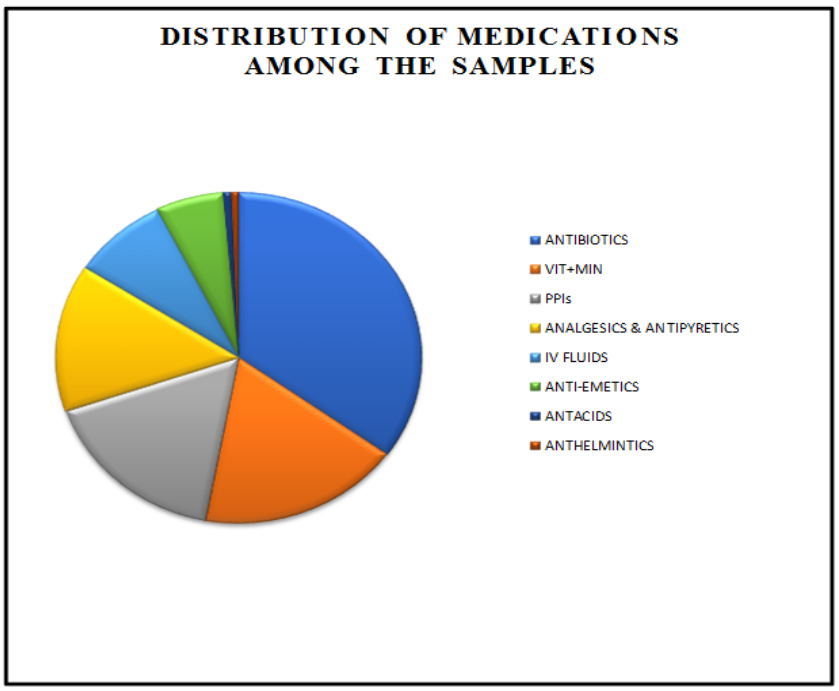


Figure 12: Distribution of medications among the samples.

DISTRIBUTION OF MEDICINES PRESCRIBED WITH BRAND VS GENERIC NAME PER PATIENT

A total of 140 samples were analyzed, among them, 286 (34.34%) medicines were prescribed with brand name, and 547 (65.66%) medicines were prescribed with brand name.

Table 09 – Distribution of Medicines Prescribed with Brand vs Generic Name.

SL. NO.	BRAND VS GENERIC NAME	NUMBER OF PATIENTS	PERCENTAGE
1.	Brand name	286	34.34%
2.	Generic name	547	65.66%
	Total	833	100%

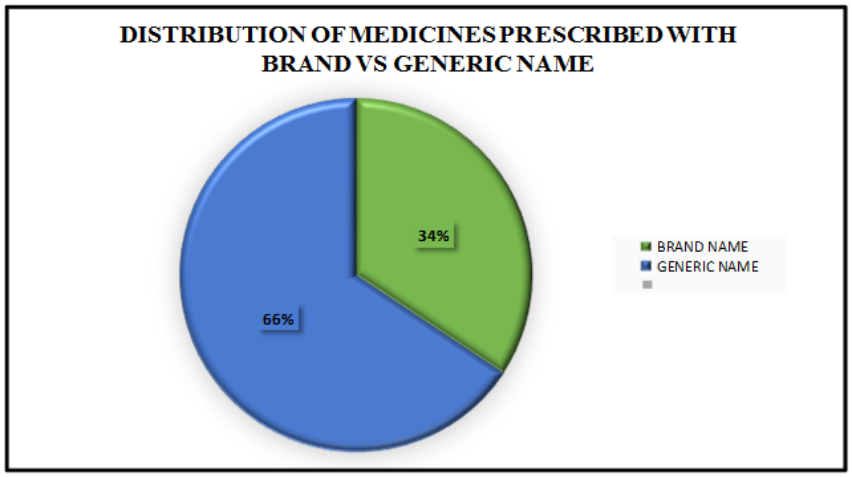


Figure 13 - Distribution of medicines prescribed with brand vs generic name.

CLASS-WISE DISTRIBUTION OF ANTIBIOTICS PRESCRIBED PER PATIENT

Table 10: Class-wise distribution of antibiotics prescribed (n=291 prescriptions in 140 patients).

SL.NO	ANTIBIOTIC CLASS	NUMBER OF PATIENTS	PERCENTAGE
1.	Penicillin's (Beta-lactams)	65	22.34%
2.	Cephalosporins	129	44.33%
3.	Macrolides	30	10.31%
4.	Fluoroquinolones	4	1.37%
5.	Carbapenems	11	3.78%
6.	Aminoglycosides	5	1.72%
7.	Tetracyclines	9	3.09%
8.	Nitroimidazoles	4	1.37%
9.	Glycopeptides	34	11.68%
	Total	291	100%

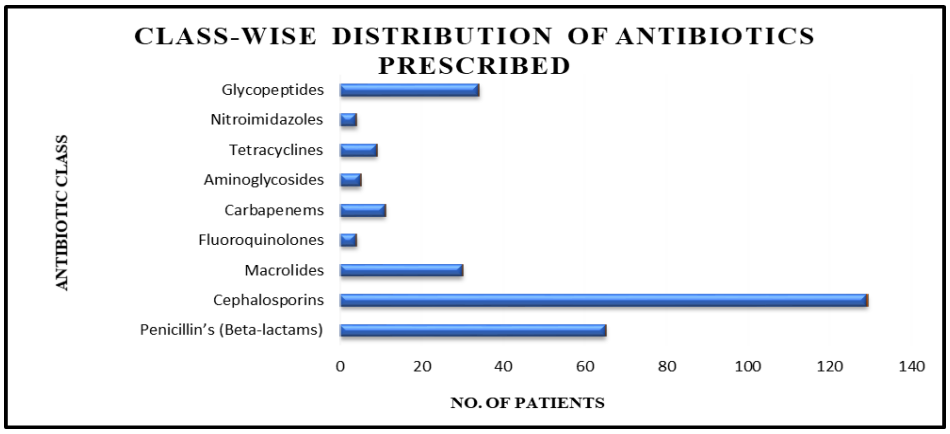


Figure 14 – Class-Wise Distribution of Antibiotics Prescribed Per Patient.

DISTRIBUTION OF ANTIBIOTIC USAGE BY CLASS

The table shows the distribution of antibiotic usage by class. Cephalosporins were most commonly prescribed (129 patients), with ceftriaxone contributing 98%. Penicillins were given to 65 patients, mainly piperacillin/tazobactam (74%). Macrolides (30), glycopeptides (34), carbapenems (11), tetracyclines (9), aminoglycosides (5), nitroimidazoles (4), and fluoroquinolones (4) were prescribed in smaller numbers. This indicates a predominant reliance on cephalosporins followed by penicillins.

Table 11: Distribution of Antibiotic Usage by Class.

SL. NO	ANTIBIOTIC CLASS	ANTIBIOTIC NAME	NUMBER OF PATIENTS	PERCENTAGE
1	Penicillin's	Augmentin	11	17%
		Amoxicillin	6	9%
		Piperacillin/Tazobactam	48	74%

		Total (Penicillin's)	65	100%
2	Cephalosporins	Ceftriaxone	124	98%
		Cefotaxime	5	2%
		Total (Cephalosporins)	129	100%
3	Macrolides	Azithromycin	30	100%
		Total (Macrolides)	30	100%
4	Fluoroquinolones	Levofloxacin	2	50%
		Ciprofloxacin	2	50%
		Total (Fluoroquinolones)	4	100%
5	Carbapenems	Meropenem	11	100%
		Total (Carbapenems)	11	100%
6	Aminoglycosides	Amikacin	5	100%
		Total (Aminoglycosides)	5	100%
7	Tetracyclines	Doxycycline	9	100%
		Total (Tetracyclines)	9	100%
8	Nitroimidazoles	Metronidazole	4	100%
		Total (Nitroimidazoles)	4	100%
9	Glycopeptides	Vancomycin	34	100%
		Total (Glycopeptides)	34	100%

DISTRIBUTION OF NUMBER OF ANTIBIOTICS PRESCRIBED PER PATIENT

A total of 140 patients were included in the study. Among them, 46 members were prescribed with 1 antibiotic, 57 members with 2 antibiotics, 25 members with 3 antibiotics, 6 members with 4 antibiotics, 4 members with 5 antibiotics and 2 members with 6 antibiotics.

Table 12 – Distribution of number of antibiotics prescribed per patient.

SL.NO	ANTIBIOTIC COUNT	NUMBER OF PATIENTS	PERCENTAGE
1.	One (1)	46	33%
2.	Two (2)	57	41%
3.	Three (3)	25	18%
4.	Four (4)	6	4%
5.	Five (5)	4	3%
6.	Six (6)	2	1%
	Total	291	100%

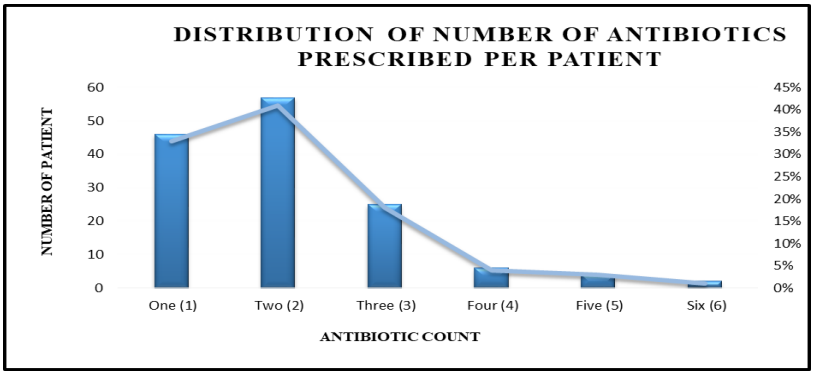


Figure 15: Distribution of number of antibiotics prescribed per patient.

DISTRIBUTION OF PATIENTS BASED ON DURATION OF HOSPITAL STAY

A total of 140 patients were included in the study. Among them, 40 patients (29%) stayed in hospital for 1-2 days, 96 patients (69%) stayed for 5-7 days, 3 patients (2%) stayed for 8-10 days and 1 patient (1%) stayed for 11-13 days.

Table 13 – Distribution of Patients Based on Duration of Hospital Stay.

SL.NO	DURATION OF HOSPITAL STAY	NUMBER OF PATIENTS	PERCENTAGE
1.	2-4 days	40	29%
2.	5-7 days	96	69%
3.	8-10 days	3	2%
4.	11-13 days	1	1%
	Total	140	100%

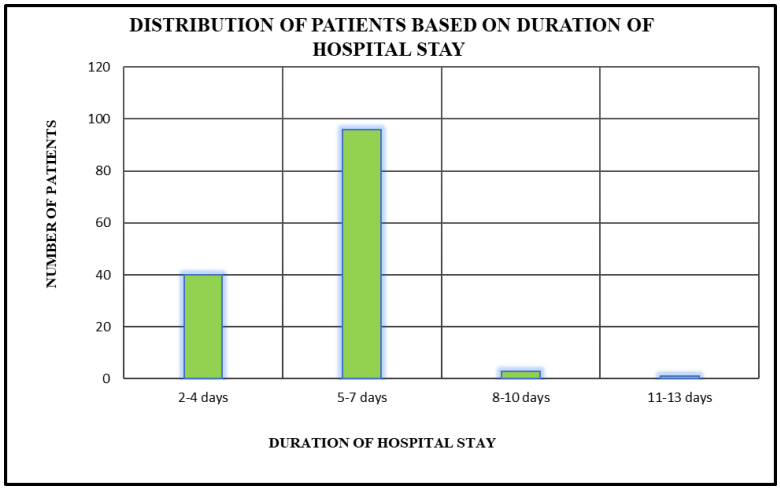


Figure 16: Distribution of Patients Based on Duration of Hospital Stay.

➢ **PRESCRIBING INDICATORS –**

Table 15: Prescribing Indicators Results.

INDICATORS	VALUES
Total number of drugs prescribed	833
Average number of medicines per encounter	5.95
Percentage of encounters with an injection prescribed.	100%
Percentage of medicines prescribed by generic name	65.66%
Total drugs from NELM	250

The prescribing indicators provide valuable insight into the drug utilization pattern in the study.

- **Total number of drugs prescribed (833):** A total of 833 medicines were prescribed during the study period, reflecting the active management of patient conditions and the efforts made to address diverse therapeutic needs.

- **Average number of medicines per encounter (5.95):** The average number of medicines prescribed per patient encounter was 5.95. Although this is higher than the WHO ideal range (1.6–1.8), it also indicates that prescribers took a comprehensive approach to therapy, aiming to manage co-morbidities and ensure symptom control.

- **Percentage of encounters with an injection prescribed (100%):** Injections were prescribed in all encounters. While this figure is higher than the WHO standard, it shows that physicians prefer rapid and effective drug delivery for immediate therapeutic outcomes, which can be especially beneficial in acute and hospital-based care settings.

- **Percentage of medicines prescribed by generic name (65.66%):** Nearly two-thirds of the drugs were prescribed by their generic names. This highlights prescribers' awareness of cost-effectiveness and accessibility of medicines, although there remains further scope to increase generic prescribing closer to the WHO recommendation of 100%.

- Total drugs from NELM (250): 250 medicines prescribed were from the national Essential List of Medicines (NELM). This refects an appreciable use of evidence based and essential medicines, contributing to rational prescribing practices.

DISSCUSION

The present study focused on evaluating the drug utilization patterns in paediatric patients with respiratory tract infections admitted to a tertiary care teaching hospital. A total of 140 children were enrolled, with almost equal representation of males (51%) and females (49%). This near balance is consistent with earlier epidemiological studies that reported a slight male predominance in paediatric respiratory illnesses, though the overall disease burden is comparable between both genders ***(Bibi S et al., 2021)***. When analysed by age, the majority of cases occurred in children between 1 and 5 years (42%), followed by infants younger than one year (29%). This finding highlights the particular vulnerability of younger children, which has been linked to immature immunity, nutritional deficiencies and greater exposure to infectious agents ***(Hasan MM et al., 2022; Begum I et al., 2020).***In terms of diagnosis, lower respiratory tract infections were more common than upper respiratory infections. Bronchopneumonia (29.3%) and pneumonia (25%) were the most frequent conditions observed, while wheeze-associated lower respiratory tract infection accounted for 19.6%. Upper respiratory tract infections made up only 9.8% of the cases. These results are in line with previous studies, where bronchopneumonia was consistently identified as the most

common cause of hospitalization among children, especially those under five years of age ***(Das SK et al., 2020; Mirkarimi M et al., 2019).*** About one-third of the children (34.3%) were also found to have comorbid conditions. The most frequent among these were respiratory distress (35.4%), grade II protein-energy malnutrition (16.7%), and anaemia (12.5%). Malnutrition and anaemia have long been recognized as major contributors to the severity of respiratory illnesses, prolonging recovery and increasing susceptibility to infections ***(Bekkam M et al., 2018; Boloursaz MR et al., 2013).*** Along with the antibiotic prescribing patterns, our study also provided an overview of the overall distribution of medications. It was observed that antibiotics remained the most frequently prescribed class (34.93%), reflecting their central role in the management of respiratory infections. This was followed by vitamins and minerals (18.0%) and proton pump inhibitors (16.8%), which were often used as supportive agents to improve nutritional status and protect the gastrointestinal tract during therapy. Analgesics and antipyretics (14.40%) were commonly given to relieve fever and discomfort, while IV fluids (8.52%) and antiemetics (6.0%) were important for maintaining hydration and controlling nausea. In contrast, antacids and anthelmintics were rarely prescribed. This pattern indicates that, in addition to antimicrobial therapy, clinicians placed considerable emphasis on supportive care measures to promote recovery. Similar trends have been reported in earlier Indian and international studies, where antibiotics formed the cornerstone of therapy while adjunctive treatments were used for symptom control and nutritional support ***(Baby B et al., 2019; Patil N et al., 2018; Mrs. Anju K.R et al., 2024).***The prescribing pattern in this study revealed a strong reliance on antibiotics, with cephalosporins being the most frequently prescribed class (44.3%), particularly ceftriaxone. This was followed by penicillin's (22.3%), largely piperacillin/tazobactam, as well as glycopeptides (11.6%) and macrolides (10.3%). This preference for broad-spectrum cephalosporins is consistent with findings from other Indian and international studies that reported a similar pattern in the treatment of paediatric respiratory infections ***(Baby B et al., 2019; Salehi S et al., 2020).*** While effective, such heavy reliance on broad-spectrum antibiotics raises concerns about antimicrobial resistance, a problem that has been highlighted globally by WHO and emphasized in antimicrobial stewardship programs ***(World Health Organization, 2014; Dar MA et al., 2022).***Polypharmacy was also evident in our study. Two antibiotics were prescribed in 41% of patients, and three antibiotics in 18% of cases. Comparable practices have been noted in studies from North India, where empirical prescribing was common even without confirmatory bacterial tests ***(Rauniyar R et al., 2025; Jaffer S et al., 2022).*** Another striking finding was that all patients (100%) received injectable medications. This figure is

considerably higher than the WHO prescribing standards and reflects the acute nature of illnesses treated in hospital settings. Similar trends of high injectable use have also been reported in other tertiary care centres ***(Syed Jaffar et al., 2022; Salehi S et al., 2020).*** When analysing prescribing indicators, it was found that 65.66% of drugs were prescribed by generic names. Although this is an encouraging figure compared to national averages, it is still below the WHO ideal standard of 100%. Brand-name prescribing was noted in 34.34% of cases, which suggests that there remains scope for improvement in adhering to essential medicine guidelines and promoting more cost-effective prescribing practices. Similar challenges in reducing branded prescriptions have been reported across India ***(Gangwar R et al., 2023; Gogineni V et al., 2018).***The duration of hospital stay was another important finding. Most children (69%) required admission for 5–7 days, with a smaller proportion staying longer. These results are consistent with earlier studies from Sri Lanka and Tanzania, where paediatric respiratory illnesses were shown to cause high hospitalization rates and average stays of 3–7 days ***(Nirubaa U, 2021; Kishamawe C et al., 2019).*** In addition, previous systematic reviews have highlighted the value of supportive therapies such as oxygen supplementation, which significantly reduce mortality in children with pneumonia and severe lower respiratory infections (Lam F et al., 2021).Overall, this study highlights both strengths and gaps in current prescribing practices. On one hand, prescribers showed reasonable adherence to the National List of Essential Medicines and demonstrated substantial use of generic prescribing. On the other hand, issues such as overuse of injectables, frequent polypharmacy, and empirical antibiotic use remain major concerns. These findings are consistent with earlier reports in Indian paediatric practice, which stress the urgent need for antimicrobial stewardship, stricter antibiotic policies, and prescriber education ***(Rauniyar R et al., 2025; Dar MA et al., 2022).*** Addressing these challenges, along with tackling comorbid risk factors such as malnutrition and anaemia, will be essential to improve treatment outcomes and reduce the growing threat of antimicrobial resistance in paediatric populations.

CONCLUSION

This prospective observational study explored drug utilization patterns among children admitted with respiratory tract infections (RTIs) in a tertiary care teaching hospital. A total of 140 children were included, with boys and girls almost equally represented. Most children were between 1–5 years of age, reaffirming that early childhood is the most vulnerable stage for RTIs. The study showed that bronchopneumonia and pneumonia were the leading causes

of hospitalization, One of the positive highlights of this study was the substantial adherence to the National List of Essential Medicines (NLEM), with 65.66% of drugs prescribed by generic names and two-thirds of prescriptions aligning with rational drug use standards. The consistent use of recommended first-line antibiotics, such as ceftriaxone and amoxicillin-clavulanate, demonstrated that prescribers were attentive to established treatment protocols. The average hospital stay of 5–7 days was in line with international reports, suggesting that supportive and pharmacological care were generally effective in stabilizing these young patients.The present study also highlights the overall distribution of prescribed drugs, where antibiotics accounted for 34.93% of prescriptions, followed by vitamins/minerals (18.0%) and proton pump inhibitors (16.8%). Analgesics/antipyretics (14.4%), IV fluids (8.52%), and antiemetics (6.0%) contributed notably, while antacids and anthelmintics were rarely used. These findings underline the dual focus on antimicrobial therapy and supportive care in the management of paediatric respiratory tract infections. Similar prescribing trends have been reported in previous studies, underscoring both the reliance on antibiotics and the supportive measures required to address comorbidities and symptom relief. Encouragingly, prescribing practices reflected a reasonable alignment with WHO indicators. The strong reliance on generics made treatment more cost-effective and accessible to families. Although the use of injectables and multiple antibiotics was higher than recommended, this also reflected clinicians determination to act swiftly and decisively in managing severe infections helping to prevent complications and improve recovery.At the same time, the findings point towards areas where further progress can be made. Reducing empirical polypharmacy and limiting unnecessary use of broad-spectrum antibiotics remain important goals. Strengthening antimicrobial stewardship, developing hospital-specific guidelines and supporting prescriber education can help address these gaps. Tackling comorbid conditions such as malnutrition and anaemia will also play a crucial role in ensuring faster recovery and lowering recurrence rates. In summary, this study shows that while paediatric RTIs continue to be a major health concern, the use of essential medicines, rational prescribing practices, and effective therapeutic interventions are already contributing to positive outcomes. By building on these strengths through better prescribing, preventive strategies like vaccination, improved nutrition and empowering caregivers healthcare systems can move closer to providing safer, more sustainable, and compassionate care for children affected by respiratory illnesses.

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