IJPSR (2026), Volume 17, Issue 2 (Research Article)

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 04 August 2025; received in revised form, 18 September 2025; accepted, 26 October 2025; published 01 February 2026

A CROSS-SECTIONAL STUDY ON ADVERSE DRUG REACTIONS AND RATIONAL PRESCRIBING PATTERNS WITH COST-EFFECTIVE ANALYSIS IN A TERTIARY CARE CENTRE OF BUNDELKHAND REGION

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Keywords:

Adverse drug reaction, Pharmacovigilance, WHO prescribing indicators, Rational drug use, Essential medicines, Cost analysis

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ABSTRACT: Background: Adverse drug reactions (ADRs) are a significant challenge in clinical medicine frequently contributing in increasing morbidity, hospital stays, and treatment costs. Despite advancements, irrational prescribing remains common and compromises patient safety. **Methods:** This prospective, cross-sectional observational study was conducted over 13 months (Feb 2024–Mar 2025) at Maharani Laxmi Bai Medical College, Jhansi. A total of 200 patients with suspected ADRs were enrolled. ADRs were assessed using the Modified Hart wig and Siegel severity scale and WHO-UMC causality scale. Post-ADR prescriptions were analyzed for WHO prescribing indicators and cost-effectiveness. **Results:** The mean patient age was 38.4±12.6 years, with males comprising 55.5%. Dermatological ADRs were predominant (46%), followed by systemic symptoms (20.5%), gastrointestinal (15%), hepatic (7%), and others (11.5%). Antibiotics (52.5%) and NSAIDs (18%) were the main offending drug classes. Most ADRs were of moderate severity (94%) and classified as "possible" (55.5%). Post-ADR, the average number of drugs per prescription was 2.37, 66.95% of which were from the National List of Essential Medicines (NLEM). The average daily prescription cost was ₹ 97.48. **Conclusion:** ADRs impose a significant clinical and economic burden. Strengthening pharmacovigilance and rational prescribing, including adherence to WHO indicators and NLEM, can reduce ADR incidence and treatment costs.

INTRODUCTION: Pharmacotherapy revolutionized medicine by providing effective disease management strategies. However, drugs can act as "double-edged swords," offering therapeutic benefits while posing risks of ADRs unintended harmful reactions at standard dosages [1, 2, 3].

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.17(2).645-47

This article can be accessed online on www.ijpsr.com

DOI link: https://doi.org/10.13040/IJPSR.0975-8232.17(2).645-47

Globally, ADRs account for about 5–10% of hospital admissions and occur in up to 20% of inpatients [4, 5]. These reactions not only prolong hospital stays but also substantially increase healthcare costs [6].

Rational drug use, as defined by WHO, involves providing medications appropriate to clinical needs, in correct doses, for adequate duration, and at the lowest cost [7]. Despite this, irrational practices such as polypharmacy and excessive antibiotic use remain common [8, 9]. Data on ADR patterns and post-ADR prescribing in the Bundelkhand region are limited, necessitating this study.

MATERIALS AND METHODS: This prospective, observational cross-sectional study was approved by the Institutional Ethics Committee (Ref. No. 6922/IEC/I/2022-2023). A total of 200 patients of any age or sex with suspected ADRs were included after informed consent.

Exclusion Criteria:

1. Patients refusing consent
2. Follow-up cases with prior ADR documentation
3. ADRs related to alternative medicine

Data were recorded using CDSCO ADR reporting forms, the Modified Hartwig and Siegel Severity Scale, WHO-UMC causality scale, and WHO core prescribing indicators.

Indicators Analyzed:

1. Average number of drugs per encounter
2. Percentage of antibiotic encounters
3. Percentage of NLEM drugs prescribed
4. Average cost per prescription per day

Data were analyzed using Microsoft Excel and SPSS software. Descriptive statistics and chi-square tests were used, with $p < 0.05$ considered significant.

RESULTS AND DISCUSSION:

Patient Demographics: Out of 200 patients, 55.5% were male and 44.5% female. The 35–40-year age group had the highest ADR prevalence (18%).

Rural residents (53.5%) reported slightly more ADRs than urban patients (46.5%), aligning with earlier reports from India [10].

Clinical Manifestations: Dermatological ADRs were most frequent (46%), followed by systemic symptoms (20.5%), gastrointestinal (15%), hepatic (7%), and others (11.5%).

TABLE 1: SYSTEM-WISE DISTRIBUTION OF ADRS

System Involved	Frequency (%)
Dermatological	46.0
General Symptoms	20.5
Gastrointestinal	15.0
Hepatic	7.0
Others (Renal, CV etc.)	11.5

Common Presentations Included:

- Skin rash (12%)
- Fixed drug eruption (12%)
- Pruritus (10.5%)
- Urticaria (8%)
- Drug-induced fever (6%)

This distribution matches prior Indian pharmacovigilance findings [11, 12].

Drug Classes Implicated:

Antibiotics (52.5%) were the Leading Cause of ADRs:

- β-lactams (35%) urticaria, eruptions
- Fluoroquinolones (28%) fixed drug eruptions, GI intolerance
- Macrolides (15%) hepatotoxicity, QT prolongation
- Aminoglycosides (8%) nephrotoxicity, ototoxicity
- Antitubercular drugs (14%) hepatitis, neuropathy

NSAIDs (18%) caused GI bleeding, renal issues, and hypersensitivity. Other implicated classes included antifungals (6%), corticosteroids (5%), anticonvulsants (4%), antihypertensives (3%), and anticoagulants (2%), consistent with published studies [13-15].

TABLE 2: DRUG CLASSES IMPLICATED IN ADRS

Drug Class	Frequency (%)
Antibiotics (β-lactams, fluoroquinolones, macrolides, aminoglycosides, antitubercular)	52.5
NSAIDs	18.0
Antifungals	6.0
Corticosteroids	5.0
Anticonvulsants	4.0
Antihypertensives	3.0
Anticoagulants	2.0

Severity and Causality: Moderate ADRs comprised 94%, severe 3.5%, and mild 2.5%. WHO-UMC causality assessment classified 55.5% as "possible" and 39% as "probable," mirroring Ramesh *et al* [16].

TABLE 3: SEVERITY AND CAUSALITY ASSESSMENT OF ADRs

Category	Subcategory	Frequency (%)
Severity	Mild	5(2.5%)
	Moderate	188 (94%)
	Severe	7(3.5%)
Causality	Certain	11(5.5%)
	Probable	78(39%)
	Possible	111(55.5%)

Rational Prescribing and Cost Analysis: Average drugs per encounter were 2.37 (WHO recommends <2). NLEM adherence was 66.95%, lower than ideal [8]. Antibiotics were used in 5% of post-ADR encounters, showing cautious prescribing. The average prescription cost/day was ₹ 97.48, posing a burden, especially for rural patients. Prior research shows ADRs can inflate treatment costs by 30–40% [7, 17]. Improved essential drug use can mitigate these costs [18].

TABLE 4: WHO PRESCRIBING INDICATORS POST-ADR

Indicator	Result
Average number of drugs per encounter	2.375
Percentage of encounters with antibiotics	5%
Percentage of drugs prescribed from NLEM	66.95%
Average cost per prescription per day (INR)	₹97.48

CONCLUSION: This study highlights the significant clinical and economic impact of ADRs in tertiary care. With antibiotics and NSAIDs being the most frequent offenders, there is an urgent need to strengthen pharmacovigilance and ensure rational drug prescribing. Adherence to WHO core prescribing indicators and the NLEM should be prioritized to optimize patient outcomes and reduce treatment costs.

ACKNOWLEDGEMENTS: Nil

CONFLICTS OF INTEREST: Nil

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How to cite this article:
Richa, Kaushik S, Goel M, Madhurmay, Srivastava N, Ratmale R, Singh HN and Kumar V: A cross-sectional study on adverse drug reactions and rational prescribing patterns with cost-effective analysis in a tertiary care centre of Bundelkhand region. Int J Pharm Sci & Res 2026; 17(2): 645-47. doi: 10.13040/IJPSR.0975-8232.17(2).645-47.