

Pharmacovigilance: pharmacists' perspective on spontaneous adverse drug reaction reporting

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Abstract: Globally, adverse drug reactions (ADRs), one of the leading causes of morbidity and mortality, will continue to pose a threat to public health as long as drugs are being used to treat various ailments. Prompt ADR reporting is crucial in ensuring drug safety. The aim of this narrative review was to highlight the role of pharmacists in pharmacovigilance and to identify barriers and facilitators toward ADR reporting documented in the literature. The perspective of pharmacy students on pharmacovigilance and ADR reporting has also been discussed with an aim to highlight the need to improve content related to ADR reporting and pharmacovigilance in undergraduate pharmacy curriculum. Globally, although the role of pharmacists within national pharmacovigilance systems varies, it is very well recognized. In general, pharmacists acknowledge that ADR reporting is part of their professional responsibility and have a positive attitude toward reporting ADRs. However, current research evidence suggests that there are still critical knowledge gaps with regard to ADR reporting among pharmacists, especially in countries where the role of pharmacists within the health care system is limited. These knowledge gaps can be fulfilled through continuous professional development programs and reinforcing theoretical and practical knowledge in undergraduate pharmacy curriculums. Without adequately identifying and fulfilling training needs of pharmacists and other health care professionals, the efficiency of national pharmacovigilance systems is unlikely to improve which may compromise patient's safety.

Keywords: pharmacist, adverse drug reaction, pharmacovigilance, patient safety

Introduction

The World Health Organization (WHO) has defined adverse drug reactions (ADRs) as “a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modifications of physiological function”.¹ Globally, ADRs, one of the leading causes of morbidity and mortality, will continue to pose threat to public health as long as drugs are being used to treat various ailments. A recent review estimated that ADRs were responsible for 3.5% of the hospital admissions.² Furthermore, ~1 in 10 hospitalized patients experienced an ADR in Europe.² ADRs are the fourth to sixth leading cause of death in the USA,³ and it has been estimated that ADRs caused ~197,000 deaths annually in Europe.⁴ In terms of burden on health care system, a prospective UK-based study estimated at any one time the equivalent of up to seven 800-bed hospitals may be occupied by patients admitted with ADRs.⁵ The economic costs associated with ADRs are significant; in the USA, the cost per ADR in intensive care unit (ICU) and

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non-ICU wards has been estimated at USD 19,685 and USD 13,994, respectively.⁶

Pharmacovigilance (PV) is defined by WHO as “the science and activities related to the detection, assessment, understanding and prevention of adverse drug effects or any other possible drug-related problems.”⁷ The scope of PV to improve patients’ safety includes detection and reporting of ADR events, medication errors, counterfeit and substandard medicines, lack of efficacy of medicines, misuse and/or abuse of medicines, and drug–drug interactions. However, ADRs remain the prime focus of PV activities. Accordingly, this review focused primarily on pharmacists’ perspective pertaining to spontaneous ADR reporting.

Spontaneous reporting system (SRS) is the most widely used system globally to report adverse reactions by health care professionals, drug companies, or patients themselves to the national authorities regulating PV activities in the country.⁸ SRS could improve the safety profile of a particular drug by detecting and reporting ADRs that may not have been detected during premarketing clinical trials or even during postmarketing surveillance.^{9,10} Therefore, it could serve as a method of detection for new, rare, or serious ADR events. One of the main advantages of SRS is that it applies to all drugs during its lifetime and not limited to a period of study.¹¹

SRS of ADR also has its limitations. Reports of low quality, known reactions, and inability to establish causal relationship are frequently associated with SRS.¹² In addition, SRS limits the potential of calculating the rates due to incomplete numerator data and undependable denominator.¹³ Moreover, SRS has been associated with underreporting which could affect new drugs and serious reactions.¹⁰ Despite its limitations, SRS is considered as the most cost-effective method in monitoring drug safety.¹⁰

Given the voluntary nature of SRS, health care professionals, including doctors, dentists, nurses, and pharmacists, have an important role in ensuring that ADRs are well documented and reported. Health care professionals’ knowledge about and access to local ADR reporting systems, clinical skills in detecting an ADR, and attitude toward reporting ADRs are the key determinants of ADR reporting. Pharmacists being the drug experts have the central role in ensuring drug safety by detecting and reporting of ADRs. The aim of this narrative review was to highlight the role of pharmacists in SRS and to identify barriers and facilitators toward ADR reporting documented in the literature. The perspective of pharmacy students on PV and ADR reporting has also been discussed with an aim to highlight the need to improve content related to ADR reporting and PV in undergraduate pharmacy curriculum.

Role of pharmacists in ADR reporting

The role of pharmacists in ADR reporting has evolved over the past decade but still vary geographically.^{14–16} Over a decade ago, in Scandinavian countries, pharmacists were not allowed to report ADRs independently.¹⁷ In the UK, pharmacists were only allowed to independently report ADRs after 10-year long debate and struggle.¹⁸ Contrastingly, in Malaysia, in 2010, pharmacists contributed more than half of the total ADR reports received by the Malaysian National Pharmacovigilance Center.¹⁵ An international survey of 41 member states participating in the WHO Drug Monitoring program published in 2004 also found considerable variations in the role of pharmacists in reporting ADRs.¹⁴ The variation in the role of pharmacists in PV activities can be explained by the variations in pharmacists’ role within health care system across the globe from mere “dispenser” to the guardian of drug safety and patient outcomes. As the role of pharmacists within the health care systems continues to evolve, their role in ADR reporting is getting recognized. Research evidence shows that recruitment of pharmacists in public hospitals can not only detect and report ADRs but also prevent ADRs and reduce associated humanistic and financial costs.^{18,19} Furthermore, hospital pharmacists are more likely to report ADRs compared with community pharmacists.¹⁴ This could be explained by the fact that pharmacists with a clinical background have greater awareness about ADR reporting system and are frequently engaged with prescribers.²⁰ Furthermore, regular contact with the patients coupled with the access to patients’ medical records allows clinical pharmacists at the hospitals to develop a better understanding of the suspected ADRs.²¹ Nevertheless, being the most accessible health care professional, community pharmacists have a crucial role in ensuring drug safety as well by detecting and reporting ADRs, especially in areas where access to general practitioners/primary care physicians is limited.

Pharmacists’ perspective on ADR reporting

Given that both community and hospital pharmacists can play an important role in ADR reporting, a number of studies have been conducted globally to evaluate knowledge, attitudes, and practices of pharmacists toward ADR reporting with an aim to identify knowledge, attitudes, practices, and barriers to ADR reporting, so that appropriate interventions can be designed and implemented to overcome these barriers.^{21–36} A summary of studies evaluating pharmacists’ knowledge and practices toward ADR reporting published between 2011 and 2016

are presented in Table 1. In general, pharmacists expressed willingness to report ADRs and considered ADR reporting as part of their professional responsibility. However, a number of barriers to ADR reporting experienced by pharmacists have also been identified in the literature.^{21–38} Broadly, these barriers can be classified as health system-related barriers and individual pharmacist-related barriers (Figure 1). Although a number of these barriers are interrelated, this broad classification is made just for ease of comprehension and to identify potential target areas for interventions aimed at improving ADR reporting rates.

The most commonly reported barrier is the lack of knowledge about local reporting guidelines and policies and establishing ADR causation with suspected drug. Another well-documented misconception among pharmacists is to report only serious and/or new ADRs. In the UK, a study evaluating the knowledge and attitudes of hospital pharmacists toward ADR reporting reported that almost half of the participants were unclear about what type of ADRs should be reported.³⁷ Similarly, another study conducted in People's Republic of China aimed to identify reasons for underreporting of ADRs by hospital pharmacists and concluded that the inability of hospital pharmacists to establish the seriousness of an ADR was one of the barriers to ADR reporting.²⁹ The uncertainty of pharmacists toward ADR reporting could have been influenced by their lack of awareness about ADR reporting. Furthermore, pharmacists may be reluctant to report minor reactions and would only report an ADR once they have established the association of the ADR with the suspected drug.³⁸ Concern of submitting inappropriate reports is also a commonly cited barrier to ADR reporting.³⁸

From the discussion above, it is evident that pharmacists' knowledge and attitudes have influence on ADR reporting. Subsequently, in almost all the cross-sectional studies conducted across the globe, pharmacists themselves have highlighted the need for more training both in detecting and reporting ADRs. Therefore, many of the studies concluded that continuous training, providing feedback to reporters and providing incentives (either financially or in term of continuous pharmacy education points) could be the effective methods in persuading more active involvement from community pharmacists in PV activities.

Strategies to improve ADR reporting

As a broad principle, strategies for improving ADR reporting should be targeted both at the health care system level and individual pharmacist level. In addition to encouraging

pharmacists to report ADRs, their knowledge and skill deficits in detecting and reporting ADRs should also be fulfilled through continuous professional development programs. Evidence suggests that provision of continuous education to health professionals is instrumental in changing their behaviors and attitudes toward ADR reporting.^{39,40} The aim of such education should not only be limited to improve the pharmacists' knowledge about ADRs but also be directed to change their attitudes and perceptions toward ADR reporting. Studies have also reported that increased training is associated with an increased likelihood to ADR reporting.^{37,41} Nonmonetary incentives (e.g., certificate of recognition) for pharmacists who report ADRs is another method of improving spontaneous reporting of ADRs.^{36,40,41}

On health-system level, to engage community pharmacists more in ADR reporting, providing community pharmacists with access to patient's medical and medication history will enable pharmacists to establish ADR causation and report ADRs as inability to establish causation deter pharmacists from reporting ADRs. Research evidence also suggests that electronic ADR tools can also improve spontaneous reporting of ADRs.^{42,43} Introduction and integration of electronic ADR reporting system with hospital information system at a 400-bed tertiary hospital in Spain led to an increase in the ADR reports submitted to the PV center.⁴³ The integrated ADR tool also allowed easier analysis of submitted ADR reports and automatic notification of suspected allergies to the allergy department.⁴³ The effectiveness of electronic reporting in improving the spontaneous reporting of ADRs has been reported at a children hospital in the UK as well.⁴² This study was conducted to assess the impact of electronic reporting and monitoring of ADRs in children and to determine whether it could supplement the conventional Medicines and Healthcare Products Regulatory Agency Yellow card reporting system (standard ADR reporting form used in the UK). During the study period, 87 ADR reports were submitted through the electronic system compared with only 8 ADR reports, which were submitted to the Yellow card scheme suggesting the superiority of electronic reporting system compared with traditional paper-based reporting system.⁴²

Perspective of undergraduate pharmacy students

It is imperative to ensure that pharmacy students, the future pharmacists, are well trained and have sufficient knowledge pertaining to procedures and importance of ADR reporting.⁴⁴ They should be able to recognize, prevent, and report an ADR. There are nine studies exploring the pharmacy students'

Table 1 Summary of studies evaluating knowledge, attitude, and practices of pharmacists toward ADR reporting

| Study ID | Methods | | | Results | |
|---|---|--|----------------------------|--|---|
| | Method/population | Sample size | Instrument | Knowledge | Attitude/practices |
| Suyagh et al ³⁵ / Jordan | Cross-sectional/ community and hospital pharmacists | 208 (130 community pharmacists; 78 hospital pharmacists) | Questionnaire | Only 19.2% and 67.7% could define PV and ADR correctly, respectively. 68.5% were not aware of the existence of PV center in Jordan and 85.4% did not know about the official ADR reporting form. | Reasons for not reporting: lack of information from patient; ADR form not available; unaware of existence of national PV system; ADR too trivial. |
| Mahmoud et al ³⁰ /Saudi Arabia | Cross-sectional/ community pharmacists | 147 | Questionnaire | Only 22.1% were familiar with ADR reporting process in Saudi Arabia and 80% were not aware of the availability of online reporting system. | 87.5% did not report ADR if they encountered one and referred patients to physicians. Unaware of reporting method, ADR reporting being physicians' responsibility, and ADRs encountered by community pharmacists are usually minor and need not to be reported were the most common reasons cited for not reporting ADRs. |
| Khan ²⁸ /Saudi Arabia | Cross-sectional/ community pharmacists | 50 | Questionnaire | 92% could define ADR and 90% were not aware of the existing ADR reporting system available in Saudi. | Major reasons for not reporting included: unavailability of professional ambience to discuss ADR; ADR form not available; reporting form is complicated; it is time consuming. |
| Elkalmi et al ²⁵ / Malaysia | Cross-sectional/ community pharmacists | 116 | Questionnaire | Only 11.6% could define PV correctly and 75% were not aware the existence of PV system. 68.3% did not know that ADR reports can be submitted online. | Reasons for not reporting ADRs included: did not know how and where to report; ADR form not available; serious ADR already detected prior registration. |
| Al-hazmi and Naylor ²³ / Saudi Arabia | Cross-sectional/ community pharmacists | 170 | Face to face interviews | Only 18% were aware of the national ADR reporting system and more than half (56%) of the respondents did not know about the existence of the national PV center. | 38.8% agreed that pharmacists are responsible for reporting ADRs. 94.1% felt that ADR reporting should be made compulsory. ADR form not available, did not care to report, ADR already known, and did not know how to report were the common reasons for not reporting ADRs. |
| Qassim et al ³³ /UAE | Cross-sectional/ community pharmacists | 223 | Questionnaire | Only 4.9% of the participants had good knowledge score. 44% were not aware about ADRs reporting program in UAE. | 93.7% had a positive attitude toward reporting ADRs. However, only 3.6% of the participants had sent ADR reports to MOH or the pharmaceutical companies at least once. |
| Jose et al ²⁷ / Oman | | 93.7% had a positive attitude toward reporting ADRs. However, only 3.6% of the participants had sent ADR reports to MOH or the pharmaceutical companies at least once. | | 88.8% of the pharmacists were aware of the national PV program in Oman. However, 20.5% thought that only adverse reactions to a new drug need to be reported. | 90.6% considered it part of their professional obligation of pharmacists. Sixty four percent rejected the notion that ADR reporting would increase unnecessary workload. 91.5% and 86.9% of pharmacists would inform patient regarding important side effects of a medication and regarding actions needed to avoid ADRs, respectively. |

(Continued)

Table 1 (Continued)

| Study ID | Methods | | | Results | |
|---|--|--|--|---|---|
| | Method/population | Sample size | Instrument | Knowledge | Attitude/practices |
| Duarte et al ²⁴ / Portugal | Mixed-methods/ community pharmacists | 154 | Questionnaire and qualitative interviews | One-quarter of the respondents were familiar with the new ADR definition. 38.3% had previously reported an ADR. Educational interventions were believed to be the main facilitator. | ADR reporting was considered as very important by 66.9% of the respondent. Unsure of causal association between drug and reactions, lack of time, and ADR already known were commonly cited barriers. |
| Yu et al ³⁶ / South Korea | Cross-sectional/ community pharmacists | 1001 | Questionnaire | 95.5% recognized pharmacists' duty to report ADRs. However, only 77% of the respondents knew about the national PV system in Korea. | 87.1% of the respondent had encountered ADR but only 29.4% had reported an ADR. Among reasons for not reporting ADRs were ADR was not serious; already known ADR; and unsure of causal relationship between drug and reactions. |
| Rabba and Mohammad ³² / Saudi Arabia | Cross-sectional/ community pharmacists | 53 | Questionnaire | Only 25% were aware of the existence of the PV system in Saudi Arabia and 74% of the participants did not know where to report ADR if encountered. | 85% considered ADR reporting as pharmacists' responsibility and 95% believed that PV is important. ADR form not available; confidentiality; and inability to establish causation were the commonly cited reasons for not reporting ADRs. |
| Hadi et al ²⁶ / Malaysia | Cross-sectional/ hospital pharmacists | 163 | Questionnaire | 95.0% and 79.1% correctly identify definitions of ADRs and PV, respectively. 97.5% were aware on how to locate an ADR form. 95.0% of the pharmacists involved also knew that ADR should be sent to MADRAC. | All pharmacists agreed that ADR reporting is part of their professional responsibility. Reasons for not reporting ADRs included: lack of information from patient; ADR already well known; minimal feedback received, and too busy to report. |
| Liu et al ²⁹ / People's Republic of China | Case-control (case – pharmacists who had reported ADR between January 2008 and December 2010; control – pharmacists who had not reported ADR for the same period)/hospital pharmacists | 558 (186 from cases and 372 from controls) | Questionnaire | Pharmacists who had reported an ADR had higher compared to those who had not ($p=0.005$). More than half were of the availability of phone reporting and e-mail reporting. | Majority agreed that reporting ADR is the professional responsibility of pharmacists. Most of the participants agreed that easier reporting system can increase reporting rate. Top three reasons cited that might affect ADR reporting were seriousness of the reaction, expected reaction to the drug, and lack of mandatory regulation on ADR reporting. |
| Obara et al ³¹ / Japan | Cross-sectional/ community pharmacists | 1795 | Questionnaire | About 77% did not understand the national ADR reporting system and pharmacists' knowledge was significantly associated with gender, age, level of education, working experience, and number of pharmacists in the hospital. | Reasons for not reporting ADR were well-known reaction, unsure of causal relation between drug and reactions, and did not know how to report and ADR. |

Abbreviations: ADR, adverse drug reaction; PV, pharmacovigilance; MADRAC, Malaysian Adverse Drug Reactions Advisory Committee; MOH, Ministry of Health.

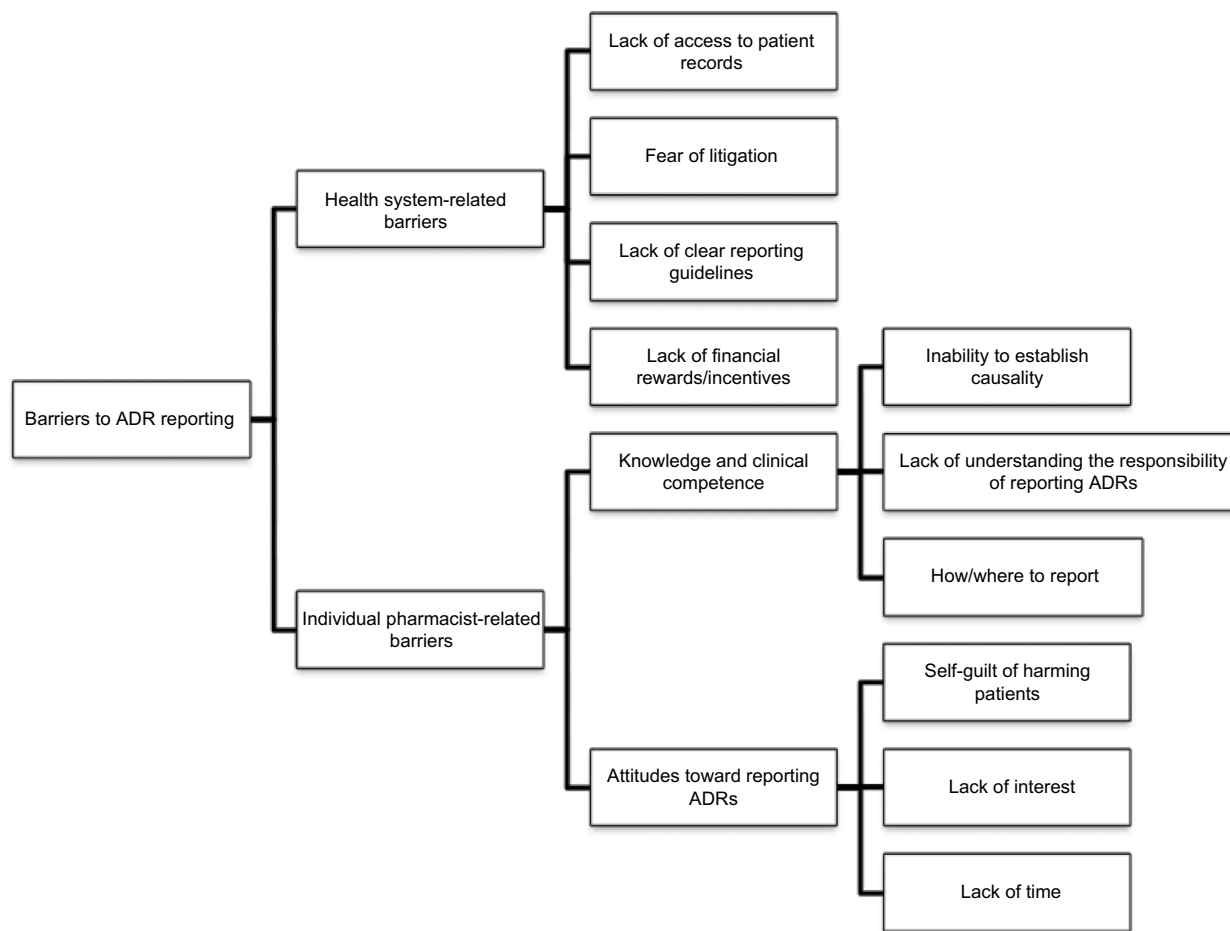


Figure 1 Barriers toward ADR reporting experienced by pharmacists.
Abbreviation: ADR, adverse drug reaction.

perspectives in PV and ADR reporting. Therefore, a number of studies have evaluated perspective of pharmacy students toward PV and ADR reporting.^{44–51} All were cross-sectional studies, using a structured validated questionnaire, involved mainly the Bachelor of Pharmacy (BPharm) students.^{44–51} Only one study⁴⁴ was conducted in the Western country (i.e., the USA), whereas the rest were carried out in Asian region.^{44–51}

The majority of the published studies investigated knowledge, attitudes, and perception of the pharmacy students on ADR reporting,^{44–51} except one that also looked into the practice aspect of PV and ADR reporting.⁴⁷ In general, most studies reported that the pharmacy students had insufficient knowledge in PV or ADR reporting.^{34,44,45,47,48} Approximately only 24.4%–62.4% of the pharmacy students were able to define PV and ADR correctly^{44,48,49,51} and less than half of them knew the exact mechanism of ADR reporting (e.g., where to obtain ADR reporting form, when to report, and whom to report).^{45,47,48} In certain studies, up to 88% of the surveyed students did not know how causality assessment of an ADR is being conducted,⁴⁹ and 70%–80% of them did

not know about the PV program in the nation,^{48,51} reflecting their poor knowledge in this area.

Of note, Doctor of Pharmacy (PharmD) students were significantly more knowledgeable in PV and ADR reporting when compared with BPharm students.^{46,47} Likewise, in the study by Saygi et al,³⁴ higher knowledge score in PV was reported among the fifth year BPharm students than those in the first year of the pharmacy study. The level of knowledge regarding PV among the pharmacy students was found to be significantly associated with their previous exposure to the relevant topics, such as PV, ADR reporting, and pharmacoepidemiology.^{45,46} Also, it was noted that pharmacy students who had any previous experience or exposure to ADR would have significantly better knowledge in PV and ADR reporting.^{45,46}

Pharmacy students generally expressed a positive attitude toward PV and ADR reporting.^{44,46–48,50} The majority of the surveyed pharmacy students agreed that PV is crucial, and all health care professionals including pharmacists should actively report ADR in their daily practices.^{46–48,50} Most believed that by reporting ADR can educate others

about the risk of the drugs, improve patient safety, and it is personally rewarding.⁴⁴ No significant difference in attitude was observed between the PharmD and BPharm students,⁴⁶ except more PharmD students considered ADR reporting as their major responsibilities being a pharmacist.

The perception and barriers toward PV and ADR reporting among the pharmacy students have been explored; most BPharm students have indicated that limited training and exposure to PV and ADR reporting were the major reasons for their poor knowledge and lack of preparedness in handling ADR reporting cases.^{44–48,50,51} About 30%–50% of the BPharm students reported that they had taken a PV course or felt that the PV-related topics had been well covered in the curriculum.^{44,45,49} However, PharmD students claimed that they were adequately trained to handle ADR reporting.⁴⁶ Accordingly, more emphasis in PV topics should be given in the BPharm courses to sufficiently prepare them for ADR monitoring and reporting when working as pharmacists in the future. In addition, the majority of the pharmacy students (i.e., 81.9%–86%) perceived that the paucity of information provided by the patients was one of the major barriers toward ADR reporting.⁴⁶ Indeed, this insufficient information had led to the difficulty in causality assessment of an ADR. The lack of encouragement and incentives by the relevant authorities in ADR reporting was another main reason of underreporting among the pharmacy students.^{44,46} The pharmacy students agreed that the use of health information technologies (e.g., online reporting system), the provision of legal protection by the relevant authorities, and the mandatory in ADR reporting would ensure a proper and effective PV process.⁴⁶

Conclusion

Pharmacists, being drug experts and guardian of safe and effective use of medicines, have an important role in not only detecting, reporting, and monitoring of ADRs but also preventing ADRs. Knowledge gaps with regard to ADR reporting still exist among pharmacists, especially in countries where the role of pharmacists is still in transition from being product oriented to patient oriented. These knowledge gaps can be fulfilled through continuous professional development programs and reinforcing theoretical and practical knowledge in undergraduate pharmacy curriculum. Engaging community pharmacists in ADR reporting by giving them access to patient's medical record and introducing electronic reporting system can also improve ADR reporting rate. Without adequately identifying and fulfilling training needs of pharmacists and other health care professionals, the efficiency of national PV systems are unlikely to improve, which may compromise patient safety.

Disclosure

The authors report no conflicts of interest in this work.

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