Indian Journal of Health Care, Medical & Pharmacy Practice Vol 6; Issue 2, July-Dec 2025, ISSN 2583-2069

Research Article

A PROSPECTIVE STUDY ON DETECTION, ASSESSMENT AND REPORTING OF ADRS IN A TERTIARY CARE HOSPITAL

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DOI: https://doi.org/10.59551/IJHMP/25832069/2025.6.2.114

Received: 27 Nov, 2025, Decision for Acceptance: 30 Dec, 2025

Abstract

Adverse Drug Reactions (ADRs) represent a major public health challenge, contributing to increased morbidity, prolonged hospitalization, and healthcare costs. This study aimed to detect, assess, and report ADRs in a tertiary care hospital, while analyzing their prevalence, severity, causality, preventability, and management strategies.

A prospective observational study was conducted over six months at Prathima Institute of Medical Sciences, Telangana, involving 107 patients with suspected ADRs. Data were collected from patient case records, medication charts, and patient interviews. ADRs were evaluated using the Hartwig Severity Scale, WHO-UMC and Naranjo's Causality Assessment Scales, and Schumock and Thornton's Preventability Scale. Statistical tools were used to assess distribution patterns and contributing factors.

The majority of ADRs were reported in females (60%) compared to males (40%), with adults (85.98%) being the most affected group. The highest number of ADRs occurred in the gynecology department (21.4%), followed by general surgery (14%). Antibiotics (32.71%) were the most commonly implicated drug class, particularly Augmentin (7.47%) and Ceftriaxone (6.54%). Most ADRs were associated with oral (46.7%) and intravenous (45.7%) routes. Skin-related reactions (41.1%), especially rashes (15.88%), were the most frequently reported. The majority of ADRs were mild (52.3%) and had probable causality (57.1%). Management strategies included drug substitution (45.7%), additional therapy (42.05%), and drug withdrawal (8.4%). Most patients (77.5%) fully recovered.

The study concludes, active ADR monitoring and robust pharmacovigilance practices are essential to improving patient safety. Strengthening ADR reporting systems and enhancing awareness among healthcare professionals can significantly reduce drug-related risks.

Keywords: Adverse Drug Reactions, Pharmacovigilance, Causality Assessment, Drug Safety, Tertiary Care Hospital, WHO-UMC Scale.

1. Introduction

Adverse Drug Reactions (ADRs) are a major contributor to patient morbidity, prolonged hospital stays, and increased healthcare costs globally. Despite the existence of national and international pharmacovigilance programs, ADRs remain significantly underreported due to limited awareness, inadequate training, and poor integration of reporting mechanisms into routine clinical practice. Previous research has consistently identified antibiotics and polypharmacy as common contributors to ADRs, particularly in hospital settings. Therefore, understanding the pattern, severity, causality, and preventability of ADRs is essential for improving patient safety and strengthening healthcare delivery systems.

This study was conducted in a tertiary care hospital to detect, assess, and report ADRs, evaluate their prevalence, causality, and severity, and analyze the role of pharmacovigilance practices in their effective management[1].

1.1 Definition of Adverse Drug Reaction (ADR)

According to the World Health Organization (1973), an adverse drug reaction is defined as any response to a drug that is noxious and unintended and occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function. In contrast, the modern definition proposed by Aronson and Ferner (2005) describes an ADR as an appreciably harmful or unpleasant reaction resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and necessitates prevention, specific treatment, dosage modification, or withdrawal of the drug[2].

1.2 Importance of ADR Monitoring

Adverse drug reactions are a significant cause of morbidity and mortality among both hospitalized and ambulatory patients. Evidence suggests that approximately 60–70% of ADRs are preventable, highlighting the importance of timely identification and appropriate intervention. Early detection and systematic reporting of ADRs are therefore critical for enhancing patient safety, optimizing therapeutic outcomes, and reducing healthcare burden.

1.3 Classification of ADRs-By Type

Type A (augmented) reactions are predictable, dose-dependent effects related to the known pharmacological action of drugs, such as insulin-induced hypoglycemia. Type B (bizarre) reactions are unpredictable, not dose-dependent, and often immune-mediated, as seen in penicillin allergy. Type C (chronic) reactions result from long-term drug use, such as corticosteroid-induced osteoporosis. Type D (delayed) reactions occur after prolonged exposure and may manifest long after drug administration, for example, carcinogenesis following diethylstilbestrol use. Type E reactions are associated with drug withdrawal, such as alcohol withdrawal symptoms, while Type F reactions indicate treatment failure, where the drug does not produce the intended therapeutic effect, such as contraceptive failure.

A. By Severity: Minor ADRs do not require treatment and resolve spontaneously. Moderate ADRs necessitate therapeutic intervention or prolong hospitalization. Severe ADRs are life-threatening or require intensive medical care, while lethal ADRs result in death.

B. Common Drugs Causing ADRs: In adults, ADRs are most frequently associated with antibiotics, corticosteroids, anticoagulants, and anticancer drugs. In pediatric populations, anti-infective agents, vaccines, and respiratory medications are commonly implicated.

C. Epidemiology: Adverse drug reactions account for approximately 5–11% of hospital admissions worldwide. Despite this substantial burden, underreporting remains a major challenge in pharmacovigilance systems. Prospective studies have consistently demonstrated higher rates of ADRs compared to retrospective studies, suggesting that many reactions remain undetected or undocumented[3].

1.4 Study Designs Used to Detect ADRs

Cohort studies are commonly used to compare the incidence of ADRs between exposed and unexposed populations over time. Case–control studies, on the other hand, identify patients who have experienced ADRs and compare them with matched controls to evaluate potential risk factors.

1.5 ADR Assessment Tools-Causality Assessment

Causality assessment of ADRs is commonly performed using the World Health Organization scale, which classifies reactions as certain, probable, possible, unlikely, conditional, or unassessable. The Naranjo scale is another widely used tool that employs a structured scoring system to determine the probability of an ADR.

A. Severity Assessment: The Hartwig severity scale categorizes ADRs as mild, moderate, or severe based on clinical outcomes and required interventions.

B. Predictability: Predictability of ADRs is assessed based on previously documented pharmacological effects and known adverse profiles of drugs.

C. Preventability: Preventability of ADRs is evaluated using the Schumock and Thornton scale, which classifies reactions as certainly preventable, possibly preventable, or not preventable.

D. Risk Factors for ADRs: Certain populations are more vulnerable to ADRs due to physiological and clinical factors. Elderly individuals and neonates are particularly susceptible because of altered drug metabolism and elimination. Gender differences may influence drug response due to variations in body composition and hormonal status. Pregnancy-related physiological changes can significantly affect drug pharmacokinetics. Lifestyle factors such as alcohol consumption and smoking may increase the risk of drug interactions and adverse effects. Polypharmacy is a well-established risk factor for ADRs, especially among hospitalized patients. Additionally, genetic factors, including conditions such as glucose-6-phosphate dehydrogenase deficiency, can predispose individuals to specific ADRs[4,5].

1.6 Role of Healthcare Professionals

Healthcare professionals play a crucial role in minimizing ADR-related harm by considering ADRs during clinical diagnosis, closely monitoring high-risk patients, and ensuring effective communication within the healthcare team. Patient education and prompt reporting of suspected ADRs are essential components of safe medication practices[6].

1.7 ADR Reporting in India

A. Who Can Report: In India, ADRs can be reported by healthcare professionals as well as consumers.

B. When to Repor: Serious ADRs should be reported immediately, while non-serious ADRs should be reported within 30 days of occurrence.

C. Where to Report: ADRs can be reported to the nearest ADR Monitoring Centre or the National Coordination Centre under the PharmacovigilanceProgramme of India. Reports may also be submitted through the toll-free number 1800 180 3024 or via email at pvpi@ipcindia.net.

D. What to Report: Serious ADRs- include reactions that are life-threatening, result in hospitalization, cause disability, or lead to congenital anomalies. Non-serious ADRs include all other suspected reactions, including those related to herbal products and vaccines.

E. How to Report: ADR- reporting forms are available on the official websites ipc.gov.in and pv_home. Mandatory information includes patient initials, age, description of the reaction, date of onset, suspected drug details, and reporter information.

F. Use of Reported Data: Reported ADR -data is reviewed at ADR Monitoring Centers and the National Coordination Centre before being forwarded to the WHO–Uppsala Monitoring Centre. These data support national and global drug safety surveillance, facilitate regulatory decision-making, and contribute to improving medication safety[7,8].

2. Materials and Methods

2.1 Study Site

The study was conducted at Prathima Institute of Medical Sciences, Nagunur, Karimnagar, a tertiary care teaching hospital that provides comprehensive healthcare services across multiple clinical departments, including inpatient, outpatient, and emergency care.

2.2 Study Design

This was a prospective observational study designed to evaluate the occurrence, pattern, and characteristics of adverse drug reactions (ADRs) among hospitalized and outpatient populations over a defined study period.

2.3 Study Duration

The study was carried out over a period of six months, from [insert start month and year] to [insert end month and year].

2.4 Sample Size

A minimum sample size of 100 patients of both sexes was included in the study. The final sample size was determined based on the eligibility criteria outlined below and the availability of complete clinical information.

2.5 Source of Data

Relevant data were collected from multiple sources, including patient profile forms, medication and treatment charts, and direct interviews with patients, caregivers, and healthcare professionals. A structured data collection form was used to ensure uniformity and consistency in recording demographic details, clinical characteristics, medication history, and suspected ADRs.

2.6 Study Procedure

The study team conducted regular visits to various hospital departments during the study period. Patients were screened and enrolled based on predefined inclusion and exclusion criteria. Verbal informed consent was obtained from all participants prior to their inclusion in the study. Clinical information such as demographic details, diagnosis, prescribed medications, and details of suspected ADRs was documented. Patients were followed up to monitor the onset, progression, and resolution of ADRs. All reported ADRs were systematically evaluated for causality, severity, predictability, and preventability using standardized assessment tools.

2.7 Selection of Subjects

Inclusion Criteria

Adult and geriatric patients of either sex from all hospital departments were included. ADRs voluntarily reported by healthcare professionals, patients, or caregivers involving prescription, over-the-counter, or herbal drugs were considered. Both serious and non-serious ADRs within the reporting period were included.

Exclusion Criteria

Patients with incomplete or missing documentation were excluded from the study. Reactions not related to drug use, such as surgical complications, were not considered. Duplicate ADR reports were excluded to avoid repetition. Animal studies and in vitro studies were not included. Reactions related to unapproved experimental or investigational drugs were excluded. Events that did not qualify as ADRs, such as medication non-compliance or natural disease progression, were also excluded.

Ethical Considerations

Ethical clearance for the study was obtained from the Institutional Ethics Committee of Prathima Institute of Medical Sciences. Verbal informed consent was obtained from each participant prior to enrollment, and confidentiality of patient information was strictly maintained throughout the study.

Assessment Tools

Causality assessment of ADRs was performed using the WHO–UMC causality assessment scale and the Naranjo algorithm. Severity of ADRs was graded using the Hartwig and Siegel Severity Assessment Scale. Predictability was evaluated based on known pharmacological profiles of the suspected drugs.

Preventability was assessed using the modified Schumock and Thornton criteria.

Statistical Analysis

Collected data were entered and managed using Microsoft Excel. Descriptive statistics, including frequencies and percentages, were used for data analysis. Tables and graphical representations were generated using Microsoft Excel and Microsoft Word to facilitate clear presentation of results.

3. Results

A total of 107 adverse drug reactions (ADRs) were analyzed in the present study. The distribution of ADRs according to demographic characteristics, clinical departments, severity, drug classes, offending drugs, route of administration, organ systems involved, outcomes, management strategies, causality assessment, and clinical manifestations is summarized below and illustrated in the corresponding tables and figures.

3.1 Gender-wise Distribution

Among the reported ADRs, females accounted for a higher proportion females (60%, n = 64) compared to males (40%, n = 43), as shown in Table 1 and Figure 1.

3.2 Age-wise Distribution

The majority of ADRs were reported in adults aged 19–65 years (85.98%, n = 92). This was followed by geriatric patients (>65 years) accounting for 8.47% (n = 8), paediatric patients (1–12 years) at 3.73% (n = 4), and adolescents (13–18 years) at 2.80% (n = 3). The age-wise distribution is presented in Table 2 and Figure 2.

Table 1: Gender wise distribution

Gender	No. of ADRs (*n=107*)	Percentage
Male	43	40%
Female	64	60%

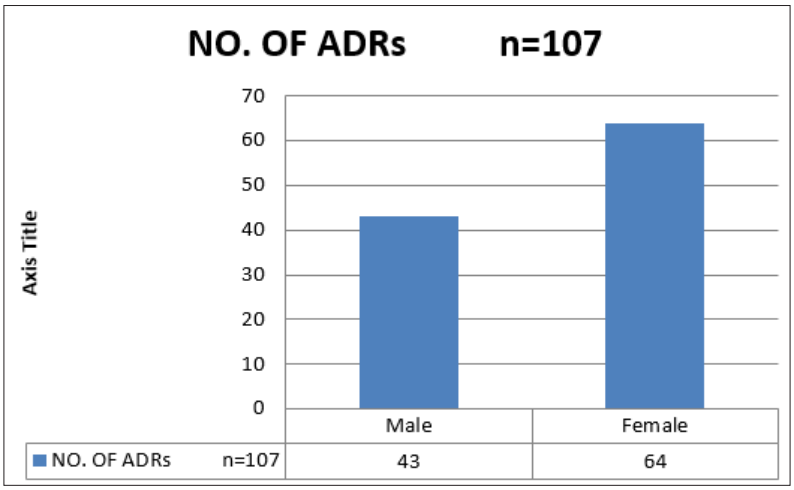

Figure 1: Gender wise Distribution

Table 2: Age wise distribution

Age	No. of ADRs (107)	Percentage%
Paediatrics (1-12)	4	3.73%%
Adolescents (13-18)	3	2.80%
Adults (19-65)	92	85.98%
Geriatrics (above65)	8	8.47%

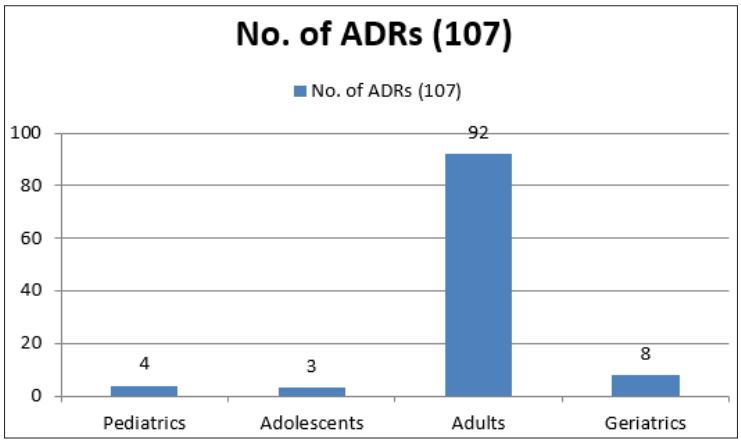

Figure 2: Distribution of patients based on the Age

Table 3: Department wise distribution

Department	No. of ADRs(107)	Percentage%
ACCU	9	8.41%
Dermatology	6	5.60%
General medicine	14	13%
General surgery	15	14%
Casuality	10	9.34%
Paediatrics	4	3.73%
Neuro surgery	2	1.86%
ENT	3	2.80%
Gynaecology	23	21.4%
Pulmonology	6	5.60%
Orthopaedics	1	0.93%
Ophthalmology	4	3.73%
Psychiatric	1	0.93%
Cardiology	5	4.67%
Nephrology	4	3.73%

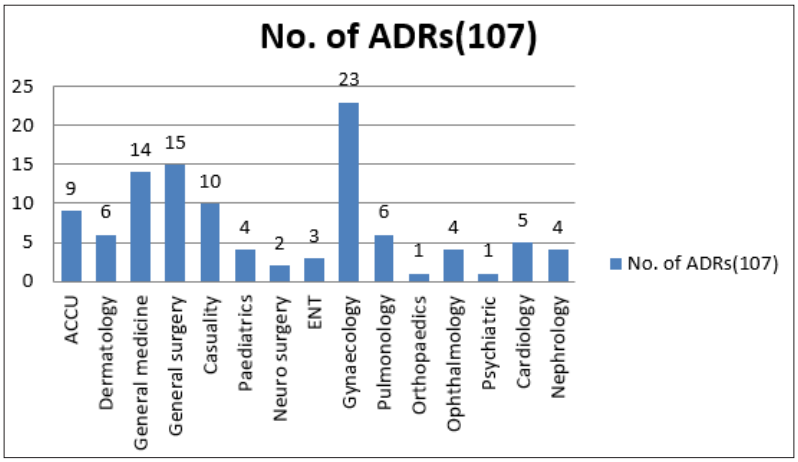

Figure 3: Distribution based on department wise

3.3 Department-wise Distribution

The highest number of ADRs was reported from the Department of Gynaecology (21.4%, n = 23), followed by General Surgery (14%, n = 15), General Medicine (13%, n = 14), and Casualty (9.34%, n = 10). Other departments contributed smaller proportions of ADRs. Detailed departmental distribution is shown in Table 3 and Figure 3.

3.4 Severity-wise Distribution

Based on severity assessment, most ADRs were classified as mild (52.3%, n = 56), followed by moderate reactions (37.3%, n = 40). Severe ADRs accounted for 10.2% (n = 11) of cases. The severity distribution is shown in Table 4 and Figure 4.

3.5 Distribution Based on Drug Class

Antibiotics were the most commonly implicated drug class, accounting for 32.71% (n = 35) of ADRs. This was followed by analgesics (9.34%, n = 10), antimicrobials (8.41%, n = 9), antihypertensive agents (6.54%, n = 7), and haematinics (5.60%, n = 6). Other drug classes contributed fewer ADRs. The distribution by drug class is presented in Table 5 and Figure 5.

Table 4: Distribution based on severity.

Severity	No.of ADRs (107)	Percentage%
Mild	56	52.3%
Moderate	40	37.3%
+Severe	11	10.2%

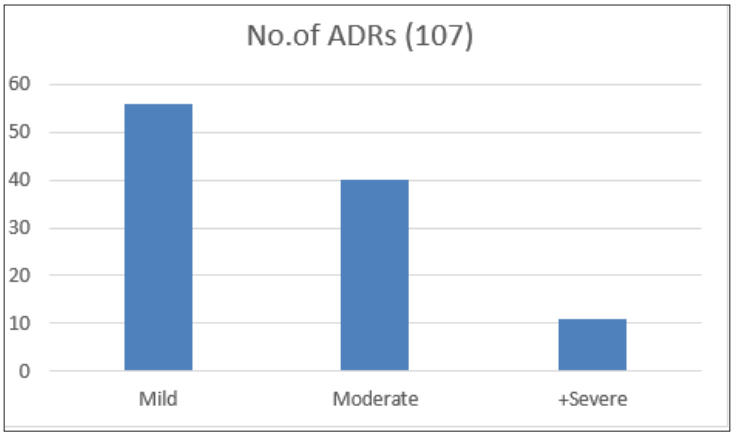

Figure 4: Distribution based on severity

Figure 5: Distribution based on drug class

Class of the drug	No. of ADRs (107)	Percentage%
Antibiotics	35	32.71%
Anticonvulsants	2	1.86%
Antimicrobials	9	8.41%
Anti neoplastics	4	3.73%
Haematinics	6	5.60%
Synthetic Nucleoside Analogues	2	1.86%
Analgesics	10	9.34%
Antacids	2	1.86%
Anti hypertensive	7	6.54%

Anti hypotensive	3	2.80%
NSAIDs	3	2.80%
Corticosteroids	1	0.93%
Antiseptics	1	0.93%
Vitamins	1	0.93%
Anti tuberculosis	3	2.80%
Anti hepatitis	1	0.93%
Herbal supplements	1	0.93%
Proton pump inhibitors	2	1.86%
Anti diuretics	1	0.93%
Mucolytic agents	1	0.93%
Anti fibrinolytics	3	2.80%
Female hormones	1	0.93%
Oxazolidones	2	1.86%
Anti psychotics	1	0.93%
Xanthine oxidase inhibitors	1	0.93%
Gastrointestinal prokinetics	1	0.93%
Progestogens	2	1.86%
Immunotherapy agents	1	0.93%

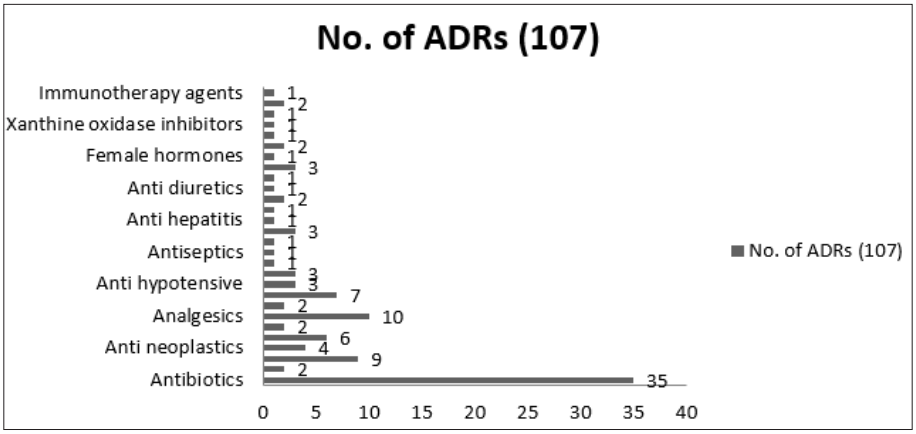

Figure 5: Distribution based on drug class

Distribution Based on Offending Drugs

Among individual drugs, amoxicillin–clavulanate (Augmentin) was the most frequent offending agent (7.47%, n = 8), followed by ceftriaxone (6.54%, n = 7), metronidazole and paracetamol(each 5.60%, n = 6). Several other drugs were associated with single or few ADRs. Details are provided in Table 6.

Table 6: Distribution based on offending drugs

Offending Drugs	Total no of ADRs%
Augmentin	8 (7.47%)
Cefpodoxime proxetil	1 (0.93%)
Levipil	2 (1.86%)
Metrinidazole	6 (5.60%)
Ceftriaxone	7 (6.54%)
Methotrexate	4 (3.73%)
Levofloxacin	1 (0.93%)
Meropenem	1 (0.93%)
Roofer	3 (2.80%)
Acyclovir	1 (0.93%)
Paracetamol	6 (5.60%)
Auxisoda	1 (0.93%)
Piperacillin	2 (2.86%)
Mannitol	2 (2.86%)
Amoxicillin	4 (3.73%)
Povidone iodine	1 (0.93%)
Gentamycin	1 (0.93%)
Ciprofloxacin	4 (3.73%)
Ferrous ascorbate	3 (2.80%)
Diclofenac&serratopeptidase	1 (0.93%)
Tramadol	4 (3.73%)
Combiflam	2 (2.86%)
Vancomycin	3(2.80%)
Folvite	1(0.93%)
Cefixime& ofloxacin	1(0.93%)
Pruvict	1(0.93%)
Allopurinol	1(0.93%)
Pyrizinamide	1(0.93%)
Ethambutal	1(0.93%)
Regestrone	2(2.86%)
Amlodipine	1(0.93%)
BCG vaccine	1(0.93%)
Sodium bicarbonate	1(0.93%)
Hepatitis B vaccine	1(0.93%)
Norad	2(2.86%)
Prednisolone	1(0.93%)
Acetylcysteine	1(0.93%)
Telmisartan	1(0.93%)
Tranexamic acid	4(3.73%)
Vasopressin	1(0.93%)
Carica papaya	1(0.93%)
Pantaprazole	2(2.86%)
Cilnidipine	3(2.80%)
Linezolid	2(2.86%)

Doxycycline	1(0.93%)
Levosulpride	1(0.93%)
Progesterone	1(0.93%)
Nitrofurantoin	3(2.80%)
Triamanolone acetamide	1(0.93%)
Rifampicin	1(0.93%)

Table7: Distribution based on Route of Administration

ROA	No. ofADRs(107)	Percentage
Intravenous	49	45.7%
Oral	50	46.7%
Topical	3	2.8%
Intradermal	1	0.9%
Intramuscular	4	3.7%

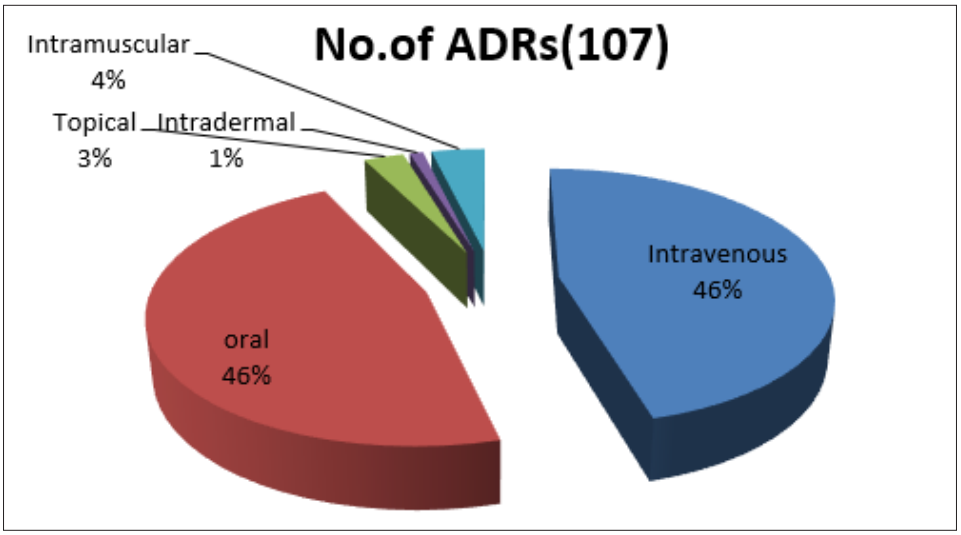

Figure 6: Distribution based on Route of Administration

Distribution Based on Route of Administration

Most ADRs occurred following oral administration (46.7%, n = 50), closely followed by the intravenous route (45.7%, n = 49). Intramuscular (3.7%, n = 4), topical (2.8%, n = 3), and intradermal routes (0.9%, n = 1) contributed fewer ADRs. The route-wise distribution is shown in Table 7 and Figure 6.

Table 8: Distribution based on System Effected

Organ system affected	Number of ADRs (n = 107)	Percentage
Skin	44	41.1%
CNS	18	16.8%
CVS	6	5.6%
Renal system	4	3.7%
GI	7	6.5%
Endocrine	1	0.9%
Eyes	3	2.8%
Blood& others	23	21.4%

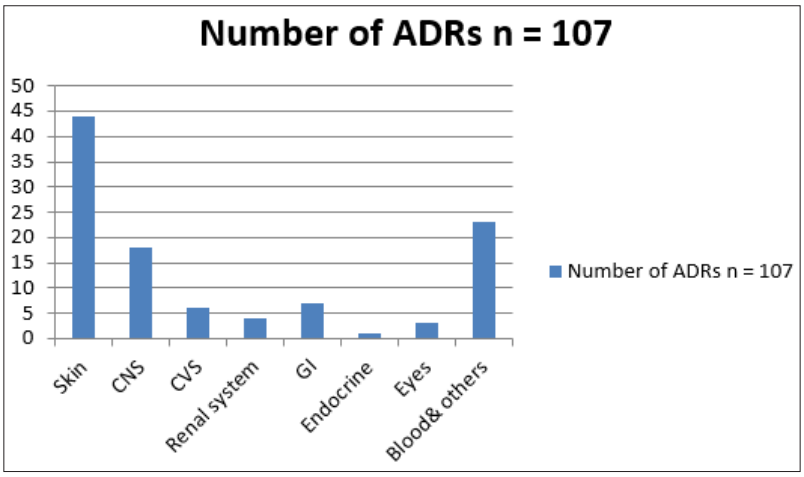

Figure 7: Distribution based on System Effected

System-wise Distribution

The skin was the most commonly affected organ system, accounting for 41.1% (n = 44) of ADRs, followed by the central nervous system (16.8%, n = 18). Blood and other systems accounted for 21.4% (n = 23). Gastrointestinal, cardiovascular, renal, ocular, and endocrine systems were less frequently involved. Details are shown in Table 8 and Figure 7.

Outcomes of ADRs

The majority of patients recovered completely from the ADRs (77.5%, n = 83), while 22.4% (n = 24) were recovering at the time of assessment. No cases of non-recovery were reported. Outcome data are presented in Table 9 and Figure 8.

Management of ADRs

Management strategies included substitution of the suspected drug with an alternative in 45.7% (n = 49) of cases. Additional drug therapy, with or without withdrawal of the offending drug, was required in 42.05% (n = 45). Drug withdrawal alone was performed in 8.4% (n = 9), while dose reduction was carried out in 3.73% (n = 4) of patients. Management details are shown in Table 10 and Figure 9

Table 9: Distribution based on outcome of ADRs

Outcome	Number of ADRs (n = 107)	Percentage
Recovering	24	22.4%
Recovered	83	77.5%
Not recovered	0	0%

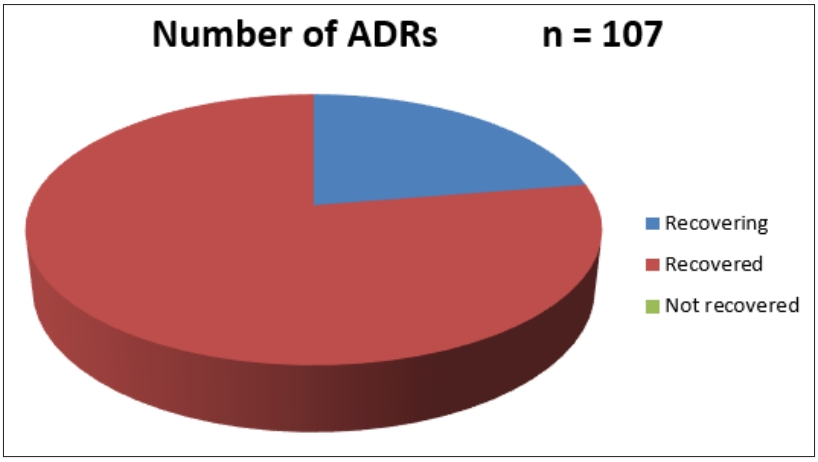

Figure 8: Distribution based on outcome of ADR

Table 10: Distribution based on management of ADRs

ADR management	Number of ADRs (n = 107)	Percentage
Addition of another drug with or without dechallenge	45	42.05%
Drug withdrew only	9	8.4%
Substituted with another drug	49	45.7%
Dose reduced	4	3.73%

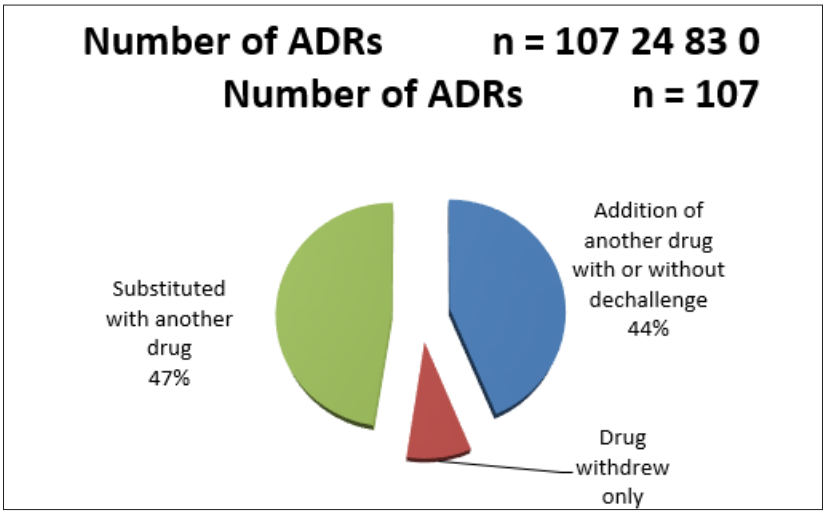

Figure 9: Distribution based on Management

Table 11: Distribution based on WHO Casuality Assessment Scale

Casuality	Number of ADRs (n = 107)	Percentage
Certain	24	22.4%
Possible	22	20.5%
Probable	61	57.1%

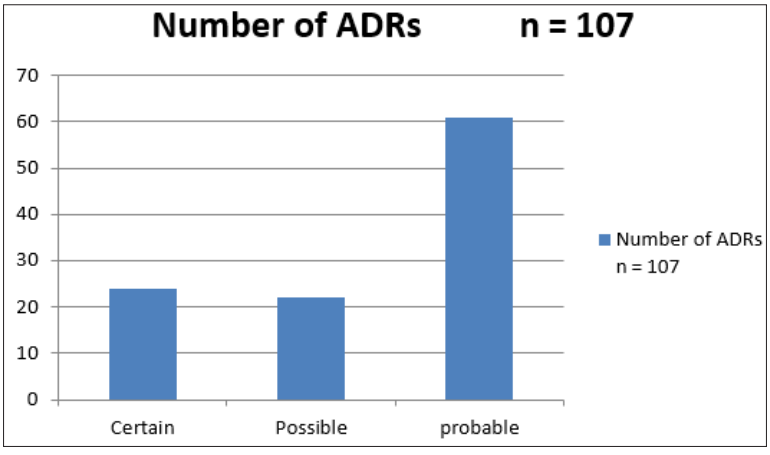

Figure 10: Distribution based on WHO casuality assessment scale

WHO Causality Assessment

According to the WHO causality assessment scale, most ADRs were classified as probable (57.1%, n = 61), followed by certain (22.4%, n = 24) and possible (20.5%, n = 22). The causality distribution is shown in Table 11 and Figure 10.

Table 12: Distribution based on drug reaction

Drug Reaction	Number of ADRs (n = 107)	Percentage
Rashes	17	15.88%
Vomitings	13	12.14%
Diarrhoea	7	6.54%
Sweating	2	1.86%
Dizziness	2	1.86%
Pedal edema	4	3.73%
Skin lesions- itchings	7	6.54%
Gangrene	1	0.93%
Erythema	5	4.67%
Swelling	5	4.67%
Facial puffiness	3	2.80%
Hypotension	2	1.86%
Blurring of vision	3	2.80%
Blisters	4	3.73%
Hepatitis	1	0.93%

Symptom-wise Distribution

Rashes were the most commonly reported clinical manifestation (15.88%, n = 17), followed by vomiting (12.14%, n = 13), diarrhoea and skin itching (each 6.54%, n = 7). Other reported symptoms included erythema, swelling, pedal edema, facial puffiness, blisters, dizziness, hypotension, and rare serious manifestations such as gangrene and hepatitis. The symptom-wise distribution is detailed in Table 12.

4. Discussion

Adverse drug reactions (ADRs) continue to be a major concern in clinical practice, adversely affecting patient safety and therapeutic outcomes. The Pharmacovigilance Programme of India (PvPI) plays a crucial role in addressing this challenge by systematically collecting ADR reports from healthcare professionals and the public, thereby enabling regulatory authorities to implement appropriate safety measures. In this context, the present prospective observational study analyzed 107 ADRs reported over a six-month period (July–December 2024) at the Department of Pharmacology, Prathima Institute of Medical Sciences, Telangana, in accordance with National Coordinating Centre (NCC) guidelines. The study evaluated demographic characteristics, departmental distribution, implicated drug classes, routes of administration, severity, causality, organ systems affected, management strategies, and outcomes of ADRs.

Females accounted for a higher proportion of ADRs (60%) compared to males (40%) (Table 1, Figure 1). This finding is consistent with studies by Medaet al[9]. and Sharma et al.[10], which attribute increased ADR susceptibility in females to physiological and hormonal factors such as menstruation, pregnancy, and menopause that may influence drug pharmacokinetics and pharmacodynamics. The higher reporting of ADRs from the Obstetrics and Gynecology department in the present study further supports this observation.

Adults aged 19–65 years constituted the majority of ADR cases (85.98%), followed by geriatric patients (8.47%), pediatric patients (3.73%), and adolescents (2.80%) (Table 2, Figure 2). Similar age-wise trends have been reported by Kauret al[11]. and Meda et al.[9] Although pediatric and geriatric populations are generally considered more vulnerable to ADRs due to altered physiology, the higher incidence

among adults may be explained by greater exposure to medications and higher healthcare utilization.

Department-wise analysis showed that the Gynecology department contributed the highest number of ADRs (21.4%), followed by General Surgery (14%) and General Medicine (13%) (Table 3, Figure 3). This pattern reflects department-specific prescribing practices and physiological factors influencing drug response. The skin was the most commonly affected organ system (41.1%) (Table 8, Figure 7), consistent with findings reported by Jose et al. and Lobo et al.[12] Rash was the most frequent clinical manifestation, followed by gastrointestinal symptoms such as vomiting and diarrhea (Table 12), which are well-recognized ADR presentations.

Severity assessment using the modified Hartwig and Siegel scale revealed that most ADRs were mild (52.3%) or moderate (37.3%), while severe reactions accounted for 10.2% of cases (Table 4, Figure 4). No fatal outcomes were observed. These findings are comparable with reports by Kharbet al.[13], Ponnusankar et al., and Rajeshreddy et al.[14], indicating that although ADRs are frequent, the majority are manageable with timely intervention.

Causality assessment using the WHO–UMC scale classified most ADRs as probable (57.1%), followed by certain (22.4%) and possible (20.5%) (Table 11, Figure 10). This distribution aligns with earlier studies by Tejaset al.[15] and Singh et al.[16], reinforcing the reliability of structured causality assessment tools in pharmacovigilance practice.

Antibiotics were the most frequently implicated drug class (32.7%) (Table 5, Figure 5), similar to findings by Ingaleet al.[18] and Ponnusankar et al.[17] Augmentin, ceftriaxone, and paracetamol were the most common offending drugs (Table 6). The predominance of antibiotics may be attributed to their widespread use for both therapeutic and prophylactic purposes in hospital settings. Oral administration was the most common route associated with ADRs (46.7%), closely followed by intravenous administration (45.7%) (Table 7, Figure 6), reflecting routine prescribing patterns in inpatient care.

Management of ADRs primarily involved substitution of the offending drug (45.7%) or the addition of supportive therapy with or without dechallenge (42.05%). Drug withdrawal and dose reduction were less frequently required (Table 10, Figure 9). Favorable outcomes were observed in most cases, with 77.5% of patients fully recovered and the remaining 22.4% showing improvement at the time of reporting (Table 9, Figure 8).

This study has certain limitations. Being a single-center study with a relatively short duration, the findings may not be generalizable to other healthcare settings. Underreporting, a recognized limitation of pharmacovigilance systems, may have resulted in underestimation of ADR incidence. In addition, detailed analysis of polypharmacy and drug–drug interactions was beyond the scope of this study.

Future research should focus on multicenter studies with larger sample sizes and longer follow-up periods. Incorporating pharmacogenomic approaches may further help identify individual susceptibility to ADRs, particularly among females and specific age groups. Continuous training and awareness programs for healthcare professionals are essential to strengthen ADR reporting and enhance patient safety.

5. Conclusion

Adverse drug reactions contribute significantly to patient morbidity, prolonged hospital stays, and increased healthcare burden. The findings of this study underscore the importance of vigilant monitoring, systematic documentation, and timely reporting of ADRs by healthcare professionals. Establishing a strong culture of pharmacovigilance supported by institutional commitment is vital for improving medication safety.

As the first pharmacovigilance study conducted at this teaching hospital, the present work provides baseline data on the pattern, severity, causality, and outcomes of ADRs across various demographic and clinical categories. These findings will serve

as a foundation for future pharmacovigilance initiatives and quality improvement efforts within the institution.

With continuous advancements in medical therapy, strengthening pharmacovigilance systems remains essential to ensure the safe and effective use of medicines. Sustained efforts in ADR monitoring, reporting, and education will contribute to improved patient care and a safer healthcare system.

6. Conflict of Interest: No

7. References

1. Walter-RondeyNagumopharmacovigilance and Adverse Drug Reaction reporting practices among Ghanaian healthcare professionals August, 2020**.**
2. Shamna M, Dilip C, Ajmal M, Linu Mohan P, Shinu C, Jafer CP, Mohammed Y. A prospective study on Adverse Drug Reactions of antibiotics in a tertiary care hospital. Saudi Pharm J. 2014 Sep;22(4):303-8.
3. Hazell L, Shakir SA. Under-reporting of adverse drug reactions : a systematic review. Drug Saf. 2006;29(5):385-96.
4. Finkelstein Y, Lador A, Seymour C, et al. The risk of drug-induced liver injury due to direct-acting antivirals for chronic hepatitis C. Drug Saf. 2016;39(6):515-27.
5. Singh H, Shrier I, Dubé C, et al. Measures to improve detection and reporting of adverse drug reactions: A systematic review. Drug Saf. 2011;34(4):311-32
6. Srisuriyachanchai W, Cox AR, Jarernsiripornkul N. Exploring Healthcare Professionals' Practices and Attitudes towards Monitoring and Reporting of Severe Adverse Drug Reactions. Healthcare (Basel). 2022 Jun 10;10(6):1077.
7. AnsumanSahu, NiharRanjan Das* Indian Journal of Pharmacy Practice., 2024; 17(3):198-204.
8. National Coordination Centre for PharmacovigilanceProgramme of India, Indian Pharmacopoeia commission.
9. Meda V, Dwarakanadha Reddy P and Satyanarayana SV: Analysis and reporting of adverse drug reactions at a tertiary care teaching hospital. Alexandria Journal of Medicine 2018; 54(4): 597–603
10. Sharma S, Jayakumar D and Palappalli DS: "Pharmacovigilance of cutaneous adverse drug reactions among patients attending dermatology department at a Tertiary Care Hospital," Indian Dermatology Online Journal 2019; 10(5): 547
11. Kaur M, Deb T, Kairi J and Arora A: A pharmacovigilance study of adverse drug reactions in a tertiary care hospital in Haryana. International Journal of Basic & Clinical Pharmacology 2019; 8(10): 2184
12. Lobo MGA, Pinheiro SMB, Castro JGD, Momenté VG, Pranchevicius MCS. Adverse drug reaction monitoring: Support for pharmacovigilance at a tertiary care hospital in Northern Brazil. BMC PharmacolToxicol. 2013;14;5.
13. Kharb P, Mittal N, Gupta MC. An evaluation of adverse drug reactions monitoring at a pharmacovigilance unit under pharmacovigilanceprogramme of India in a tertiary care hospital of Haryana. Int J Basic Clin Pharmacol2015;4:556-60.
14. Rajeshreddy V., S. G. S., &Patil, L. V. (2017). Causality assessment and the severity of the adverse drug reactions in tertiary care hospital: a pharmacovigilance study. *International Journal of Basic & Clinical Pharmacology*, *6*(12), 2800–2803
15. Tejas A: "A study of agreement between WHO-UMC Causality Assessment System and the naranjo algorithm for causality assessment of adverse drug reactions observed in medical ICU of a tertiary care teaching hospital. Biomedical and Pharmacology Journal, 2020; 13(1): 79–83.
16. Singh H, Dulhani N, Singh P and Tewari P: A pharmacovigilance study in Medicine Department of Tertiary Care Hospital in Chhattisgarh (Jagdalpur), India. Journal of Young Pharmacists 2010; 2(1): 95–100.
17. Ponnusankar S, Tejaswini M and Chaitanya M: Assessment of adverse drug reactions based on

spontaneous signals at Secondary Care Public Hospital. Indian Journal of Pharmaceutical Sciences 2015; 77(4): 490.

18. Ingale AM, Nadig P and Chakraborty A: Analysis of the adverse drug reactions collected through active surveillance in the pharmacovigilance unit of a tertiary care hospital. Asian Journal of Pharmaceutical and Clinical Research 2018; 11(8): 383.

Cite this article Harshitha B et al., A Prospective Study on Detection, Assessment and Reporting of ADRs in a Tertiary Care Hospital. Indian Journal of Health Care, Medical & Pharmacy Practice. 2025;6(2):117-132.