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Antibiotic misuse in children with acute upper respiratory tract infection: A cross-sectional study from Eastern India

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Abstract:
Upper respiratory tract infections (URTIs) in children are predominantly viral, yet antibiotics are frequently used, driving avoidable antimicrobial resistance. We conducted a cross-sectional study of 88 children with acute URTI attending a tertiary-care paediatric outpatient department in Eastern India to estimate the prevalence of antibiotic misuse before presentation, its source, the agents used and caregiver knowledge and attitudes. Antibiotic use before presentation was judged inappropriate in 75 children (85.2%), a doctor was the source in 79 (89.8%) and Watch-group agents accounted for 53 of 93 products (57.0%). Although 73 caregivers (83.0%) agreed that unnecessary antibiotics should be avoided, only 22.1% recognised that most URTIs are viral and 37.5% wanted an antibiotic prescribed. Thus, data shows that antibiotic misuse before presentation in this setting is predominantly physician-initiated and dominated by Watch-group agents and that it coexists with a caregiver knowledge–practice gap, which together identifies prescriber-directed stewardship, supported by targeted caregiver education, as the priority intervention.

Keywords: Antibiotic misuse, antimicrobial stewardship, upper respiratory tract infection (URTIs), world health organization (WHO) access, watch and reserve (AWaRe), India

Background:
Acute upper respiratory tract infections (URTIs) in children - the common cold, pharyngitis, rhinosinusitis and uncomplicated acute bronchitis - are mostly viral and self-limiting **[1]**. Antibiotics neither shorten their course nor prevent complications in most children **[2]**. Antibiotics nevertheless remain among the commonest prescriptions for childhood respiratory illness **[3]** and much of this use is inappropriate **[4]**. The 2021 Global Burden of Disease analysis attributed approximately 1.14 million deaths to bacterial antimicrobial resistance (AMR) and forecast a further rise by 2050 **[5]**. This burden falls disproportionately on low- and middle-income countries, where antibiotic use in children has responded only weakly to national stewardship policies **[6]**. The World Health Organization (WHO) classifies antibiotics into Access, Watch and Reserve (AWaRe) groups and recommends that Access-group agents predominate in national consumption, with Watch and Reserve agents restricted to narrower indications **[7]**. India is one of the largest global consumers of antibiotics and nationally representative household survey data show that 18.7% of Indian children under three years with acute respiratory infection symptoms received an antibiotic **[8]**. Among children presenting to a North Indian tertiary centre, 20.7% had pre-hospital antibiotic exposure **[9]**. Caregiver expectation of an antibiotic prescription for childhood respiratory illness is a recognised driver of this pattern **[10]**. Indian prescription audits and systematic reviews have described prescribing patterns and self-medication separately **[11, 12]**. Caregiver knowledge, attitude and practice surveys have likewise been reported independently of prescribing data, so that the prescriber and caregiver contributions to misuse have rarely been measured in the same children **[13]**. Therefore, it is of interest to estimate the prevalence of physician-guided antibiotic misuse source and the agents involved using the WHO AWaRe classification and to document caregiver-reported reasons for antibiotic use without a prescription.

Methods and Materials:

Study design, setting and participants:
This was a single-centre, cross-sectional descriptive study conducted in the paediatric outpatient department of the All India Institute of Medical Sciences (AIIMS), Kalyani, West Bengal - a tertiary-care teaching hospital in eastern India. Children were enrolled by consecutive sampling from September 2022 to March 2023. Children aged under 18 years of either sex who presented with acute URTI and had received at least one antibiotic for the current illness episode before the study visit were included.

Data collection:
Demographic, socioeconomic, clinical and antibiotic-related information was collected using a structured case record form and a ten-item knowledge-and-attitude questionnaire scored on a five-point Likert scale (1 = strongly agree to 5 = strongly disagree), via verbal interview.

Outcomes:
The primary outcome was antibiotic misuse, defined as prior antibiotic use graded by the treating physician as justified, unjustified or grossly inappropriate. Secondary outcomes were the source of the antibiotic, the number of agents used and their category according to the WHO AWaRe 2023 classification **[7]**, caregiver-reported reasons for use without a prescription and the distribution of the ten knowledge-and-attitude items.

Sample size:
The sample size of 88, specified in the protocol, was calculated for the estimation of a single proportion, assuming a baseline antibiotic-use rate of approximately 15% among children with URTI reported in a previous Indian study **[14]**, with 95% confidence and an absolute precision of 7.5%.

Statistical analysis:
All analyses were performed in R version 4.5.3. Categorical variables are expressed as counts and percentages. Age and

body weight were non-normally distributed on the Shapiro–Wilk test and are summarised as median and interquartile range (IQR). The association between the source of the antibiotic and physician-graded misuse was tested with Fisher's exact test. Exploratory associations between misuse and caregiver characteristics (place of residence, guardian education, household income, guardian age, family self-medication, a household contact working in healthcare and child age) were also examined with Fisher's exact test, with Holm's method used to control the family-wise error rate. Records with incomplete information for a variable were excluded only from the corresponding analysis.

Ethics:
The study was approved by the Institutional Ethics Committee of AIIMS Kalyani (IEC/AIIMS/Kalyani/Meeting/2023/004-R). Written informed consent was obtained from the parent or legal guardian of each participant, with assent from older children where appropriate.

Results:
Eighty-eight children were enrolled and included in the analysis. 45 (51.1%) of them were boys and the median age was 4.0 years (IQR 1.5–6.2). The mother was the informant for 59 children (67.0%) and the father for 25 (28.4%). A guardian aged 31–45 years was commonest (53.4%); the highest attained education was college for 29 guardians (33.0%). Forty-three children (51.8% of 83 with data) lived in rural areas. Baseline demographic and clinical characteristics are shown in **Table 1** and **Table 3**. Cough was the commonest presenting symptom (87.5%), followed by low-grade fever (68.2%), rhinorrhoea (54.5%) and nasal congestion (46.6%) and sneezing (44.3%) **(Figure 1).** The treating physician judged prior antibiotic use to be not justified in 75 of the 88 children, giving a misuse prevalence of 85.2% (95% CI 76.3–91.2); 70 children (79.5%) were graded unjustified and 5 (5.7%) grossly inappropriate (**Table 2**). A doctor was the source of the antibiotic in 79 children (89.8%, 95% CI 81.7–94.5). Nine children (10.2%, 5.5–18.3) obtained the antibiotic without a prescription - 6 by self- or caregiver decision (6.8%) and 3 from a pharmacist (3.4%). The proportion graded as misuse did not differ between these groups (Fisher's exact test, p = 0.345). Most children received a single antibiotic agent (83, 94.3%); 3 received two and 2 received three, giving 93 named products in total. Amoxicillin–clavulanate was most frequently used (29 of 93, 31.2%), followed by cefpodoxime (23.7%) and azithromycin (18.3%) **(Figure 2).** As per, WHO AWaRe 2023 classification, 53 products (57.0%) were Watch, 39 (41.9%) Access and 1 (1.1%) Reserve (linezolid) **(Table 2)**. The detailed breakdown of prescribed drugs before presentation has been mentioned in **Table 4**. Antibiotics were prescribed at the study visit itself for only 11 children (12.5%). Among the 9 children whose antibiotics were obtained without a prescription, all caregivers (100%) cited that it saved time; being easier and past experience were each cited by 6 (66.7%) and use of leftover medicine by 4 (44.4%). Responses to the ten knowledge-and-attitude items are summarised in **Table 5** and **Figure 3**. Seventy-three caregivers (83.0%) agreed that children should avoid antibiotics when not necessary and only 4 (4.5%) agreed that self-prescription should be allowed. However, only 22.1% agreed that most URTIs are viral and cannot be treated with antibiotics, while 37.5% wanted an antibiotic to be prescribed. No caregiver-level factor was significantly associated with misuse after adjustment for multiple comparisons (all Holm-adjusted p > 0.05); guardian age had the lowest unadjusted p-value (0.018) but was not significant after adjustment.

Table 1: Baseline demographic and clinical characteristics of the study population (N = 88)

Characteristic	n (%)
Age, years, median (IQR)	4.0 (1.5–6.2)
Sex (n = 88)	
Male	45 (51.1)
Female	43 (48.9)
Body weight, kg, median (IQR) (n = 85)	15.2 (10.2–24.6)
Height, cm, median (IQR) (n = 79)	101.5 (84.0–124.0)
Primary guardian age, years (n = 88)	
18–30	30 (34.1)
31–45	47 (53.4)
46–60	10 (11.4)
61–80	1 (1.1)
Primary guardian education (n = 88)	
Illiterate	4 (4.5)
Incomplete high school	22 (25.0)
High school	26 (29.5)
College	29 (33.0)
Postgraduate	7 (8.0)
Monthly household income (INR) (n = 68)	
2,000–4,999	1 (1.5)
5,000–9,999	20 (29.4)
10,000–19,999	20 (29.4)
20,000–49,999	19 (27.9)
≥50,000	8 (11.8)
Place of residence (n = 83)	
Rural	43 (51.8)
Urban	40 (48.2)
Self-medication by another family member (past year) (n = 88)	
No	75 (85.2)
Yes	13 (14.8)
Family member/friend working in healthcare (n = 87)	
No	51 (58.6)
Yes	36 (41.4)

Values are n (%) unless stated. Denominators differ where data were missing (shown per row). Age and body weight were non-normally distributed (Shapiro-Wilk p < 0.001) and are summarised as median (IQR). INR, Indian rupees.

Table 2: Antibiotic use before presentation (N = 88 children; 93 antibiotic products)

Characteristic	n (%)
Source of antibiotic (n = 88)	
Doctor	79 (89.8)
Pharmacist	3 (3.4)
Self/caregiver	6 (6.8)
Treating physician assessment of prior use (n = 88)	
Justified	13 (14.8)
Unjustified	70 (79.5)
Grossly inappropriate	5 (5.7)
Number of antibiotics received (n = 88)	
1	83 (94.3)
2	3 (3.4)
3	2 (2.3)
WHO AWaRe group of product (n = 93)	
Access	39 (41.9)
Watch	53 (57.0)
Reserve	1 (1.1)
Antibiotic prescribed at the study visit (n = 88)	
No	77 (87.5)

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Yes	11 (12.5)

Source, physician grading, number of agents and study-visit prescription use N = 88 as denominator. Individual products and WHO AWaRe 2023 groups use the 93 named products as denominator. Reasons for use without a prescription use the 9 children who obtained antibiotics without a prescription as denominator; categories are not mutually exclusive. AWaRe, Access/Watch/Reserve.

Table 3: Additional baseline and healthcare-seeking characteristics

Characteristic	n (%)
Informant (n = 88)	
Mother	59 (67.0)
Father	25 (28.4)
Aunt	1 (1.1)
Brother	1 (1.1)
Grandmother	1 (1.1)
Orphanage administrator	1 (1.1)
Duration of current illness (n = 86)	
2–3 days	8 (9.3)
3–6 days	15 (17.4)
1–2 weeks	28 (32.6)
3–4 weeks	10 (11.6)
1–3 months	15 (17.4)
>3 months	10 (11.6)
Medical consultation dURTIng the previous 6 months (n = 88)	
No	3 (3.4)
Once or twice a month	41 (46.6)
Once or twice in the previous 6 months	44 (50.0)
Preferred healthcare provider for minor illness (n = 88)	
Government hospital	43 (48.9)
Private practice	40 (45.5)
Homeopathic practice	4 (4.5)
Self-medication	1 (1.1)

Values are n (%) unless stated. Denominators differ where data were missing (shown per row). Age and body weight were non-normally distributed (Shapiro-Wilk $p < 0.001$) and are summarised as median (IQR). INR, Indian rupees.

Table 4: details of antibiotic use before presentation

Characteristic	n (%)
Antibiotic products used (n = 93)	
Amoxicillin–clavulanate	29 (31.2)
Cefpodoxime	22 (23.7)
Azithromycin	17 (18.3)
Cefixime	5 (5.4)
Amoxicillin	4 (4.3)
Clarithromycin	3 (3.2)
Doxycycline	2 (2.2)
Metronidazole	2 (2.2)
Cefpodoxime–clavulanate	1 (1.1)
Ceftriaxone	1 (1.1)
Cefuroxime	1 (1.1)
Cotrimoxazole	1 (1.1)
Faropenem	1 (1.1)
Linezolid	1 (1.1)
Ofloxacin	1 (1.1)
Ofloxacin–metronidazole	1 (1.1)
Tinidazole	1 (1.1)
Reasons for antibiotic use without prescription (n = 9)	
Saves time	9 (100.0)
Easier	6 (66.7)
Past experience	6 (66.7)
Leftover medicine	4 (44.4)
Long waiting times	3 (33.3)
Lack of easy access to healthcare	2 (22.2)
Previously advised by a doctor	1 (11.1)
Worked for relatives	1 (11.1)

Table 5: Caregiver knowledge and attitudes towards antibiotic use (5-point Likert items).

Statement	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
	n (%)	n (%)	n (%)	n (%)	n (%)
1. Sought another physician when antibiotics were not prescribed (n = 79)	10 (12.7)	24 (30.4)	10 (12.7)	22 (27.8)	13 (16.5)
2. Would prefer antibiotics for a child's URTI (n = 88)	8 (9.1)	25 (28.4)	19 (21.6)	24 (27.3)	12 (13.6)
3. Would prefer antibiotics for a child's diarrhoea (n = 88)	4 (4.5)	25 (28.4)	23 (26.1)	21 (23.9)	15 (17.0)
4. It is acceptable to allow an URTI to resolve without antibiotics (n = 86)	8 (9.3)	17 (19.8)	5 (5.8)	29 (33.7)	27 (31.4)
5. Most URTIs are viral and cannot be treated with antibiotics (n = 86)	6 (7.0)	13 (15.1)	32 (37.2)	20 (23.3)	15 (17.4)
6. Children should avoid antibiotics when not necessary (n = 88)	38 (43.2)	35 (39.8)	10 (11.4)	4 (4.5)	1 (1.1)
7. Symptomatic treatment differs from antibiotic treatment (n = 88)	27 (30.7)	19 (21.6)	14 (15.9)	17 (19.3)	11 (12.5)
8. Expect the physician to treat URTI with antipyretics/analgesics (n = 88)	19 (21.6)	46 (52.3)	7 (8.0)	12 (13.6)	4 (4.5)
9. Aware of antibiotic resistance and its disadvantages (n = 88)	14 (15.9)	19 (21.6)	3 (3.4)	20 (22.7)	32 (36.4)
10. Self-prescription of antibiotics should be allowed (n = 88)	1 (1.1)	3 (3.4)	3 (3.4)	32 (36.4)	49 (55.7)

Values are presented as n (%). Response coding: 1 = strongly agree to 5 = strongly disagree. Denominators differ where items were left blank. URTI = upper respiratory tract infection.

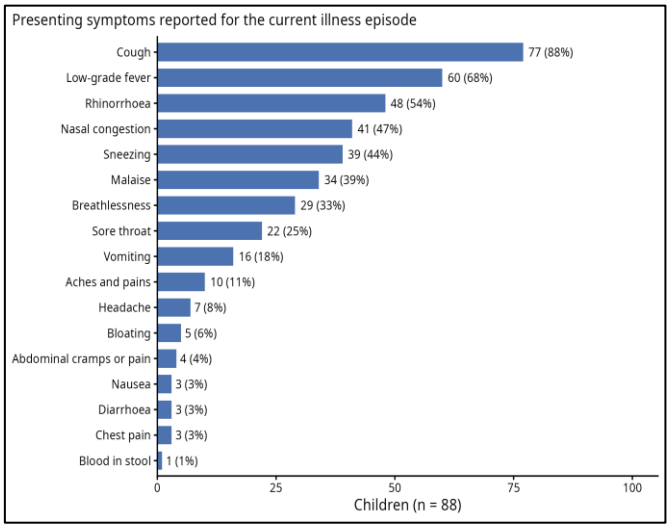
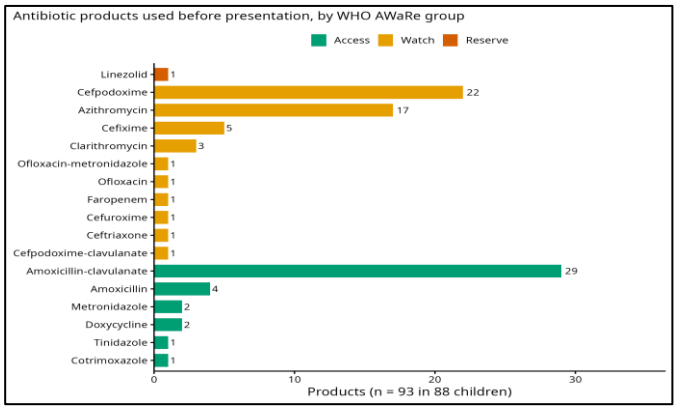


Figure 1: Presenting symptoms reported at the study visit, as the number and percentage of the 88 children. Symptoms are not mutually exclusive (each child could report several)



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Figure 2: Antibiotic products used before presentation (93 products in 88 children), coloured by WHO AWaRe 2023 group (Access, Watch, Reserve). Bars show the number of products; two fixed-dose combinations account for the difference from the recorded agent count

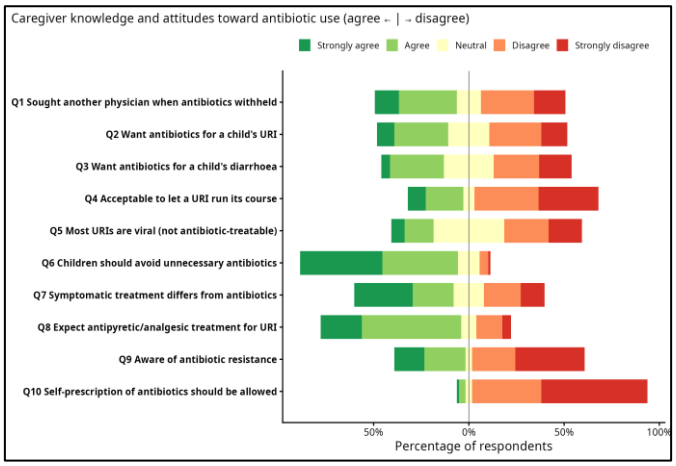


Figure 3: Caregiver responses to the ten knowledge-and-attitude items on a five-point Likert scale, shown as a diverging bar chart (agreement to the left, disagreement to the right, neutral split at the centre). Denominators differ by item where responses were missing

Discussion:

Antibiotic use before presentation was judged not justified by the treating physician in 85.2% of children. This high prevalence is consistent with published evidence that most acute respiratory infections in children are viral yet frequently treated with antibiotics **[1–3]** and it reflects the enrolment of only children who had already received an antibiotic. Misuse was predominantly physician-initiated: a doctor was the source in 89.8% of children and the proportion graded as misuse did not differ between doctor-sourced and non-prescription antibiotics. Self-medication and over-the-counter supply are established concerns in this region **[12]**, but an audit of 1219 outpatient prescriptions in a North Indian public facility likewise found amoxicillin–clavulanate-led, frequently irrational prescribing **[15]**. By contrast, a parent-reported survey from Saudi Arabia found that although 81% of children had received at least one antibiotic course, 71% of these courses were obtained without consulting a general practitioner, indicating a caregiver-driven rather than physician-driven pattern of misuse in that setting **[16]**. The predominance of doctor-sourced antibiotics in the present cohort suggests that the balance between these two drivers of misuse is setting-specific, and stewardship strategies should be calibrated accordingly. Stewardship in this setting must therefore target prescribers as well as caregivers. Watch-group antibiotics accounted for 57.0% of products, inverting the WHO recommendation that Access-group agents predominate **[7]**. Oral cephalosporins and macrolides were prominent; mirroring paediatric AWaRe audits from other low- and middle-income countries that report Watch-group predominance for respiratory indications **[17–20]**. A two-cycle audit with prescriber education in a paediatric outpatient department improved the appropriateness of antibiotic choice without reducing overall prescribing, indicating that feedback can shift agent selection towards Access-group drugs **[21]**. The attitudinal data reveal a knowledge–practice gap. Although 83.0% of caregivers agreed that antibiotics should not be used unnecessarily, only 22.1% recognised that most URTIs are viral and 37.5% wanted an antibiotic for their child's URTI. Comparable dissociation between general awareness and specific beliefs has been reported among Indian parents, over half of whom were unsure whether antibiotics are indicated for all URTIs **[22]** and in caregiver surveys from Egypt, the United States and Georgia **[10, 24–26]**. A health-belief-model-based survey of the general public in China similarly found that irrational antibiotic use for URTIs was associated less with a simple deficit of knowledge than with a constellation of health beliefs - perceived threat of the illness, perceived benefit of antibiotics, self-efficacy, ease of antibiotic access and social influence - and that greater knowledge could even promote irrational use indirectly, by heightening perceived threat and self-efficacy **[23]**. This offers a plausible explanation for why most caregivers in the present study endorsed avoiding unnecessary antibiotics in principle while a substantial minority still wanted one prescribed for their own child. Education that delivers the specific, actionable message that URTIs is viral and self-limiting is therefore more likely to change behaviour than generic warnings about resistance. No caregiver-level factor was independently associated with misuse after adjustment for multiple comparisons; the small sample and the high prevalence of misuse limited power to detect such associations. Combining physician grading of appropriateness with the source of the antibiotic, the WHO AWaRe group and caregiver knowledge and attitudes in the same children allows the prescriber and caregiver contributions to misuse to be assessed together. The study has limitations. It was conducted at a single tertiary centre with consecutive sampling, so the findings may not be generalisable to primary or community settings. Only children who had already received an antibiotic were enrolled, so the prevalence does not estimate antibiotic prescribing in the general population. Appropriateness was graded by a single physician without a reference standard or inter-rater agreement. Antibiotic names, doses and durations were caregiver-reported and subject to recall bias. Finally, although the protocol also permitted enrolment of children with acute diarrhoea, few such cases were recruited and the analysis was confined to URTI.

Conclusion:

In children presenting with acute URTI at a tertiary-care centre in Eastern India, most antibiotic use before presentation was judged inappropriate and was physician-initiated, Watch-group agents predominated and few caregivers recognised the viral aetiology of URTI. Prescriber-directed stewardship combined with targeted caregiver education is therefore required and larger multicentre studies are needed to confirm these patterns.

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Conflict of interest:
The authors declare no conflict of interest. This manuscript has not been posted as a preprint on any server and has not been published elsewhere, in whole or in part.

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