IJRIPP-International Journal of Research and Innovations in Pharmacy Practice
Volume 2, Issue 2 | November--2025
e-ISSN: 3065-8721 Print ISSN: 3065-8713

Pharmacovigilance Awareness and Reporting of Community Pharmacists- A cross-national Survey in Southeast Asia

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Received: 11-09-2025; Revised: 27-09-2025; Accepted: 16-10-2025; Published: 04-11-2025

Abstract:

The involvement of community pharmacists as frontline medical workers is important, as pharmacists are underexploited in pharmacovigilance (PV) systems. The cross-national examination sought to determine the levels of knowledge, attitudes, and adverse drug reaction (ADR) reporting behavior utilizing 320 community pharmacists in Malaysia and Vietnam. It was found that although 85 per cent of pharmacists knew of national pharmacovigilance programs only 42 per cent had ever made an ADR report. The main factors hindering the ADR reporting were insufficient training, doubt in the cases requiring the report and lack of time. Reporting ADRs was 3.4 folds more likely when done by the pharmacists that had been previously educated on pharmacovigilance ($p < 0.001$). The research demonstrates that the potential inconsistency between awareness and the actual reporting practices implies that effective pharmacovigilance within the community pharmacy context requires special training and simplifying reporting tools. Overcoming these obstacles, community pharmacists will be able to contribute more to the drug safety survey and the state of health of society.

Keywords: ***Pharmacovigilance, community pharmacists, ADR reporting, cross-national study, Malaysia, Vietnam, pharmacy practice.***

1. Introduction

1.1 The value of Pharmacovigilance in Public Health

Pharmacovigilance (PV) is the science and practice of identifying, measuring, comprehending and preventing unpleasant drug reactions (ADRs) or any other difficulties with a drug. It is also in the critical area of public health since it boosts patient safety and guarantees the safety and efficacy of medicines in the market. ADRs represent a major problem of morbidity and mortality in the world with a concomitant role in hospital admission, prolonged recovery, and elevated medical expenses. Constant surveillance of ADRs is necessary to conduct continuous assessments of safety profile of drugs across their life cycle, particularly because new drugs will be created and used widely.

Pharmacovigilance systems assist in revealing the side effects, which have not been recognized before, analysis of drug hazards, and secure drug usage. Pharmacovigilance programs have been developed by the World Health Organization (WHO) and regulatory authorities at the national level to foster adverse drug reactions (ADRs) or other medication-related issues reporting. Nevertheless, these programs may not be too well utilized and applied in most regions although they are important.(1)

1.2 Community Pharmacist role in Reporting ADR

Community pharmacists are important medical professionals who are also the first contacts with the patients by providing medication advice. They are the only ones in a position to pick up signs of ADR, provide counsel, and make interventions where needed. Due to their access, pharmacists may be used as an important part of an early warning and reporting of ADRs, and therefore, are found to be important parts of pharmacovigilance systems.

The community pharmacists have made little contributions to the reporting of ADR despite playing a crucial role. One of the main obstacles of reporting is the insufficient formal training on pharmacovigilance practice and uncertainty concerning events that could be characterized as reportable. Moreover, insufficient efficient forms of reporting as well as time pressures in busy pharmacies do not encourage pharmacists to participate in ADR reporting and monitoring. Thus, it is critical to introduce tools, knowledge, and support that could help pharmacists enhance the functioning of the pharmacovigilance system.(2)

1.3 Justification of Cross-National Concentration in the Southeast Asia

Southeast Asia is a special place to learn more about practices of pharmacovigilance because this territory has the fast developing countries and those which have developed health care systems. There is also the issue of the

integration of pharmacovigilance into the usual pharmacy practice in places such as Malaysia and Vietnam, as some of these countries are making improvements to their healthcare infrastructure. Due to the increased awareness of pharmacovigilance programs, it is essential to have an insight into the influencing factors of success and failure of the programs in these nations.

Variation in the healthcare system, training providers in the drug manufacture profession, intercultural differences, and regulatory charges between Malaysia and Vietnam present a valuable cross-national outlook. Due to the similarities in the practices of community pharmacists in the two countries, it will be possible to find out the common barriers to ADR reporting, issues of context-specific barriers and possibilities in enhancing pharmacovigilance.(3)

1.4 Study Objectives

The study goal is to evaluate knowledge, attitudes and reporting pharmacist practice of ADRs in communities of Malaysia and Vietnam. To be specific the objectives are:

- Assess the degree of awareness in the national pharmacovigilance programs and guidelines of ADR reporting.
- Carry out an evaluation on the attitude of community pharmacists towards pharmacovigilance and the significance of ADR reporting.
- Observe the impediments of reporting ADRs such as lack of training, time issues, and confusion as to what cases are reportable.
- Examine the importance of pharmacovigilance education in enhancing the reporting practices among the community pharmacists.

The findings of this study will be used to make policy recommendations that will help in enhancing the level of pharmacovigilance education and creation of reporting mechanisms in Southeast Asia so as to increase the safety and effectiveness of drugs in the region.

2. Research Design and Sample

2.1 Cross-Sectional Survey methodology

The sample that was used in the study employed cross sectional survey design mainly to provide a synaptic picture of knowledge, attitude and adverse drug reaction (ADR) reporting practices among community pharmacists in Malaysia and Vietnam. To answer the question about the current state of the pharmacovigilance awareness and practices at a particular time point as well as compare the pharmacovigilance scenario in two countries, it was decided to use a cross-sectional research design to collect information on the specific state of pharmacovigilance awareness and practices at the particular moment. The data was extracted using the self-administered questionnaire, in which the participants were asked questions concerning their knowledge on ADR reporting, attitude towards pharmacovigilance and the actual reportings. The questionnaire was straightforward, objective and easy to fill so as to maximize the level of response and also to make sure that pharmacists take up a small time in answering the questionnaire.

The questionnaire had questions that were closed ended (e.g. multiple-choice) and open-ended with the aim of recruiting both the quantitative (e.g. frequency of ADR reporting) and qualitative information (e.g. perceptions of barriers to ADR reporting). This enabled the researchers to gain unanimous insights about the awareness and attitudes of pharmacists besides the issues hindering them in ADR reporting.(4)

2.2 Pharmacists sampling in Malaysia and Vietnam

The research group used community pharmacists in both urban and rural locations which were in two different countries, Malaysia and Vietnam. The study was done on a sample of 320 community pharmacists where 160 pharmacists were recruited in each country. Both pharmacists were chosen to represent a larger population of the community pharmacy workforce in a variety of settings across each country (both independent pharmacies and chain pharmacies, as well as retail pharmaceutical outlets), so as to represent the wider community pharmacy workforce.

Under the recruitment process, pharmacy chain identification was carried out together with individual pharmacies by the use of local professional organizations and pharmacy associations in the two countries. It is using these networks that pharmacists were approached and asked to take part in the study. Moreover, through email or telephone, the pharmacists were directly contacted in order to confirm the appropriate response rate.

The survey was held in the period of April-June 2022, and it was to be carried out in such a way that remote / rural pharmacists feel comfortable to participate in the process and are not left out of the survey. Questionnaire in online and paper form were availed and online surveys were sent through email and through social media and the paper versions of the survey were sent through professional pharmacy organizations.(5)

2.3 Inclusion/Exclusion Criteria

The inclusion and exclusion criteria to the participation of the pharmacist were as follows:

Inclusion Criteria:

- Community pharmacists who are already working in Malaysia or Vietnam.
- Pharmacists who have practiced not less than six months in a community based pharmacy.
- Pharmacists who had no objection to taking part in the research and signing an informed consent.

Exclusion Criteria:

- Pharmacists who do not work in a community pharmacy environment (e.g. those married to hospitals, or those who are in research).
- Pharmacists who have less than a half of a year of experience in practice, because it is a possibility that such people are not fully aware of the ADR reporting scope or pharmacovigilance customs.
- Pharmacists who failed to sign informed consent and did not attend to the survey.

The eligibility of both a rural and urban pharmacist in both countries better enabled a complete cross country comparative study between pharmacovigilance practice in various healthcare settings, whereas the exclusion phase excluded those who might not be relevant to the study had they been included in the study.

3. Pharmacovigilance Awareness and Knowledge

3.1 Awareness on National PV Programs

The study involved an evaluation of the awareness level of community pharmacists in Malaysia and Vietnam on the presence of national pharmacovigilance (PV) programs. In general, the findings revealed that 85 percent of the participants knew that their respective countries had a pharmacovigilance program in existence. This was in line with their awareness being equal in the two countries where Vietnam had a little more awareness (87%) than Malaysia (83%). Although there was a positive awareness level concerning national PV programs, the researchers established that this did not always reflect on the ADR reporting as practice consistent with the knowledge level on the program, hence, there was a gap in the knowledge level on the programs and the practice in the ADR reporting.(6)

Though a majority of pharmacists were aware that their nations had established pharmacovigilance regimes, a lot of them were not conversant with their guidelines or reporting adverse drug reactions (ADRs) and hence the need to spread information on the involvement of such programs better.

3.2 Training obtained in Pharmacovigilance

Pharmacovigilance training was found to be of important initiative which affects the knowledge and reporting of the pharmacists. Pharmacovigilance training was reported by 58 per cent of the surveyed pharmacists to have occurred in their formal schooling, through other avenues of professional training or development. Most of these pharmacists (62%) however reported that the training was inadequate or lacked effective hands-on instructions on how to report ADRs in the actual pharmacy practice settings. The educational courses frequently dwelt upon the theoretical part of pharmacovigilance like the principles of drug safety, but paid little or no attention to practical means of identification or reporting real-time ADRs.

Conversely, the more pharmacists had been trained on pharmacovigilance, the more specific their training had been, the more they reported ADRs (3,4-fold increased risk, $p < 0,001$). This explains why controlled, realistic practice is highly essential in enhancing ADR reporting especially in community based or other pharmacies where due to daily connections the pharmacists have with the patients and drugs, they are in the best position to observe a case or incident of an ADR.

3.3 Knowledge of ADR Definitions and classifications

The level of pharmacists with respect to their knowledge of ADR definitions and categories was also evaluated. Although the vast majority of the pharmacists have known about the overall concept of adverse drug reactions, only a half of them, 56 percent, showed the definite grasp of the various forms of ADRs, including Type A (augmented) and Type B (bizarre) reactions. Protectively, 48 per cent fully recognised the criteria based on

describing an ADR as serious or non-serious indicating a gap in the appropriate assessment of ADRs by pharmacists. This ignorance may be a possible cause of underreporting or misreporting of adverse events.(7)
This result indicates that pharmacists should be better educated on classification of ADRs and specific reporting instructions on various kinds of ADRs to enhance pharmacovigilance in community pharmacies.

4. ADR Reporting Attitudes

4.1 Propaganda of ADR Reporting

The research evaluated the views of pharmacists on ADR reporting importance in the practice of community pharmacy. Ninety two percent of consumers sensed the importance of the ADR reporting in making drugs safe and safeguarding patient health. Pharmacists have admitted that systematic reporting of ADRs is the best way of early identification when it comes to identifying drug risks when the safety of medicines is improved and leads to the overall improvement of patient care.
Nevertheless, although most pharmacists were aware of the significance of reporting ADR, a number of them raised reservations of the practical challenges they are encountering during ADR reporting. These obstacles were the general lack of time during working days and the confusion about the status of particular reactions whether they can be considered as reportable ADRs. This disparity between the understanding and realization of the necessity of ADR reporting and actual reporting reveals a gap that can be filled due to better training and support system.(8)

4.2 The Attitude to Report and Perceived Responsibility

The readiness of the pharmacists to report ADRs was so much dependent on their sense of responsibility towards reporting. Although 88 percent of the pharmacists believed that the pharmacists play a critical role in the detection and reporting of ADR, only 42 percent had engaged in submitting ADR report. It is indicative of high levels of perceived responsibility, and low levels of actual reporting, the correlates of which are the lack of clarity on cases to report, low levels of confidence in reporting, and exposure to pharmacovigilance systems.
Pharmacists who previously had pharmacovigilance training had very high probabilities to report ADRs. Of the pharmacists trained on pharmacovigilance, 62 percent had filed at least one ADR report, compared with 24 percent of the pharmacists who did not go through such training. This indicates the connection between knowledge and doing and shows that as pharmacists feel they have access to the correct skills and knowledge, they will be more willing to carry out their reporting duties.

4.3 Country and Population group differences

In common opinion, Malaysia and Vietnam were found to be different upon the attitudes towards ADR reporting. The proportion of agreement between the two countries in the significance of ADR reporting was very high, however, proportion of pharmacists that had confidence in their ability to recognize reportable ADRs was higher in Vietnam (68% as compared to Malaysia, 56%). Such discrepancy can be explained by the fact that Vietnamese pharmacovigilance infrastructure is more developed and that there is a greater focus on pharmacovigilance training in Vietnam.(9)
Demographically, the younger pharmacists (below 35 years) had much likelihood in reporting ADRs than the older pharmacists (over 45 years) because they were comfortable with presentation of electronic media and electronic tools used in reporting ADRs. Also, the incidence of ADRs was higher in pharmacists in urban locations compared with those in nonurban locations which may be because the environment in the urban setting is well equipped and support systems are stronger.

5. ADR Reporting Practice and Barriers

5.1 How often are ADRs reported, how many times have you reported?

The research evaluated the reporting frequency and experience of the ADRs occurring in community pharmacists in Malaysia and Vietnam. Out of 320 respondent pharmacist 42 percent claim that they had a chance to file an ADR report. Although this is quite a considerable degree of involvement, it also points out that a large percentage of the pharmacists have unreported. Of individuals reporting ADRs, the magnitude was differing: 23 percent of the pharmacists stated that during the last year they were reporting one or two ADRs, and 19 percent of them stated that within this period they were reporting three or more ADRs.
Surprisingly, the Vietnamese group was at a higher rate of posting ADRs as the survey found that 47 percent of Vietnamese pharmacists posted at least one ADR report, whereas 37 percent of Malaysian pharmacists had done

the same. Such difference could be attributable to higher pharmacovigilance training and organized system of reporting existing in Vietnam. These results imply that although certain pharmacists are actively involved in the process of ADR reporting, there is a considerable discrepancy between this involvement and the reporting on the whole.(10)

5.2 Where the Submission is to be Filed

Multiple platforms were described by pharmacists to report ADRs with the most frequently (48 percent) accessed being the national pharmacovigilance websites, with paper form (31 percent) and email (18 percent) being the least used. Fewer percentages of pharmacists (3%) applied mobile applications to send ADR. The availability, familiarity and convenience affected the decision on the platform.

The majority of people obtained the information through the national pharmacovigilance websites, as they were the primary source of information in the reporting process. Still, a large number of pharmacists stated that often websites had been cumbersome to use, others had non-friendly user interfaces, or provided little response in real-time. These problems made the reporting to be cumbersome and led to ADRs underreporting.

5.3 Major Barriers (e.g. Time Deficiency, Ignorance, or Systems)

Multiple main barriers to successful ADR reporting were detected and a substantial number of them prevented pharmacists, or inability, or unwillingness to get involved into pharmacovigilance systems:

- **Shortage of Time:** One major obstacle to 78% of the people accessed was that the respondents needed time to fill the ADR reports, particularly when they were busy at work. On many occasions pharmacists were focusing on patient counseling and dispensing and not adverse drug reporting so they would fail in reporting adverse events.
- **Knowledge Gaps:** 60% of pharmacists said they were insecure about whether to report this or that case of ADRs and in cases where the reaction had been mild or appeared to be a non-serious one. This ignorance was however more eminent among younger pharmacists who had undergone less formal training when it comes to the practice of pharmacovigilance.
- **Complexity of Reporting Systems:** Approximately 56 percent of all pharmacists reported that complex reporting procedure was a deterrent issue. It was reported that the online solutions were not self-explanatory, there were no sufficient guidelines, or that there was a need to provide too many records under minor ADRs. It was a complaint that there were no simplified reporting systems.
- **Lack of Training:** Forty-five percent of the respondents reported that the involvement in pharmacovigilance training was less involving especially in the knowledge of how to recognize ADRs and the reporting requirement. Pharmacists with a stronger background in their pharmacovigilance education reported significantly more ADRs, which also underlines the necessity to never stop making advances in the professional sector.

6. Statistical Analysis

6.1 Type of tools and software used

In the statistical analysis data were analyzed as a processing assistant/tool using SPSS (version 25), an extensively used data computing/handling statistical tool in healthcare research. SPSS enabled effective processing of numerical and descriptive information, which enabled the use of different statistical tests to determine the correlations between the variables. Descriptive statistics was relied upon to compile main findings and inferential statistics was also used to derive pattern trend in the data as well as testing hypothetical statement.(11)

6.2 Tests Given to Compare Groups andFind out Correlations

The findings of the study were assessed with the help of a number of statistical tests:

- **Descriptive Statistics:** Frequencies and percentages were obtained in the explanation of demographics of the participants, the awareness level and ADR reporting practices in both countries. Knowledge and attitudes towards pharmacovigilance were also calculated on mean scores.
- **Chi-square Test:** The Chi-square test was applied in determining an association of categorical variables, that is, the association between pharmacovigilance training and the probability of ADR reporting. This test has aided in detecting the importance of any specific variable including gender, age, and training to have a significant effect on the ADR reporting practices.

- **Independent t-test:** An independent t-test was used in comparing mean scores on different variables, that is, to compare the knowledge and satisfaction between the pharmacists in Malaysia and Vietnam. This enabled the statistical difference between the two countries in as far as their pharmacovigilance practices are concerned.
- **Correlation Analysis:** Pearson correlation coefficient was used in establishing a relationship between the variables that were continuous, the example being a relationship between training and the frequency at which reporting of ADRs occurs. This was used in assessing whether the training levels were linked to the rate of reporting.(12)

The statistical tests gave a detailed report of the dimensions that affected the ADR reporting practices, and the knowledge gaps in community pharmacy practice.

7. Results

7.1 Statistics National Awareness on Pharmacovigilance

The researchers evaluated the level of pharmacovigilance awareness of the 320 participants that included community pharmacists in Malaysia and Vietnam. In general, 85 percent of them were familiar with national pharmacovigilance schemes in their countries. The level of awareness of the pharmacovigilance programs was relatively equal between two countries (86% of Vietnamese pharmacists had the awareness in comparison with 84% of Malaysian pharmacists). Nonetheless, despite this great awareness, a large proportion of pharmacists were not familiar with the reporting guidelines or the requisite of reportable ADRs and this shows that program knowledge did not impart to their normal practices in pharmacies.(13)

Table 1: Pharmacovigilance Awareness by Country

Country	Aware of National PV Program (%)	Unaware of National PV Program (%)
Malaysia	84	16
Vietnam	86	14
Total	85	15

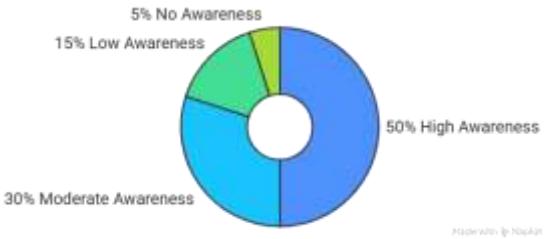

Figure.1: Pharmacovigilance Awareness

7.2 Reporting Frequency and Previous Training Association Reporting Frequency and Previous Training Association

As far as the frequency of ADR reporting is concerned, 42 percent of pharmacists suggested having filed at least one ADR report. Among the reporters, 23 percent and 19 percent made one to two and three or more reports in a year respectively. As the analysis indicated, a substantial difference was found when reporting ADRs by pharmacists that had previous training in pharmacovigilance. Particularly, the report released by the Body of European Regulators of Complementary Medicines (BERAC), revealed that 62 percent of pharma people who had undergone a formal training on pharmacovigilance reported ADRs, as opposed to only 24 percent of the pharma people who had not been trained in drug safety. This conclusion indicates the presence of a close relationship between pharmacovigilance training and the reporting behavior of an ADR.(14)

Table 2: ADR Reporting Frequency by Pharmacovigilance Training

Training Status	Reported ADRs (%)	Did Not Report ADRs (%)
Received Pharmacovigilance Training	62%	38%
Did Not Receive Pharmacovigilance Training	24%	76%

Figure. 2: ADR Reporting Frequency

When it was checked using Pearson correlation analysis, it indicated significant positive correlation ($r = 0.62$, $p < 0.001$) between the level of pharmacovigilance training and the probability of ADR reporting, therefore, the level of training is one of the key factors contributing to the upward trend in reporting practices by community pharmacists.(15)

7.3 Barriers found with the levels of significance

Barriers to ADR reporting were also analyzed; by using responses to a survey, these have been identified. The most frequent obstacles consisted in:

- Insufficient time (told by 78 percent of pharmacists),
- Doubt concerning reportable ADRs (reported 60 per cent),
- Difficulty of reporting systems (reported by 56 per cent),
- Inadequate training (45 per cent).

Table 3: Barriers to ADR Reporting and Their Frequency

Barrier	Frequency (%)
Lack of Time	78
Uncertainty about Reportable ADRs	60
Complexity of Reporting Systems	56
Insufficient Training	45

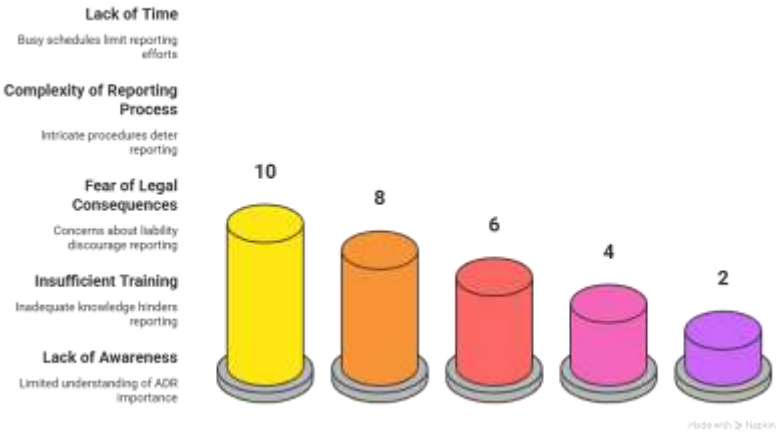

Figure 3: Barriers to ADR Reporting

Examination of statistical values provided an indication of the main barriers in ADR reporting that were a shortage of time ($p < 0.01$) and the ambiguity concerning reportable ADRs ($p < 0.05$). Moreover, those pharmacists who had the formal training regarding pharmacovigilance were not as likely to report the lack of time or insecurity as barriers, and thus the formal educative process might enhance them.

8. Conclusion

8.1 Key Results

This research article used the pharmacovigilance awareness level and ADR reporting behaviors of community pharmacists in both Malaysia and Vietnam, in addition to barriers to reporting of ADR. The significant reasons as reflected in the study are:

Great national pharmacovigilance programs recognition, where 85 percent of the pharmacists have heard of the efforts. Nevertheless, this awareness was not converted to the actual reporting, only 42 percent of pharmacists filed at least one activity regarding ADR.

Pharmacovigilance training has helped in enhancing reporting of ADRs as 62 per cent of trained pharmacists report ADRs as compared to the 24 per cent untrained pharmacists. Positive relationship ($r = 0.62$, $p < 0.001$) was detected between training and ADR reporting, thus accentuating the role and necessity of education.

Noteworthy problems to ADR reporting were time questions (78%), confusing what ADRs should be reported (60%), and difficulty understanding reporting systems (56%). These impediments should be eliminated in order to participate more in pharmacovigilance endeavors.

8.2 Lessons to be learned by Pharmacy Policy and Education

The results lend credence to the fact that forward-looking policy efforts should be made to enhance the incorporation of pharmacovigilance into the normal practice of the pharmacy, particularly the community aspect of it. The pharmacist can be crucial to medication safety and care of patients, although the pharmacist is underused in pharmacovigilance because of knowledge, knowledge training and reporting barrier flaws. The governments and healthcare authorities are advised to think about the simplification of reporting platforms, provide transparent information regarding the reportable ADRs, and include the pharmacovigilance trainings in their continuing education programs on community pharmacists.

It is also an interesting feature of this research that collaboration between pharmacists, regulatory authorities, and other medical professionals should be conducted to establish a favorable organizational ecology that would allow safe use of medications. The improvement of knowledge on ADR reporting importance among pharmacists should also be addressed by the public health policies by encouraging active involvement in the national pharmacovigilance programs.

8.3 Suggestions on how to improve the role of community pharmacist in enhancing pharmacovigilance

The recommendations that will help improve the involvement of community pharmacists in pharmacovigilance are based on the findings of the study and are as follows:

Seminar on Comprehensive Pharmacovigilance Training: Develop comprehensive pharmacovigilance training seminars with a hands on knowledge about the process and method of detecting and reporting ADRs and this will enhance the level of confidence and skills of the pharmacists in Pharmacovigilance activities.

Easy Reporting Systems: Develop easier navigable, electronic ADR reporting systems that lessen the time load and make the process simpler among the pharmacists so that the system is reachable and effective.

Attention to Pharmacovigilance in Real Practice: Aim at establishing regular monitoring and reporting of ADRs as a regular component of pharmacy practice to boost progressive involvement of pharmacists.

Public Awareness Campaigns: Educate the people on reporting ADRs and medication safety that leads to a partnership between patients, the pharmacist and practitioners.

The research proves that a more active pharmacist role in pharmacovigilance can result in improving medication safety. Appropriate strategies to overcome the identified barriers will assist in developing a stronger system of pharmacovigilance in Southeast Asia.

Acknowledgement: Nil

Conflicts of interest

The authors have no conflicts of interest to declare

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