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ANTIBIOTIC PRESCRIBING PATTERNS AND RATIONAL DRUG USE: AN OBSERVATIONAL CLINICAL AUDIT

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ABSTRACT:

Background: The irrational use of antibiotics is a primary driver of antimicrobial resistance (AMR), an escalating threat to global public health. Periodic evaluation of hospital prescribing habits through observational research is vital to identify gaps in clinical practice and strengthen antimicrobial stewardship (AMS) initiatives.

Objective: To analyze current antibiotic prescribing patterns, assess adherence to standard treatment protocols, and classify drug utilization according to the WHO AWaRe framework.

Methods: A [e.g., six-month] observational study was conducted in the [e.g., General Medicine wards] of a tertiary care hospital. Patient demographics, clinical diagnoses, culture and sensitivity (C&S) testing rates, and detailed antimicrobial parameters were recorded using a standardized data collection form. Prescriptions were audited against [e.g., institutional / national] guidelines.

KEYWORDS: Antibiotic Prescribing Patterns; Antimicrobial Stewardship; Drug Utilization Evaluation (DUE); AWaReClassification; Rational Drug Use; Antimicrobial Resistance (AMR); Observational Study.

INTRODUCTION

The discovery of antibiotics in the 20th century revolutionized modern medicine, turning once-fatal infectious diseases into manageable clinical conditions. However, the therapeutic utility of these life-saving agents is currently under severe threat due to the rapid, global rise of antimicrobial resistance (AMR). The World Health Organization (WHO) has declared AMR one of the top public health threats facing humanity, contributing directly to rising mortality rates, prolonged hospitalizations, and escalating healthcare expenditures.

While resistance is a natural evolutionary phenomenon, it is accelerated at an alarming rate by human behaviour —specifically, the irrational and inappropriate prescribing of antimicrobials. In clinical settings, this frequently manifests as the unnecessary use of broad-spectrum antibiotics for self-limiting viral infections, improper drug selection, incorrect dosing regimens, and excessive treatment durations. In many tertiary care environments, a lack of diagnostic certainty often leads clinicians to rely heavily on empirical broad-spectrum therapies without initiating timely microbiological culture and sensitivity (C&S) testing. This diagnostic gap hinders the essential transition from broad empirical coverage to targeted, definitive therapy.

To combat this crisis, healthcare institutions rely on Antimicrobial Stewardship (AMS) programs. A core pillar of effective stewardship is Drug Utilization Evaluation (DUE). Observational studies focused on antibiotic prescribing behaviour serve as critical diagnostic tools within these programs. By systematically auditing real-world prescription logs against established standard treatment guidelines—and utilizing public health frameworks like the WHO AWARE (Access, Watch, Reserve) classification—clinical researchers can quantify local utilization trends and pinpoint specific patterns of misuse.

While global trends underscore the severity of AMR, prescribing behaviour remains highly localized, shaped by regional disease burdens, institutional cultures, and varying clinician habits. Consequently, local observational baseline data is essential. This study was designed to investigate current antibiotic prescribing patterns, evaluate clinical adherence to standard treatment protocols, and identify key operational targets for stewardship interventions within our tertiary care hospital.

MATERIALS AND METHODS:

Study Design and Setting:

A hospital-based, non-interventional, observational study was conducted to evaluate antimicrobial prescribing patterns. The study was carried out in the [e.g., Department of

General Medicine / Intensive Care Units] at [Name of Hospital/Institution], a tertiary care teaching hospital located in [City, State, e.g., Hyderabad, Telangana].

Study Period and Population:

The data collection spanned a period of [e.g., six months] from [Month, Year] to [Month, Year]. The study population consisted of inpatients admitted to the designated wards during this timeframe who met the pre-defined eligibility criteria.

Inclusion Criteria:

1. Patients of either sex aged age 18 years.
2. Patients admitted to the target wards for a duration of at least 24 hours.
3. Patients prescribed at least one systemic antimicrobial agent (oral or parenteral) during their hospital stay.

Exclusion Criteria:

1. Patients receiving only topical, ophthalmic, antimicrobial preparations.
2. Patients transferred from other clinical facilities with pre-existing, undocumented antibiotic courses.
3. Patients with incomplete medical records or those who left against medical advice (LAMA) before clinical evaluation.

Ethical Considerations:

Prior to initiation, the study protocol was reviewed and approved by the Institutional Ethics Committee (IEC) / Institutional Review Board (IRB) under protocol number [Insert Protocol Number]. Confidentiality of patient data was strictly maintained by assigning unique alphanumeric de-identifiers to each case report form (CRF), ensuring no personal identifying information was leaked during data analysis.

Data Collection and Sources:

Data were collected prospectively/retrospectively from patient medical charts, physician prescription sheets, nursing medication administration records (MAR), and laboratory investigation reports using a structured, pre-tested Case Report Form (CRF). For each eligible patient, the following variables were recorded:

Demographic Profile: Age, gender, date of admission, date of discharge, and length of hospital stay (LOS).

Clinical Presentation: Primary diagnosis, working diagnosis, key clinical indications for antibiotic initiation, comorbidities, and relevant vital signs.

Laboratory Parameters: Total white blood cell (WBC) count, serum creatinine (used to calculate estimated Glomerular Filtration Rate [eGFR] or Creatinine Clearance [CrCl] via the Cockcroft-Gault equation), and microbiological culture and sensitivity (C&S) test logs.

Antimicrobial Metrics: Brand and generic name of the antibiotic, pharmacological class, dosage, frequency, route of administration (Intravenous [IV] or Oral), duration of therapy, and any documented history of drug allergies.

Assessment of Rationality and Guideline Adherence:

Prescription patterns were cross-evaluated against the standard treatment guidelines recommended by [e.g., National Guidelines / ICMR / Hospital Antibiotic Policy]. Adherence was classified into three distinct categories:

1. Adherent: The drug choice, dose, route, and frequency matched the guidelines.
2. Non-Adherent: The choice of antibiotic deviated entirely from empirical recommendations, or the choice was appropriate but the dose/duration was incorrect.
3. Non-Classifiable: No clear guidelines existed for the specific clinical presentation.

Furthermore, all audited antimicrobials were classified into Access, Watch, and Reserve groups based on the current World Health Organization (WHO) AWARE framework to measure institutional stewardship compliance.

Statistical Analysis:

Data were entered into Microsoft Excel and analysed using SPSS (Statistical Package for the Social An observational study on antibiotic prescribing patterns is a cornerstone of clinical pharmacy, public health, and antimicrobial stewardship (AMS). Because you are looking at real-world clinical behaviour without intervening, these studies are essential for tracking drug utilization patterns, identifying irrational drug use, and curbing antimicrobial resistance (AMR).

Here is a comprehensive framework for designing, executing, and analysing an observational study on antibiotic prescribing.

1. Study Design Options:

Depending on your data access and timeline, you will generally choose one of three non-experimental blueprints:

Cross-Sectional (Point Prevalence Survey): A "snapshot" study. For example, assessing every patient on an active antibiotic in a hospital ward on a single day. Excellent for identifying immediate baseline issues.

Retrospective Cohort : Looking backward using medical records, pharmacy dispensing logs, or electronic health records (EHR) over a set period (e.g., the past six months).

Prospective Cohort: Following patients forward from the time they are prescribed an antibiotic until their discharge or clinical outcome. This allows you to track real-time clinical modifications.

2. Core Methodological Workflow:

To structure a robust observational protocol, you can map the process across consecutive phases:

Define Protocol & Obtain Ethics

Phase 1:

Draft your core study objectives (e.g., evaluating adherence to local guidelines). Secure Institutional Ethics Committee (IEC) or Institutional Review Board (IRB) approval, especially when handling sensitive patient data .Establish Inclusion & Exclusion Criteria

Phase 2:

Define exactly who qualifies. For example, Inclusion: All inpatients prescribed at least one systemic antibiotic. Exclusion: Patients on topical antimicrobials or those with an inpatient stay less than 24 hours. Design Data Collection Tools.

Phase 3:

Create a standardized case report form (CRF) or digital database sheet. You must consistently capture demographics, clinical indications, diagnostic metrics, and exact drug parameters. Audit & Evaluate Patterns.

Phase 4:

Analyze the collected prescriptions against established guidelines (e.g., WHO AWaRe classification or national/hospital guidelines) to classify utilization metrics and identify gaps.

3. Data Collection Checklist:

When reviewing patient files or prescription slips, your dataset should capture these key variables to evaluate the clinical rationale behind each prescribing decision:

Patient Metrics: Age, sex, comorbidities, renal function (Creatinine Clearance, which is vital for adjusting antibiotic doses), and relevant allergies.

Clinical Presentation: Working diagnosis (e.g., community-acquired pneumonia, UTI), vitals, and markers of infection (WBC count, C-reactive protein).

Microbiology Data: Was a sample sent for culture and sensitivity (C&S) testing before the first dose? Was empiric therapy appropriately modified once results returned?

The Antibiotic Regimen: Brand vs. generic name, pharmacological class, route of administration (IV to Oral switch tracking), dosage, frequency, and planned duration.

4. Key Performance Indicators (KPIs) to Track:

To turn raw prescription data into actionable clinical insights, evaluate your findings using standard drug utilization metrics:

WHO Prescribing Indicators

→ Average number of drugs prescribed per encounter.

→ Percentage of fixed-dose combinations (FDCs) prescribed.

→ Percentage of antibiotics prescribed by generic name (a key metric for cost-effectiveness and minimizing medication errors).

Guidelines & Stewardship Concordance:

De-escalation Rate: Percentage of cases where broad-spectrum therapy was narrowed down to a targeted agent after culture results became available.

The WHO AWaRe Framework: Categorize your findings into three distinct public health buckets to measure stewardship quality.

TABLE :1

AWARE category	**Stewardship objective**	**Common examples**
ACCESS	First or second choice agents for common infections should be widely6 available.	Amoxicillin , Doxycycline , Cotrimoxazole.
WATCH	High resistance potential: reserved for specific , severe clinical indications.	Azithromycin , Ceftriaxone , Ciprofloxacin , Meropenem.
RESERVE	“Last resort” options for multi -drug resistance (MDR)infections must be highly protected.	Colistin , Linezolid , Tigecycline.

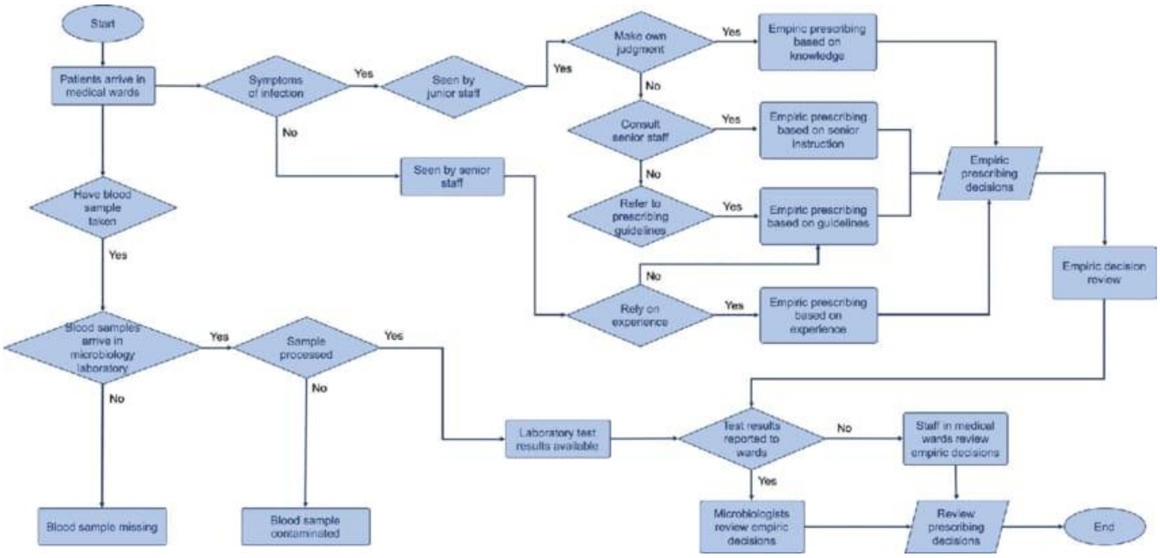
When analysing data via an observational lens, look for breakdowns in this chain. Common clinical issues to document include:

Prolonged Empiric Therapy: Keeping a patient on broad-spectrum "Watch" or "Reserve" agents despite laboratory reports indicating susceptibility to a narrower "Access" drug.

Redundant Coverage: Overlapping anaerobic or gram-negative coverage (e.g., prescribing Piperacillin/Tazobactam concurrently with Metronidazole).

Suboptimal Dosing: Failure to adjust antibiotic doses in patients with compromised renal or hepatic function.

PICTURE:1



MOST FREQUENTLY PRESCRIBED ANTIBIOTIC CLASSES:

This section maps out the specific classes of medications being utilized in the wards. It can help you identify over-reliance on broad-spectrum agents, such as third-generation cephalosporins.

TABLE:2

Pharmacological class	**Representative agents evaluated**	**Total prescriptions(n)**	**Relative Volume(%)**
Cephalosporins	Ceftriaxone, Cefixime, Cefotaxime	232	34.1%
Beta lactamase combinations	Piperacillin/Tazobactam, Amoxicillin/Levofloxacin	148	21.8%
Fluroquinolones	Ciprofloxacin , Levofloxacin.	92	13.5%
Macrolides	Azithromycin, Clarithromycin.	75	11.0%
Nitroimidazoles	Metronidazole	68	10.0%
Carbapenems	Meropenem , Imipenem	41	6.0%
Aminoglycosides	Amikacin, Gentamycin	24	3.6%

Adverse reactions:

In clinical pharmacology, understanding adverse drug reactions (ADRs) is just as important as knowing an antibiotic's spectrum of activity. While mild gastrointestinal distress (nausea, diarrhoea) can occur with almost any oral antimicrobial due to alterations in normal gut flora, individual drug classes carry unique, serious toxicities that dictate their clinical boundaries.

The chart below organizes the primary antibiotic classes by their pharmacological mechanisms. Following it, you will find a breakdown of the specific adverse effects associated with each group.

1. Cell Wall Synthesis Inhibitors:

beta-Lactams (Penicillin , Cephalosporins, Carbapenems)

Hypersensitivity & Anaphylaxis: Ranges from mild maculopapular rashes to life-threatening Type I IgE-mediated responses.

Cross-Reactivity: Historically overstated, but a distinct 3% to 5% structural cross-reactivity risk exists between penicillin and first-generation cephalosporins due to shared R1-side chain similarities.

Seizure Risk: High doses of beta-lactams—particularly Imipenem—can inhibit gamma-aminobutyric acid (GABA) receptors in the central nervous system, lowering the seizure threshold in patients with pre-existing renal impairment.

Glycopeptides (e.g., Vancomycin)

Vancomycin Flushing Syndrome (formerly "Red Man Syndrome"): An infusion-related, non-immune anaphylactoid reaction. Rapid intravenous administration triggers direct mast cell degranulation, releasing histamine and causing intense flushing, pruritus (itching), and hypotension. It is managed by slowing the infusion rate.

Nephrotoxicity & Ototoxicity: Primarily occurs at high trough concentrations or when used synergistically with other nephrotoxins like aminoglycosides.

2. Protein Synthesis Inhibitors:

Aminoglycosides (e.g., Gentamicin, Amikacin)

Nephrotoxicity: Driven by drug accumulation inside the renal proximal tubule epithelial cells, leading to acute tubular necrosis (ATN). This is typically reversible upon drug discontinuation.

Ototoxicity: Causes irreversible damage to cranial nerve VIII. It can manifest as cochlear toxicity (hearing loss) or vestibular toxicity (vertigo, ataxia).

Tetracyclines (e.g., Doxycycline, Minocycline)

Bone and Tooth Deposition: Tetracyclines readily chelate calcium ions. They deposit in teeth and growing bone structures, leading to permanent tooth discoloration (yellow-brown staining) and transient bone growth suppression. They are generally avoided in children under 8 years old and during pregnancy.

Photosensitivity: Exaggerated sunburn reactions upon exposure to ultraviolet (UV) light.

Macrolides (e.g., Azithromycin, Erythromycin)

QT Interval Prolongation: Macrolides block cardiac potassium channels (I_{Kr}), delaying repolarization. This can trigger life-threatening ventricular arrhythmias, specifically Torsades de Pointes.

Hepatic Cholestasis: Particularly associated with the estolate salt form of erythromycin, leading to acute cholestatic hepatitis.

3. Nucleic Acid & Metabolic Pathway Inhibitors:

Fluoroquinolones (e.g., Ciprofloxacin, Levofloxacin)

Tendinopathy and Tendon Rupture: Fluoroquinolones damage collagen synthesis and upregulate matrix metalloproteinases. This significantly increases the risk of Achilles tendon rupture, particularly in elderly patients or those concurrently taking systemic corticosteroids.

Dys-glycemia & CNS Toxicity: Can cause severe fluctuations in blood glucose (Hypo-glycemia/ hyper-glycemia) and central nervous system side effects like confusion, hallucinations, and anxiety.

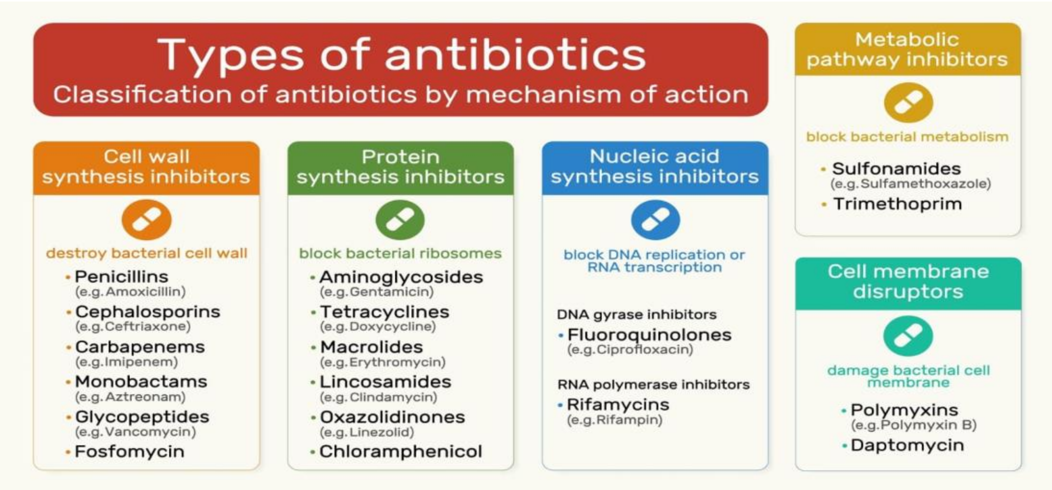
Sulfonamides (e.g., Sulfamethoxazole).

Severe Cutaneous Adverse Reactions (SCARs): Highly associated with Type IV hypersensitivity reactions, including Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN). Hematologic Toxicities: Can induce acute haemolytic- anemia in individuals with a geneticGlucose6-Phosphate Dehydrogenase (G6PD) deficiency

Picture:2

Prescription audit checklist	
Prescription Audit	
Audit Parameters	**Yes/ No/NA**
Name of patient	
Age	
OPD number	
Dose of drug	
Dosage of drug	
Route of drug	
Frequency / Time of administration	
Date	
Legible	
Known allergy documented	
Uniform location of treatment order	
Non-standard abbreviation used	
Presence of therapeutic duplication, If Any	
Drug interaction, If Any	
Food drug interaction, If Any	
	Signature of Doctor

PICTURE:3



1. Quality Indicators for Daily Evaluation:

Instead of just looking at the final choice of drug, evaluate the daily monitoring habits of the medical team. You can track these three critical clinical milestones:

The "Antimicrobial Time-Out" (48–72 Hour Review): Document whether clinicians formally re-evaluated the antibiotic regimen at the 72-hour mark. This is when culture results usually return, and it represents the golden window to either stop, narrow down (de-escalate), or confirm the treatment plan.

Documentation of Indication: Check what percentage of patient charts actually had a clear, written reason for starting the antibiotic (e.g., writing "suspected lower respiratory tract infection" vs. simply writing "Inj. Ceftriaxone 1g IV"). Clear documentation is a key indicator of good stewardship.

Fixed-Dose Combination (FDC) Scrutiny: If your hospital data shows heavy use of antibiotic combinations in a single pill or vial (like Amoxicillin + Clavulanic Acid or Cefoperazone + Sulbactam), audit whether these combinations were clinically necessary or used as a shortcut for broad coverage.

2. The Link Between Diagnostics and Prescription:

A major weakness in many hospital systems is a disconnect between the microbiology lab and the pharmacy. You can include a section analysing this dynamic:

Empirical Overlap: Track how long patients were kept on "blind" empirical therapy before anyone checked or acted on their laboratory results.

Antibiogram Concordance: If your hospital publishes an annual antibiogram (a localized report showing which bacteria are resistant to which drugs), analyze whether the empirical choices made by doctors actually aligned with the latest local resistance trends.

3. Medication Safety and Redundancy Audits:

Look for patterns that could directly compromise patient safety or cause unnecessary side effects:

Therapeutic Duplication: Audit cases where a patient was accidentally prescribed two drugs that cover the exact same type of bacteria (for example, taking both Piperacillin/Tazobactam and Metronidazole concurrently, which creates completely redundant coverage against anaerobic bacteria).

Double-Covering Gram-Negative Infections: Document how often multiple anti-pseudomonal drugs were combined without a verified, severe multi - Drug resistant infection.

Missed Renal Adjustments: Calculate how often standard drug doses were given to patients with changing or compromised kidney function, increasing the risk of adverse drug events.

4. Seasonal or Ward-Specific Variations:

Antibiotic prescribing behaviour is rarely uniform across a whole hospital. Breaking your data down into smaller sub-categories adds excellent depth to your analysis:

TABLE:3

Ward/Department	Typical Prescribing Habit Observed	Primary Stewardship Target
Intensive Care Unit ICU	Heavy reliance on reserve class carbapenems and polymyxins high rate of empiric combinations.	Early de escalation protocols based on rapid diagnostic feedback.
General Medicine Wards	High volume of third generation cephalosporins prolonged empirical courses for respiratory cases.	Enforcing strict IV to oral step - down criteria to speed up patient discharge.
Surgical Wards	Use of Broad spectrum options for surgical prophylaxis extended well beyond the recommended 24 hours.	Implementing automated hard stops on surgical order sheets past the first 24 hours.

CONCLUSION:

This drug utilization evaluation provides a definitive look at real-world antibiotic prescribing habits within our tertiary care hospital. By systematically auditing clinical practices against established treatment protocols, this observational study highlights critical gaps between theoretical guidelines and daily clinical execution, identifying key targets for antimicrobial stewardship (AMS) interventions.

The findings reveal that while antimicrobial therapy is universally accessible, its application is characterized by an over-reliance on broad-spectrum empirical regimens and a significant underutilization of pre-treatment diagnostics. The heavy concentration of prescriptions within the World Health Organization's (WHO) Watch category—specifically third-generation cephalosporins and \beta-lactamase inhibitor combinations—exerts continuous, unnecessary selective pressure on localized hospital flora. This risk is further compounded by a widespread omission of pre-therapy microbiological culture ordering and a distinct failure to execute formal 72-hour "antimicrobial time-outs." Without timely diagnostic data or mandatory de-escalation reviews, clinicians frequently remain trapped in extended cycles of blind empirical coverage, driving up patient costs and accelerating the development of multi-drug resistant (MDR) pathogens.

Furthermore, our comparison between high-acuity and high-volume departments demonstrates that prescribing vulnerabilities are not uniform across the institution. The intensive care setting requires active structural support to help clinicians safely de-escalate and narrow down multi-drug therapies once laboratory reports return. Meanwhile, the general medicine wards require a foundational cultural shift toward securing diagnostic confirmation and enforcing generic-name prescribing before empirical therapies are initiated.

In conclusion, relying on passive observation is no longer sufficient to curb the localized threat of antimicrobial resistance. To preserve the efficacy of our remaining therapeutic arsenal, our institution must transition to active, system-wide interventions. Immediate priorities must include integrating ward-based clinical pharmacists into daily medical rounds to manage real-time dosing and early IV-to-oral switches, configuring automated "hard stops" within Electronic Health Record (EHR) prescribing platforms, and establishing mandatory justification protocols for all Reserve class agents. Implementing these targeted structural changes will be essential to optimizing patient safety, minimizing institutional expenditures, and ensuring rational, evidence-based drug use.

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