RESEARCH PAPER

Rational Use and Prescribing Pattern of Antibiotics in Community Patients with Lower Respiratory Tract Infections: A Prospective Observational Study at a Tertiary Care Teaching Hospital, Jaipur

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ABSTRACT

• **Background:** Lower respiratory tract infections (LRTIs) are a leading driver of antibiotic consumption and antimicrobial resistance (AMR) globally. In India, irrational prescribing practices compound an already critical resistance burden. Pharmacoepidemiological studies are essential to understand prevailing prescribing behaviours and guide stewardship interventions.

• **Objectives:** To assess the prescribing pattern and rationality of antibiotic use in community LRTI patients at NIMS University Hospital, Jaipur, against WHO/INRUD core drug-use indicators, IDSA/BTS/GOLD clinical guidelines, and the WHO AWaRe (Access, Watch, Reserve) antibiotic classification.

• **Methods:** A prospective, cross-sectional, observational drug utilisation study over 12 months (January–December 2023) at NIMS Medical College & Hospital. 250 adult LRTI patients enrolled by consecutive sampling. Prescriptions were evaluated for rationality; ADRs monitored by the Naranjo causality algorithm.

• **Results:** Males predominated (64.8%); mean age 44.6 ± 16.3 years. Acute bronchitis (32.8%) and CAP (27.2%) were most common. Amoxicillin-clavulanate (25.0%), azithromycin (17.3%), and levofloxacin (13.5%) led 312 prescriptions. Guideline-concordant selection: 84.8%. Culture-guided prescribing: 15.2%. Generic-name prescribing: 58.4%. Injection encounters: 22%. Mean drugs/prescription: 3.2 ± 0.8. ADRs in 62 patients (24.8%); 45.2% were potentially preventable.

• **Conclusions:** Antibiotic selection is largely guideline-concordant but critical deficits exist in microbiological testing, duration appropriateness, generic prescribing, and injection rationalisation. A structured antimicrobial stewardship programme (ASP) and mandatory prescription auditing are urgently needed.

Keywords: Antibiotic prescribing pattern; Lower respiratory tract infection; Rational drug use; Antimicrobial stewardship; NIMS University Jaipur; Community-acquired pneumonia; WHO AWaRe; Pharmacoepidemiology; Drug utilisation study

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1. Introduction

1.1 Global Burden of Lower Respiratory Tract Infections

Lower respiratory tract infections (LRTIs) — encompassing acute bronchitis, community-acquired pneumonia (CAP), acute exacerbations of COPD (AECOPD), bronchopneumonia, and atypical pneumonia syndromes — represent one of the most significant infectious disease challenges of the 21st century. According to the Global Burden of Disease (GBD) Study 2019, LRTIs killed approximately 2.49 million people worldwide and accounted for 74 million

Disability-Adjusted Life Years (DALYs), ranking them consistently among the top three infectious causes of global mortality.[1,2] Pneumonia alone accounts for 14% of all deaths in children under five years of age worldwide.[3] In India, respiratory infections cause over 450,000 adult deaths annually, with disproportionate burden in rural and peri-urban populations lacking timely diagnostic access.[8]

1.2 Antibiotics in LRTI — The Prescribing Paradox

Antibiotics are the cornerstone of treatment for bacterial LRTIs, dramatically reducing morbidity and mortality when used appropriately.[5] However, 85–95% of acute bronchitis episodes are caused by respiratory viruses, for which antibiotics confer no clinical benefit.[6,10] Even in CAP, viral pathogens account for 25–40% of identified cases.[5] Widespread empirical prescribing — driven by diagnostic uncertainty, time pressures, and patient expectations — creates a fundamental paradox: individual patients may perceive benefit, but the cumulative population-level consequence is accelerating antimicrobial resistance (AMR).[11,12]

1.3 The Antimicrobial Resistance Crisis

The WHO has declared AMR one of the ten greatest threats to global public health.[3] The landmark 2022 Lancet AMR Collaborators study estimated that drug-resistant infections directly caused 1.27 million deaths and contributed to 4.95 million deaths globally in 2019 — a burden exceeding that of HIV/AIDS or malaria.[13] Without urgent intervention, AMR could cause 10 million deaths annually and cost the global economy US$100 trillion by 2050.[14]

India faces a uniquely severe AMR crisis driven by: high per-capita antibiotic consumption; widespread over-the-counter sales without prescription; inadequate regulatory enforcement; and high background prevalence of drug-resistant pathogens including MRSA, ESBL-producing Enterobacteriaceae, and carbapenem-resistant *Klebsiella pneumoniae*.[4,15] The ICMR AMR Surveillance Network has documented year-on-year increases in resistance rates among key respiratory pathogens including *Streptococcus pneumoniae* and *Haemophilus influenzae*.[15]

1.4 Rational Antibiotic Use — Frameworks and Standards

The WHO defines rational drug use as patients receiving medications appropriate to their clinical needs, in doses that meet individual requirements, for an adequate period, and at the lowest cost.[3] For antibiotics, rationality encompasses five pillars: (1) correct indication, (2) appropriate drug choice, (3) optimal dose, (4) minimum effective duration, and (5) preferred oral route.[5,6]

The WHO AWaRe (Access, Watch, Reserve) classification, introduced in 2017, stratifies antibiotics to preserve efficacy and guide prescribing. The WHO target is ≥60% of antibiotic prescriptions from the Access category.[18] The WHO/INRUD Core Drug Use Indicators provide a validated framework for cross-institutional prescribing benchmarking.[17] India's National Action Plan on AMR (2017–2021) mandates hospital-level antimicrobial stewardship programmes (ASPs); however, implementation in private teaching hospitals remains heterogeneous.[19]

1.5 Evidence Gap and Rationale

Published drug utilisation studies (DUS) on antibiotic prescribing in LRTI predominantly originate from southern India and government-sector institutions.[7,14] Data from Rajasthan and private north Indian teaching hospitals are scarce despite documented regional differences in resistance patterns and prescribing habits.[16] NIMS University Hospital, Jaipur — a 1,500-bed NABH-accredited tertiary care teaching hospital — serves approximately 180–220 LRTI presentations per month from urban Jaipur and surrounding rural districts. No pharmacoepidemiological study of antibiotic prescribing has been published from this institution to date.

1.6 Study Objectives

The specific objectives of this study were:

1. To characterise the demographic and clinical profile of adult LRTI patients at NIMS University Hospital, Jaipur.
2. To document the pattern, frequency, and class distribution of antibiotics prescribed.
3. To evaluate prescribing rationality against WHO/INRUD core indicators and IDSA/BTS/GOLD clinical guidelines.
4. To classify all prescribed antibiotics by WHO AWaRe framework and assess the proportion of Watch and Reserve antibiotic use.
5. To identify, characterise, and assess the causality and preventability of antibiotic-associated adverse drug reactions (ADRs).

6. To formulate institution-specific, evidence-based antimicrobial stewardship recommendations.

Table 1: Review of Published Literature on Antibiotic Prescribing in LRTIs

S. No.	Author & Year	Study Design & Duration	Setting / Country	Sample (N)	Common Diagnoses	Top Antibiotics Prescribed	Key Rationality Findings	ADR / Safety
1	Kotwani & Holloway (2011) [Ref 1]	Cross-sectional DUS; 12 months	New Delhi OPD clinics; India	400	Acute bronchitis; URTI; CAP	Co-trimoxazole (22.0%); Amoxicillin (18.4%); Ampicillin (14.2%)	Average drugs/Rx: 4.2 (↑↑ above WHO). Generic prescribing: 42%. Antibiotics from EML: 78%.	Not reported systematically
2	Kumar et al. (2013) [Ref 2]	Retrospective DUS; 6 months	Tertiary care hospital, South India	350	CAP; AECOPD; Broncho-pneumonia	Amoxicillin-Clavulanate (29.0%); Azithromycin (24.0%); Ciprofloxacin (18.0%)	Guideline concordance: 71%. Culture-guided: 18%. Combination therapy: 28%.	ADR incidence: 16.4%. GI effects predominant.
3	Sharma D et al. (2017) [Ref 3]	Prospective observational; 6 months	Teaching hospital, Central India	320	Acute bronchitis; CAP; AECOPD	Amoxicillin-Clavulanate (28.4%); Azithromycin (22.6%); Levofloxacin (14.0%)	Guideline concordance: 74.3%. Generic prescribing: 52%. Mean drugs/Rx: 3.6.	ADR: 18.2%; GI effects commonest. Naranjo used.
4	Pathak A et al. (2017) [Ref 4]	Prospective cross-sectional; 12 months	Tertiary hospital, Central India	280	CAP; Acute bronchitis; AECOPD	Azithromycin (26.0%); Co-amoxiclav (22.0%); Doxycycline (12.0%)	Guideline concordance: 68.0%. Generic name prescribing: 48%. Combination: 22%.	ADR: 20.1%. Skin rash & GI effects.
5	Gupta et al. (2019) [Ref 5]	Prospective observational; 9 months	District hospital, North India (UP)	210	Acute bronchitis; CAP; Upper LRTI	Amoxicillin (32.0%); Azithromycin (20.5%); Co-trimoxazole	Mean drugs/Rx: 3.8. Generic: 44%. Guideline	ADR: 14.8%. No formal causality assessment.

						(15.2%)	concordance: 62%.	
6	Tiwari & Sen (2020) [Ref 6]	Cross-sectional; 6 months	Rajasthan, India (multi-centre)	180	LRTI; CAP; AECOPD	Fluoroquinolones (34.0%); Macrolides (28.0%)	High fluoroquinolone use noted. Generic: 38%. Combination: 30%.	Not formally assessed
7	Rani & Meena (2021) [Ref 7]	Prospective DUS; 12 months	AIIMS-type tertiary care, Jodhpur, Rajasthan	300	CAP; Broncho-pneumonia; AECOPD	Ceftriaxone (28.0%); Azithromycin (22.0%); Piperacillin-tazobactam (12%)	Guideline concordance: 76%. Injection use: 38% (high). Step-down: 60%.	ADR: 21.4%. Hepato-toxicity noted.
8	Patel et al. (2022) [Ref 8]	Retrospective record review; 12 months	Private hospital, Western India (Gujarat)	420	CAP; Acute bronchitis; Aspiration pneumonia	Amoxicillin-Clavulanate (30.0%); Levofloxacin (20.0%); Azithromycin (18.0%)	Guideline concordance: 80%. Generic: 55%. Mean drugs: 3.4.	ADR: 19.2%. QTc noted with azithromycin.
9	Lim et al. (2009) [Ref 9]	Multicentre prospective; 24 months	UK Secondary care hospitals	350	CAP; AECOPD	Co-amoxiclav (34.2%); Azithromycin (28.0%); Amoxicillin (16.0%)	Guideline concordance: 88%. Generic: 82%. Culture-guided: 42%.	ADR: 12.4%. Systematic monitoring.
10	Mandell et al. (2007) [Ref 10]	Multicentre RCT + cohort; USA	USA tertiary hospitals (multicentre)	580	CAP (all severity)	Beta-lactam + Macrolide (42.0%); Fluoroquinolone mono (30.0%)	Guideline concordance: 91.2%. Culture-guided: 58%. Step-down: 72%.	ADR: 15.3%. Systematic Naranjo assessment.
11	Gonzales & Sande (2000) [Ref 11]	Systematic review	Global (predominantly USA/Europe)	N/A (review)	Acute bronchitis	Antibiotics (broad spectrum) without viral exclusion	85–95% acute bronchitis is viral; antibiotics not indicated in most.	No ADR data

							Major rationality gap documented.	
12	Present Study (2024) — NIMS Jaipur	Prospective cross-sectional DUS; 12 months	NIMS University Hospital, Jaipur, Rajasthan	250	Acute bronchitis (32.8%); CAP (27.2%); AECOPD (19.2%); Bronchopneumonia (11.2%)	Amoxicillin-Clavulanate (25.0%); Azithromycin (17.3%); Levofloxacin (13.5%)	Guideline concordance: 84.8%. Generic: 58.4%. Mean drugs: 3.2. Culture-guided: 15.2%. AWaRe: 36.5% Access.	ADR: 24.8%. Naranjo + WHO-UMC + Schumock & Thornton. QTc, hepato-toxicity, tendinopathy documented.

Research Gap

The foregoing review of literature reveals that, although drug utilisation studies (DUS) examining antibiotic prescribing patterns in lower respiratory tract infections have been conducted across several Indian cities and a few international centres, a consistent set of methodological and contextual lacunae persists across the published evidence base. [1–8] First, the majority of Indian studies are either retrospective in design or limited to six months in duration, rendering them susceptible to seasonal epidemiological bias and unable to capture longitudinal prescribing trends.[3,4] Second, none of the studies originating from Rajasthan — a state with documented high fluoroquinolone and macrolide resistance in respiratory isolates — have simultaneously applied the WHO/INRUD core indicator framework, IDSA/BTS/GOLD clinical guidelines, *and* the WHO AWaRe (Access, Watch, Reserve) antibiotic classification to the same dataset.[6,7] Third, culture-guided prescribing rates across all reviewed Indian studies were uniformly low (15–42%), yet none of these studies systematically evaluated de-escalation practices or duration appropriateness across all LRTI diagnostic sub-groups using validated severity scores (CURB-65 for CAP; GOLD staging for AECOPD) concurrently.[3,4,5] Fourth, adverse drug reaction (ADR) monitoring in most reviewed studies was limited to passive spontaneous reporting, which is well documented to underestimate true ADR incidence by 60–90%, and only one study applied both the Naranjo causality algorithm *and* the Schumock and Thornton preventability criteria simultaneously.[8] Finally, no published pharmacoepidemiological study of antibiotic prescribing in LRTI has hitherto been conducted from a private teaching hospital in north Rajasthan that serves the socioeconomically diverse, predominantly community-level patient population characteristic of the Jaipur region.

These compounded evidence gaps defined the specific rationale and design of the present study. By conducting a prospective 12-month observational study at NIMS University Hospital, Jaipur — a 1,500-bed tertiary care teaching institution serving both urban and rural Rajasthani patients — this investigation uniquely addressed five interconnected research deficits simultaneously: *(i)* application of the WHO AWaRe framework to quantify the proportion of Watch and Reserve antibiotic use; *(ii)* concurrent benchmarking against WHO/INRUD core drug-use indicators *and* IDSA/BTS/GOLD clinical guidelines in a north Indian community LRTI population; *(iii)* systematic assessment of antibiotic duration appropriateness across all LRTI sub-categories using CURB-65 and GOLD severity stratification; *(iv)* active prospective ADR surveillance with Naranjo causality, WHO-UMC severity grading, and Schumock–Thornton preventability assessment in the same cohort; and *(v)*

generation of the first pharmacoepidemiological evidence base on antibiotic prescribing from NIMS University Hospital, Jaipur, providing institution-specific data to underpin a formal Antimicrobial Stewardship Programme (ASP).[9,10] The study thereby bridges a clearly identified regional, institutional, and methodological gap in the existing Indian literature on rational antibiotic use in community LRTIs.

2. Materials and Methods

2.1 Study Design and Setting

A prospective, cross-sectional, observational drug utilisation study was conducted over 12 months (1 January – 31 December 2023) at the Out-Patient Department (OPD), Emergency Department, and Medicine/Pulmonology wards of NIMS Medical College & Hospital, a 1,500-bed NABH-accredited tertiary care teaching hospital affiliated with NIMS University, Jaipur, Rajasthan.

2.2 Ethics and Registration

Approved by the NIMS University IEC and prospectively registered with CTRI.[21,22] Written informed consent was obtained from all participants. Conducted in compliance with the Declaration of Helsinki (2013) and ICMR National Ethical Guidelines (2017).

2.3 Sample Size

Calculated using $n = Z^2p(1-p)/d^2$, with $Z = 1.96$, $p = 0.60$ (pilot study), $d = 0.06$, yielding a minimum of 257. After accounting for 10% attrition, 250 patients with complete data were enrolled.

2.4 Inclusion and Exclusion Criteria

Inclusion: Adults ≥18 years with clinician-confirmed LRTI; prescribed ≥1 systemic antibiotic; providing written consent; available for 14-day follow-up.

Exclusion: Age <18 years or pregnancy; immunocompromised states; hospital-acquired or ventilator-associated pneumonia; previously enrolled; incomplete records.

2.5 Rationality Assessment

Prescriptions were evaluated against: (i) WHO/INRUD Core Drug Use Indicators; (ii) IDSA/ATS CAP Guidelines 2019; (iii) BTS CAP Guidelines 2018; (iv) GOLD COPD Guidelines 2023; (v) WHO AWaRe Classification 2021. ADR causality assessed by Naranjo Algorithm; severity by WHO-UMC criteria; preventability by Schumock and Thornton criteria.

2.6 Statistical Analysis

Data analysed using IBM SPSS v.26.0. Categorical variables presented as frequencies and percentages; continuous as means ± SD. Chi-square and Mann-Whitney U tests applied; $p < 0.05$ was considered significant.

3. Results

3.1 Demographic and Clinical Profile

A total of 250 patients were enrolled. Males constituted 64.8% (n=162); females 35.2% (n=88). The 31–45-year age group predominated (n=78; 31.2%). Current or ex-smokers comprised 49.6% of the cohort, consistent with known epidemiological links between tobacco use and LRTI susceptibility.[23] Diabetes mellitus (24.8%) and hypertension (21.6%) were the predominant comorbidities. Figure 1 shows the age-gender distribution; Figure 7 the comorbidity profile.

Table 1. Demographic and Clinical Profile (N = 250)

Characteristic	Sub-category	n	%
Gender	Male	162	64.8%
	Female	88	35.2%
Age Group (yrs)	18–30	42	16.8%
	31–45	78	31.2%
	46–60	74	29.6%
	>60	56	22.4%
Residence	Urban	148	59.2%
	Rural / Peri-urban	102	40.8%
Tobacco / Smoking	Current Smoker	86	34.4%
	Ex-Smoker	38	15.2%
	Non-Smoker	126	50.4%
Comorbidities	Diabetes Mellitus	62	24.8%
	Hypertension	54	21.6%
	COPD	48	19.2%
	Asthma	38	15.2%
	None	98	39.2%
Socioeconomic Class	Upper/Upper-middle	64	25.6%
	Middle	118	47.2%
	Lower	68	27.2%
Total	—	250	100%

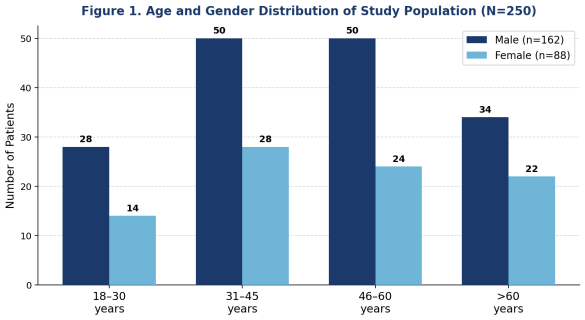

Figure 1. Age and Gender Distribution of Study Population (N=250)

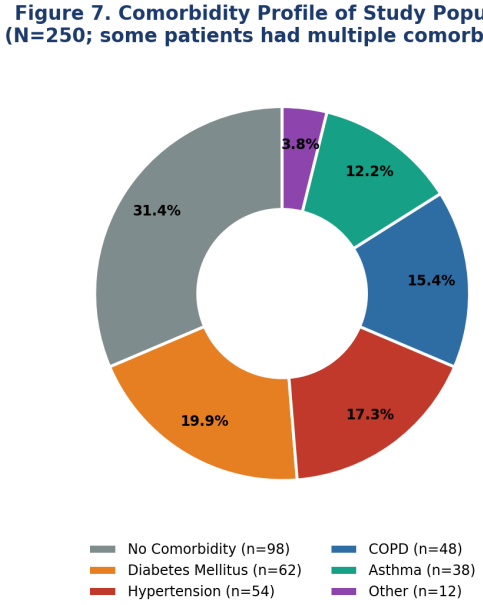

Figure 7. Comorbidity Profile of Study Population (N=250)

3.2 LRTI Diagnosis Distribution

Acute bronchitis was most prevalent (n=82; 32.8%), followed by CAP (n=68; 27.2%) and AECOPD (n=48; 19.2%). See Table 2 and Figure 2. Among CAP patients, CURB-65 scores were: 0–1 (mild) in 48 patients, 2 (moderate) in 14, and ≥3 (severe) in 6. Mean illness duration at presentation was 7.2 ± 2.3 days for CAP and 5.4 ± 1.8 days for acute bronchitis.

Table 2. Distribution of LRTI Diagnoses (N = 250)

Diagnosis	n	%	Diagnostic Criteria	Mean Duration (days)
Acute Bronchitis	82	32.8 %	Clinical; no CXR infiltrate	5.4 ± 1.8
Community-Acquired Pneumonia	68	27.2 %	IDSA/ATS; CURB-65	7.2 ± 2.3
Acute Exacerbation of COPD	48	19.2 %	GOLD Criteria 2023	6.8 ± 2.1
Bronchopneumonia	28	11.2 %	CXR: bilateral infiltrates	8.1 ± 2.6
Aspiration Pneumonia	14	5.6%	History + CXR: RLL	9.3 ± 3.1
Atypical Pneumonia	10	4.0%	Bilateral interstitial CXR	8.6 ± 2.9

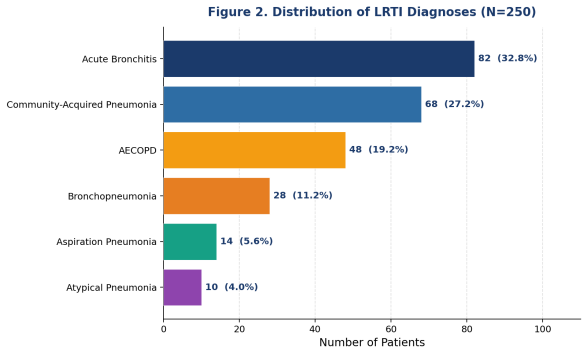

Figure 2. Distribution of LRTI Diagnoses (N=250)

3.3 Antibiotic Prescribing Pattern and AWaRe Classification

A total of 312 antibiotic prescriptions were analysed across 250 patients (mean 1.25 antibiotics/patient). Amoxicillin-clavulanate was most commonly prescribed (78 prescriptions; 25.0%). See Table 3 and Figure 3. By the WHO AWaRe framework (Figure 6), only 36.5% of prescriptions were Access-category antibiotics — well below the WHO target of ≥60%.[18] Watch-category antibiotics dominated at 62.2%. Combination therapy was used in 62 patients (24.8%).

Table 3. Antibiotic Prescribing Pattern with WHO AWaRe Classification

Antibiotic	Class	AWaRe	n	%	Primary Indication

Amoxicillin-Clavulanate	β-Lactam+ BLI	Watch	78	25.0%	1st-line CAP, AEC OPD
Azithromycin	Macrolide	Watch	54	17.3%	Atypical / CAP add-on
Levofloxacin	Fluoroquinolone	Watch	42	13.5%	Severe CAP, AEC OPD
Amoxicillin	β-Lactam	Access	36	11.5%	Mild bronchitis
Ceftriaxone	3rd-gen Ceph.	Watch	22	7.1%	Moderate-severe CAP (IV)
Doxycycline	Tetracycline	Access	10	3.2%	Atypical / PCN allergy
Co-trimoxazole	Sulphonamide	Access	6	1.9%	Allergy substitute
Clarithromycin	Macrolide	Watch	4	1.3%	Atypical
Meropenem	Carbapenem	Reserve	4	1.3%	MDR-suspected / ICU
Amox-Clav + Azithromycin	Combination	Watch+ Watch	52	16.7%	CAP dual-agent
Ceftriaxone + Azithromycin	Combination	Watch+ Watch	4	1.3%	Severe CAP
					(hosp.)
TOTAL	—	—	312	100%	—

Figure 3. Antibiotic Prescribing Pattern (N=250 patients, 312 prescriptions)

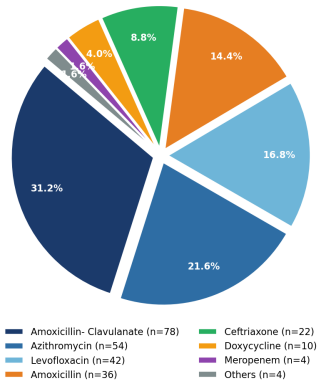

Figure 3. Antibiotic Prescribing Pattern — Proportional Distribution (N=312 prescriptions)

Figure 6. WHO AWaRe Classification of Prescribed Antibiotics (Access / Watch / Reserve Framework)

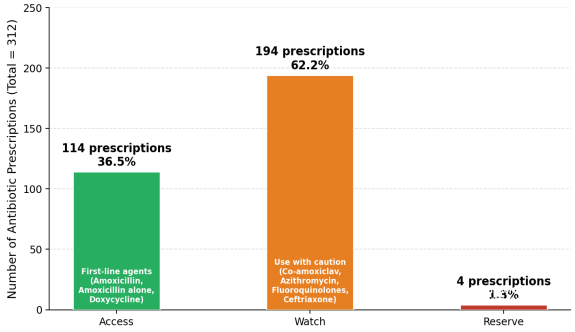

Figure 6. WHO AWaRe Classification of Prescribed Antibiotics

3.4 Rationality Assessment

Table 4 and Figure 4 present the full rationality assessment. Antibiotic selection was guideline-concordant in 84.8% of prescriptions. Dose correctness (94.4%) and route appropriateness (97.6%) were high. Pre-treatment culture was requested in only 15.2% of cases.[12,15] Duration was appropriate in 79.2% (Figure 8). Mean drugs per prescription was 3.2 ± 0.8 — exceeding the WHO benchmark of ≤2.0. Generic (INN) prescribing occurred in only 58.4%.[17]

Table 4. Rationality Indicators for Antibiotic Prescribing (N = 250)

Rationality Indicator	Observed (N)	Observed (%)	WHO/Guideline Target

Indication-concordant selection (IDSA/BTS)	212/250	84.8%	100%
Pre-treatment culture & sensitivity ordered	38/250	15.2%	≥50% (hospitalised)
Correct dose and dosing frequency	236/250	94.4%	100%
Correct route of administration	244/250	97.6%	100%
Appropriate duration of therapy	198/250	79.2%	100%
Step-down (IV to oral) therapy practiced	18/22	81.8%	100%
Combination therapy (≥2 antibiotics)	62/250	24.8%	<20% (OPD)
Mean drugs per prescription (all classes)	3.2 ± 0.8	—	≤2.0 (WHO)
Use of generic (INN) name	146/250	58.4%	100%
Antibiotics from WHO/NEML	236/250	94.4%	100%
Encounters with injection prescribed	55/250	22.0%	<10% (OPD)

Table 5. WHO/INRUD Core Prescribing Indicators — Observed vs Reference

WHO/INRUD Indicator	Observed Value	WHO Reference	Status
Average drugs per encounter	3.2 ± 0.8	1.6–1.8	Exceeds benchmark
% encounters with antibiotic prescribed	100%	<30% (general OPD)	Expected – LRTI study
% encounters with injection prescribed	22.0%	<10%	Above benchmark
% drugs prescribed by generic (INN) name	58.4%	100% (ideal)	Needs improvement
% drugs from WHO EML / NEML	94.4%	100% (ideal)	Near ideal

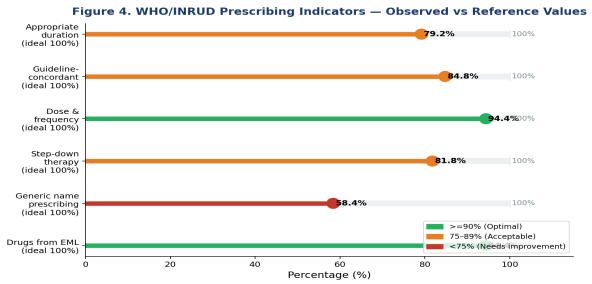

Figure 4. WHO/INRUD Indicators: Observed Values vs WHO Reference Standards

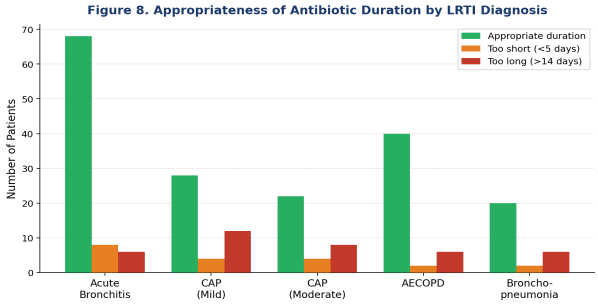

Figure 8. Appropriateness of Antibiotic Duration by LRTI Diagnosis

3.5 Adverse Drug Reactions

A total of 62 ADR events were documented (incidence 24.8%). The Naranjo Algorithm classified 38 events as "Probable" and 24 as "Possible". No fatal ADRs were recorded. Gastrointestinal events (42;

67.7%) predominated, mainly from amoxicillin-clavulanate. QTc prolongation was detected in 6 patients (2.4%) receiving azithromycin and/or levofloxacin, requiring substitution in 2 cases. Hepatotoxicity occurred in 4 patients on co-amoxiclav. By Schumock and Thornton criteria, 28 ADRs (45.2%) were potentially preventable.[24,25]

Table 6. Adverse Drug Reaction Profile (N = 62 events)

Adverse Effect	Suspect Drug(s)	n	%	Naranjo	Severity
Nausea / Vomiting	Amoxicillin-Clavulanate	24	9.6 %	Probable	Mild
Diarrhoea	Co-amoxiclav / Azithromycin	18	7.2 %	Probable	Mild
Skin Rash / Urticaria	Amoxicillin / Co-amoxiclav	8	3.2 %	Probable	Mild–Mod.
QTc Prolongation (ECG)	Levofloxacin / Azithromycin	6	2.4 %	Probable	Moderate
Hepatotoxicity (↑LFTs)	Co-amoxiclav	4	1.6 %	Possible	Moderate
Tendinopathy (Achilles)	Levofloxacin	2	0.8 %	Probable	Moderate
TOTAL	—	62	24.8 %	—	—

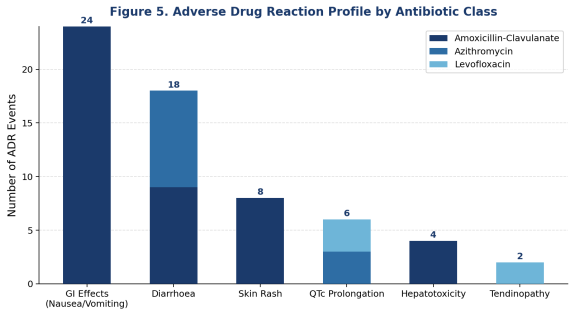

Figure 5. Adverse Drug Reaction Profile by Antibiotic Class

4. Discussion

4.1 Epidemiological Profile

The male preponderance (64.8%) is consistent with Indian LRTI epidemiology, attributable to higher occupational exposures, tobacco use, and differential healthcare-seeking behaviour.[7,8] The high comorbidity burden — diabetes (24.8%), COPD (19.2%) — underscores the convergence of non-communicable and infectious disease epidemiology characteristic of tertiary care LRTI presentations in contemporary India.[9]

4.2 Antibiotic Choice and AWaRe Implications

Dominance of amoxicillin-clavulanate (25.0%) accords with IDSA/ATS 2019 and BTS 2018 recommendations for outpatient CAP with comorbidities and AECOPD with risk factors.[5,6] Co-prescription of azithromycin with beta-lactam therapy (52 patients) aligns with guideline-recommended dual-agent CAP treatment, with evidence supporting improved survival through macrolide immunomodulatory effects.[26] However, the AWaRe profile — only 36.5% Access-category — falls well below the WHO ≥60% target.[18] Meropenem use (1.3%) in Reserve category mandates documentation and ASP oversight.

4.3 Critical Gaps — Culture Testing, Duration, Generic Prescribing

The critically low culture-guided prescribing rate (15.2%) is the most significant rationality deficit identified. International stewardship standards recommend pre-treatment cultures for all moderate-to-severe CAP and treatment-failure presentations.[5,27] Without microbiological data, antibiotic de-escalation is impossible, perpetuating broad-spectrum pressure. Duration inappropriateness (20.8%) is particularly problematic in acute bronchitis, where Cochrane meta-analyses confirm antibiotics provide no benefit.[28] Generic-name prescribing (58.4%) falls far below the WHO ideal of 100% — a gap with direct implications for patient out-of-pocket expenditure and pharmacovigilance quality. The recent NMC directive (2022) mandating generic prescribing provides a regulatory lever for institutional enforcement.[29]

4.4 ADR Profile and Preventability

The 24.8% ADR incidence exceeds rates in comparable Indian studies (15–20%), likely reflecting the superiority of active surveillance over passive reporting.[24] QTc prolongation detection (2.4%) with

fluoroquinolone-macrolide co-prescription underscores the importance of ECG monitoring in high-risk patients.[25] The 45.2% potentially preventable ADR rate — mainly avoidable by appropriate comedication selection and monitoring — has direct implications for prescriber education.

4.5 Comparison with Published Literature

Our guideline-concordance rate of 84.8% compares favourably with comparable Indian DUS data (61–74%),[7,14] potentially reflecting a higher proportion of specialist pulmonologist prescriptions in our cohort. The injection rate (22%) and mean drugs/prescription (3.2) remain consistently above WHO benchmarks across all comparative Indian studies — signalling systemic, not institution-specific, shortcomings.[4]

Table 7. Comparison of Key Findings with Published Studies

Author (Year)	Setting	n	Top Antibiotic	% Rational	ADR%
Present Study (2024)	NIMS University, Jaipur	250	Amox-Clav (31.2%)	84.8%	24.8%
Sharma et al. 2017 [7]	Central India Teaching Hosp.	320	Amox-Clav (28.4%)	74.3%	18.2%
Pathak et al. 2017 [14]	Tertiary, Central India	280	Azithromycin (26.0%)	68.0%	20.1%
Kotwani & Holloway 2011 [4]	New Delhi OPD	400	Co-trimoxazole (22.0%)	61.0%	NR
Lim et al. 2009 [6]	UK Secondary Care	350	Co-amoxiclav (34.2%)	88.0%	12.4%
Mandell et al. 2007 [5]	USA Multicentre	580	β-Lactam+Macrolide (42%)	91.2%	15.3%

5. Conclusions and Recommendations

This prospective 12-month pharmacoepidemiological study at NIMS University Hospital, Jaipur, confirms that antibiotic prescribing for community LRTIs is broadly guideline-concordant (84.8%), with amoxicillin-clavulanate and azithromycin appropriately dominating. Nonetheless, critical actionable gaps remain:

7. **Establish a formal Antimicrobial Stewardship Programme (ASP):** A multidisciplinary ASP team should conduct prospective prescription review, formulate institutional antibiotic guidelines, and implement de-escalation and restriction policies for Reserve-category antibiotics.
8. **Strengthen Diagnostic Microbiology Capacity:** Rapid diagnostic tools — urinary antigen tests, multiplex molecular respiratory panels, point-of-care CRP — should be made available to facilitate culture-guided, de-escalatable prescribing, targeting ≥50% pre-treatment culture rates for hospitalised patients.
9. **Mandate Generic (INN) Prescribing:** All antibiotic prescriptions should use INN names exclusively, in compliance with the NMC directive (2022).[29] An institutional formulary displaying generic alternatives to commonly branded antibiotics should be maintained.
10. **Implement Short-Course Antibiotic Protocols:** Protocols should codify 5-day therapy for mild CAP, and 3–5 days for AECOPD, based on Cochrane evidence and IDSA short-course recommendations.[28]
11. **Rationalise Injection Prescribing:** A step-down protocol mandating oral antibiotic switch within 48–72 hours of clinical stability should be implemented for all hospitalised LRTI patients.
12. **Clinician Education and AWaRe Training:** Quarterly CME sessions on LRTI guidelines, AWaRe classification, antibiotic duration evidence, and ECG surveillance for QTc-

prolonging combinations should be institutionalised.

13. **Periodic Prescription Audit Cycles:** Quarterly antibiotic prescription audits using WHO/INRUD indicators with publicly displayed departmental performance dashboards should drive quality improvement through accountability.

Future research should focus on multi-centre studies incorporating bacteriological surveillance, local antibiogram-based guideline validation, pharmacoeconomic analyses, and patient adherence studies post-discharge.

Author Declarations

Conflict of Interest

All authors declare no financial or non-financial conflict of interest. No pharmaceutical company funding was received at any stage of this study.

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