https://doi.org/10.31925/farmacia.2025.1.24 **ORIGINAL ARTICLE**

EVALUATION OF PHARMACOVIGILANCE AWARENESS, ATTITUDES, AND REPORTING PRACTICES OF ADVERSE DRUG REACTIONS IN COMMUNITY PHARMACIES – AN ARMENIAN EXPERIENCE

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Abstract

Adverse drug reactions (ADRs) represent a significant global health issue, imposing serious risks to patient safety and incurring substantial healthcare costs. This study aimed to evaluate the knowledge, attitudes, and practices of community pharmacists in Armenia regarding pharmacovigilance and ADR reporting, identifying barriers and gaps to improve ADR management within community pharmacies. A cross-sectional study was conducted with 590 community pharmacists selected using a random sampling technique. A validated questionnaire assessed socio-demographic characteristics, knowledge, attitudes, and practices related to pharmacovigilance. Data were analysed using SPSS version 23.0. The majority of respondents were aged 26-30 years (60.7%) and predominantly female (89.7%). Knowledge regarding pharmacovigilance was insufficient, with 71.4% of participants unfamiliar with its concepts. Only 9.3% consistently reported ADRs, reflecting significant gaps in practice. While most recognized the importance of pharmacovigilance in drug safety, confidence in their reporting abilities was low, with 78.3% not believing pharmacists should encourage patient reporting of ADRs. Challenges such as lack of knowledge, time constraints, and perceived inefficiencies in the reporting system were prevalent. The findings highlight critical deficiencies in knowledge and practice among community pharmacists concerning ADR reporting. Targeted educational programs and resources, such as training workshops and informative booklets, are essential to enhance pharmacists' engagement in pharmacovigilance efforts, ultimately improving drug safety and patient care.

Rezumat

Reacțiile adverse la medicamente (RAM) reprezintă o problemă semnificativă de sănătate la nivel mondial, impunând riscuri grave pentru siguranța pacienților și implicând costuri substanțiale de asistență medicală. Acest studiu și-a propus să evalueze cunoștințele, opiniile și practicile farmaciștilor din Armenia cu privire la farmacovigilență și raportarea RAM, identificând problemele și barierele, pentru a îmbunătăți gestionarea RAM în farmaciile comunitare. A fost efectuat un studiu transversal cu 590 de farmaciști de comunitate, selectați aleator. Un chestionar validat a evaluat caracteristicile socio-demografice, cunoștințele, opiniile și practicile legate de farmacovigilență. Datele au fost analizate folosind SPSS versiunea 23.0. Majoritatea respondenților aveau vârste cuprinse între 26-30 de ani (60,7%) și au fost predominant femei (89,7%). Cunoștințele privind farmacovigilența s-au dovedit insuficiente, 71,4% dintre participanți fiind nefamiliarizați cu conceptele acesteia. Doar 9,3% au raportat în mod constant reacții adverse, ceea ce reflectă lacune semnificative în practică. Deși cei mai mulți au recunoscut importanța farmacovigilenței pentru siguranța medicamentelor, un procent de 78,3% nu cred că farmaciștii ar trebui să încurajeze raportarea reacțiilor adverse de către pacient. Au fost identificate provocări precum: lipsa de cunoștințe, constrângerile de timp și neîncrederea în sistemul de raportare. Rezultatele evidențiază deficiențe importante în cunoștințele și practicile farmaciștilor de comunitate, în ceea ce privește raportarea ADR. Programele și resursele educaționale direcționate, cum ar fi atelierele de instruire și broșurile informative, sunt esențiale pentru a spori implicarea farmaciștilor în eforturile de farmacovigilență, îmbunătățind în cele din urmă siguranța medicamentelor și îngrijirea pacientului.

Keywords: adverse drug reactions, pharmacovigilance, community pharmacists

Introduction

Adverse drug reactions (ADRs) are defined by the WHO as unexpected, harmful, and dangerous reactions that occur at therapeutic doses that are the norm in medical practice for disease prevention, diagnosis, therapy, or alteration of physiological function [1]. Adverse drug reactions (ADRs) are a global health concern, posing serious risks to patient safety and leading to high healthcare costs. Numerous studies show that ADRs place a significant and continuously increasing burden on both patients and the healthcare systems of various countries, resulting in substantial

financial costs and losses. Based on patient-level costing data, the annual projected cost of ADR-related admissions to the National Health Service in England has been estimated at £2.21 billion [2].

ADRs can cause various issues, including morbidity and mortality worldwide [3]. This necessitates a strict surveillance system capable of effectively monitoring drug exposure in the general population [4]. All healthcare professionals play a crucial role in the spontaneous reporting of ADRs [5], which not only reduces the economic and financial burden but also improves patients' quality of life, making subsequent drug therapy more effective [6]. Pharmacovigilance addresses the risks associated with medicines, with a primary emphasis on the informed and competent involvement of healthcare professionals, active participation, and patient accountability. Comprehensive analysis and effective communication play indispensable roles in the management of adverse effects, including those that may be previously unknown [7, 8]. It addresses concerns such as irrational drug use, overdoses, polypharmacy, interactions, traditional/herbal medicines, illegal sales, self-medication, substandard drugs, errors, and lack of efficacy. The global acknowledgement of harm caused by medication is essential for inclusion in public health agendas. Enhanced accountability, research, and empowerment within the healthcare system are crucial to improving therapy effectiveness, diagnosing and managing medicine-induced diseases, and ultimately reducing harm to patients [7].

Pharmacovigilance research endeavours will enhance the pharmacist's contribution towards valuable clinical outcomes. Pharmacists, as drug experts, play important roles in promoting rational and safe medicine use. Optimizing pharmacists' contributions improves pharmacotherapy outcomes and reduces global health costs. Educational training programs and workshops can provide clarification and improve understanding of ADR reporting and the process of assessing causality for ADR [9, 10].

This study aimed to evaluate community pharmacists' knowledge, attitudes, and practices regarding pharmacovigilance. By identifying current gaps and obstacle in ADR reporting, this research intends to provide insights that can support improvements in ADR management within community pharmacies, contributing to overall public health safety.

Materials and Methods

Study design and participants

This cross-sectional study investigates the knowledge, attitudes, and practices of community pharmacists in Armenia regarding pharmacovigilance and ADR reporting.

Sampling technique and sample size calculation

The sample size was determined using the Cochran's Sample Size Formula [11]. In this study, a sample size of 597 was estimated with a 97% confidence interval and a 3% margin of error.

Study instruments

The research survey employed in this study was meticulously developed subsequent to an extensive and comprehensive review of the literature on the subject matter [12, 13]. The questionnaire encompassed socio-demographic variables, including education level, age, gender, and work experience.

Instrument validity and reliability

The study questionnaire demonstrated a commendable degree of reliability. The subscales for knowledge, attitudes, and practices also showed acceptable reliability, with Cronbach's alpha values of 0.80, 0.78, and 0.82, respectively. These alpha coefficients serve as robust indicators of the questionnaire's internal consistency and, by extension, its suitability as a dependable research instrument.

Data collection

The study was carried out between September 2023 and April 2024. The study was conducted in a community pharmacy. To ensure the reliability and impartiality of the data, an Excel random number generator was used to select participants.

Ethical approval

The Ethics Committee of Yerevan State Medical University formally approved the questionnaire during a scheduled session, affirming the study's adherence to the principles outlined in the Declaration of Helsinki.

Strengths and limitations of the study

This study has limitations, including its focus on community pharmacists and exclusion of hospital pharmacists and doctors. Future research should include these groups. Despite this, the study has strengths, such as a high response rate exceeding the required sample size and successfully measuring ADR report awareness.

Data analysis

Data were analysed using SPSS version 23.0, which provided frequency and percentage statistics. Descriptive statistics summarized pharmacists' demographics, knowledge, practices, and attitudes towards ADR reporting. Continuous variables are presented as means and standard deviations, with $p < 0.05$ considered statistically significant.

Results and Discussion

Socio-demographic characteristics of the study participants

A total of 590 out of 597 pharmacists participated, resulting in a response rate of 98.83%. Most respondents were aged 26-30 (60.7%) and female (89.7%). Educationally, 54.2% were pharmacy technicians with vocational education. Experience levels varied, with 35.4% having 2 - 3 years of experience. Socio-demographic characteristics are summarized in Table I.

Table I

Socio- demographic characteristics of the study participants (n = 590)

Variables		Frequency Percentage (%) (M ± SE) Std. Deviation
Age	20-25 26-30 31-35 36-40 41-45 46-50	112 (19%) 358 (60.7%) 75 (12.7%) 29 (4.9%) 14 (2.4%) 2 (0.3%) 2.1203 ± 0.03608 0.876
Gender	Female Male	529 (89.7%) 61 (10.3%) 1.8966 ± 0.01255 0.30473
Level of education	Pharmacist (bachelor's, master's degree) Pharmacy technician **(**vocational education) Student	204 (34.6%) 320 (54.2%) 66 (11.2%) 2.42 ± 0.044 1.077
Years of practice	up to 1 year 2-3 year 4-7 year 8-10 year 11 years and more	143 (24.2%) 209 (35.4%) 130 (22.0%) 67 (11.4%) 41 (6.9%) 2.41 ± 1.172

Response rate = 98.83%**,** n = 590

Description of Pharmacists' Knowledge, Attitudes, and Practices Towards ADR Reporting

Based on the data presented in Table II, a significant portion of the participants showed insufficient familiarity with the concept of pharmacovigilance (n= 421; 71.4%). According to the research data, most of the pharmacy employees had knowledge deficiencies and gaps and did not understand the field of managing unexpected adverse reactions to drugs (Table II).

Table II

Knowledge of pharmacovigilance and ADR reporting (n = 590)

Questions	**Responses**	**Frequency**	**Percentage** (%) (M ± SE) Std. Deviation
1. Are you familiar with the concept of pharmacovigilance?	No Yes	421 169	71.4% 28.6% 1.71 ± 0.018 0.45
2. Are you aware of the process for reporting adverse reactions of new drugs?	No Yes	380 210	64.4% 35.6% 1.64 ± 0.0197 0.48
3. Are serious adverse drug reactions those that result in death, life-threatening situations, hospitalization, or significant disability?	No Yes	530 60	89.8% 10.2% 1.9 ± 0.01245 0.3
4. Is the World Health Organization (WHO) involved in international pharmacovigilance efforts?	No Yes	497 93	84.2% 15.8% 1.1576 ± 0.015 0.3647
5. Are Rx drugs also monitored under pharmacovigilance?	No Yes	515 75	87.3% 12.7% 1.8729 ± 0.01373 0.34

Response rate = 98.83%, n = 590

Description of participants' attitudes toward pharmacovigilance and ADR reporting.

Table III shows participants' attitudes toward pharmacovigilance and ADR reporting. Most expressed positive views on pharmacovigilance's role in drug safety but many lacked confidences in their ability to report ADRs effectively (Table III).

Table III

Attitude of pharmacovigilance and ADR reporting (n = 590).

Questions	Responses	Frequency	Percentage (M ± SE) Std. Deviation
1. Do you believe it is important to report all adverse drug reactions (ADRs) encountered in your practice?	No Yes	407 183	69% 31% 1.31 ± 0.019 0.46
2. Should pharmacists encourage patients to report any suspected adverse drug reactions?	No Yes	462 128	78.3% 21.7% 1.21 ± 0.017 0.4
3. Do you think that patient confidentiality is a key consideration in the reporting process of adverse drug reactions?	No Yes	264 326	44.7% 55.3% 1.55 ± 0.02 0.49
4. Do you feel that reporting adverse drug reactions can contribute to the safer use of medicines?	No Yes	236 354	40% 60% 1.6 ± 0.02 0.49
5. Do you agree that staying informed about pharmacovigilance can improve your practice?	No Yes	225 365	38.1% 61.9% 1.61 ± 0.02 0.48

Response rate = 98.83%**,** n = 590

Description of participants' practices related to pharmacovigilance and ADR reporting.

Table IV shows participants' practices related to pharmacovigilance and ADR reporting. Most rarely report ADRs, with many never having reported one, indicating a significant gap in practice. Additionally, most participants have not attended pharmacovigilance training sessions (Table IV).

Table IV

Practice of the participants toward pharmacovigilance and ADR reporting (n = 590)

Questions	Responses	Frequency	Percentage
1. Do you report adverse drug reactions (ADRs) you encounter to the relevant authorities?	No Yes	535 55	90.7% 9.3%
2. Do you report an adverse drug reaction even if you are not certain the drug caused it?	No Yes	530 60	89.8% 10.2%
3. Have you participated in any pharmacovigilance training programs or courses that specifically covered the topic of pharmacovigilance?	No Yes	532 58	90.2% 9.8%
4. Do you stay updated with the latest safety information on the medications you dispense?	No Yes	442 147	74.9% 24.9%
5. Do you educate patients on the importance of reporting any adverse drug reactions they experience?	No Yes	523 67	88.6% 11.4%

Response rate = 98.83%, n = 590

The sources of professional information about pharmacovigilance and ADRs were also identified during the research. According to the data, the main sources of information are the Internet and drug labels (Figure 1). As shown in Figure 1, the chi-square test revealed a significant relationship between the variables ($\chi^2 = 112.672$, $p < 0.001$). This result suggests that the notification association is unlikely to be due to chance.

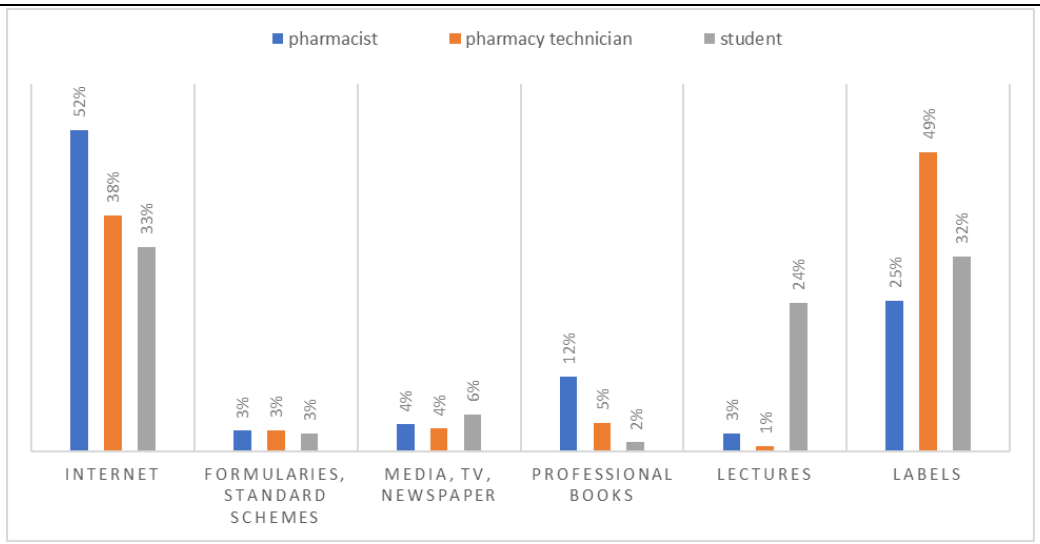

Figure 1.
Main sources of professional information about pharmacovigilance and ADRs. $x^2 = 112.672$, $p = < 0.001$

Over half of pharmacy technicians (58%) find the ADR reporting system in their country accessible and easy to use, while 42% don't agree. For pharmacists, a larger majority (74%) view the system user friendly, but 26% find it challenging. Among students, 63% find the system reachable, though 37% perceive it as difficult to use (Figure 2).

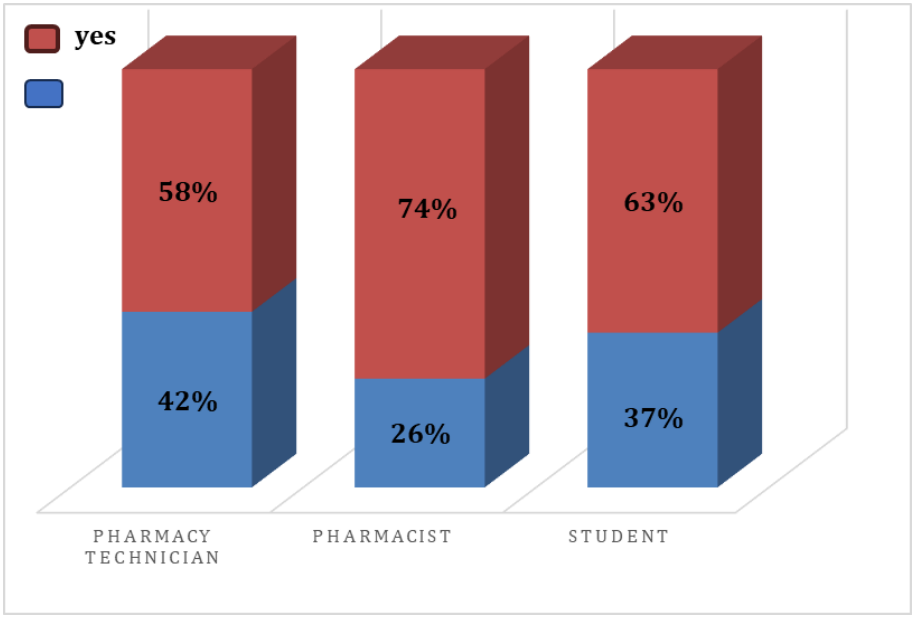

Figure 2.
Pharmacists' perspectives on the accessibility and usability of the national ADR reporting system.
$x^2 = 15.448$ $p \leq 0.001$

One of the most important challenges faced by pharmacists in ADR reporting is the recognition of the inefficiency of the current reporting system, which was cited by 34.2% of respondents, another issue was lack of knowledge or training, which was identified by 24.1% of respondents, time constraints were cited by 15, 1% participants, indicating that busy schedules may hinder their ability to fully engage in reporting activities. The complexity of reporting systems was also noted, with 13.6% of respondents expressing that existing processes were too complex, indicating a need for simplification to facilitate reporting. Finally, 13.1% of pharmacists mentioned the lack of incentives for reporting (Figure 3).

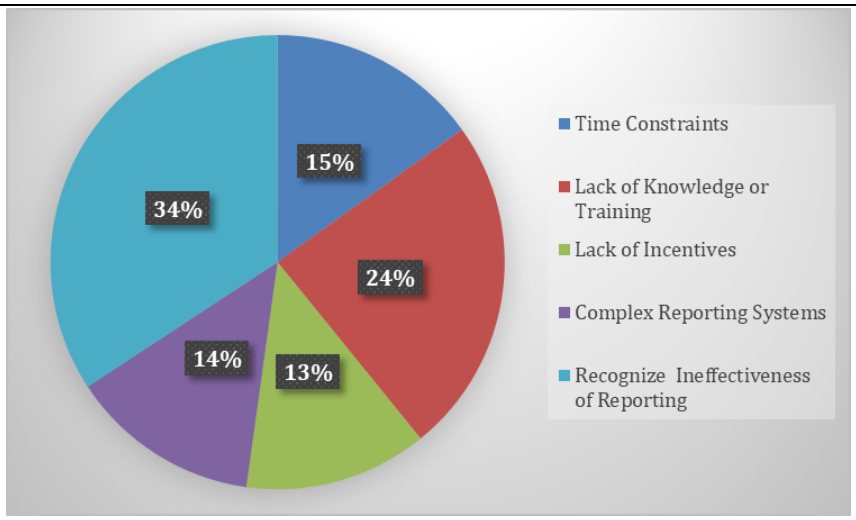

Figure 3.
Common challenges faced in ADR reporting among pharmacists

Factors that might encourage individuals to report ADRs more frequently. Booklets and Guides 40% are the most preferred option, suggesting that easily accessible written resources may help in increasing ADR reporting. Trainings 39% are also significant, indicating a demand for more hands-on or practical learning experiences. Workshops, certificate courses, and online courses show lower interest, which could mean that respondents may prefer more direct and accessible formats for learning rather than formal or digital courses (Figure 4).

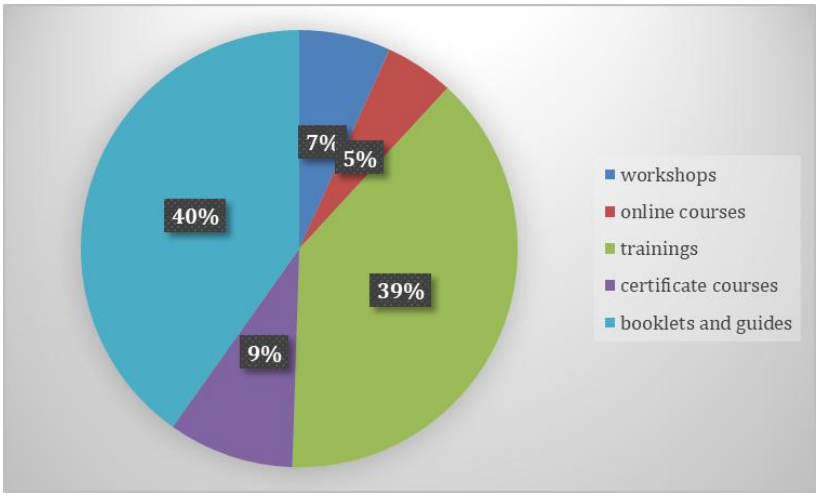

Figure 4.
Pharmacists' preferred resources for increased ADR reporting participation

Most respondents are aged 26-30 (60.7%), followed by 20-25 (19%). The gender distribution is predominantly female at 89.7%, while males make up 10.3%. Education levels include 54.2% pharmacy technicians, 34.6% pharmacists, and 11.2% students. Experience varies: 35.4% have 2-3 years, 24.2% up to 1 year, and 22% have 4-7 years, with few having over 8 years (Table I).

The research participants demonstrated insufficient familiarity with pharmacovigilance and ADR reporting, aligning with the findings of previous studies in the field [14, 15]. The results presented in Table II of this study highlight a concerning gap in knowledge regarding pharmacovigilance and ADR reporting among the surveyed population. A significant majority (71.4%) of respondents indicated they were not familiar with the concept of pharmacovigilance. This lack of awareness is troubling, given the importance of pharmacovigilance in ensuring drug safety and efficacy. The implication here is that educational efforts in pharmacovigilance need to be substantially enhanced, particularly in medical and pharmaceutical education settings. Similarly, 64.4% of respondents were unaware of the process for reporting adverse reactions to new drugs. This is an important shortcoming, as effective and proactive

ADR reporting is essential for the timely detection and mitigation of potential drug-related risks. There is also a lack of understanding regarding what constitutes a serious adverse drug reaction, with 89.8% of respondents misidentifying such reactions. Given that serious ADRs can result in death, life-threatening conditions, hospitalization, or significant disability, this knowledge gap poses a substantial risk to patient safety [16]. Awareness of the World Health Organization's involvement in international pharmacovigilance efforts was quite low, with 84.2% of respondents unaware of this important aspect. This highlights the need for broader, more effective dissemination of information on international efforts and guidelines to improve global drug safety. Additionally, 87.3% of respondents were completely unaware that prescription drugs are monitored under pharmacovigilance. This underscores the need for improved communication and education about the ongoing monitoring, surveillance, and safety evaluations of prescription drugs (Table II). Similar findings were observed in both Northeast Ethiopia and Pakistan, where healthcare professionals were found to be unaware and uninformed about ADR reporting. Consequently, these results emphasize the significance of implementing training programs in other countries as well [17, 18].

The data in Table III provide a comprehensive overview of study participants' attitudes toward pharmacovigilance and adverse drug reaction (ADR) reporting. Insights from these attitudes are extremely important for understanding the behavioural factors that influence pharmacovigilance. A significant number of respondents (69%) do not believe that it is important and necessary to report all adverse drug reactions encountered in their practice. Only 31% recognize and accept the importance of comprehensive ADR reporting. The overwhelming majority (78.3%) do not believe that pharmacists should encourage and educate patients to report suspected ADRs, with only 21.7% agreeing with that notion. This attitude demonstrates a gap in understanding the role of patient engagement in pharmacovigilance.

Educating pharmacists about the benefits and importance of patient-reported outcomes can increase ADR reporting rates and improve drug safety monitoring. It is important to adopt a patient-centered approach using a system of continuous monitoring of drug safety profiles, surveillance through pharmacovigilance. Such an approach would enable drug regulatory authorities to make controlling decisions based on evidence and collected data and further strengthen the country's healthcare system [19].

More than half of the respondents (55.3%) believe that patient confidentiality is important in ADR reporting, while 44.7% do not, which may prevent adequate data collection. This divide suggests a need for clearer guidelines and training on maintaining confidentiality when reporting ADRs.

Emphasizing the importance of confidentiality can build trust and encourage more consistent reporting practices. A majority of respondents (60%) believe that reporting ADRs can contribute to the safer use of medicines, with 40% expressing skepticism. This positive attitude among the majority is encouraging, as it underscores a recognition of the value of pharmacovigilance. However, efforts must continue to convince the remaining 40% of the critical role ADR reporting plays in ensuring medication safety.

The belief that staying informed about pharmacovigilance can improve practice is held by 61.9% of respondents, while 38.1% do not share this view (Table III).

This attitude highlights a general acknowledgment of the benefits of continuous education in pharmacovigilance. Encouraging ongoing professional development and providing accessible resources can help maintain and enhance this positive attitude. A significant majority of participants (90.7%) reported not notifying relevant authorities about all the ADRs they encounter. Only 9.3% of the respondents consistently report all ADRs. This low reporting rate may hinder the overall pharmacovigilance efforts, as unreported ADRs can lead to a lack of comprehensive safety data on medications. Established in 1997, the Pharmacovigilance Center of Armenia operates as an integral part of the Scientific Center of Drug and Medical Technologies Expertise which is a Closed Joint-Stock Company (CJSC) [20]. Despite its long-standing presence, the level of information among pharmacy employees remains relatively low, mirroring the findings of a study conducted in Jordan. In Jordan, the Pharmacovigilance Center has also been operational for an extended period, yet health professionals continue to display limited awareness of ADR reporting [21].

When it comes to reporting ADRs without certainty about the drug causing the reaction, 89.8% of participants refrain from reporting, while only 10.2% do so. This cautious approach might stem from concerns about the accuracy of reports, but it underscores a need for clearer guidelines and training on reporting suspected ADRs. Homologous challenges endure globally; for example, insights gleaned from research undertaken in Saudi Arabia, India, and Iraq highlight the persistent imperative to enhance the education of healthcare personnel regarding pharmacovigilance and adverse drug reaction reporting. A pivotal determinant in this context is the establishment of a robust reporting culture conducive to spontaneous reporting, coupled with the fortification of a comprehensive pharmaco-vigilance system to safeguard medicine safety [22-24].

The survey revealed that 90.2% of participants have not participated in pharmacovigilance training

programs or courses, leaving only 9.8% who have received formal education on this topic. Training is crucial for understanding the importance and methods of effective ADR reporting, suggesting a gap that needs addressing to improve overall pharmacovigilance practices.

Only 24.9% of participants stay updated with the latest safety information on the medications they dispense, whereas 74.9% do not. This lack of current knowledge can impede the ability to identify and report ADRs promptly and accurately. A majority of participants (88.6%) do not educate their patients on the importance of reporting any ADRs they experience. Only 11.4% actively engage in educating patients. Patient education is a critical component of pharmacovigilance, as informed patients can contribute valuable information to ADR reporting systems (Table IV).

Figure 1 provides insight into the preferred sources of information among pharmacists, pharmacy technicians, and students, highlighting significant differences in their information-seeking behaviours. Despite the ideal that drug information should primarily be obtained from professional books such as Emdex and the British National Formulary (BNF), as is practiced in many countries [25], the chart shows that the internet is the most popular source of information across all three groups. Pharmacists show the highest usage at 52%, followed by pharmacy technicians at 38% and students at 33%. This trend is concerning given that information on websites is generally unreliable due to the lack of regulatory oversight. Formularies and standard schemes are minimally used by all groups- at only 3%- indicating they are not the primary reference. Media sources are utilized by 4% of pharmacists and technicians and 6%, by students. Professional books are more favoured by pharmacists (12%) than technicians (5%) and students (2%), highlighting the need for reliable references. Lectures serve mainly as a source for students (24%), while only 3% of pharmacists and 1% of technicians rely on them, reflecting a shift towards practical information sources.

Labels are essential for pharmacy technicians (49% reliance), while 32% of students and 25% of pharmacists use them. Medication leaflets should be accessible to patients, featuring appropriate font sizes, with clear and concise information. Pharmacists should encourage consumers to consult the medication leaflet, but these should not be the primary source of information for pharmacists themselves [26].

Pharmacy employees encounter minimal difficulty when using the National ADR Reporting System (Figure 2), however, research data indicates that the majority of participants did not report newly discovered drug side effects to the relevant authorities (Table IV).

A study in Jordan shows that community pharmacists' awareness of pharmacovigilance, its practical application and ADR reporting remain low, the reasons for which need to be understood and addressed [27]. This investigation identified several challenges pharmacists face in reporting adverse drug reactions (ADRs). A considerable proportion of pharmacists (34%) believe that ADR reporting does not lead to meaningful outcomes, and this perception of ineffectiveness discourages them from appealing in the reporting process. Additionally, many pharmacists lack adequate knowledge or training related to ADR reporting (24%), which may limit their effective participation in pharmacovigilance efforts and this suggests a need for targeted educational programs. Time constraints (15%) also affect the ability of pharmacists to complete ADR reports, while a lack of incentives (14%) poses another barrier. Providing incentives could potentially increase motivation and participation in reporting efforts. Some pharmacists (13%) find the reporting systems too complex, making it challenging for them to fulfill their reporting responsibilities effectively (Figure 3).

Although a study conducted in Saudi Arabia indicates that most community pharmacists possess strong knowledge, attitudes, and practices regarding pharmacovigilance and ADR reporting, the researchers suggest that the government should implement comprehensive pharmaceutical practice guidelines and standards, as well as continuing education programs, to further improve current practices among community pharmacists [28]. According our research pharmacists have specific preferences for resources that can increase their participation in adverse drug reaction (ADR) reporting. The majority, 40%, prefer booklets and guides, while 39% prefer training courses as a way to improve their skills and knowledge related to ADR reporting. The popularity of certificate courses (9%) indicates that pharmacists value formal recognition and in-depth learning opportunities, which may motivate them to become more actively involved in ADR reporting. Workshops are chosen by 7% of respondents. Workshops offer an interactive, hands-on learning experience, though they may not be as comprehensive as full training programs, which may explain their lower preference. Finally, only 5% of pharmacists prefer online courses. The lower interest in online courses may be due to limitations in interactivity or hands-on involvement, which some pharmacists may find less effective for ADR reporting education (Figure 4).

Conclusions

This study underscores the need for improved education and awareness in pharmacovigilance and adverse drug reaction (ADR) reporting to enhance drug safety. It identifies barriers, including reluctance, operational challenges, and privacy concerns, which hinder effective ADR reporting. Enhancing education and awareness can strengthen pharmacovigilance practices and positively impact health outcomes. Additionally, understanding pharmacists' preferences for information resources - such as training and guidelines - can aid in tailoring resources to better support pharmacy practice and education.

Conflict of interest

The authors declare no conflict of interest.

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