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Evaluation of Pharmacists' knowledge and Adherence to Pharmacovigilance Practices: A cross-sectional study

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ABSTRACT

Pharmacovigilance (PV) is essential for detecting and preventing adverse drug reactions (ADRs), yet underreporting by pharmacists is a persistent global issue. This study aimed to assess pharmacists' knowledge and adherence to PV practices in Minia Governorate, Egypt. A cross-sectional, survey-based study was conducted among 345 pharmacists working in public and private sectors, including hospital and community pharmacies across rural and urban areas. Data were collected through structured face-to-face interviews by trained final-year pharmacy students using a validated questionnaire covering demographics, PV knowledge, and practice. The mean age of participants was 35.44 years, with 67.25% under 36 years and a slight female majority (53.04%). Most pharmacists (66.09%) had less than 10 years of experience, and 52.47% worked in both public and private sectors. Although 84.06% were aware of PV concepts and national centers, only 57.97% knew what happens after an ADR is reported. Formal education was the primary source of PV training (45.22%), yet 16.81% had never learned how to report ADRs. Only 32.17% of pharmacists had ever reported an ADR, most commonly to the Egyptian Pharmaceutical Vigilance Center (24.32%). Reporting methods included on-site, online, and phone submissions. Colleagues and e-learning were commonly cited sources of information on medicine safety. Despite high awareness of PV concepts, actual ADR reporting practices among pharmacists were suboptimal. These findings highlight the need for improved training, clearer reporting procedures, and enhanced institutional support to strengthen PV engagement and promote medication safety.

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Introduction

Pharmacovigilance (PV) has many components (**Figure 1**) [1-3], and plays a vital role in ensuring the safety of medications by detecting, assessing, understanding, and preventing adverse drug reactions (ADRs) and other drug-related problems [4-6]. The goal of PV systems is to protect public health by promoting the safe and effective use of medicines. Since the World Health Organization (WHO) launched its Program for International Drug Monitoring in 1968, numerous countries have established national PV systems to support early detection of safety issues related to drug therapy [7]. Pharmacists, as accessible and knowledgeable healthcare professionals, are well positioned to contribute significantly to PV activities. Their direct involvement in medication dispensing, patient counseling, and monitoring of drug-related problems places them at the frontline of ADR detection and reporting. However, the effectiveness of pharmacists in contributing to PV efforts largely depends on their knowledge, attitude, and actual reporting behavior [8]. Despite efforts to raise awareness, underreporting of ADRs by healthcare providers, including pharmacists, remains a global challenge, particularly in low- and middle-income countries [9]. In Egypt, the national PV system is managed by the Egyptian Pharmaceutical Vigilance Center (EPVC) [10]. Although the infrastructure for reporting exists, studies suggest that awareness and engagement with PV practices among pharmacists remain suboptimal [11]. Factors such as inadequate training, lack of clarity about the reporting process, and low confidence in identifying ADRs may contribute to this gap [12] Given the pivotal role of pharmacists in medicine safety surveillance, it is important to evaluate their current knowledge and adherence to PV practices. Such evaluations can inform targeted educational interventions, regulatory policies, and strategies to strengthen the national PV system. Therefore, the aim of this study is to assess pharmacists' knowledge of PV and their adherence to ADR reporting practices, using a cross-sectional design to identify key areas of strength and gaps in current practice.

Methods

Study Design: This is a cross-sectional, survey-based study conducted in public and private pharmacies, including hospitals and community pharmacies across rural, and urban regions of Minia Governorate, Egypt. All methods used in this study are summarized in Figure 2.

Inclusion and Exclusion Criteria: Pharmacists with at least one year of professional experience and those who consented to participate were included. Those who refused to complete the survey or were no longer practicing were excluded.

Participants and Recruitment Strategy

Participants include pharmacists. A convenience sampling strategy was employed due to feasibility considerations. To enhance representativeness, recruitment was purposively distributed across both public and private sectors, as well as urban and rural areas. Pharmacists were approached directly at their workplaces (hospital and community pharmacies) by trained final-year pharmacy students. The study objectives were explained, and voluntary participation was requested.

Data Collection

Final-year pharmacy students enrolled in the "Clinical Research and Pharmacovigilance" course received structured training on the study protocol, ethical considerations, and interview techniques. Using a pre-designed questionnaire, the trained students conducted face-to-face interviews and personally collected data from eligible participants.

Questionnaire Development and Validation: The survey instrument was designed based on extensive literature review using PubMed, Google Scholar, and the Cochrane Library. The questionnaire included three core sections: demographics, knowledge, and practice. To ensure content validity, the questionnaire was reviewed by three clinical pharmacy experts. A pilot test was conducted with 20 pharmacists to assess clarity, relevance, and response consistency. Feedback from the pilot phase was used to refine the questions. Reliability testing using Cronbach's alpha was performed for the knowledge and practice sections, and a coefficient of 0.78 was obtained, indicating acceptable internal consistency.

Ethical Considerations: Participation in the study was voluntary. No personal identifiers were collected, ensuring participant anonymity and data confidentiality.

Sample Size Calculation: The minimum required sample size was calculated with a 95% confidence interval and 5% margin of error. Based on previous studies conducted in similar settings, the estimated prevalence of knowledge about PV practices was assumed to be 70% ($p = 0.70$) [13]. Using these parameters, the calculated sample size was approximately 323 participants. However, to enhance the study's precision and account for potential non-response or incomplete data, a total of 345 pharmacists were ultimately included in the study.

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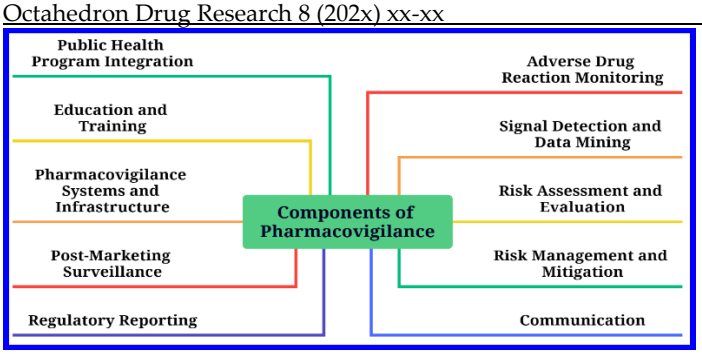

Figure 1. Components of Pharmacovigilance

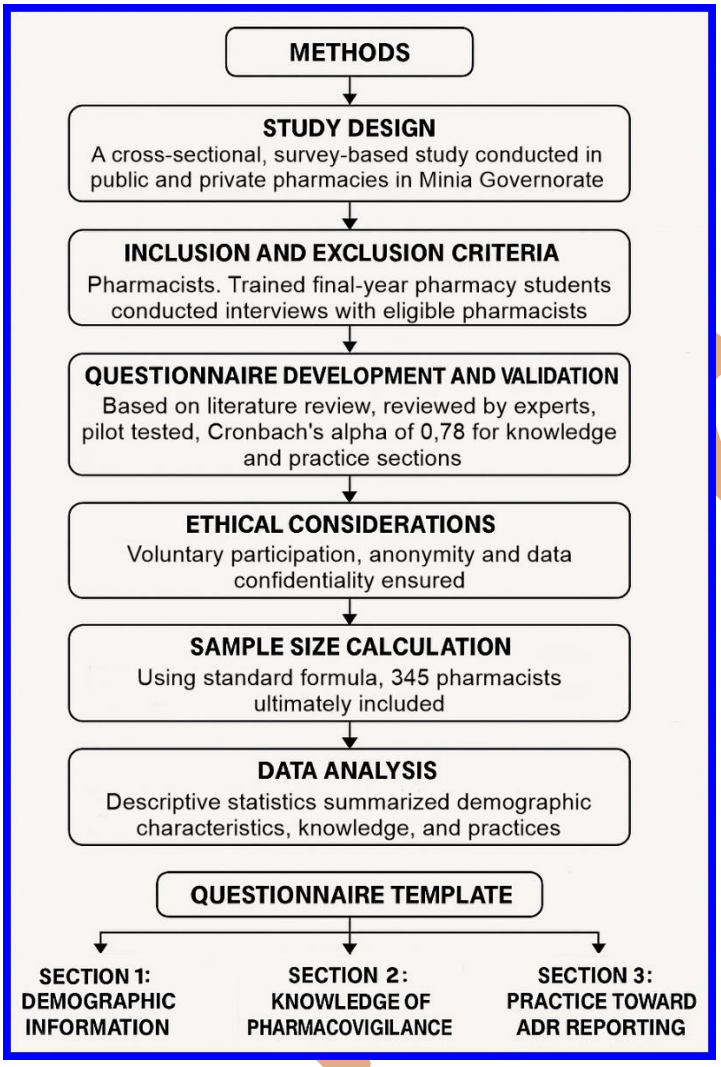

Figure 2. Study methods flow diagram

Data Analysis: Data were analyzed using SPSS software version 26. Descriptive statistics were used to summarize participants' demographic characteristics, as well as their knowledge and practices related to PV and ADR reporting. Frequencies and percentages were calculated for categorical variables, while means and standard deviations were used for continuous variables. Chi-square test was applied to assess associations between ADR reporting and categorical variables. Results were presented in tables and figures to clearly illustrate the distribution of responses.

Results

The present study included 345 pharmacists from various healthcare settings across Minia Governorate. **Table 1** summarizes the demographic characteristics of the study participants, including age, gender, years of experience, work sector, and geographic region of practice.

Table 1. Demographic characteristics of the study sample

Characteristics	
Age/year	
Mean (SD)	35.44 (8.43)
Age group (years), n (%)	
< 36 years	232 (67.25)
36-45 years	64 (18.55)
46-55 years	36 (10.43)
> 55 years	13 (3.77)
Gender, n (%)	
Male	162 (46.96)
Female	183 (53.04)
Years of experience (years), n (%)	
< 10	228 (66.09)
10-19	68 (19.71)
≥ 20	49 (14.20)
Work sector, n (%)	
Public	108 (31.30)
Private	56 (16.23)
Both	181 (52.47)
Region of practice, n (%)	
Urban	196 (56.81)
Rural	149 (43.19)

SD, standard deviation

Table 1 presents that the study sample had a mean age of 35.44 years, with most participants (67.25%) under 36 years. The gender distribution was nearly balanced, with a slight female predominance (53.04% female). Most pharmacists (66.09%) had less than 10 years of experience. Over half of the participants (52.47%) worked in both public and private sectors, while the rest were divided between public (31.30%) and private (16.23%) sectors. Geographically, 56.81% practiced in urban areas and 43.19% in rural settings, offering a diverse representation of work environments.

Table 2. Knowledge of Pharmacovigilance

	Question	Response Options	
		Yes n (%)	No n (%)
Q1	Do you have any prior knowledge about PV?	278 (80.58)	67 (19.42)
Q2	Are you aware of the existence of a PV center in Egypt?	290 (84.06)	55 (15.94)
Q3	Are you aware of the drug information center (DIC)	302 (87.54)	43 (12.46)
Q4	Do you know what types of ADRs should be reported?	295 (85.51)	50 (14.49)
Q5	Do you know who is eligible to report ADRs?	233 (67.54)	112 (32.46)
Q6	Are you aware of where to report ADRs?	217 (62.90)	128 (37.10)
Q7	Do you know what happens to the information after an ADR is reported?	200 (57.97)	145 (42.03)

Table 2 presents that most pharmacists demonstrated good general awareness of PV, with 80.58% reporting prior knowledge and awareness of the national PV center and Drug Information Center. Most also knew what types of ADRs should be reported (85.51%), but fewer understood who can report them (67.54%) or where to report (62.90%). Only 57.97% knew what happens after an ADR is reported, indicating limited knowledge about the reporting process itself.

Table 3. Association of ADR reporting with age, gender, practice region and years of experience

	Yes n (%)	No n (%)	P
Age category			
< 36 years	72 (64.87%)	160 (68.38%)	0.69
36-45 years	24 (21.62%)	40 (17.09%)	
46-55 years	12 (10.81%)	24 (10.26%)	
> 55 years	3 (2.70%)	10 (4.27%)	
Gender			
Male	52 (46.85%)	110 (47.01%)	0.97
Female	59 (53.15%)	124 (52.99%)	
Years of experience			
< 10 years	70 (63.06%)	158 (67.52%)	0.64
10 - 19 years	25 (22.52%)	43 (18.38%)	
≥ 20 years	16 (14.42%)	33 (14.10%)	

Table 3 demonstrates that there were no statistically significant associations between ADR reporting and pharmacists' demographic or practice-related variables, including age, gender, or years of experience (all p-values > 0.05). The distribution of reporting behavior was relatively consistent across categories. These findings suggest that demographic characteristics alone are unlikely to be the main drivers of ADR reporting, underscoring the importance of other factors such as knowledge of reporting processes, training, and system-level support in shaping PV practices.

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Table 4. Practice toward ADRs reporting

	Question	Response Options n	%
Q1	**To whom did you report the ADRs?**		
	Doctors	17	15.32
	EDA	10	9.01
	EPVC	27	24.32
	Hospital Manager	13	11.71
	Medical representative	7	6.31
	Pharmacist manager and clinical pharmacy department	12	10.81
	Others	25	22.52
Q2	**Which reporting form do you usually use to report ADRs?**		
	Phone	27	24.32
	Online	30	27.03
	Electronic	11	9.91
	Yellow card	7	6.31
	On place	36	32.43
Q3	**What sources do you routinely use to obtain information about the benefits and risks of medicines?**		
	Colleague	42	37.84
	Professional body	22	19.82
	Undergraduate course	17	15.32
	e-learning	30	27.02

EDA = Egyptian Drug Authority; EPVC = Egyptian Pharmaceutical Vigilance Center; e-learning = Electronic learning; Others = Colleagues, Drug Information Center (DIC), Emergency Department, Patients, Pharmaceutical Companies, PV Specialists.

Table 4 presents that reports were most frequently sent to the Egyptian Pharmaceutical Vigilance Center (24.32%), though many were also directed to informal or unclear recipients. The most common reporting methods included on-place reporting (32.43%), online systems (27.03%), and phone (24.32%), with limited use of structured tools like the yellow card system. In terms of information sources on medicine safety, pharmacists mainly relied on colleagues (37.84%) and e-learning (27.02%), with less input from professional bodies or formal education. These findings highlight the gap between knowledge and actual reporting practice, and emphasize the need for clearer procedures, better training, and greater institutional support.

Figure 3. Sources through which pharmacists learned about reporting ADRs

Figure 3 shows that most pharmacists (45.22%) learned about ADR reporting through formal education, followed by workplace training (17.68%) and colleagues (16.23%). A smaller portion used online resources (4.06%), while 16.81% had not learned about ADR reporting at all. These findings highlight the importance of academic instruction in PV and the need for ongoing professional development to address existing knowledge gaps and improve ADR reporting practices.

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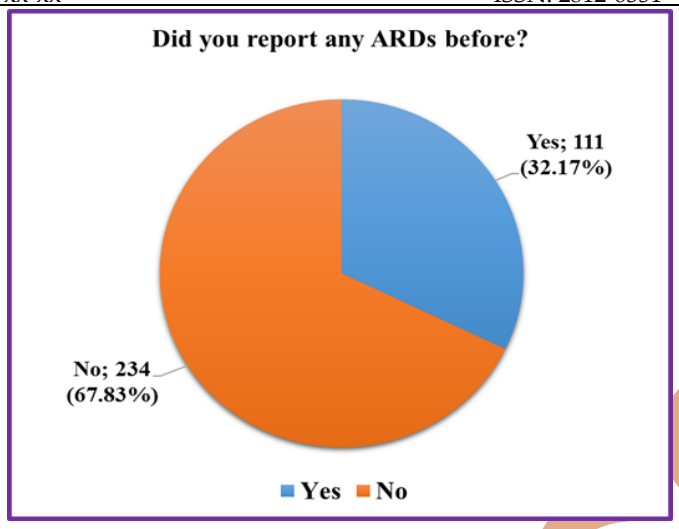

Figure 4. Previous reporting of ARDs

Figure 4 demonstrates a significant gap in pharmacists' actual reporting of ADRs, with only 111 (32.17%) having reported an ADR compared to 234 (67.83%) who had not. This low reporting rate suggests a disconnect between theoretical knowledge of PV and practical implementation.

Discussion

This study highlights that while pharmacists have high awareness of PV concepts and national reporting centers; their actual ADR reporting is suboptimal. Demographic factors like age, gender, and experience do not significantly influence reporting, suggesting that other factors, such as clear reporting procedures, training availability, and institutional support, are more critical. The findings emphasize the need for targeted interventions to address structural and educational gaps to improve PV practices.

The current study describes pharmacist with an average age of 35.44 years, practicing in both urban and rural areas. Rural pharmacists face barriers such as limited training, fewer reporting tools, and inadequate regulatory support, which hinder effective PV implementation compared to their urban counterparts [14]. Several studies have demonstrated rural–urban differences in the types of drugs associated with ADRs. These differences may reflect variations in prescribing practices, drug availability, and patterns of healthcare access across different geographical settings. In rural areas, limited access to specialists and diagnostic tools may influence the choice of medications, potentially increasing the risk of certain ADRs [15]. Urban healthcare settings often provide a wider range of medications, which may lead to different ADR profiles. Understanding these contextual factors is essential for designing targeted PV interventions and ensuring safe medication practices in both urban and rural populations [16]. A study revealed that both rural and urban pharmacists have poor knowledge of reporting timelines and causality assessment tools, with few having received formal training. While rural pharmacists were more affected by infrastructure and time limitations, urban pharmacists more often cited knowledge gaps. The majority of pharmacists in both groups reported a lack of regular updates on PV [17].

The present study found that pharmacists have awareness and knowledge of PV concepts and national reporting centers. However, gaps in procedural knowledge, such as knowing who can report ADRs and where to report them, were evident and align with previous research highlighting pharmacists' lack of clarity on reporting mechanisms [18]. This limitation, combined with insufficient training on how to report ADRs, may reduce the perceived value of reporting and contribute to underreporting [19].

The findings of the current study highlight the central importance of formal academic education as the main source of knowledge about ADR reporting, while non-academic sources such as workplace training, online resources, and colleagues also contributed to pharmacists' PV knowledge. More than half of the participants in one study reported obtaining information from the internet, with textbooks being the next most common source, followed by colleagues [13]. The findings illustrated in the current study reveal that only 32.17% of pharmacists have reported an ADR. This is consistent with a study examining pharmacists' attitudes toward ADR reporting; only 13.57% of participants indicated that they had reported a suspected ADR [13], possibly due to barriers such as complex reporting systems, lack of time, or insufficient institutional encouragement. The present study revealed that nearly a quarter of participants

submitted their reports to the EPVC; many pharmacists directed their reports to informal or ambiguous recipients such as supervisors or colleagues. Another study found that less than half of the participating pharmacists correctly identified the national ADR monitoring center as the appropriate authority [13]. One study found that most surveyed pharmacists reported ADRs to hospital, pharmaceutical company, PV system, and lastly health officers or doctors [20].

In the current study, pharmacists reported ADRs through different channels such as on-place reporting, online systems, and phone, reflecting accessibility and flexibility. However, the limited use of the yellow card system, a globally recognized tool for spontaneous reporting, highlights the underutilization of formal national reporting mechanisms [21]. Underreporting remains a worldwide problem, with only a small proportion of serious reactions reported, often due to barriers such as lack of time, uncertainty about causality, and concerns over patient confidentiality [22]. In another study, although more than half of participants (51.8%) expressed a preference for the yellow card system, most admitted they did not use it regularly, citing the unavailability of the form in their workplaces as the main barrier [23]. In the current study, the sources of medicine safety reported by pharmacists raise concerns, as colleagues and e-learning platforms were the predominant sources, while formal education and professional bodies played a minor role. Reliance on informal sources may not guarantee accurate or updated PV practices and could contribute to inconsistencies and under-reporting of ADRs [24]. Another study reported that more than half of the respondents (56.1%) relied on the National Drug Formulary and Standard Treatment Guidelines, followed by 46.5% who used standard textbooks as their main reference [23]. Clear and practical policies that mandate and streamline ADR reporting are essential and should be developed in consultation with pharmacists [25].

Comprehensive training programs, integrated into both academic curricula and continuing professional development, with practical sessions and case studies, are needed to improve pharmacists' knowledge and have been shown to increase reporting rates [26]. Simplifying the reporting process, integrating it with electronic health records and pharmacy systems, and using digitalization and automation can enhance efficiency and quality. Providing regular feedback on submitted reports may further encourage engagement and highlight the value of pharmacists' contributions [27].

Limitations

This study has several limitations that should be acknowledged. First, cross-sectional design limits the ability to establish a causal relationship between knowledge levels and actual PV practices. Second, the study was conducted in a single governorate in Egypt, which may limit the generalizability of the findings to other regions. Furthermore, although data were collected by trained final-year pharmacy students to ensure feasibility and wide coverage, this approach may have introduced interviewer bias despite the use of standardized training and a validated questionnaire.

Conclusion

This study found that while pharmacists demonstrate good general awareness of PV and ADRs, actual reporting practices remain limited. Only 32.17% reported an ADR, and many lacked knowledge of specific reporting procedures. Pharmacists mainly learned about ADR reporting through formal education, but informal sources like colleagues were also present. Reporting was inconsistent, with limited use of official tools like the yellow card system. These results highlight a significant gap between knowledge and practice, underscoring the need for better training, clearer procedures, and stronger institutional support to enhance ADR reporting and improve patient safety.

Declarations

Competing interests The authors declare no competing interests.

Ethics approval and consent to participate

This study was approved by the research ethical committee of Minia University with an approval number (MPEC-240606). Written informed consent was obtained from the study participants after describing the study's goals and advantages.

Human Ethics

All study steps were performed in accordance with the Declaration of Helsinki.

Consent for publication Not applicable.

Data availability All data generated or analysed during this study are included in this published article.

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Authors' contributions

Soad A. Mohamad and Asmaa A. Hamed developed the study concept and design. Noha A. Abdelazim collected the data. Asmaa S. Mohamed and Hosam M. A. Refaei drafted the manuscript. All authors read, reviewed, and approved the final manuscript.

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