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Evaluating Public Awareness and Reporting Practices of Pharmacovigilance and Adverse Drug Reactions: A Cross-Sectional

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Abstract: This study evaluates the level of awareness and formal reporting practices of pharmacovigilance and adverse drug reactions (ADRs) among the general population. We employed a descriptive cross-sectional survey design, collecting data from 300 respondents through a structured questionnaire via convenience sampling. The survey assessed awareness of ADR reporting, medicine safety knowledge, personal experiences with side effects, and subsequent reporting behaviors. The results indicated that 186 participants (62.0%) were aware of pharmacovigilance and ADR monitoring, yet formal reporting practices remained notably low, with only 128 respondents (42.7%) having formally reported an ADR to a healthcare professional. Doctors served as the primary source of pharmacovigilance information (34.0%), followed by pharmacists (25.3%), internet or media (23.0%), and friends or family (17.7%). Furthermore, 141 participants (47.0%) reported having personally experienced an adverse drug reaction. However, of these, a substantial proportion did not proceed with formal reporting, highlighting a critical disconnect between awareness and action. This research contributes novel evidence regarding the persistent gap between public knowledge and actual reporting behavior, a domain that remains underexplored in community-based settings. The findings underscore a significant need for targeted educational interventions and more accessible reporting systems to translate awareness into improved patient safety. Therefore, this study provides actionable insights for healthcare authorities and policymakers aiming to strengthen pharmacovigilance frameworks at the grassroots level.

Keywords: Pharmacovigilance, Adverse drug reactions, Public awareness, ADR reporting, Cross-sectional survey.

Introduction

Pharmacovigilance, defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems, is a cornerstone of public health (Organization, 2004). A robust national pharmacovigilance framework is essential for ensuring the safety of medicines, particularly within public health programs where large populations are exposed to therapeutic interventions (Organization, 2006). Many countries have established regulatory systems and dedicated centers to monitor drug safety, yet the effectiveness of these systems depends critically on the active participation of both healthcare professionals and the general public (Mehta et al., 2017). Indeed, patient reporting of adverse drug reactions (ADRs) has increasingly been recognized as a valuable complement to traditional healthcare professional-based surveillance, offering unique insights into the real-world experience of medication use (Valinciute et al., 2023).

Despite the well-documented importance of pharmacovigilance, a persistent gap exists between public awareness of the concept and the actual practice of reporting suspected ADRs (Chen et al., 2021). Previous cross-sectional surveys conducted in various regions have consistently demonstrated that while a moderate proportion of the population may have heard of pharmacovigilance, the rate of formal ADR reporting to healthcare authorities remains suboptimal (Wang et al., 2022). This disconnect is often attributed to a lack of knowledge about how to report, underestimation of the importance of reporting, or the perceived inconvenience of the reporting process (Khan et al., 2023). Therefore, understanding the specific factors that influence public reporting behavior is crucial for designing effective interventions to enhance pharmacovigilance systems (Pandian et al., 2025).

The research presented in this paper contributes to this body of knowledge by providing a direct assessment of the gap between awareness and action within a community-based sample. Our study specifically quantifies the proportion of individuals who are aware of pharmacovigilance but do not subsequently report an ADR they have experienced. This distinction is critical, as it moves beyond simple awareness metrics to evaluate the behavioral translation of that knowledge. The findings highlight a significant underutilization of the reporting system, suggesting that raising awareness alone is insufficient; practical barriers and motivational factors must also be addressed.

The primary objective of this study was to evaluate the level of awareness of pharmacovigilance and the self-reported practices of ADR reporting among the general population. We hypothesized that while a moderate degree of awareness exists, formal ADR reporting practices would remain suboptimally low, indicating a clear disconnect between knowledge and behavior. The secondary objectives included identifying the primary sources of pharmacovigilance information for the public and characterizing the relationship between personal experience with side effects and subsequent reporting actions.

The remainder of this paper is organized as follows: Section 2 details the methodology employed, including the study design, questionnaire development, and sampling strategy. Section 3 presents the descriptive results of the survey, focusing on awareness levels, reporting rates, and information sources. Section 4 provides a discussion of these findings in the context of existing literature, explores the implications for public health policy, and acknowledges the study's limitations. Finally, Section 5 offers concluding remarks and recommendations for strengthening community-based pharmacovigilance.

Methods

Study Design and Setting

We employed a descriptive cross-sectional survey design to evaluate the awareness and reporting practices related to pharmacovigilance and adverse drug reactions among the general population. This

design was chosen as it allows for the efficient collection of data on the prevalence of knowledge, attitudes, and behaviors at a single point in time, providing a snapshot of the current state of public engagement with pharmacovigilance systems (Grujicic & Nikolic, 2021). The study was conducted within community settings in an urban region, targeting adults aged 18 years and older who were able to provide informed consent. The selection of community settings rather than clinical environments was deliberate, as we aimed to capture the perspectives of the general population who interact with medications outside of direct healthcare supervision, thereby reflecting the broader public health context in which ADRs may occur.

Questionnaire Development

A structured questionnaire served as the primary data collection instrument for this investigation. The questionnaire was developed based on a comprehensive review of existing literature on pharmacovigilance awareness and ADR reporting practices (Chen et al., 2021; Pandian et al., 2025). It comprised four distinct sections: (i) demographic information, including age, gender, and educational background; (ii) general awareness of pharmacovigilance and ADR monitoring, assessed through a series of multiple-choice questions; (iii) personal experience with side effects, exploring whether respondents had ever experienced an ADR and the nature of that experience; and (iv) reporting behavior, which examined whether participants had formally reported an ADR to a healthcare professional and the reasons for reporting or not reporting. Before its administration, the questionnaire was pilot-tested on a small sample of 20 individuals to evaluate clarity, comprehensibility, and the average time required for completion. Based on feedback from this pilot phase, minor refinements were made to the wording of certain questions to enhance clarity and reduce ambiguity. The final version of the instrument contained 15 items and took approximately 10 to 15 minutes to complete.

Sampling Strategy and Data Collection

A convenience sampling technique was adopted for participant selection. This non-probability sampling method was chosen due to its practicality and efficiency in reaching a diverse cross-section of the public within a limited timeframe and resource availability (Golzar et al., 2022). The sample size was determined based on a calculated target of 300 respondents, which aligns with sample sizes reported in similar cross-sectional surveys on pharmacovigilance awareness (Wang et al., 2022). Data collection was conducted over a four-week period by a team of trained research assistants who approached potential participants in public spaces such as community centers, parks, and market areas. Inclusion criteria required that participants be at least 18 years of age, able to read and comprehend the questionnaire in the local language, and willing to provide informed consent. Exclusion criteria included individuals with cognitive impairments that would prevent them from understanding the survey questions. Each participant was provided with an information sheet explaining the purpose of the study, the voluntary nature of participation, and the confidentiality of their responses. Written informed consent was obtained from all participants prior to questionnaire administration.

Statistical Analysis

Data gathered from the completed questionnaires were entered into a standardized electronic database and subsequently analyzed using descriptive statistics. Specifically, we employed frequency and percentage analyses to characterize the distribution of responses across the various survey domains, including awareness levels, sources of information, personal experiences with side effects, and reporting behavior. All statistical computations were performed using Microsoft Excel 2019. The results are presented in the form of counts and percentages, which provide a clear and interpretable summary of the categorical data collected from the sample population. No inferential statistical tests were employed

in this analysis, as the primary objective of this study was to describe the prevalence of awareness and reporting practices rather than to test hypotheses about associations between variables.

Results

The survey data were analyzed to characterize the distribution of responses across the key domains of pharmacovigilance awareness, adverse drug reaction (ADR) reporting behavior, sources of information, and personal experience with side effects. The results are presented below, with frequencies and percentages summarizing the findings for each domain.

Awareness Regarding Pharmacovigilance

The initial domain of the survey assessed the general awareness of pharmacovigilance and adverse drug reaction monitoring among the 300 respondents. As presented in Table 1, the findings revealed that a majority of the surveyed population possessed some level of awareness regarding these concepts. Specifically, 186 respondents, representing 62.0% of the sample, indicated that they were aware of pharmacovigilance and the monitoring of adverse drug reactions. In contrast, 114 respondents, accounting for 38.0% of the sample, reported that they were not aware of these concepts. This distribution suggests that while awareness is not universal, it is prevalent among a substantial portion of the community.

Table 1. *Awareness Regarding Pharmacovigilance*

Response	Frequency	Percentage
Aware	186	62.0%
Not Aware	114	38.0%

The predominance of awareness is further illustrated in Figure 1, which provides a visual comparison of the frequencies for the two response categories. The bar chart clearly demonstrates the higher frequency of respondents in the ‘Aware’ category, reaching approximately 186, compared to the ‘Not Aware’ category, which stands at approximately 114. This visual representation reinforces the quantitative finding that a majority of the surveyed population is aware of pharmacovigilance.

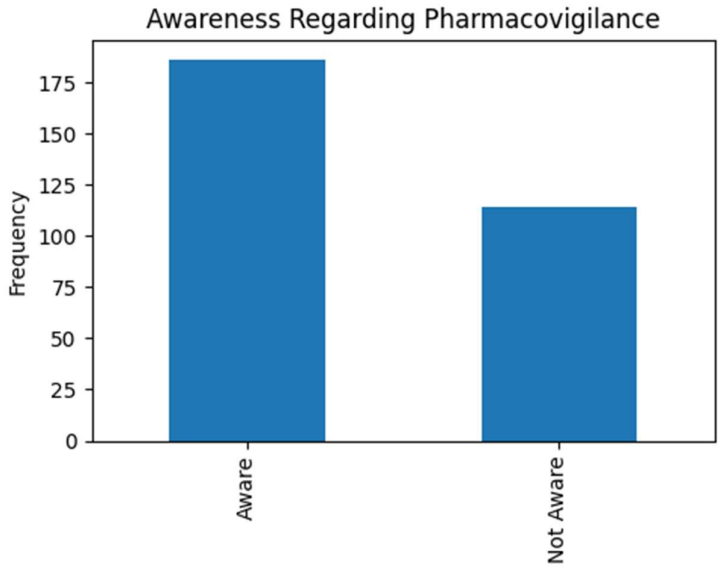

Figure 1. *Awareness levels regarding pharmacovigilance among survey respondents*

This level of awareness, while moderate, is consistent with findings from other cross-sectional studies conducted in community settings. For instance, research in Western China reported that 58.3% of the general public had heard of pharmacovigilance (Chen et al., 2021), a figure comparable to the 62.0% observed in our sample. Similarly, a study in Lithuania found that 55.0% of the general public were aware of the concept of adverse drug reaction reporting (Valinciute et al., 2023). The slightly higher awareness in our study may be attributable to differences in the demographic composition of the sample or the specific phrasing of the awareness question. However, it is important to note that awareness alone does not guarantee appropriate action, as the subsequent results on reporting behavior will demonstrate. The fact that over a third of the respondents (38.0%) were not aware of pharmacovigilance highlights a significant gap in public health knowledge that warrants attention from healthcare authorities and policymakers. This lack of awareness represents a missed opportunity for early detection and reporting of potential drug safety issues, which are critical for the effective functioning of national pharmacovigilance systems (Organization, 2006). Therefore, while the moderate level of awareness is encouraging, it also underscores the need for continued and enhanced public education campaigns to reach the remaining unaware population.

ADR Reporting Behavior

Despite the moderate level of awareness regarding pharmacovigilance observed in the previous subsection, the formal reporting of adverse drug reactions (ADRs) to healthcare professionals was found to be notably limited. As summarized in Table 2, only 128 participants, or 42.7% of the sample, reported having formally reported an ADR to a healthcare professional. In stark contrast, a clear majority of 172 respondents, representing 57.3% of the study population, indicated that they had not engaged in such formal reporting behavior. This finding reveals a substantial gap between the 62.0% of individuals who were aware of pharmacovigilance and the 42.7% who actually acted upon that potential knowledge by filing a report.

Table 2. *ADR Reporting Behavior*

Response	Frequency	Percentage
Reported ADR	128	42.7%
Did Not Report	172	57.3%

This trend is visually reinforced in Figure 2, which presents a pie chart of the reporting behavior distribution. The chart clearly shows that the segment representing respondents who “Did Not Report” (57.3%) occupies a larger proportion of the total area than the “Reported ADR” segment (42.7%), graphically confirming that formal reporting is a minority behavior within this sample.

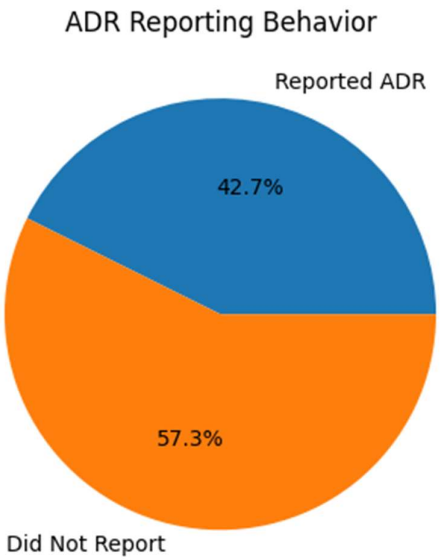

Figure 2. *ADR Reporting Behavior*

This observed low reporting rate is consistent with the global trend of under-reporting of adverse drug reactions, which is a well-documented challenge in pharmacovigilance systems worldwide (Chen et al., 2021; Khan et al., 2023). The discrepancy between awareness and action is particularly salient. While it is encouraging that a majority of the public understands the concept of drug safety monitoring, this knowledge does not appear to translate into proactive reporting behavior. This suggests that the barriers to reporting are not solely cognitive (i.e., a lack of knowledge) but may also include practical, attitudinal, or systemic factors. For instance, individuals may not know the specific procedure for reporting a suspected ADR, may underestimate the severity of their own experience, or may not trust the reporting system to act on their information (Wang et al., 2022). The fact that 57.3% of respondents did not report, despite the overall awareness level being 62.0%, implies that a significant number of individuals who are aware of the concept are still failing to report. This finding underscores the urgent need to move beyond simple awareness campaigns and to develop targeted interventions that address the specific barriers preventing the public from formally reporting ADRs. Future efforts should prioritize making the reporting process more accessible, convenient, and transparent to bridge this critical action gap and ultimately strengthen patient safety within the community.

Source of Information About Pharmacovigilance

To understand how the surveyed population acquired their knowledge about pharmacovigilance, participants were asked to identify their primary source of information on the topic. The results, presented in Table 3, reveal a clear hierarchy of information channels, with professional medical sources dominating over informal or media-based channels. Doctors were the most frequently cited source, reported by 102 respondents, which constituted 34.0% of the sample. Pharmacists were the second most common source, identified by 76 respondents (25.3%). The internet or media was cited by 69 respondents (23.0%), while friends or family were the least common source, mentioned by only 53 respondents (17.7%).

Table 3*. Source of Information About Pharmacovigilance*

Source	Frequency	Percentage
Doctors	102	34.0%
Pharmacists	76	25.3%
Internet/Media	69	23.0%
Friends/Family	53	17.7%

The predominance of doctors as the primary information source is visually confirmed in Figure 3, which displays a vertical bar chart of the frequency distribution across the four categories. The bar representing 'Doctors' is the tallest, reaching just above 100, clearly indicating its status as the most influential channel. The bar for 'Pharmacists' follows with a frequency near 80, while 'Internet/Media' is slightly lower at approximately 70. The bar for 'Friends/Family' is the shortest, appearing just above 50, reinforcing its position as the least utilized source.

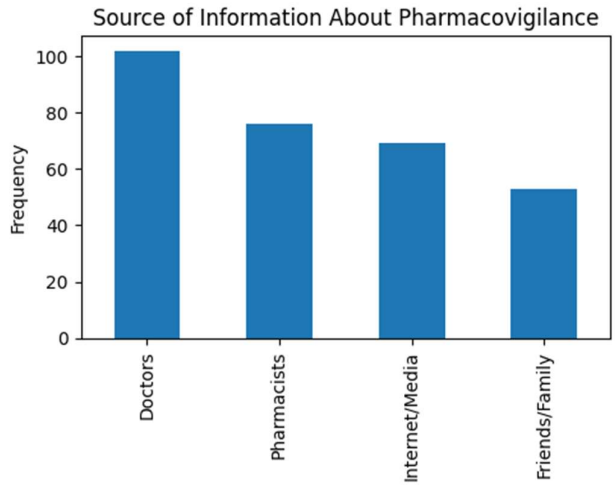

Figure 3. *Sources of Information About Pharmacovigilance*

This distribution highlights the critical role that healthcare professionals, particularly doctors and pharmacists, play in disseminating pharmacovigilance information to the public. The combined contribution of doctors and pharmacists accounts for 59.3% of all information sources, underscoring the trust and reliance that the public places in professional medical advice for drug safety matters. This finding aligns with previous research that has identified healthcare professionals as the most trusted and influential source of health information for patients (Valinciute et al., 2023). The significant role of doctors is particularly noteworthy, as they are often the first point of contact for patients experiencing side effects and are in a prime position to educate patients about the importance of reporting ADRs (Khan et al., 2023).

However, the data also reveal a substantial reliance on non-professional sources. The internet or media, cited by nearly a quarter of respondents (23.0%), represents a growing and influential channel for health information in the digital age. While this can facilitate wider dissemination of knowledge, it also raises concerns about the accuracy and reliability of the information being accessed, as online sources may not always be vetted for medical accuracy (Chen et al., 2021). Similarly, the role of friends and family (17.7%) indicates that informal social networks also contribute to public awareness, though the quality of information transmitted through these channels may be variable.

The implications of these findings for public health strategy are twofold. First, they suggest that strengthening the role of doctors and pharmacists as educators is a highly effective strategy for improving public awareness. This could involve integrating pharmacovigilance education into routine clinical consultations or providing pharmacists with specific training materials to share with patients when dispensing medications. Second, the significant presence of internet and media sources indicates a need for official health authorities to establish a strong, credible, and accessible online presence. By providing accurate, easy-to-understand information on official websites and social media platforms, health authorities can ensure that the public has access to reliable information when they turn to digital channels. Addressing the information gap through these professional and digital avenues is a crucial step toward translating awareness into the desired reporting behavior.

Experience of Adverse Drug Reactions

The final domain of the survey assessed the personal experience of respondents with adverse drug reactions (ADRs). Understanding the prevalence of personal ADR experience is crucial, as it provides context for interpreting the reporting behavior observed in the previous subsection. The findings, presented in Table 4, reveal that a substantial minority of the surveyed population had directly encountered an adverse drug reaction. Specifically, 141 respondents, representing 47.0% of the sample, reported that they had personally experienced an adverse drug reaction while using a medication. In contrast, the majority, 159 respondents (53.0%), indicated that they had not experienced such a reaction.

Table 4. *Experience of Adverse Drug Reactions*

Response	Frequency	Percentage
Experienced	141	47.0%
Not Experienced	159	53.0%

This near-even split between those who have and have not experienced an ADR is visually illustrated in Figure 4. The bar chart displays two columns of comparable height, with the “Not Experienced” bar reaching a frequency of approximately 159, slightly exceeding the “Experienced” bar at approximately 141. This visual representation confirms that while personal ADR experience is not universal, it is a common occurrence within this community sample.

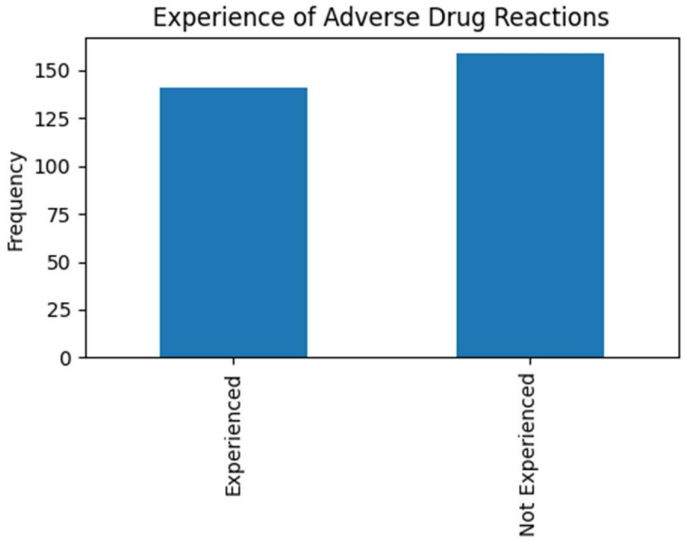

Figure 4. *Experience of Adverse Drug Reactions among survey respondents*

The finding that nearly half (47.0%) of the respondents have personally experienced an adverse drug reaction is a significant observation. This prevalence is notably higher than what might be expected based on spontaneous reporting rates, which typically capture only a fraction of actual ADR occurrences (Organization, 2004). This discrepancy between the high rate of personal experience and the low rate of formal reporting (42.7%) underscores a critical missed opportunity in the pharmacovigilance system. It suggests that a large number of individuals who could have contributed valuable information about drug safety by filing a report are instead remaining silent. This finding directly supports the hypothesis of our study that a significant disconnect exists between personal experience and subsequent formal reporting action.

The high prevalence of self-reported ADR experience also has important implications for understanding the burden of adverse drug reactions within the community. While this survey did not capture the severity or nature of the reported reactions, the data suggest that ADRs are a common reality for a substantial portion of the population (Pandian et al., 2025). This aligns with previous research that has documented high rates of self-reported ADRs among the general public, particularly in community-based surveys that ask directly about such experiences (Wang et al., 2022). The fact that over 47 out of every 100 individuals in this sample reported a personal experience with a side effect highlights the importance of robust pharmacovigilance systems that can effectively capture and analyze this real-world data.

Furthermore, the finding that 53.0% of respondents had not experienced an ADR does not necessarily imply that they are safe from future occurrences. Many individuals may be taking medications that have a low risk of immediate side effects, or they may not have experienced a side effect yet due to the duration or nature of their therapy. However, this group also represents a potential target for preemptive education. If these individuals are aware of the importance of reporting before they ever experience a side effect, they may be more likely to do so when the need arises. The overall picture, therefore, is one of a community where personal ADR experience is common, yet the formal reporting system is underutilized. This disconnect between the lived experience of the public and the official surveillance mechanisms represents a fundamental weakness in the current pharmacovigilance framework and highlights the urgent need for strategies to bridge this gap and encourage reporting from those who have firsthand knowledge of potential drug safety issues.

Discussion

The findings of this cross-sectional survey reveal a persistent and concerning disconnect between public awareness of pharmacovigilance and the actual practice of formal adverse drug reaction (ADR) reporting. While 62.0% of respondents indicated awareness of pharmacovigilance, only 42.7% had ever formally reported an ADR to a healthcare professional. This gap, which is consistent with the well-documented phenomenon of under-reporting in pharmacovigilance systems globally (Chen et al., 2021; Khan et al., 2023), suggests that awareness alone is insufficient to drive reporting behavior. The theoretical implication of this finding is that current models of health behavior change, which often assume a linear progression from knowledge to action, may be inadequate for explaining ADR reporting. Instead, our data support a more nuanced framework where practical barriers, attitudinal factors, and systemic obstacles mediate the translation of awareness into reporting. For instance, individuals may lack knowledge of the specific reporting procedure, may perceive their own side effect as too minor to report, or may distrust the reporting system's ability to act on their information (Wang et al., 2022). From a practical standpoint, this implies that healthcare authorities and policymakers should move beyond simple awareness campaigns and instead develop targeted interventions that

address these specific barriers. For example, integrating a simple, user-friendly digital reporting tool into routine pharmacy dispensing systems could significantly lower the procedural hurdle for patients. Furthermore, public health campaigns should explicitly address common misconceptions about what constitutes a reportable ADR, emphasizing that even mild or suspected reactions are valuable for signal detection. The finding that doctors (34.0%) and pharmacists (25.3%) are the primary sources of pharmacovigilance information suggests that these professionals are ideally positioned to serve as educators and facilitators of reporting. Therefore, training programs for healthcare professionals should include practical guidance on how to encourage and assist patients in filing ADR reports during routine consultations.

Several methodological limitations of this study should be acknowledged when interpreting the results. First, the use of convenience sampling, while practical for a cross-sectional survey, limits the generalizability of the findings to the broader population. The sample of 300 respondents may not be representative of the demographic, socioeconomic, or geographic diversity of the general public, and the observed awareness and reporting rates may differ in other settings. Second, the reliance on self-reported data introduces the potential for recall bias and social desirability bias. Respondents may have over-reported their awareness of pharmacovigilance or under-reported their failure to report an ADR, potentially inflating the observed awareness rate and deflating the reporting gap. Third, the survey did not capture the severity, type, or clinical significance of the ADRs experienced by the 47.0% of respondents who reported having had a side effect. Without this contextual information, it is difficult to assess whether the low reporting rate is partially attributable to the fact that many experienced reactions were mild and self-limiting, which patients might reasonably consider not worth reporting. Finally, the study did not explore the specific reasons or barriers behind the decision not to report an ADR, which limits our ability to design targeted interventions. Future research should therefore employ qualitative methods, such as in-depth interviews or focus groups, to explore the cognitive, attitudinal, and systemic factors that underpin the decision-making process of individuals who experience an ADR but choose not to report it.

Based on the gaps and inconsistencies uncovered in this study, several directions for future research are warranted. There is a clear need for longitudinal studies that track changes in awareness and reporting behavior over time, particularly in response to targeted public health interventions. Such studies could help establish causal relationships between educational campaigns and improved reporting rates, moving beyond the cross-sectional snapshot provided here. Future research should also explore the role of digital health technologies in facilitating ADR reporting. Given that 23.0% of respondents cited the internet or media as their primary source of pharmacovigilance information, there is a significant opportunity to develop and evaluate mobile applications or web-based platforms that allow patients to report suspected ADRs directly and conveniently. Understudied areas include the influence of cultural beliefs and health literacy levels on reporting behavior, as these factors may vary significantly across different communities and could explain some of the observed variation in reporting rates. Furthermore, future studies should specifically examine the reporting behavior of individuals who have experienced an ADR but did not report it, using qualitative methods to uncover the specific barriers they faced. This could include investigating whether patients are aware of the existence of national pharmacovigilance systems, whether they know how to access reporting forms, and whether they believe their report would make a difference. Finally, comparative studies across different countries with varying pharmacovigilance systems and public health infrastructures could provide valuable insights into which systemic features are most effective at promoting public reporting.

Conclusion

This cross-sectional survey was designed to evaluate the level of awareness and formal reporting practices of pharmacovigilance and adverse drug reactions among the general population. The core findings reveal a persistent and critical disconnect: while a moderate majority of respondents (62.0%) were aware of pharmacovigilance, formal ADR reporting behavior remained notably suboptimal, with only 42.7% having ever reported a reaction to a healthcare professional. This study contributes novel evidence by quantifying this awareness-action gap within a community-based sample, thereby confirming that knowledge alone is insufficient to drive reporting behavior. The research challenges the simplistic assumption that public education campaigns alone will automatically translate into improved pharmacovigilance practices, instead highlighting the need for a more nuanced understanding of the practical, attitudinal, and systemic barriers that prevent individuals from filing reports.

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