



Assessment of Adverse Drug Reactions and Pharmacological Awareness in Hospital Patients: A Prospective Observational Study

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Abstract:

Background: Adverse drug responses (ADRs), which are unintentional and harmful side effects of drugs taken at therapeutic doses, are a significant contributor to patient morbidity, prolonged hospital admissions, and increased medical costs. Despite well-established initiatives like the Pharmacovigilance Programme of India (PvPI), patient awareness of ADR reporting is still poor. Pharmacovigilance is essential for detecting, assessing, and preventing adverse drug reactions (ADRs).

Objectives: To identify and document ADRs among hospitalized patients and assess their awareness of pharmacovigilance and ADR reporting.

Methods: A one-month prospective observational study involved one hundred adult inpatients in the general medicine department of Malla Reddy Hospital in Hyderabad. Patients were enlisted by sequential sampling after obtaining informed consent. Data on demographics, the incidence of adverse drug reactions (ADRs), suspected drugs, their severity, and their outcomes were collected using a standardized form. Pharmacovigilance awareness was assessed using a seven-item questionnaire. The data were evaluated using descriptive statistics and then shown as frequencies and percentages.

Results: 55% of the 100 participants were women and 45% were males. The largest age group (32%) was those between the ages of 31 and 45. Adverse drug reactions (ADRs) occurred in 50% of patients, with rash (16%), nausea (20%), and dizziness (22%) being the most common. Of the reported adverse drug reactions, 22% were severe, 34% were moderate, and 44% were mild. All participants accepted that pharmaceuticals may have bad effects, but just 52% were aware of adverse drug reactions (ADRs), 50% knew they could be reported, and 17% had previously reported a side effect. Reporting adverse drug reactions (ADRs) improves patient safety, according to the majority of participants (79%), and 86% expressed a need for further information.

Conclusion: Although ADRs were common, reporting protocols and awareness remained inadequate. Hospital-based pharmacovigilance programs and targeted patient education are necessary to improve medication safety and ADR reporting.

Keywords: Adverse Drug Reactions, Pharmacovigilance, Patient Awareness, ADR Reporting, Prospective Observational Study, PvPI, Hospital Patients, Drug Safety

1. INTRODUCTION

An adverse drug response (ADR) is any unpleasant, unexpected, and undesired side effect of a medicine that occurs at levels used in humans for disease prevention, diagnosis, treatment, or modification of physiological function [1]. One of the most pressing problems in contemporary medicine, adverse drug reactions (ADRs) impact patients in all treatment settings, from complex tertiary care settings to primary care outpatient clinics. Unlike adverse events caused

by medication errors or overdoses, adverse drug reactions (ADRs) occur at normal therapeutic levels, making them particularly difficult to predict and prevent. Adverse drug reactions (ADRs) are thought to affect 10% to 20% of hospitalised patients, and epidemiological data indicates that ADRs are responsible for 5-7% of all hospital admissions worldwide [2]. In a groundbreaking prospective study, Davies et al. discovered ADRs in 14.7% of hospital patient-episodes. The majority of them were associated with cardiovascular and antimicrobial drug classes and had a moderate intensity [1]. Adverse drug reactions (ADRs) are a significant contributor to prolonged hospital stays, increased healthcare expenses, worse quality of life, and in severe cases, patient mortality, in addition to clinical morbidity. Since ADR-related hospitalisations cost healthcare systems worldwide billions of dollars annually, strict drug safety monitoring is essential.

Early detection and thorough monitoring of adverse drug reactions (ADRs) are necessary to safeguard patient health and optimise treatment outcomes. Adverse drug reactions (ADRs) that go unnoticed or unreported may increase or persist, sometimes with potentially deadly outcomes that may have been prevented with timely care. Monitoring provides the safety information needed for regulatory authorities to update prescription recommendations and drug labelling, aids doctors in identifying causal drug-patient connections, and enables the prompt removal or dosage modification of offending drugs [3]. Considerable reactions might not be found until considerable harm has been done at the population level since many ADR detection procedures are retrospective in nature. This limitation emphasises the need for prospective, real-time surveillance in hospital environments where medical professionals regularly watch patients. Polypharmacy, or the concurrent use of many medications, has been linked to a proportionally higher incidence and severity of adverse drug reactions (ADRs), according to additional studies conducted in Indian tertiary care facilities. Patients with co-occurring chronic illnesses are increasingly exhibiting this tendency [3]. Proactive monitoring not only reduces patient harm but also generates the post-marketing safety signals required to continuously enhance clinical pharmacology knowledge and medication regulatory decisions.

Pharmacovigilance is specifically defined by the World Health Organization (WHO) as the science and activities connected to the detection, assessment, understanding, and avoidance of side effects or any other drug-related problems [7]. It includes the whole lifespan of medicine safety monitoring, from pre-clinical research and regulatory approval to decades of post-marketing surveillance. An effective pharmacovigilance system collects unplanned reports of adverse drug reactions (ADRs) from patients and medical professionals, examines signal patterns, alerts stakeholders to potential risks, and, when necessary, implements regulatory remedies. The Central Drugs Standard Control Organization (CDSCO) established the Pharmacovigilance Programme of India (PvPI), which is managed by the Indian Pharmacopoeia Commission (IPC), Ghaziabad. PvPI has 976 functioning ADR Monitoring Centers (AMCs) around the country, according to the most recent figures [5]. Despite this expanding infrastructure, the overall number of ADR complaints filed to PvPI remains disproportionately low as compared to the vast patient population in India. A critical knowledge gap that threatens the nation's pharmacovigilance program is highlighted by the fact

that over half of the medical professionals surveyed in a systematic review of 28 Indian studies were unaware of PvPI [7].

Patients have a unique advantage in the pharmacovigilance ecosystem since they are always the first to experience adverse drug reactions. When given the tools to recognise, document, and communicate their drug-related experiences, patients offer a distinct and therapeutically beneficial perspective that improves professional reporting systems [10]. Patient-reported adverse drug reactions (ADRs) have been shown to provide more thorough descriptions of symptom impact, duration, and quality-of-life consequences than data gathered only by healthcare personnel. However, for this potential to be fulfilled, enough patient knowledge is required. Data from cross-sectional surveys consistently demonstrates how poorly patients still comprehend the fundamentals of pharmacovigilance. A study of 360 patients at primary healthcare institutions in Nigeria found that less than one-fifth of individuals who had previously had adverse drug reactions (ADRs) had reported them [4]. Similarly, just 8% of participants in a study examining public awareness of ADR reporting in Malaysia knew of the nation's ADR monitoring system [10]. Patients from a range of socioeconomic and educational levels in India confront additional problems, including language barriers, limited health literacy, and a general lack of institutional channels for patient-initiated ADR reporting. All of our findings point to a significant and mostly unmet patient engagement gap in pharmacovigilance systems.

Despite the growing amount of research on ADR incidence and pharmacovigilance practices among healthcare workers, very few prospective studies have simultaneously assessed the prevalence of ADRs and the level of pharmacovigilance knowledge among patients in the Indian hospital context. Underreporting of adverse drug reactions (ADRs), which is believed to be the cause of up to 94% of all responses that go unreported in some healthcare systems, continues to be the largest obstacle to the effectiveness of pharmacovigilance programs worldwide [8]. Given the high rate of sickness, polypharmacy, and uneven patient health literacy in India, this discrepancy is particularly noteworthy. The majority of research in Indian tertiary care settings has either on ADR patterns or professional awareness independently; very few have employed an integrated approach that combines both elements into a unified prospective framework [3][9]. Furthermore, the published literature contains very few patient-level awareness studies from hospital settings in Telangana and the wider Deccan region. Closing this evidence gap is essential to developing targeted, context-appropriate interventions that can improve ADR reporting and detection at the institutional level.

In order to inform strategies to improve drug safety practices at the institutional and regional levels, the current study was designed to both concurrently assess the level of pharmacovigilance awareness among the same patient cohort and prospectively assess the occurrence of adverse drug reactions among hospitalised patients at Malla Reddy Hospital in Hyderabad.

METHODOLOGY

3.1 Study Design

Patients admitted to the inpatient wards of Hyderabad's Malla Reddy Hospital were the subjects of this prospective observational research. In order to minimise recall bias and enable direct patient interviews at the point of treatment, a prospective design was used to identify and record adverse drug reactions in real-time as they occurred throughout the patient's hospital stay. Patients' prescription drug regimens were not altered, and they were observed and interviewed in their regular clinical settings without the use of any investigational therapies. This strategy complies with established scientific frameworks that are utilised in pharmacovigilance studies to gauge patient awareness and the frequency of adverse drug reactions in hospital environments.

3.2 Study Site

The study was conducted at the Malla Reddy Hospital's General Medicine Department in Hyderabad, Telangana, India. Malla Reddy College of Pharmacy is associated with Malla Reddy Hospital, a tertiary care teaching hospital. In order to gather a representative sample of adverse drug reactions and evaluate pharmacovigilance awareness across a range of clinical presentations, the General Medicine Department was selected as the study site due to its diverse patient population, high patient turnover, and wide range of medications prescribed across multiple disease categories.

3.3 Study Duration

Over the course of a month, the inquiry was conducted. Data was collected every day during working days for the duration of the study. The duration was judged adequate to enlist the 100 patients in the intended sample and to document a variety of diagnoses, drug exposures, and clinical results for perceptive descriptive analysis.

3.4 Study Population

The study population consisted of adult patients 18 years of age and older who were admitted to the general medicine department of Malla Reddy Hospital and were taking at least one prescription medication during the study period. Patients had to be conscious, attentive, able to communicate, and prepared to provide informed consent in order to take part. The study concentrated on the general inpatient medicine population, which included a wide range of acute and chronic disease conditions, in order to reflect the variety of pharmacotherapy encountered in routine clinical practice and enable a representative assessment of ADR occurrence and pharmacovigilance awareness.

3.5 Sample Size

A total of 100 individuals were recruited for this study using a sequential sampling strategy. Patients who fit the inclusion criteria were recruited one after the other throughout the study period until the target sample size was attained. A sample of 100 was found to be adequate for this prospective observational study in order to identify common ADR patterns, compute descriptive statistics, and assess pharmacovigilance awareness with reasonable precision, which is consistent with similar published studies conducted in Indian tertiary care settings.

3.6 Inclusion and Exclusion Criteria

Patients were enrolled based on the following pre-defined criteria:

Inclusion Criteria	Exclusion Criteria
✓ Age 18 years and above	✗ Critically ill patients in the Intensive Care Unit (ICU) or requiring emergency resuscitation
✓ Receiving at least one prescribed medication during the study period	✗ Unconscious or deeply sedated patients unable to respond to the questionnaire
✓ Conscious and able to communicate clearly in English or the local language	✗ Patients with psychiatric illness or cognitive impairment preventing valid responses
✓ Willing to provide written informed consent for study participation	✗ Patients who were unwilling to participate or who withdrew consent at any stage

3.7 Data Collection Procedure

Data was gathered prospectively using a standardised, pre-designed, three-section data collection form made specifically for this study. Prior to each interview, patients were informed about the purpose and voluntary nature of the study, and formal informed consent was obtained. Each interview was conducted one-on-one at the patient's bedside to ensure patient privacy, confidentiality, and data accuracy.

Section A of the data collection form contained the patient identifying code, age, gender, primary diagnosis, department, and total number of currently prescribed medications. By asking patients if they had experienced any side effects after taking a medicine, Section B assessed the frequency of adverse drug reactions (ADRs). When an adverse drug reaction (ADR) was reported, it included information about the type of reaction (nausea, vomiting, rash, headache, dizziness, diarrhoea, or others), the suspected causative medication, the severity of the reaction (mild, moderate, or severe), and the clinical outcome (recovered, recovering, or not recovered). A seven-item pharmacovigilance awareness questionnaire (Q1–Q7) in Section C evaluated patients' understanding of adverse drug reactions (ADRs), awareness of reporting mechanisms, past reporting behavior, and desire to learn more about ADR reporting.

Throughout the research period, all interviews were conducted by the same investigator to ensure inter-rater consistency. Current prescription charts and patient medical records were reviewed concurrently to confirm self-reported information regarding medications and diseases. Other than the anonymised ID code, no patient-identifying information was included in the data collection forms.

3.8 ADR Assessment

Reported adverse reactions were categorized based on the nature of clinical presentation. Severity of each identified ADR was graded according to the following classification:

Grade	Severity	Clinical Description
Grade 1	Mild	Symptoms are self-limiting, require no specific treatment, and do not interfere significantly with the patient's daily functioning.
Grade 2	Moderate	Symptoms require medical intervention or a change in therapy; may cause some disruption to daily activities but are not life-threatening.
Grade 3	Severe	Symptoms are incapacitating, potentially life-threatening, require immediate medical attention, or result in significant patient harm.

A standardised measure for evaluating causality was not specifically used in the current investigation. Reactions reported by patients were noted, and if clinical records were accessible, they were confirmed. If formal causality evaluation is required in later stages of this study, the Naranjo Adverse Drug Reaction Probability Scale is recommended as the standard validated instrument.

3.9 Statistical Analysis

After all collected data was entered into Microsoft Excel, descriptive statistical analysis was carried out. The data were displayed as absolute frequencies (counts) and relative frequencies (percentages) for all categorical variables, including gender, ADR occurrence, ADR type, severity categorisation, clinical outcome, and responses to the seven pharmacovigilance awareness questions (Q1–Q7). Continuous data, such age and the quantity of medications each patient took, were summarised using means. The data were organised into summary tables and displayed using pie charts and bar charts to facilitate simple visual comprehension. No inferential statistical tests were employed because the primary objective of this study was descriptive.

3.10 Ethical Considerations

The study was carried out in accordance with the ethical principles of the Declaration of Helsinki and the applicable Indian Council of Medical Research (ICMR) guidelines for biomedical research involving human beings. All recruited

patients gave written informed consent before to participation. Patients were informed that participation in the study was entirely voluntary and that it would not interfere with their ability to continue receiving medical treatment.

Patient confidentiality was strictly maintained during the experiment. No personally identifying information, like name, address, or phone number, was included in the data collection forms. Participants were only identified by their anonymised patient ID numbers. The securely stored data was only accessible to the primary investigator. The data will be displayed in aggregate form to ensure that no particular patient may be identified from the published results.

Note: The Ethics Committee of Malla Reddy Hospital and Malla Reddy College of Pharmacy must get Institutional Ethics Committee (IEC) approval before starting data collecting. The date and approval reference number should be placed here after receipt.

RESULTS

A total of 100 patients were enrolled in this study. All participants met the pre-defined inclusion criteria and completed the structured data collection form in full.

4.1 Demographic Characteristics

There were a total of 100 patients in this study. Of these, 45 (45%) were men and 55 (55%) were women (Figure 1). Thirty-two (32%) of the research participants were between the ages of 31 and 45. Twenty-seven (27%) of the participants were between the ages of 46 and 60, while twenty-five (25%) were above 60. The youngest age group, those between the ages of 18 and 30, had sixteen (16%) participation. The mean age of the research sample was in the mid-adult range, which is in line with the typical inpatient demographics of the general medicine ward.

4.2 ADR Occurrence and Distribution

With 50 out of 100 patients reporting adverse drug reactions, the study population's ADR prevalence was 50%. Among the 50 patients who reported an adverse drug response (ADR), dizziness was the most frequent occurrence, occurring in 11 patients (22%), followed by nausea in 10 patients (20%) and rash in 8 patients (16%). Vomiting and diarrhoea were reported by five people (10% each). Four patients (8% each) suffered headaches and pedal oedema, while three individuals (6%) reported experiencing gastritis. The distribution of ADR types is displayed in Table 2 and Figure 2.

ADR Prevalence: ADRs were reported in 50 of 100 patients — a prevalence rate of 50.0% in the study population.

4.3 Severity Classification of ADRs

Twenty-two (44%) of the fifty patients who experienced negative drug reactions had mild reactions, seventeen (34%) had moderate reactions, and eleven (22%) had severe reactions. The majority of ADRs were mild, indicating that over half of the reported reactions were self-limiting and did not require extensive therapeutic intervention. The distribution of ADR severity is displayed in Table 3 and Figure 3.

4.4 Pharmacovigilance Awareness Among Participants

The pharmacovigilance awareness questionnaire (Q1–Q7) was distributed to each of the 100 participants. All 100 patients (100%) correctly acknowledged that drugs can occasionally have negative side effects (Q1). Fifty-two percent of patients cited "adverse drug reactions" (Q2). Fifty patients (50%) were aware that ADRs might be formally reported (Q3). Only 17 people (17%) had ever reported a side effect to a healthcare provider, indicating a serious gap between awareness and practice (Q4). 45% of patients reported knowing where to report adverse drug reactions (ADRs) (Q5). Reporting adverse drug reactions (ADRs) enhances patient safety, according to 79 patients (79%) (Q6). Eighty-six patients (86%) said they would like further information on reporting adverse drug reactions (Q7). The complete awareness profile is summarized in Table 4 and Figure 4.

4.5 Patient Awareness of ADR Reporting

When questioned directly about their understanding of ADR reporting as a formal process, 50 out of 100 patients (50%) said that they were aware that adverse drug reactions might be reported to a healthcare authority. Of the remaining patients, half were unaware that adverse medication responses might be reported. This result, which is consistent with the response pattern observed in Q3 of the pharmacovigilance awareness questionnaire, emphasises the gap between experiencing an adverse reaction and being aware of the official channels by which such responses should be reported.

ADR Reporting Awareness	Frequency (n)	Percentage (%)
Aware (Yes)	50	50%
Not Aware (No)	50	50%
Total	100	100%

5. DISCUSSION

The current prospective observational study was conducted among 100 inpatients of the Department of General Medicine, Malla Reddy Hospital, Hyderabad, with the dual objectives of estimating the incidence of adverse drug responses and evaluating patient-level pharmacovigilance knowledge. Below, the findings are analysed in light of published literature.

5.1 ADR Prevalence

The study's overall ADR prevalence of 50% (50 out of 100 patients) indicates that medication-related side effects are rather frequent among general care inpatients. This outcome emphasises the significant impact of pharmaceutical costs on hospital patient safety. The prevalence found in this study may be higher than several previously reported estimates

from Indian and international hospital-based studies because of the prospective design of the current study, which is known to improve ADR detection compared to retrospective approaches because clinicians and investigators actively sought and documented reactions at the point of care rather than relying on discharge records or passive spontaneous reporting [1].

In a groundbreaking prospective study covering hospital in-patient occurrences, Davies et al. found an ADR incidence of 14.7% [1]. The FORWARD study found similar outcomes in hospital wards throughout Europe [2]. According to a prospective research carried out at a rural tertiary care teaching hospital in India, around 3% of all hospitalised patients experienced adverse drug reactions (ADRs). But when the investigation was restricted to individuals taking high-risk drug groups, such as chemotherapeutic drugs, this number increased dramatically [3]. The greater prevalence in our research may be explained by the diverse diagnostic mix of a general medicine ward, which includes illnesses including diabetes, hypertension, infections, and chronic respiratory illness, all of which require several concurrent medications. The 50% percentage is also in line with research results where polypharmacy patients were over-represented in the study population.

5.2 Common ADR Types

Among the 50 patients who reported adverse drug reactions (ADRs), dizziness was the most frequent reaction (22%), followed by nausea (20%) and rash (16%). Of those affected, 10% had diarrhoea and vomiting, 8% had pedal oedema, 8% had headaches, and 6% had gastritis.

Antibiotics, diuretics, and antihypertensives like amlodipine and enalapril—all of which are known to cause vestibular and cardiovascular-mediated dizziness—are the drug classes that are most often given in general medicine wards, and this is consistent with the incidence of dizziness [1]. Nausea, the second most common reaction, is also expected due to the high prescription rates of metformin, antibiotics, and iron supplements among the research sample, all of which have well-established gastrointestinal side effect profiles [3]. Rash, which accounts for 16% of adverse medication events, is consistent with the skin reactions linked to antibiotics that are often reported in pharmacovigilance literature, particularly when sulfonamides and beta-lactam antibiotics are involved [2]. Pedal oedema (8%) is consistent with the known fluid retention linked to calcium channel blockers and amlodipine, a drug often used for hypertension in this population. Gastritis is one recognised adverse effect of corticosteroids and non-steroidal anti-inflammatory drugs (NSAIDs), both of which are often used in general medicine practice (6%). The overall distribution of ADR types in our study is in line with other hospital-based prospective studies carried out globally and in India [9].

5.3 Severity Classification of ADRs

44% of the 50 patients who reported adverse medication responses were classified as mild, 34% as moderate, and 22% as severe. The fact that most ADRs were mild is encouraging since it shows that very few individuals had the most severe and potentially lethal reactions.

Numerous factors might account for this distribution. The study's prospective design and daily patient follow-up allowed for the early discovery of nascent reactions before they may worsen. In settings with proactive pharmacovigilance monitoring, reactions are more likely to be identified and treated in their mild or early phases, delaying their progression to moderate or severe grades [8]. Additionally, patients in a supervised inpatient environment benefit from prompt nurse evaluation, regular prescription review, and meticulous clinical monitoring, all of which support early treatment. The relatively short research duration of one month may have contributed to the higher percentage of moderate responses because some delayed-onset or cumulative adverse drug reactions (ADRs), such as drug-induced organ damage, might not have shown during the observation window.

Notably, though, 22% of ADRs were classified as severe. This percentage—11 out of 100 enrolled patients—indicates a non-trivial burden of significant drug-related harm, even in a general practice setting. Similar severity distributions have been observed in tertiary care studies in India, where antibiotics and cardiovascular drugs were associated with 15–25% of reported adverse drug reactions (ADRs) [3][9].

5.4 Pharmacovigilance Awareness and Reporting Behaviour

The study's pharmacovigilance awareness results reveal a complex and clinically significant pattern: while patients demonstrated a high awareness of the potential side effects of medications, their actual reporting behaviour and knowledge of formal ADR reporting mechanisms remained notably low.

At the most fundamental level, all 100 participants (100%) correctly recognised that drugs can have negative consequences (Q1), demonstrating a common experience with drug-related damage. However, this cursory knowledge did not lead to a more profound comprehension of pharmacovigilance. Only 52% of respondents had heard of the term "adverse drug reactions" (Q2), and only 50% of respondents were aware that ADRs may be formally reported (Q3). The most shocking discovery was that just 17% of patients had ever told a medical practitioner about a side effect (Q4). This result shows a substantial gap between awareness and practice and is in line with the global literature on ADR underreporting [4].

Adisa and Omitogun's evaluation of patients in basic healthcare facilities in Nigeria revealed that less than one-fifth of those who had experienced ADRs had ever reported them to a medical professional [4]. This result is almost identical to the 17% found in the present investigation. Similarly, Suke et al.'s systematic review and meta-analysis of 28 Indian studies found that more than 55% of the population under study was not aware of the Pharmacovigilance Programme of India (PvPI) and that a significant portion of health professionals, let alone patients, lacked practical knowledge of how to report an adverse drug reaction (ADR) [7]. These findings all suggest that the national pharmacovigilance system is structurally deficient in patient participation.

Positively, 79% of participants believed that ADR reporting enhances patient safety (Q6), and 86% of participants expressed a willingness to learn more about ADR reporting (Q7). This positive attitude profile suggests that hospital-

level organised awareness initiatives have a significant deal of potential to close the awareness-to-action gap and that patients are receptive to targeted pharmacovigilance education. A cross-sectional interventional study published in *Frontiers in Pharmacology*, which demonstrated that structured patient education on ADR reporting significantly improved awareness scores and self-reported willingness to report, directly supports the case for institutionalising patient-facing pharmacovigilance education [10].

Key awareness gap: 100% of patients knew medicines can cause side effects — but only 17% had ever reported one. This disparity defines the central challenge for patient-level pharmacovigilance.

5.5 Importance of Pharmacovigilance and Implications of Practice

The World Health Organization (WHO) defines pharmacovigilance as the study and practice of identifying, assessing, understanding, and preventing adverse drug reactions [7]. This definition captures the four pillars of an effective drug safety system: detection, which relies on robust spontaneous and active reporting; assessment, which comprises clinical and epidemiological analysis of reported signals; understanding, which transforms signals into mechanistic and population-level knowledge; and prevention, which turns that knowledge into interventions pertaining to prescription, regulation, and patient education.

The Pharmacovigilance Programme of India (PvPI), which is supervised by the Indian Pharmacopoeia Commission (IPC) under the auspices of the Central Drugs Standard Control Organization (CDSCO), has greatly expanded its ADR monitoring infrastructure, with 976 active ADR Monitoring Centers currently operating throughout the country [5]. Despite this infrastructural growth, patient-initiated complaints remain relatively low, and healthcare personnel account for the great majority of ADR reports. The results of the current study provide direct, prospective, hospital-level evidence of this engagement gap and emphasise the need for patient-centered pharmacovigilance interventions within PvPI's outreach strategy. Only 17% of patients had ever reported an adverse drug reaction (ADR), and only 45% knew where reporting could be done.

Effective pharmacovigilance has various tangible benefits beyond a single patient's safety. Patient-reported data, which frequently covers symptom load, quality-of-life effect, and reaction length that professional reports alone do not reflect, enhances the pharmacovigilance database with therapeutically valuable information at the signal detection level [10]. A large number of ADR reports allows CDSCO and WHO's international program partners to identify previously unidentified drug-drug interactions, population-specific susceptibilities, and dose-response relationships that may necessitate label updates or modifications to prescribing guidelines at the regulatory level [8]. Hospital-based ADR monitoring programs, like the one suggested in this study, improve prescribing quality, decrease avoidable ADR recurrence, and foster a culture of medication safety at the institutional level by establishing a feedback loop between clinical pharmacists, prescribers, and patients.

Malla Reddy Hospital and other comparable tertiary care institutions in Telangana are immediately impacted by the study's findings. The 50% ADR prevalence observed here, combined with only 17% patient-level reporting, indicates a clear institutional priority: structured patient education on ADR recognition and reporting should be incorporated into routine admission counselling, medication dispensing interactions, and discharge instructions. Practical, low-cost interventions that have the potential to greatly improve ADR reporting rates and, consequently, patient safety outcomes at the institutional and regional levels include clinical chemists' bedside counselling, the distribution of multilingual patient information leaflets on ADR reporting, and awareness camps targeted at high-risk drug users, such as those taking antibiotics, antihypertensives, and antidiabetic medications.

6. LIMITATIONS OF THE STUDY

Even though the current study was conducted with careful regard to methodological rigour, there are a number of intrinsic limitations that should be acknowledged when interpreting the findings. These limitations provide important context for the data's scope and generalisability and recommend future research directions, but they do not invalidate the findings.

1. Single Centre Study

This study was conducted only in the General Medicine Department of Malla Reddy Hospital in Hyderabad. The patient demographic, ailment mix, prescription trends, and institutional practices of a particular facility may not be typical of other hospitals in Telangana, India, or of other socioeconomic and geographic locations.

***Implication:** Since the results may have limited external validity, they should be considered institution-specific findings. Multi-center studies would be required to draw broad conclusions about the prevalence of adverse drug reactions (ADRs) and pharmacovigilance expertise at the regional or national level.*

2. Limited Sample Size

Over the course of a month, 100 patients were enrolled using a consecutive sampling approach. This sample size is appropriate for a descriptive observational study, but it is inadequate for statistically significant subgroup analyses, including comparing the incidence of adverse drug reactions (ADRs) across certain disease categories, age groups, or drug classes.

***Implication:** The results should be seen as suggestive and preliminary. Larger sample sizes in future studies would allow for more precise prevalence estimates and inferential statistical comparisons.*

3. Short Study Duration

Data was collected over the course of a month. This limited time frame may not capture adverse drug reactions (ADRs) with delayed start, cumulative dose-dependent toxicities, or responses associated with long-term drug use, such as

drug-induced organ damage, nephrotoxicity, or hepatotoxicity, which may only become clinically apparent after weeks or months of treatment.

Implication: *The reported ADR range in this study most likely reflects early-onset and acute reactions. A extended monitoring period of three to six months would provide a more complete picture of the ADR burden in this patient sample.*

4. Reliance on Patient Self-Reporting

The primary technique for collecting ADR data in this investigation was structured patient interviews. Patients may have underreported or misattributed symptoms, particularly those with mild or sluggish onset, due to poor memory, inadequate health literacy, or the tendency to normalise moderate discomforts as an expected element of their illness rather than a drug-related reaction.

Implication: *This increases the risk of recall bias and might lead to an underestimation of the true incidence of ADRs. If future study is supported by objective clinical indicators such as lab findings, nursing notes, or unpleasant events recorded by physicians, it may be more accurate.*

5. Absence of Formal Causality Assessment

The relationship between the reported adverse responses and the suspected medications was not explicitly examined using a validated technique, such as the Naranjo Adverse Drug Reaction Probability tool or the WHO-UMC causality evaluation system. Reactions were reported based on patient accounts and clinical record reviews without the use of likelihood grading.

Implication: *Without a methodical causality assessment, it is hard to distinguish clearly between likely, prospective, and definite ADRs. Future studies should employ the Naranjo scale or a similar tool to enhance the pharmacological validity of reported responses.*

6. Restriction to a Single Department

The study was restricted to the general medicine department and did not include patients from high-risk specialities such as oncology, nephrology, cardiology, or the intensive care unit—departments known to have higher ADR incidence due to the use of chemotherapeutic, immunosuppressive, and narrow therapeutic index drugs.

Implication: *The ADR categories and severity distribution shown here may underestimate the overall hospital-wide ADR burden. Expanding the study's scope to include additional departments would yield a more comprehensive institutional pharmacovigilance profile.*

7. Cross-Sectional Awareness Assessment

Pharmacovigilance awareness was assessed at one stage of the patient's hospital stay using a closed-ended yes/no questionnaire. This approach is useful, but it doesn't assess whether awareness translates into consistent reporting behaviour after discharge or capture the scope, precision, or origin of the patient's knowledge.

Implication: *A longitudinal approach including pre- and post-intervention assessments, as well as the addition of open-ended questions and knowledge-testing items, may yield richer data on the quality and durability of pharmacovigilance awareness.*

8. Exclusion of Critically Ill and Psychiatric Patients

Critically ill ICU patients and those with mental illness or cognitive impairment were excluded from the research. Ironically, due to polypharmacy, changed drug metabolism, and complex treatment regimens, these individuals are among the most susceptible to significant adverse drug reactions (ADRs).

Implication: *The distribution of ADR frequency and severity shown here may not accurately reflect the most vulnerable hospital subpopulations. Specialised study designs with appropriate precautions would be needed to document these communities' experiences with ADR.*

7. CONCLUSION

The current prospective observational study found that 50% of the study group had ADRs, indicating a considerable prevalence of adverse medication reactions among hospitalised patients. The majority of adverse drug reactions (ADRs) were mild, and rash, nausea, and dizziness were the most frequent side effects. Concurrently, the study revealed that formal pharmacovigilance awareness remained incredibly low: only 52% had heard of adverse drug reactions (ADRs), only 50% knew that reactions could be reported, and only 17% had ever reported a side effect to a medical professional, despite the fact that all patients agreed that medications can have adverse effects.

These findings demonstrate a substantial and clinically relevant disparity between patients' usage of formal reporting procedures and their experiences with adverse drug reactions. Underreporting adverse reactions makes the Pharmacovigilance Programme of India (PvPI) less effective and makes it more difficult for regulatory agencies to find novel drug safety indicators. The 50% ADR frequency on a general medicine ward demonstrates that medication-related harm is a widespread clinical reality that necessitates institutional-level treatment and is not exclusive to high-risk specialities.

Structured patient education on ADR detection and reporting should be included into routine hospital care through multilingual patient information brochures, clinical chemists' bedside counselling, and institutional awareness campaigns targeted at high-risk drug users. Raising patient knowledge of pharmacovigilance has the potential to greatly boost ADR reporting rates, enhance drug safety monitoring, and eventually result in safer pharmaceutical usage throughout the healthcare system, all of which are in accordance with the goals of the World Health Organization and PvPI.

"The discrepancy between the 100% of people who are aware that medications have adverse effects and the 17% who actually report them is a systemic issue rather than just a knowledge issue. Education, institutional will, and patient empowerment are necessary to bridge it.

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TABLES

Table 1: Demographic Characteristics of Study Participants (n = 100)

Characteristic	Category	Frequency (n)	Percentage (%)
Gender	Male	45	45%
	Female	55	55%
Age Group	18–30	16	16%
	31–45	32	32%
	46–60	27	27%
	> 60	25	25%

Table 2: Distribution of Adverse Drug Reactions Among Affected Patients (n = 50)

ADR Type	Frequency (n)	Percentage of ADR Patients (%)
Dizziness	11	22%
Nausea	10	20%
Rash	8	16%
Vomiting	5	10%
Diarrhea	5	10%
Pedal Edema	4	8%
Headache	4	8%
Gastritis	3	6%
Total	50	100%

Table 3: Severity Classification of Adverse Drug Reactions (n = 50)

Severity	Frequency (n)	Percentage (%)
Mild	22	44%
Moderate	17	34%
Severe	11	22%
Total	50	100%

Table 4: Pharmacovigilance Awareness Responses Among Study Participants (n = 100)

Question	Question Summary	Yes (n)	Yes (%)	No (n)	No (%)
Q1	Do medicines sometimes cause side effects?	100	100%	0	0%
Q2	Have you heard of adverse drug reactions (ADRs)?	52	52%	48	48%
Q3	Do you know that ADRs can be reported?	50	50%	50	50%
Q4	Have you ever reported a side effect?	17	17%	83	83%
Q5	Do you know where ADRs can be reported?	45	45%	55	55%
Q6	Do you think reporting ADRs improves patient safety?	79	79%	21	21%
Q7	Would you like more info about ADR reporting?	86	86%	14	14%

Table 5: Comparison of ADR Prevalence Across Selected Studies

Study	Year	Setting	ADR Prevalence / Key Finding
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<i>Davies et al. (2009)</i>	2009	Tertiary hospital, UK	14.7% of patient-episodes
<i>FORWARD Study — Moretti et al.</i>	2018	Hospital wards, Europe	Antibiotics most implicated; structured reporting increased detection
<i>Pirmohamed et al. (India)</i>	2010	Rural tertiary care, India	~3% overall; rises with polypharmacy
<i>Saveetha Medical College, Chennai</i>	2024	Tertiary care, South India	252 ADRs over 5 years; anti-infectives led
<i>Present Study</i>	2026	General Medicine, MRCP/Hyderabad	50% prevalence — prospective real-time detection

FIGURES

Figure 1: Gender Distribution of Study Participants — Males 45%, Females 55%

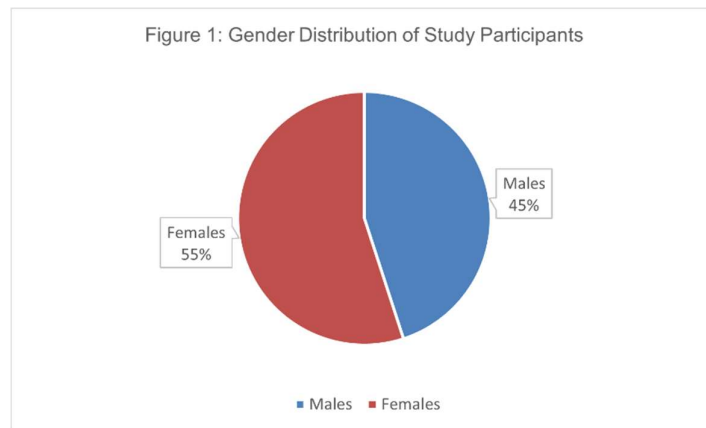


Figure 2: Distribution of Adverse Drug Reactions — Dizziness was the most common ADR (n=11)

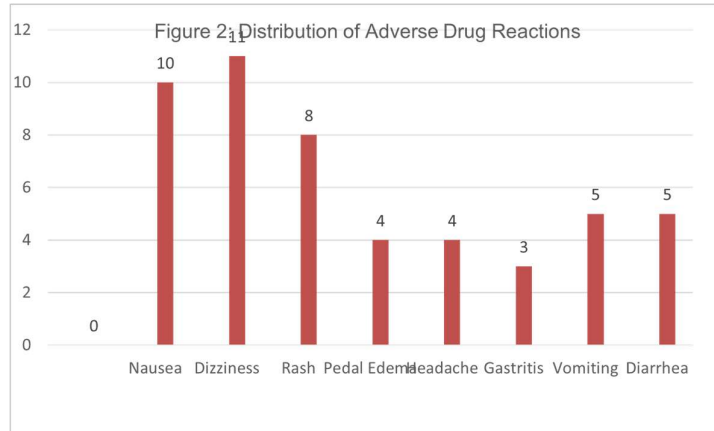


Figure 3: Severity Classification of ADRs — Mild 44%, Moderate 34%, Severe 22%

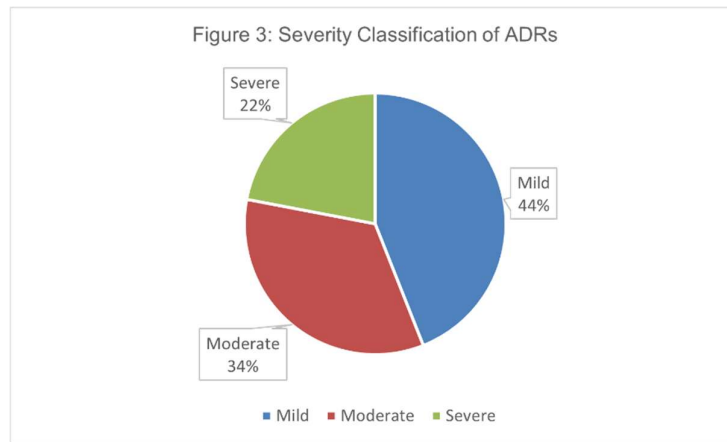


Figure 4: Pharmacovigilance Awareness Among Participants — Number of 'Yes' responses per question

