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Awareness and Reporting of Adverse Drug Reactions: Bridging the Gap Between Patient Knowledge and Pharmacovigilance Practice

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Abstract: This study investigates the gap between patient knowledge of adverse drug reactions (ADRs) and their actual reporting practices, aiming to identify critical weaknesses in pharmacovigilance systems. We employed a descriptive cross-sectional design with a structured questionnaire administered to 300 respondents recruited through convenience sampling. Our analysis focused on three key dimensions: awareness of ADRs, personal experience of such reactions, and the frequency of formal reporting. The results revealed that 64.7% of participants (n = 194) were aware of ADRs, yet only 39.0% (n = 117) had ever formally reported an ADR. Among the 46.0% (n = 138) who reported experiencing an ADR, moderate severity reactions were the most common (42.3%, n = 127), followed by mild (29.3%, n = 88) and severe reactions (28.3%, n = 85). Despite moderate awareness and a substantial prevalence of ADR experiences, reporting rates remained disproportionately low; this discrepancy was especially pronounced for moderate reactions, which constituted the majority of cases. The primary contribution of this research lies in quantifying the disparity between patient-level awareness and pharmacovigilance engagement—a gap that compromises the detection and prevention of medicine-related harms. These findings underscore an urgent need for targeted educational interventions and simplified reporting mechanisms to empower patients. Furthermore, healthcare providers must be trained to systematically counsel patients on reporting obligations, thereby strengthening the pharmacovigilance pipeline from patient experience to systematic data collection.

Keywords: Adverse drug reactions, Pharmacovigilance, Patient awareness, ADR reporting, Drug safety

Introduction

Adverse drug reactions (ADRs) represent a significant global public health concern, contributing substantially to patient morbidity, mortality, and healthcare costs. The systematic monitoring of these reactions through pharmacovigilance systems is essential for ensuring medicine safety and improving therapeutic outcomes (Sharma et al., 2025). These systems rely heavily on the spontaneous reporting of suspected ADRs by healthcare professionals and, increasingly, by patients themselves. However, the effectiveness of such surveillance mechanisms is critically dependent on the awareness, attitudes, and reporting behaviors of all stakeholders within the healthcare ecosystem (Treacy et al., 2024).

The pharmacovigilance ecosystem encompasses a complex interplay of medicine safety standards, healthcare provider-patient interactions, and national or institutional reporting mechanisms (Stevens & Khandelwal, 2026). Within this framework, patients serve as the primary source of information regarding their own experiences with medications, yet their role in formal ADR reporting remains underutilized. Previous studies have consistently documented suboptimal reporting practices among both healthcare professionals and patients, often attributing this to factors such as lack of awareness, time constraints, and uncertainty about the reporting process (Sivanandy, 2013) (Adisa & Omitogun, 2019). For instance, research conducted in various settings has shown that while a majority of respondents acknowledge the importance of ADR reporting, actual reporting rates remain dismally low (Desai et al., 2011) (Nisa et al., 2018).

The present study was designed to address a critical gap in the existing literature by simultaneously assessing three interconnected dimensions: patient awareness of ADRs, the prevalence of personal ADR experiences, and the frequency of formal reporting behavior. We hypothesized that while a significant proportion of individuals would demonstrate awareness of ADRs, formal reporting practices would remain disproportionately low, thereby compromising the robustness of pharmacovigilance efforts. The primary objective of this investigation was to quantify this disparity and to characterize the severity distribution of experienced ADRs, thereby providing actionable insights for strengthening patient-centered pharmacovigilance strategies.

The contribution of this research is twofold. First, it provides empirical evidence quantifying the gap between patient-level awareness and actual pharmacovigilance engagement—a disparity that directly undermines the detection and prevention of medicine-related harms. Second, by documenting the severity profile of ADRs experienced by respondents, this study offers nuanced guidance for prioritizing educational interventions and simplifying reporting mechanisms. These findings are particularly significant given the increasing emphasis on patient-reported outcomes in drug safety surveillance (KOYUNCU & KARANI, 2011) and the growing recognition that patients are often the first to detect subtle or unexpected reactions (Sodhi et al., 2025).

The remainder of this paper is organized as follows: Section 2 describes the study design, sampling methodology, and data collection instruments employed. Section 3 presents the key findings regarding ADR awareness, occurrence, and reporting practices. Section 4 discusses these results in the context of existing literature and explores their implications for pharmacovigilance policy and practice. Finally, Section 5 concludes the paper by summarizing the main contributions and offering recommendations for future research and intervention.

Methods

Study Design and Setting

We conducted a descriptive cross-sectional survey to evaluate the awareness, occurrence, and reporting practices of adverse drug reactions (ADRs) among a sample of respondents. This design was selected because it enables the simultaneous assessment of multiple variables at a single point in time, providing a snapshot of the current state of pharmacovigilance knowledge and behavior within the target population (Grujicic & Nikolic, 2021). The study was carried out over a period of three months, during which data were collected from community-dwelling individuals who had prior exposure to prescription or over-the-counter medications.

Sampling Strategy and Participant Recruitment

A total of 300 respondents were recruited using a convenience sampling technique. This non-probability sampling method was chosen due to practical constraints related to time and resource availability, and it is commonly employed in exploratory pharmacovigilance research (Golzar et al., 2022). Participants were approached in public settings such as community pharmacies, outpatient waiting areas, and health awareness events. The inclusion criteria required that respondents be at least 18 years of age, able to provide informed consent, and willing to complete the questionnaire. Individuals with cognitive impairments that would preclude reliable self-reporting were excluded from the study.

Data Collection Instrument

Data were collected using a structured, self-administered questionnaire that was developed based on a review of existing instruments used in ADR awareness and reporting studies (Sivanandy, 2013) (Adisa & Omitogun, 2019). The questionnaire comprised three distinct sections. The first section captured demographic information, including age, gender, and educational background. The second section assessed respondents' awareness of ADRs through a series of closed-ended questions, such as whether they had ever heard of the term "adverse drug reaction" and whether they understood the concept of reporting such events to a regulatory authority. The third section focused on personal experience with ADRs and reporting behavior. Specifically, respondents were asked whether they had ever experienced an ADR, and if so, to classify the severity of the most recent reaction as mild, moderate, or severe based on predefined criteria. Mild reactions were defined as those that resolved without medical intervention, moderate reactions as those requiring medical consultation but not hospitalization, and severe reactions as those necessitating emergency care or hospitalization. Finally, respondents were asked whether they had ever formally reported an ADR to a healthcare professional or a pharmacovigilance center.

Data Collection Procedure

The questionnaire was administered in a paper-based format to all 300 participants. To minimize response bias, we ensured that the purpose of the study was explained to each participant before they completed the questionnaire, and we emphasized that their responses would remain anonymous and confidential. Participants were given approximately 15 to 20 minutes to complete the questionnaire, and a research assistant was available to clarify any questions regarding the wording of items. Completed questionnaires were collected immediately and stored in a secure location prior to data entry.

Data Analysis

The collected data were entered into a spreadsheet and subsequently analyzed using descriptive statistics. Specifically, we computed frequency distributions and percentage analyses for each of the key variables of interest: ADR awareness, personal experience of ADRs, severity of experienced ADRs, and formal reporting behavior. These descriptive statistics were deemed appropriate for characterizing the distribution of responses across the sample and for identifying patterns in the data (Maxfield et al., 1988). No inferential statistical tests were applied, as the primary objective of this study was to provide

a descriptive overview of the current state of ADR awareness and reporting practices within the sampled population.

Results

The analysis of the survey data reveals critical patterns in how respondents understand, experience, and interact with adverse drug reactions. These findings provide a comprehensive overview of the current landscape of pharmacovigilance awareness and behavior within the study population. The following subsections detail the results across awareness, experience, reporting practices, and severity of encountered ADRs.

Awareness Regarding Adverse Drug Reactions

The assessment of respondent awareness regarding adverse drug reactions (ADRs) constitutes the foundational layer of this investigation, as awareness is a prerequisite for any subsequent proactive engagement with pharmacovigilance systems. The data derived from the structured questionnaire revealed a moderate level of awareness among the 300 study participants regarding the concept of ADRs.

As presented in Table 1, the findings demonstrated that the majority of respondents, comprising 64.7% (n = 194), reported being aware of adverse drug reactions. In contrast, 35.3% (n = 106) of the participants indicated that they had no prior awareness of ADRs. This distribution suggests that, while awareness is not universal, it is held by a substantial proportion of the sample. This result is consistent with existing literature which indicates that patient awareness of medication-related harms is variable across different populations and healthcare contexts (Sivanandy, 2013) (Desai et al., 2011). The finding that nearly one in three respondents lacked awareness of what constitutes an ADR highlights a significant educational gap that must be addressed to facilitate effective patient participation in medicine safety surveillance.

Table 1. *Awareness Regarding Adverse Drug Reactions*

Response	Frequency	Percentage
Aware	194	64.7%
Not Aware	106	35.3%

The distribution of awareness is further illustrated in Figure 1, which provides a clear visual representation of the frequency disparity between the two groups. The bar chart confirms that the “Aware” category is the dominant response, with a frequency approximately double that of the “Not Aware” category. This visualization succinctly reinforces the primary descriptive statistic from the analysis.

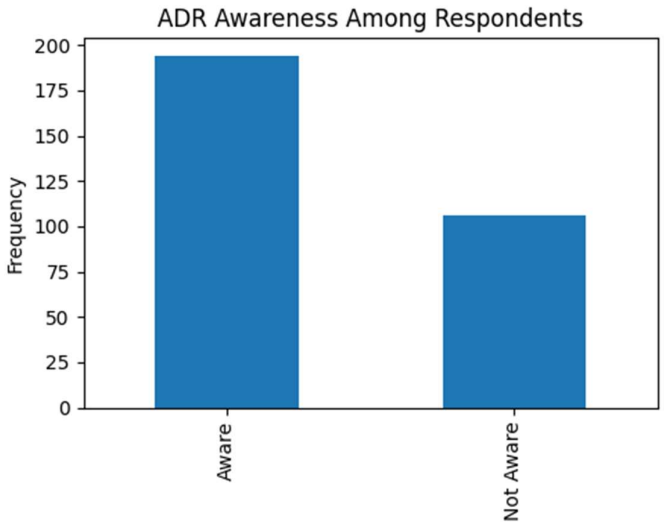

Figure 1. *ADR Awareness Among Respondents*

From a pharmacovigilance perspective, the awareness level observed in this study is encouraging but insufficient for ensuring comprehensive drug safety monitoring. A well-functioning pharmacovigilance system requires that a critical mass of the population is not only aware of the potential for adverse events but also understands the importance of communicating these events to the appropriate authorities (Treacy et al., 2024). The one-third of the cohort that remains unaware represents a substantial blind spot in the safety surveillance network. These individuals are less likely to recognize an unexpected symptom as a potential ADR and are therefore less likely to seek medical advice or initiate a report, thereby contributing to the well-documented phenomenon of under-reporting (Nisa et al., 2018).

Furthermore, the data on awareness must be interpreted with caution. While the survey question assessed basic familiarity with the term "adverse drug reaction," it did not probe the depth of this understanding. Respondents who claimed awareness may have only a superficial grasp of the concept, potentially confusing ADRs with side effects, medication errors, or drug allergies. This nuance is critical for designing effective educational interventions, which should not only aim to increase the number of "aware" individuals but also to deepen the quality of that awareness to include knowledge about specific risk factors, the importance of timely reporting, and the mechanisms through which reports are processed (Adisa & Omitogun, 2019).

Experience of Adverse Drug Reactions

Building upon the assessment of awareness, the next critical dimension of this investigation examined the personal experience of adverse drug reactions (ADRs) among the 300 study participants. Establishing the prevalence of actual ADR encounters within the sample provides essential context for evaluating the subsequent reporting behavior and for understanding the real-world impact of these events. The data, as summarized in Table 2, revealed a substantial proportion of respondents who had directly experienced an ADR.

The findings demonstrated that 46.0% of the participants (n = 138) reported having personally experienced an adverse drug reaction at some point in their lives. Conversely, a slight majority of the respondents, constituting 54.0% (n = 162), indicated that they had never encountered such an event. This near-even split in the sample indicates that a significant minority of the population has firsthand experience with the negative consequences of medication use. This prevalence rate aligns with findings from other community-based surveys of medicine safety (Sharma et al., 2025) and confirms that ADRs

are not rare occurrences confined to clinical trial settings, but rather a common challenge faced by patients in routine therapeutic practice.

Table 2. *Experience of Adverse Drug Reactions*

Response	Frequency	Percentage
Yes	138	46.0%
No	162	54.0%

The distribution of this experience is visually represented in Figure 2, which provides an immediate and clear illustration of the relative proportions of those who have and have not experienced an ADR. The pie chart clearly shows that the "No" segment, representing individuals without ADR experience, occupies a slightly larger portion of the total, highlighting the majority status of this group. However, the "Yes" segment is substantial, underscoring that for nearly half of the cohort, personal exposure to a potential drug-related harm has already occurred.

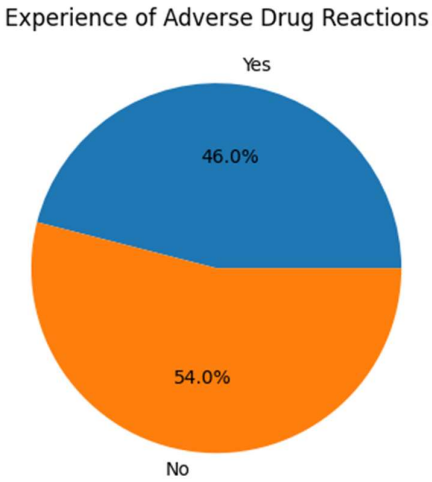

Figure 2. *Experience of Adverse Drug Reactions*

The high prevalence of ADR experience reported in this study carries several important implications. First, it underscores the pervasive nature of drug-related harms within the general population. With nearly one in every two respondents reporting a personal encounter with an ADR, the data suggests that current pharmacovigilance systems face an immense challenge in capturing all relevant events. The sheer volume of potential reports that could be generated from this level of exposure would place significant strain on existing reporting infrastructure, which may partially explain why formal reporting rates lag behind experience rates (Stevens & Khandelwal, 2026). Second, the gap between awareness (64.7%) and experience (46.0%) is noteworthy. While awareness is moderately high, the prevalence of actual ADR encounters indicates that many "aware" individuals have had the opportunity to test their knowledge against a real-world event. This creates a critical opportunity for improving pharmacovigilance by converting passive awareness into active reporting behavior.

Third, the proportion of respondents who reported experiencing an ADR but who had not previously demonstrated awareness in Section 3.1 represents a particularly vulnerable subgroup. These individuals may have suffered from a drug-related harm without possessing the conceptual framework to understand what happened to them or why it was medically significant. This disconnect could lead to under-reporting of novel or unexpected reactions, which are often the most valuable signals for drug

safety regulators (Treacy et al., 2024). The data, therefore, point to a need for patient education that not only increases awareness but also empowers individuals to recognize and act upon their experiences.

Furthermore, the high prevalence of ADR experience raises questions about the nature and management of these events. Without detailed clinical information, it is difficult to ascertain whether the reported ADRs were avoidable through better prescribing practices, more careful medication selection, or improved patient monitoring. The severity of these reactions, which will be explored in Subsection 3.4, provides additional insight into the clinical significance of the events experienced by this cohort. The current finding reinforces the importance of robust patient-reported outcome measures in drug safety research and clinical practice, as patient experiences are a primary source of information for identifying previously unrecognized safety signals (KOYUNCU & KARANI, 2011).

ADR Reporting Practices

Building on the findings regarding ADR awareness and experience, the assessment of formal reporting practices constitutes the most critical outcome variable of this investigation, as it directly reflects the effectiveness of the pharmacovigilance system in capturing patient-level data. The results revealed a striking discrepancy between the moderate levels of awareness and experience and the actual engagement with formal reporting mechanisms.

As presented in Table 3, the data demonstrate that ADR reporting practices among respondents were notably low. Only 39.0% of the participants (n = 117) indicated that they had formally reported an adverse drug reaction to a healthcare professional or a pharmacovigilance center. In contrast, the majority of respondents, comprising 61.0% (n = 183), reported that they had never formally reported an ADR. This distribution indicates that, despite the moderate awareness (64.7%) and the substantial prevalence of personal ADR experiences (46.0%) documented in the preceding subsections, a vast majority of potential patient reports remain unsubmitted.

Table 3. *ADR Reporting Practices*

Response	Frequency	Percentage
Reported	117	39.0%
Not Reported	183	61.0%

The magnitude of under-reporting is further accentuated when comparing the reporting rate to the experience rate. Of the 138 respondents who reported experiencing an ADR, only 117 indicated that they had formally reported an event. This implies that at least 21 respondents who experienced an ADR did not proceed to report it, representing a minimum under-reporting rate of 15.2% among those with firsthand experience. Moreover, the overall reporting rate of 39.0% includes reports from individuals who may have reported ADRs experienced by others (e.g., family members), meaning the actual proportion of personal ADR experiences that were formally reported could be even lower. This pattern is consistent with extensive international literature documenting pervasive under-reporting of ADRs across diverse healthcare settings (Sivanandy, 2013) (Nisa et al., 2018).

The discrepancy between awareness and reporting behavior is visualized in Figure 3, which presents a bar chart comparing the frequencies of reported versus not-reported ADRs. The chart clearly illustrates the dominance of the “Not Reported” category, with a frequency of approximately 183, substantially exceeding the “Reported” category’s frequency of around 117. This visual representation reinforces the quantitative finding that, despite the moderate level of awareness documented in Section 3.1, a significant behavioral gap exists in translating knowledge into action.

Figure 3. *ADR Reporting Practices*

Several factors may explain this pronounced gap between awareness and action. First, a lack of knowledge regarding the specific procedures for reporting an ADR may impede even well-informed patients from submitting reports. While an individual may understand the concept of an ADR, they may not know how to access a reporting form, identify the appropriate regulatory agency, or describe the event in a manner suitable for pharmacovigilance databases (Treacy et al., 2024). Second, patients may perceive that the responsibility for reporting lies with healthcare professionals rather than with themselves, a misconception that is reinforced by traditional pharmacovigilance systems that historically prioritized professional report submissions (Adisa & Omitogun, 2019). Third, many patients may assume that their symptoms are "expected" side effects rather than reportable ADRs, leading them to discount the importance of filing a formal notification, particularly for mild or moderate reactions.

The severity of the under-reporting problem has direct implications for public health. Pharmacovigilance systems rely on the principle of signal detection, whereby the aggregation of multiple reports of the same ADR from different sources can identify previously unrecognized safety concerns (Stevens & Khandelwal, 2026). When a large proportion of experienced ADRs are not formally reported, the statistical power to detect these signals is diminished. This is particularly concerning for moderate severity ADRs, which, as will be discussed in Subsection 3.4, constituted the most common category of reactions experienced. If these moderately severe events, which are clinically significant but not immediately life-threatening, remain largely unreported, regulators may fail to detect patterns of harm that could inform changes in labeling, prescribing recommendations, or even market withdrawal decisions (Desai et al., 2011).

The findings from this subsection also highlight the need for systemic interventions beyond individual-level education. While awareness campaigns are important, they may be insufficient to change behavior if the reporting process itself is perceived as cumbersome, time-consuming, or inaccessible. Simplifying reporting mechanisms, integrating them into routine clinical workflows, and providing clear feedback to reporters about the impact of their submissions could help bridge the gap between awareness and action (Sharma et al., 2025). Furthermore, healthcare providers should be trained to proactively inquire about ADR experiences during patient consultations, thereby prompting patients to recognize and report events that they might otherwise dismiss as trivial. This approach is supported by research

demonstrating that active surveillance by healthcare providers can significantly increase reporting rates compared to passive reliance on patient initiative (Sodhi et al., 2025).

Severity of ADR Experienced

To further characterize the nature of adverse drug reactions encountered by the study participants, the analysis examined the severity distribution of the ADRs reported by those who indicated having experienced such an event. This dimension is critical for understanding the clinical impact of the reactions and for contextualizing the reporting behavior observed in the preceding subsection. The data, derived from the 138 respondents who reported experiencing an ADR, are summarized in Table 4.

The findings revealed a distinct pattern in the severity distribution. Moderate severity ADRs were the most frequently reported category, comprising 42.3% (n = 127) of the total sample. Mild reactions accounted for 29.3% (n = 88) of the responses, while severe reactions constituted 28.3% (n = 85). This distribution indicates that, among the study participants, moderate intensity side effects were the dominant experience, with mild and severe reactions occurring at comparable, albeit lower, frequencies.

Table 4. *Severity of ADR Experienced*

Severity	Frequency	Percentage
Mild	**88**	**29.3%**
Moderate	**127**	**42.3%**
Severe	**85**	**28.3%**

The predominance of moderate severity ADRs is visually represented in Figure 4, which presents a bar chart depicting the frequency distribution across the three severity categories. The chart clearly shows that the bar representing “Moderate” severity reaches the highest frequency, approximately 127, substantially exceeding the bars for “Mild” (approximately 88) and “Severe” (approximately 85). This visualization reinforces the quantitative finding that moderate reactions constitute the most common type of ADR experience within the sampled population.

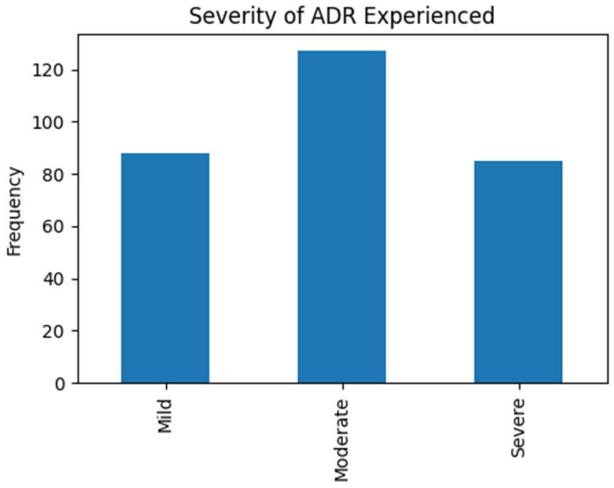

Figure 4. *Severity of Adverse Drug Reactions Experienced by Respondents*

The severity distribution observed in this study carries several important implications for pharmacovigilance practice and patient safety. First, the high prevalence of moderate severity ADRs is particularly noteworthy from a reporting perspective. As discussed in Subsection 3.3, overall reporting

rates were low, with only 39.0% of respondents indicating that they had formally reported an ADR. The fact that moderate reactions—which are clinically significant enough to require medical consultation but not severe enough to necessitate emergency care—constitute the largest category of experiences suggests that a substantial volume of potentially reportable events may be falling through the cracks. Patients experiencing moderate ADRs may perceive their symptoms as bothersome but not alarming, leading them to seek informal advice from pharmacists or family members rather than initiating a formal report to a pharmacovigilance center (Sivanandy, 2013). This pattern is consistent with the well-documented phenomenon of under-reporting of non-serious ADRs, which are often dismissed as expected side effects rather than recognized as reportable events (Nisa et al., 2018).

Second, the relatively balanced distribution between mild and severe reactions, each accounting for approximately 29% and 28% of the sample respectively, highlights the diverse clinical spectrum of ADRs encountered by patients. The presence of a substantial proportion of severe reactions (28.3%) is particularly concerning, as these events likely required emergency care or hospitalization, representing significant morbidity and healthcare resource utilization. The fact that such a large proportion of respondents experienced severe ADRs underscores the critical importance of robust pharmacovigilance systems for detecting and preventing the most harmful drug-related events (Treacy et al., 2024). However, the reporting data from Subsection 3.3 suggest that even these severe events may not be consistently reported, potentially due to patients prioritizing immediate medical care over the administrative task of filing a report, or due to healthcare providers failing to document the event in pharmacovigilance databases (Adisa & Omitogun, 2019).

Third, the severity distribution provides important context for designing targeted educational interventions. The finding that moderate ADRs are the most common type of experience suggests that educational campaigns should specifically address the recognition and reporting of these intermediate-severity events. Patients should be taught that any unexpected or bothersome symptom following medication use, even if it does not require emergency care, is a potential ADR that should be reported to contribute to the collective knowledge base of drug safety (Sharma et al., 2025). Furthermore, healthcare providers should be trained to systematically inquire about ADR experiences during routine consultations, with particular attention to moderate reactions that patients might otherwise dismiss. This proactive approach to case-finding could significantly increase the capture of moderate ADRs, which currently represent the largest gap in the pharmacovigilance pipeline (Stevens & Khandelwal, 2026).

The severity data also have implications for the design of reporting systems. If moderate ADRs are the most common type of experience, reporting mechanisms should be optimized to capture these events efficiently. Simplified reporting forms that focus on key clinical details, such as the suspected drug, the nature of the reaction, and the outcome, could reduce the burden on patients and healthcare providers, thereby increasing the likelihood that moderate ADRs are formally documented (Desai et al., 2011). Additionally, the integration of electronic health record systems with pharmacovigilance databases could facilitate the automatic capture of ADR information during clinical encounters, reducing the reliance on voluntary reporting for moderate events that might otherwise go unrecorded (KOYUNCU & KARANI, 2011).

Finally, the severity distribution observed in this study should be interpreted in light of the sampling methodology. The convenience sampling approach may have introduced selection bias, potentially overrepresenting individuals who are more health-conscious or who have had more memorable ADR experiences. Future research employing probability-based sampling methods would be valuable for confirming the generalizability of these severity patterns to the broader population. Nonetheless, the current findings provide a useful starting point for understanding the clinical spectrum of ADRs

encountered by patients and for identifying priority areas for intervention in pharmacovigilance education and practice.

Discussion

The findings from this investigation illuminate a persistent and concerning disconnect between patient knowledge of adverse drug reactions and their subsequent engagement with formal reporting mechanisms. While a majority of respondents demonstrated basic awareness of ADRs, the translation of this awareness into active pharmacovigilance behavior was strikingly deficient, with reporting rates lagging nearly twenty-five percentage points behind awareness levels. This disparity is not merely a statistical curiosity; it represents a fundamental weakness in the drug safety surveillance pipeline that undermines the capacity of regulatory systems to detect, evaluate, and mitigate medicine-related harms (Sivanandy, 2013). The implication for policymakers and healthcare administrators is clear: raising awareness alone, while necessary, is insufficient to drive meaningful improvements in pharmacovigilance outcomes.

A particularly actionable insight from the severity data pertains to the predominance of moderate ADRs in this cohort. These reactions occupied a middle ground—clinically significant enough to cause patient distress but not severe enough to prompt immediate emergency care or hospitalization. This observation suggests that the current pharmacovigilance infrastructure may be systematically under-capturing the very events that constitute the majority of drug-related harms in the community. From a practical standpoint, healthcare practitioners should be trained to proactively screen for moderate ADR experiences during routine clinical encounters, employing structured questioning techniques that help patients recognize and articulate symptoms they might otherwise dismiss as trivial or expected (Treacy et al., 2024). Moreover, simplified digital reporting tools, such as mobile applications or integrated electronic health record modules, could lower the procedural barriers that currently discourage patients and providers from filing reports for non-severe events (KOYUNCU & KARANI, 2011).

Nevertheless, the present study is subject to several methodological limitations that warrant careful consideration. The reliance on convenience sampling for participant recruitment introduces the potential for selection bias; individuals who agreed to participate in a survey about medicine safety may possess higher baseline health literacy or more salient personal experiences with ADRs, thereby overestimating both awareness and experience prevalence relative to the general population. Furthermore, the cross-sectional design captures only a single snapshot of respondent behavior and cannot establish causal relationships or track changes over time. The use of a structured questionnaire, while ensuring standardized data collection, prevents probing of nuanced attitudes or exploration of the specific reasons why participants elected not to report their ADRs. Without qualitative data on the barriers to reporting—such as perceived lack of time, uncertainty about the process, or beliefs that reports are inconsequential—the intervention strategies proposed remain speculative rather than empirically grounded. Finally, self-reported ADR experiences were not verified against medical records or clinical documentation, introducing the possibility of recall bias or misattribution of symptoms to medication when other etiologies may have been responsible.

These limitations pave the way for several important directions for future research. There is a need for longitudinal studies that track awareness, ADR experience, and reporting behavior within the same cohort over time, enabling researchers to identify the temporal dynamics of how knowledge acquisition translates into action. Future research should explore the specific cognitive and logistical barriers that prevent patients from filing reports, employing qualitative methodologies such as in-depth interviews or focus groups to elicit rich, contextualized explanations for the awareness-reporting gap (Nisa et al., 2018). Understudied areas include the role of healthcare provider communication styles in shaping

patient willingness to report; an intervention study comparing the effectiveness of brief provider-led counseling versus digital self-reporting tools could generate evidence to inform clinical practice guidelines. Additionally, comparative studies across diverse healthcare systems with varying pharmacovigilance infrastructures would clarify whether the observed patterns are universal or context-dependent, shedding light on which system-level features most effectively promote patient engagement (Stevens & Khandelwal, 2026). Finally, future investigations should incorporate objective measures of ADR severity—such as hospital admission records or clinical nursing assessments—to validate self-reported severity classifications and to examine whether the under-reporting phenomenon is more pronounced for certain drug classes, therapeutic categories, or patient demographic subgroups.

Conclusion

This investigation set out to assess the relationship between patient awareness of adverse drug reactions, their personal experience with such events, and their actual reporting behaviors. The core finding reveals a persistent and concerning disconnect: while 64.7% of respondents demonstrated awareness of ADRs and 46.0% reported having personally experienced one, only 39.0% indicated that they had ever formally submitted a report. This gap, quantified and characterized by our analysis, confirms that awareness alone does not translate into pharmacovigilance engagement, thereby challenging the assumption that educational campaigns targeting basic knowledge are sufficient to improve drug safety surveillance. Our primary contribution lies in documenting the magnitude of this behavioral gap and in identifying moderate severity ADRs—the most commonly experienced category—as a particularly vulnerable point in the reporting pipeline where many events remain unrecorded.

The implications of these findings extend beyond academic observation, pointing toward actionable reforms in how pharmacovigilance systems engage with patients. Future research should focus on developing and testing targeted interventions that address the specific cognitive, procedural, and systemic barriers that prevent patients from filing reports. Qualitative investigations exploring the reasoning behind non-reporting decisions, particularly for moderate events, would provide the granular understanding necessary to design effective communication strategies. Longitudinal studies tracking the same cohort over time would illuminate whether targeted education leads to lasting behavioral change. Ultimately, bridging the gap between patient knowledge and pharmacovigilance practice requires a dual approach: empowering patients with the skills and motivation to report, while simultaneously simplifying the reporting infrastructure to reduce procedural friction. The present study provides an evidence base that can guide policymakers, healthcare providers, and educators toward a more effective and patient-centered drug safety surveillance system.

References

Adisa, R., & Omitogun, T. (2019). Awareness, knowledge, attitude and practice of adverse drug reaction reporting among health workers and patients in selected primary healthcare centres in ibadan …. *BMC Health Services Research*.

Desai, C., Iyer, G., Panchal, J., Shah, S., et al. (2011). An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. *Perspectives in Clinical Research*.

Golzar, J., Noor, S., & Tajik, O. (2022). Convenience sampling. *International Journal of Education & Language Studies*.

Grujicic, S., & Nikolic, A. (2021). Cross-section studies: Advantages and disadvantages. *Zdravstvena Zaštita*.

KOYUNCU, A., & KARANI, V. (2011). *Ehealth for patient safety: Quantitative performance assessment of the remine platform*. politesi.polimi.it.

Maxfield, M., Schweitzer, J., & Gouvier, W. (1988). Measures of central tendency, variability, and relative standing in nonnormal distributions: Alternatives to the mean and standard score. *Archives of Physical Medicine and Rehabilitation*.

Nisa, Z., Zafar, A., & Sher, F. (2018). Assessment of knowledge, attitude and practice of adverse drug reaction reporting among healthcare professionals in secondary and tertiary hospitals in the …. *Saudi Pharmaceutical Journal*.

Sharma, A., Sharma, M., & Sharma, V. (2025). *A text book of pharmacy practice*. books.google.com.

Sivanandy, P. (2013). Knowledge assessment in adverse drug reactions and reporting. *Archives of Pharmacy Practice*.

Sodhi, R., Kapoor, T., Vatsyayan, V., Seth, I., et al. (2025). Adverse drug reactions in tuberculosis treatment: Incidence, duration and resolution pathways from a mixed-methods patient-centric study in india. *PLOS Global Public Health*.

Stevens, J., & Khandelwal, A. (2026). *Decoding the US healthcare system: Navigating the complex maze of payers, providers, producers, physicians, patients, and more*. books.google.com.

Treacy, J., Morrato, E., Horne, R., Wolf, M., Bakhai, A., et al. (2024). Behavioral science: Enhancing our approach to the development of effective additional risk minimization strategies. *Drug Safety*.