

## Drug Utilization Pattern and Adherence to the National List of Essential Medicines in Hospitalized Pediatric Patients: A Retrospective Observational Study

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### Abstract

**Background:** Rational prescribing in children deserves close attention because pediatric therapy relies on weight-based dosing and frequently falls outside licensed indications. Auditing what is actually prescribed on the wards, and how much of it comes from the National List of Essential Medicines, shows where prescribing can be tightened and where antimicrobial stewardship should focus.

**Objectives:** To describe the drug utilization pattern in hospitalized pediatric patients using the WHO core prescribing indicators, and to measure adherence of prescriptions to the National List of Essential Medicines.

**Methodology:** This was a hospital-based, retrospective, observational study of 600 case records of children aged up to 18 years admitted to the pediatric ward of Sri Guru Ram Rai Institute of Medical & Health Sciences, Dehradun, between June 2021 and May 2022. Demographic details, diagnosis, length of stay and every drug prescribed were extracted onto a structured proforma. Prescribing was assessed against the WHO core prescribing indicators. Each drug was checked against the National List of Essential Medicines 2015, which was the list in force during the study period, and against the WHO Model List of Essential Medicines for Children. Antibiotics were classified using the WHO AWaRe system. Data were analysed with descriptive statistics using SPSS version 25.

**Results:** The 600 children received 2,412 drugs, giving an average of 4.02 drugs per admission. Boys accounted for 57.0% and children aged 1 to 5 years formed the largest group (36.0%). Lower respiratory tract infection (26.0%) and acute gastroenteritis (22.0%) were the commonest diagnoses. Only 38.5% of drugs were prescribed by generic name. An antibiotic was prescribed in 72.3% of admissions and an injectable in 81.5%. Adherence to the National List of Essential Medicines 2015 was 65.5%, and 70.6% of drugs appeared on the WHO children's list. Antimicrobials were the largest therapeutic group (34.2%), and adherence was lowest for vitamins and nutritional supplements (22.4%). Of 826 antibiotic prescriptions, 45.0% were Access, 53.3% Watch and 1.7% Reserve, short of the WHO target of at least 60% Access.

**Conclusion:** Prescribing was broadly reasonable in volume but fell short on generic naming, injectable use, antibiotic exposure and essential-medicine adherence. The predominance of Watch antibiotics and the poor

showing of supplements are the two clearest targets for a hospital stewardship and prescription-audit programme.

**Keywords:** drug utilization; pediatrics; WHO prescribing indicators; National List of Essential Medicines; AWARe classification; antimicrobial stewardship.

## **1. Introduction**

Drug utilization studies examine what is prescribed, to whom and how well that prescribing matches accepted standards. The World Health Organization built a set of core prescribing indicators for exactly this purpose, so that a hospital can measure its own practice against reproducible benchmarks rather than impressions [1]. Standard values were later derived for these indicators, giving an optimal figure or range for each [2]. Together they allow a ward audit to say something concrete about polypharmacy, generic prescribing, antibiotic exposure, injection use and reliance on essential medicines.

Children are a group where this matters more than most. Doses are calculated per kilogram and change as the child grows, age-appropriate formulations are often unavailable, and a large share of what is given to children has never been formally licensed for them. Systematic reviews of hospitalized children put off-label prescribing anywhere between 12% and 71%, and unlicensed use between 0.2% and 48%, with newborns carrying the heaviest exposure [14]. Indian work has reported similar patterns, and off-label use has been linked to a higher risk of adverse drug reactions in children [15,17]. Prescribing carefully in this group is therefore a safety issue rather than an administrative one.

The essential medicines concept offers one practical anchor. Since the first WHO model list in 1977, national lists have been used to focus procurement and prescribing on a limited set of medicines chosen for efficacy, safety, quality and cost [3]. India published its first National List of Essential Medicines in 1996 and revised it in 2003, 2011 and 2015; the 2015 list, carrying 376 medicines, was the version in force throughout our study period, with the 384-medicine revision arriving in September 2022 [4,5,6]. A parallel children's list is maintained by WHO to make sure pediatric needs and formulations are considered separately [7]. Alongside this, the AWARe classification sorts antibiotics into Access, Watch and Reserve groups and gives hospitals a simple way to see whether their antibiotic use leans towards narrow-spectrum first-line agents or towards broader ones [8,9].

Sri Guru Ram Rai Institute of Medical & Health Sciences is a teaching hospital serving a mixed urban and hill population in and around Dehradun. Published prescribing audits from pediatric wards in this part of northern India are few, and the AWARe framework has rarely been applied to them. We carried out this retrospective audit to describe our own prescribing pattern, to measure how much of it drew on the national essential medicines list, and to identify where a stewardship programme would gain the most ground.

## **2. Review of Literature**

Indian pediatric drug utilization studies have reported a fairly consistent picture over the past fifteen years. Dimri and colleagues, auditing drug use in children at a teaching hospital, documented the everyday reliance on antimicrobials and symptomatic medicines that most subsequent studies have echoed [11]. Thiruthopu and colleagues, working in a South Indian pediatric unit, found an average of 4.56 drugs per patient, generic prescribing at only 19.2%, and just under half of all drugs drawn from the essential medicines list [10]. Vishwanath and colleagues, assessing hospitalized children at a tertiary teaching hospital, and Akhtar and colleagues, in a North Indian university hospital, reported comparable levels of polypharmacy and low

generic use [12,13]. The recurring theme is not excessive prescribing volume so much as weak generic naming and patchy essential-list adherence.

Beyond India, audits using the same WHO methodology allow direct comparison. Atif and colleagues, applying the WHO and INRUD indicators at primary care centres in Pakistan, recorded 3.4 drugs per encounter, generic prescribing at 71.6%, antibiotics in 48.9% of encounters and 93.4% of drugs from the national list [26]. Desalegn, auditing an Ethiopian teaching hospital, found a similar pattern of high antibiotic exposure with better essential-list adherence than generic naming [27]. These studies suggest that essential-list adherence and generic prescribing move somewhat independently of each other, and that a hospital can perform well on one while failing on the other.

The off-label question runs alongside all of this. Choonara and Conroy set out early on why unlicensed and off-label use in children carries a safety cost [18], and later reviews have quantified the association with adverse drug reactions [19,20]. Aronson and Ferner have argued that much of the confusion in this literature comes from inconsistent terminology [16], and professional bodies have since issued guidance acknowledging that off-label use is often clinically necessary rather than avoidable [22]. Surveys of prescribers show that awareness of the issue is uneven [23], and cross-sectional audits from Australia and Iran confirm that the practice is widespread in paediatric inpatient and neonatal settings [24,25]. Our study does not attempt to classify off-label status drug by drug. It asks the narrower and more auditable question of what was prescribed and how much of it came from the national essential medicines list.

### 3. Objectives

**Primary objective:** To assess the drug utilization pattern in hospitalized pediatric patients using the WHO core prescribing indicators, and to determine adherence of prescriptions to the National List of Essential Medicines.

**Secondary objectives:**

- To describe the demographic and clinical profile of children admitted during the study period.
- To identify the therapeutic classes and individual drugs most frequently prescribed.
- To classify prescribed antibiotics according to the WHO AWaRe system and compare the Access share against the WHO target.

### 4. Methodology

#### Study design and setting

This was a hospital-based, retrospective, observational study conducted by the Department of Pharmacology in collaboration with the Department of Pediatrics at Sri Guru Ram Rai Institute of Medical & Health Sciences, Dehradun. Case records of children admitted to the pediatric ward between June 2021 and May 2022 were reviewed.

#### Study population and sample size

The WHO manual on investigating drug use in health facilities recommends that at least 600 encounters be examined in a cross-sectional survey of prescribing, and that figure was adopted as the target sample [1]. Six hundred case records were selected by systematic random sampling from the pediatric admission

register, drawing 50 records from each month of the study period so that seasonal variation in admissions would be represented evenly.

### **Data collection**

A pre-designed, pre-tested proforma was used to record age, sex, residence, admitting diagnosis, length of hospital stay and the details of every drug prescribed during the admission, including name, dosage form, route and whether the drug was written by generic or brand name. Fixed-dose combinations were recorded as single entries. Data extraction was carried out by two investigators independently, and disagreements were settled by discussion with a third.

### **Study parameters**

Prescribing was assessed against the WHO core prescribing indicators: the average number of drugs per encounter, the percentage of drugs prescribed by generic name, the percentage of encounters with an antibiotic prescribed, the percentage of encounters with an injection prescribed, and the percentage of drugs prescribed from the essential medicines list [1]. Observed values were compared with the standard values derived by Isah and colleagues [2].

Each prescribed drug was checked against the National List of Essential Medicines 2015, which contained 376 medicines and was the list in force for the whole of the study period [4]. Because the 2022 revision was published in September 2022, after the study window closed, it was not used as the reference standard, although its implications are considered in the discussion [5,6]. Drugs were separately checked against the WHO Model List of Essential Medicines for Children [7]. Antibiotics were classified as Access, Watch or Reserve using the WHO AWaRe classification, and the Access share was compared with the WHO target of at least 60% of total antibiotic consumption [8,9].

### **Statistical analysis**

Data were entered in Microsoft Excel and analysed with SPSS version 25. Categorical variables are presented as frequencies and percentages, and continuous variables as mean with standard deviation. Findings are reported descriptively and set alongside WHO reference values; no inferential comparison between groups was planned.

### **Ethical considerations**

Approval was obtained from the Institutional Ethics Committee of Sri Guru Ram Rai Institute of Medical & Health Sciences before data collection began. Because the study was retrospective and drew only on existing hospital records, a waiver of individual informed consent was granted. Patient identifiers were removed at the point of extraction and no prescriber was identified in the analysis.

## **5. Inclusion and Exclusion Criteria**

### **Inclusion criteria:**

- Case records of patients aged up to 18 years admitted to the pediatric ward during the study period.
- Records containing complete drug treatment details for the admission.
- Admissions of at least 24 hours.

### **Exclusion criteria:**

- Incomplete or illegible case records, and records with missing drug charts.
- Patients admitted to the neonatal intensive care unit, whose prescribing follows separate protocols.
- Patients who left against medical advice within 24 hours of admission, and day-care or outpatient encounters.

## 6. Results and Analysis

Six hundred case records were analysed. Boys outnumbered girls and preschool children formed the largest age group. Just over half the admissions came from rural or peri-urban areas around Dehradun. The demographic profile is presented in Table 1.

| Characteristic                | Frequency (n) | Percentage (%) |
|-------------------------------|---------------|----------------|
| Age below 1 year              | 138           | 23.0           |
| Age 1-5 years                 | 216           | 36.0           |
| Age 6-12 years                | 162           | 27.0           |
| Age 13-18 years               | 84            | 14.0           |
| Male                          | 342           | 57.0           |
| Female                        | 258           | 43.0           |
| Rural or peri-urban residence | 348           | 58.0           |
| Urban residence               | 252           | 42.0           |
| Hospital stay 1-3 days        | 222           | 37.0           |
| Hospital stay 4-7 days        | 288           | 48.0           |
| Hospital stay above 7 days    | 90            | 15.0           |

Table 1. Demographic profile of the study population (n = 600). Mean age 5.6 (SD 4.3) years; mean hospital stay 4.8 (SD 2.6) days.

Infections dominated the admission diagnoses, with lower respiratory tract infection and acute gastroenteritis together accounting for almost half of all admissions. The distribution is given in Table 2.

| Admitting diagnosis                    | Frequency (n) | Percentage (%) |
|----------------------------------------|---------------|----------------|
| Lower respiratory tract infection      | 156           | 26.0           |
| Acute gastroenteritis                  | 132           | 22.0           |
| Enteric or undifferentiated fever      | 84            | 14.0           |
| Seizure disorder                       | 54            | 9.0            |
| Severe anaemia or nutritional disorder | 42            | 7.0            |
| Dengue or other viral fever            | 36            | 6.0            |
| Renal or nephrotic disorder            | 24            | 4.0            |
| Other diagnoses                        | 72            | 12.0           |

Table 2. Distribution of admitting diagnoses (n = 600).

A total of 2,412 drugs were prescribed across the 600 admissions, giving an average of 4.02 drugs per encounter. Generic prescribing was low, and both antibiotic and injectable exposure were well above the WHO reference ranges. Adherence to the National List of Essential Medicines 2015 reached 65.5%. The indicator values and their reference standards are set out in Table 3 and shown graphically in Figure 1.

| WHO core prescribing indicator        | Observed | Reference   | Met? |
|---------------------------------------|----------|-------------|------|
| Average number of drugs per encounter | 4.02     | 1.6-1.8     | No   |
| Drugs prescribed by generic name (%)  | 38.5     | 100         | No   |
| Encounters with an antibiotic (%)     | 72.3     | 20.0-26.8   | No   |
| Encounters with an injection (%)      | 81.5     | 13.4-24.1   | No   |
| Drugs from NLEM 2015 (%)              | 65.5     | 100         | No   |
| Drugs from WHO children's list (%)    | 70.6     | Not defined | -    |
| Drugs as fixed-dose combinations (%)  | 14.2     | Not defined | -    |

Table 3. WHO core prescribing indicators with reference values [1,2]. Total drugs prescribed = 2,412.

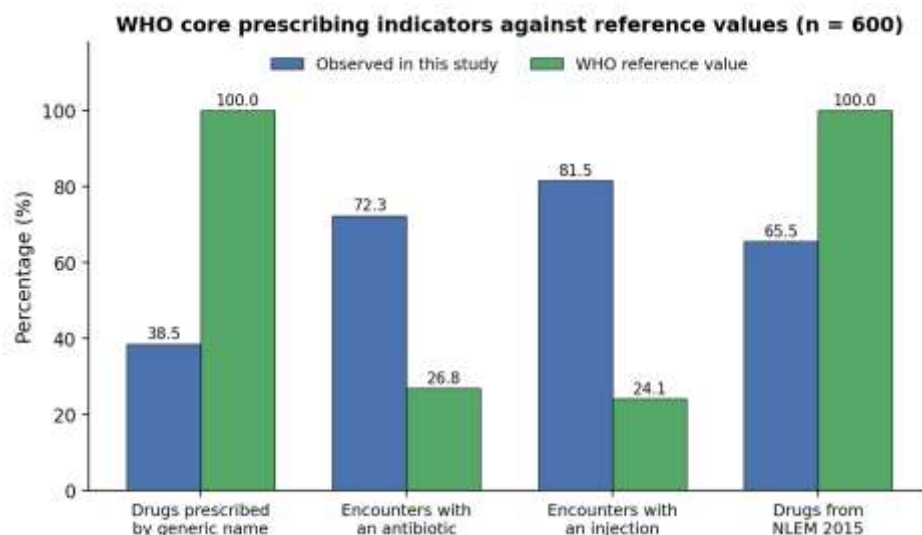


Figure 1. Observed values of the percentage-based WHO core prescribing indicators against their reference values. For antibiotic and injection use the upper limit of the reference range is plotted.

Antimicrobials were the single largest therapeutic group, followed by antipyretics and analgesics. Vitamins and nutritional supplements made up almost a tenth of all prescribing. The distribution by therapeutic class, together with the proportion of each class drawn from the national essential medicines list, is shown in Table 4.

| Therapeutic class                       | Drugs (n) | % of total | From NLEM 2015 (%) |
|-----------------------------------------|-----------|------------|--------------------|
| Antimicrobials                          | 826       | 34.2       | 68.2               |
| Antipyretics and analgesics             | 446       | 18.5       | 89.9               |
| Intravenous fluids and electrolytes     | 297       | 12.3       | 87.9               |
| Respiratory agents                      | 261       | 10.8       | 57.1               |
| Vitamins and supplements                | 219       | 9.1        | 22.4               |
| Gastrointestinal agents and antiemetics | 178       | 7.4        | 39.9               |
| Anticonvulsants                         | 101       | 4.2        | 77.2               |
| Other agents                            | 84        | 3.5        | 10.7               |
| Total                                   | 2,412     | 100.0      | 65.5               |

Table 4. Therapeutic class distribution and essential-medicine adherence by class (n = 2,412 drugs).

Among the 826 antibiotic prescriptions, third-generation cephalosporins led the list, with ceftriaxone alone accounting for a quarter. The ten most frequently prescribed antibiotics and their AWARe categories are listed in Table 5.

| Antibiotic              | Prescriptions (n) | % of 826 | AWaRe category |
|-------------------------|-------------------|----------|----------------|
| Ceftriaxone             | 214               | 25.9     | Watch          |
| Amoxicillin-clavulanate | 138               | 16.7     | Access         |
| Cefotaxime              | 96                | 11.6     | Watch          |
| Amikacin                | 78                | 9.4      | Access         |
| Azithromycin            | 66                | 8.0      | Watch          |
| Ampicillin              | 58                | 7.0      | Access         |
| Gentamicin              | 52                | 6.3      | Access         |
| Metronidazole           | 46                | 5.6      | Access         |
| Vancomycin              | 24                | 2.9      | Watch          |
| Meropenem               | 20                | 2.4      | Watch          |
| Other antibiotics       | 34                | 4.1      | Mixed          |

Table 5. Ten most frequently prescribed antibiotics with AWARe classification (n = 826 antibiotic prescriptions).

Grouped by AWARe category, 372 prescriptions (45.0%) were Access agents, 440 (53.3%) were Watch agents and 14 (1.7%) were Reserve agents. The Access share therefore fell below the WHO target of at least 60%, as shown in Figure 2.

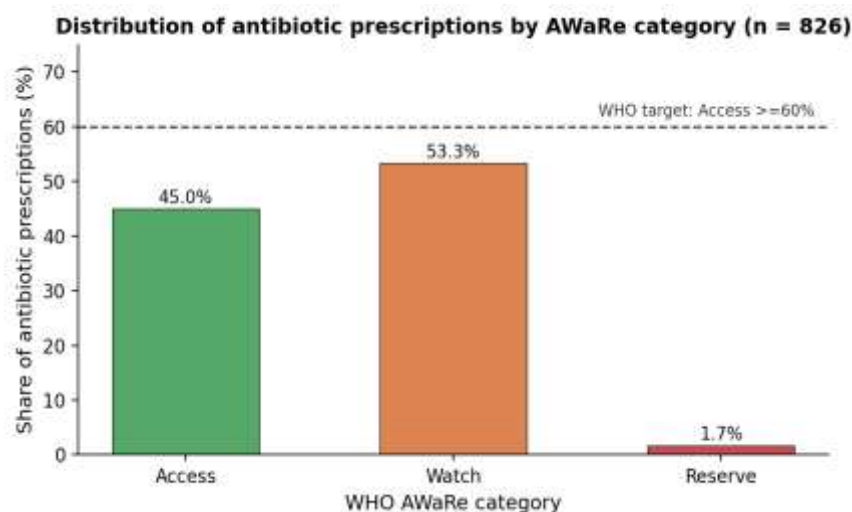


Figure 2. Distribution of antibiotic prescriptions by WHO AWARe category, with the WHO Access target shown as a dashed line.

## 7. Discussion and Interpretation

Four findings deserve comment: prescribing volume was moderate, generic naming was poor, antibiotic and injectable exposure were high, and essential-medicine adherence sat at roughly two-thirds. None of these is unique to our hospital, but taken together they point clearly to where an audit-and-feedback programme would pay off.

The average of 4.02 drugs per admission exceeds the WHO reference range of 1.6 to 1.8, though that range was derived largely from outpatient encounters and is a demanding standard for inpatients who need fluids, antipyretics and often more than one antimicrobial. Our figure sits close to the 4.56 drugs per patient reported by Thiruthopu and colleagues in a South Indian pediatric unit [10], and to the levels described by Vishwanath and colleagues and by Akhtar and colleagues in Indian teaching hospitals [12,13]. Polypharmacy in this range is common on pediatric wards and is not by itself alarming, but each additional drug adds a dosing calculation and an interaction to track in a patient whose weight is the denominator for everything.

Generic prescribing at 38.5% is the weakest indicator in our audit, and it is the one most easily fixed. Thiruthopu and colleagues recorded an even lower 19.2% [10], while Atif and colleagues in Pakistan achieved 71.6% [26], which shows that the difference is institutional rather than inevitable. Writing in generic terms lowers cost, reduces the confusion that comes from multiple brand names for the same molecule, and makes substitution safer when a particular brand is unavailable. A printed formulary and a prescription-audit loop would move this number without requiring any change in clinical decision-making.

Antibiotic exposure in 72.3% of admissions is far above the WHO reference range, although the comparison needs care: our population was dominated by respiratory and gastrointestinal infections, which are the usual reasons for admitting a child, and a ward sample will always exceed an outpatient benchmark. The more informative measure is the AWARe breakdown. With Access agents at 45.0% and Watch agents at 53.3%, our hospital sits below the WHO goal of at least 60% Access [8]. Ceftriaxone alone accounted for a quarter of antibiotic prescriptions. The multinational paediatric survey by Hsia and colleagues found exactly this pattern in many low and middle income settings, and proposed the AWARe index as a simple traffic-light metric for stewardship [9]. Shifting empirical therapy for uncomplicated pneumonia and gastroenteritis towards Access agents, guided by a local antibiogram, is the single change most likely to move that figure. Injectable use in 81.5% of admissions is similarly high and partly reflects the inpatient setting, but it also suggests scope for earlier switching from intravenous to oral therapy once a child is stable.

Essential-medicine adherence at 65.5% is broadly in line with Indian reports, which have ranged widely depending on setting and on whether inpatient or outpatient prescriptions were audited [10,12]. What our class-wise breakdown adds is a clear explanation for the shortfall. Antipyretics, intravenous fluids and anticonvulsants all drew heavily on the national list, at 88% to 90%, whereas vitamins and nutritional supplements managed only 22.4% and miscellaneous agents 10.7%. In other words, the core therapeutic decisions were largely essential-list compliant, and the gap came from adjunctive prescribing that arguably adds little. Trimming unnecessary supplements would raise adherence and reduce pill burden at the same time. Our reference standard was the 2015 list, since the 2022 revision appeared after our study closed; a repeat audit against the newer list, which adds several anti-infectives, would be expected to shift these figures somewhat [5,6]. The critique by Manikandan that the 2022 list does not itself categorise antibacterials by AWARe is relevant here, because it means hospitals must apply the two frameworks separately, as we have done [6]. The broader case for essential medicines lists, set out by Laing and colleagues, still holds: a shorter, well-chosen list improves quality and lowers cost [3], and comparative work across Indian state lists has shown how much local selection practices vary [28]. Finally, although we did not classify off-label status drug by drug, the reliance on adult formulations and weight-based adjustment in this population sits squarely within the concerns raised by the paediatric off-label literature [14,15,21], and reinforces the argument for auditing pediatric prescribing on its own terms rather than folding it into a general hospital audit.

## **8. Conclusion**

Prescribing for hospitalized children at this centre was moderate in volume but fell short of WHO standards on generic naming, antibiotic exposure, injectable use and essential-medicine adherence. Two-thirds of drugs came from the National List of Essential Medicines 2015, with the shortfall driven largely by vitamins, supplements and miscellaneous agents rather than by core therapeutic choices. Just under half of antibiotic prescriptions were Access agents, leaving the hospital short of the WHO stewardship target and heavily reliant on third-generation cephalosporins. Three measures follow directly from these findings: adopt a pediatric hospital formulary built around the national list and require generic prescribing, introduce a regular prescription audit with feedback to prescribers, and set up an antimicrobial stewardship committee that promotes Access agents for common infections and encourages early intravenous to oral switching. For a teaching hospital serving Dehradun and the surrounding hill districts, these are low-cost changes that would improve both the safety and the affordability of pediatric care.

## **9. Limitations of the Study**

- The retrospective design relies on the completeness and legibility of case records, and some prescribing detail such as exact indication or duration may have been missing or inconsistently documented.
- This was a single-centre audit over twelve months, so the findings describe local practice and may not extend to other hospitals or regions.
- Appropriateness of drug choice, dose and duration against standard treatment guidelines was not assessed, so a high antibiotic rate cannot be equated with inappropriate prescribing.
- Off-label and unlicensed status was not classified drug by drug, and no clinical outcome or adverse drug reaction data were collected.
- Adherence was measured against the 2015 essential medicines list, which was in force during the study period; results may differ if the 2022 revision is used. Prospective, multi-centre audits linking prescribing indicators to clinical outcomes would strengthen the evidence base.

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