

## RESEARCH ARTICLES

### Pharmacy Students' Knowledge and Perceptions About Pharmacovigilance in Malaysian Public Universities

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**Objective.** To assess senior pharmacy students' knowledge of and perceptions about pharmacovigilance and reporting of adverse drug reactions (ADRs) at 5 public universities in Malaysia

**Methods.** A cross-sectional study was conducted between December 1, 2010, and January 31, 2010, using a validated self-administered questionnaire delivered to a sample of 510 final-year (fourth-year) pharmacy students at 5 Malaysian public universities.

**Results.** Four hundred twenty-one (84%) students responded to the survey. About 60% (n = 240) indicated that they had taken courses on the concept of pharmacovigilance during their current pharmacy curriculum. The mean score for knowledge about pharmacovigilance and ADR reporting was  $6.9 \pm 1.4$ . There was a significant difference in the mean scores for knowledge about pharmacovigilance across the 5 universities. The majority (82.3%) of respondents felt it was necessary to confirm the causal relationship between the drug and the ADR. About 57.8% (n = 241) of the respondents believed that pharmacy students are competent and capable of reporting ADRs during their clerkships. The majority (87.0%) of respondents perceived that pharmacy students should be taught how to report ADRs.

**Conclusion.** The results of this study demonstrate that the majority of final-year pharmacy students in Malaysian public universities have insufficient knowledge about pharmacovigilance and ADR reporting.

## INTRODUCTION

Adverse drug reactions (ADRs) are common causes of morbidity and mortality in both hospital and community settings. ADRs are responsible for about 5% to 20% of hospital admissions.<sup>1,2</sup> The roles of pharmacists have moved from traditional aspects of preparing and dispensing medicines to a more vital role that includes many aspects of pharmaceutical care, such as preventing ADRs and medication errors, improving patient satisfaction and quality of life, and improving economic outcomes.<sup>3-5</sup> Pharmacists can play a crucial role in both ADR reporting and pharmacovigilance activities.<sup>6</sup>

Pharmacists are more likely to detect ADRs than are other healthcare professionals, either in the hospital or community setting.<sup>5,7</sup> As drug experts, pharmacists should be equipped with the skills to prevent, identify, and resolve drug-related problems and counsel patients on drug therapy.<sup>8</sup> In the hospital setting, pharmacists can play an important role in ADR reporting because they have access to the information necessary to report ADRs.<sup>9,10</sup> Because they may be the first to be contacted by patients for information about ADRs, community pharmacists are an important source of ADR reports.<sup>11</sup> Involvement of pharmacy students in ADR reporting has led to a significant increase in the number of documented ADRs.<sup>12</sup>

Malaysia established its own pharmacovigilance system in 1987 and became a member of the World Health Organization (WHO) Program for International Drug Monitoring in 1990. The Malaysian Adverse Drug Reaction Adverse Committee (MADRAC), which is part of the

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Malaysian Ministry of Health, oversees and has run the pharmacovigilance program since that time. The number of ADR reports received from healthcare professionals by MADRAC reached 5,850 in 2009. However, according to WHO recommendations for the optimal National Pharmacovigilance Centre, this number is considered low. The Malaysian pharmacovigilance system, like most others around the world, suffers from underreporting of ADRs by healthcare professionals.<sup>13</sup> There is a lack of information about the reasons behind this underreporting by healthcare professionals in general and community pharmacists in particular, and few studies have explored this issue in Malaysia.<sup>13-15</sup>

Although previous studies indicated that pharmacists are pivotal players in ADR monitoring and reporting, most pharmacists are unaware or not knowledgeable about the guidelines used by their respective countries' drug regulatory bodies responsible for assessing ADRs.<sup>16,17</sup> As future pharmacy practitioners, pharmacy students need to be well trained on how to recognize, prevent, and report ADR.

Few studies have been conducted to evaluate pharmacy students' knowledge and attitudes about ADR reporting.<sup>5,12,18</sup> The aim of the study was to evaluate the perceptions of and knowledge about pharmacovigilance and ADR reporting among pharmacy students at public universities in Malaysia.

## **METHODS**

The initial draft of the survey questionnaire was developed using information from the literature about ADR reporting among healthcare professionals<sup>19-23</sup> as well as the findings of our previous qualitative study, which involved interviews with community pharmacists.<sup>14</sup> Permission to approach the students and to conduct the study was obtained from the respective deans of the pharmacy faculties and schools in each university. A total of 25 survey items organized into 3 sections were included. The first section consisted of 4 questions about student demographics and general information, such as age, gender, and current university, and 2 questions about whether the students had previously taken any course related to pharmacovigilance and whether they had been told to what the term "adverse drug reaction" refers.

The second section included elements designed to measure knowledge about pharmacovigilance and ADR reporting. Students were asked to select the correct answer from multiple-choice response options. A score of 1 was given for each correct answer and 0 for each wrong answer. The maximum score obtainable was 10 and the minimum was 0.

The third section of the survey included 10 items designed to evaluate the perceptions of pharmacy students

toward pharmacovigilance activities and ADR reporting. The questions were framed into a 5-point Likert-scale format (1 = strongly agree, 2 = agree, 3 = neutral, 4 disagree, and 5 = strongly disagree). In order to avoid acquiescence, affirmation, or agreement bias, both positively- and negatively-worded items were included within each section.<sup>24</sup>

Three pharmacy lecturers with experience in drug-use research and ADR reporting studies were asked to evaluate the relevance, clarity, and conciseness of the items included in the questionnaire. The observations and comments of the lecturers were taken into account. In order to test the validity and reliability of the survey form, the revised questionnaire was pilot-tested by administering it to a sample of 20 pharmacy students who did not participate in the main study. The overall Cronbach's alpha value was 0.762.

The sampling frame included all final-year (fourth-year) pharmacy students who were enrolled full-time at 5 public universities during the study period. The number of enrolled students during the study period was obtained from the respective lecturer coordinators in each university. The study was conducted for a period of 2 months from December 1, 2010, through January 31, 2010.

Students were informed about the objectives of the survey by means of an explanatory letter attached to the survey questionnaire that was distributed to all participants. The students received the survey questionnaire through the respective lecturer coordinators at each university. Anonymity and confidentiality were ensured. Consent for participation was implied by the completion and return of the survey instrument. Descriptive statistical analyses such as frequencies and percentages were used to represent the respondents' demographic information. When appropriate, student *t* tests were performed by comparing the means of 2 continuous variables. The Mann-Whitney U test, the Kruskal-Wallis test, and one-way ANOVA with Post Hoc Tukey HSD (honestly significant difference). A post hoc analysis has been used for multiple comparisons in order to detect the existence of differences between pair-wise groups. The relationship between the categorical data was examined with the chi-square test.<sup>25</sup> Fisher Exact test is preferred over the chi-square test for skewed data if 25% or more of the cells in the table have expected frequencies of less than 5, or if any expected frequency is less than 1, as in this survey.<sup>26-28</sup> For these survey data, a default Monte Carlo simulation in SPSS software (SPSS Inc., Chicago, IL) was used to estimate Fisher's exact *P* values because the data set was large and normal exact computations require a great amount of computer time and memory.<sup>26,28</sup> A 2-sided 99% confidence level Monte Carlo estimate of the Fisher exact *P* value was computed and found to be significant at *P* < 0.05.

## RESULTS

By the end of the 2-month study period, 421 (84%) of 501 final-year pharmacy students had responded to the survey, yielding 417 usable survey instruments. The average age of respondents was  $22.7 \pm 1.1$  years. One hundred eighty-one (43.4%) of the respondents were aged 22 years, 277 of them (66%) were female, and 240 (57.6%) indicated having previously taken formal courses on pharmacovigilance. During their pharmacy education, almost all respondents had been told what the term “adverse drug reactions” meant. Responses and demographic characteristics of the respondents are presented in Table 1. The knowledge of pharmacovigilance and ADR reporting among pharmacy students was assessed by asking 10 questions with true/false options. A score of 1 was given for each correct answer and 0 for each wrong answer. The maximum score obtainable was 10 and the minimum was 0. The mean knowledge score of pharmacovigilance and ADR reporting for the final-year pharmacy students was  $6.9 \pm 1.4$ . There was no significant difference in the mean score of the knowledge domain by gender ( $P = 0.359$ ), but there was a significant difference in the mean score of pharmacovigilance concept knowledge current university attended ( $P < 0.01$ ).

There also was a significant difference in the mean scores of pharmacovigilance knowledge between those who had taken a related course and those who had not ( $P = 0.003$ ). There was a significant association between university group and those taking a course related to pharmacovigilance ( $P = 0.019$ ) however, most of those who claimed to have taken a course related to pharmacovigilance were from university 5. There was no association

between those taking a course related to pharmacovigilance and gender ( $P = 0.101$ ) or being told to what the term ADR refers ( $P = 0.424$ ).

The mean scores of knowledge among pharmacy students classified according to their demographic characteristics are shown in Table 1. Almost all respondents ( $n = 392$ , 94.0%) correctly identified MADRAC as the body that regulates ADR reporting in Malaysia. Most students who responded ( $n = 383$ , 82.5%) incorrectly noted that an ADR related to a particular drug should be confirmed before it is reported.

A remarkably high number of respondents ( $n = 288$ , 69.1%) wrongly believed that ADRs associated with herbal products should be reported. Approximately all ( $n = 380$ , 91.1%) respondents knew the minimum information required for the submission of an initial ADR report. A portion of the students ( $n = 55$ , 13.2%) failed to recognize the consequences of serious ADRs. Table 2 shows the responses to questions related to knowledge of the final-year pharmacy students.

Approximately half of the students ( $n = 228$ , 54.7%) either agreed or strongly agreed that the pharmacovigilance concept should be included as a core topic in pharmacy education. There was a significant difference ( $P = 0.002$ ) in response to this question among students who had taken a pharmacovigilance course. Approximately one-third ( $n = 136$ , 32.6%) of the respondents either agreed or strongly agreed that the topic of pharmacovigilance is well-covered in their pharmacy school curriculum. There was a significant difference in response to this statement by students who had taken a pharmacovigilance course ( $P = 0.002$ ). Only 13.4% ( $n = 55$ ) of these students indicated that they did not have any idea how to report an ADR. There was a significant difference ( $P < 0.001$ ) in response to this statement between students at different universities.

Students were asked whether pharmacy students were capable of ADR reporting during their clerkships. More than half ( $n = 241$ , 57.8%) of the students either agreed or strongly agreed with the question. There was a significant difference ( $P < 0.001$ ) in responses to this question, according to where the students were currently enrolled.

About two-thirds of the students strongly disagreed or disagreed that reporting of known ADRs made any significant contribution to the reporting system, and around 12.7% ( $n = 53$ ) agreed. Significant differences were found in response to this question by both gender ( $P < 0.001$ ) and university ( $P = 0.01$ ).

Students were asked whether they believed that, with their current knowledge, they were well-prepared to report any ADR in their future practice. Slightly more than one-third ( $n = 156$ ; 37%) of the students either strongly

Table 1. Interrelation of the Knowledge Score of Final-Year Pharmacy Students with their Demographic Characteristics (n=417)

Demographics	Mean (SD)	P
Gender		
Male (n=140)	6.8 (1.3)	0.359 <sup>a</sup>
Female (n=277)	7.0 (1.4)	
Pharmacovigilance course		
Yes (n=240)	7.1 (1.2)	0.003 (<0.01) <sup>a</sup>
No (n=177)	6.7 (1.5)	
Current university		
1(n=45)	7.2 (1.0)	<0.001 <sup>b</sup>
2(n=55)	6.5 (1.5)	
3(n=108)	6.5 (1.6)	
4(n=86)	7.2 (1.2)	
5(n=123)	7.1 (1.2)	

<sup>a</sup> Independent sample t test

<sup>b</sup> One-way ANOVA with Post Hoc Tukey HSD.

Table 2. Final-Year Pharmacy Students Who Responded Correctly to Knowledge Questions on Adverse Drug Reactions

Survey Item	Answered Item Correctly, No. (%)
Pharmacoepidemiology definition	401 (96.2)
Pharmacovigilance is the process of	253 (60.7)
Which is the following regulatory body in Malaysia that regulates ADR reporting: MADRAC	392 (94.0)
Which of the following terms refers to the definition: adverse drug reactions	318 (76.3)
It is necessary to confirm that an ADR is related to a particular drug before reporting it.	74 (17.7)
What is the consequence of serious ADR?	362 (86.8)
The minimum information required for the submission of an initial ADR report?	380 (91.1)
Adverse drug reaction related to the following products should be reported: herbal products	129 (30.9)
Type A ADR definition	319 (76.5)
Type B ADR definition	249 (59.7)

Abbreviations: ADR=adverse drug reaction

agreed or agreed with this statement. A significant difference was noted among responses from the students according to their current universities ( $p = 0.001$ ).

Students were asked whether they perceived a pharmacist as one of the most important healthcare professionals to report ADR. Almost all ( $n = 377, 90.4\%$ ) of the students either strongly agreed or agreed with this statement, and only  $1.9\%$  ( $n = 8$ ) either disagreed or strongly disagreed. A significant difference ( $P = 0.020$ ) was found in responses according to the university of enrollment.

To explore awareness of students about ADR reporting guidelines, they were asked whether serious and unexpected reactions that were neither fatal nor life-threatening during clinical trials had to be reported. Nearly  $80\%$  ( $n = 333$ ) of the students either agreed or strongly agreed with this statement, leaving only  $9.4\%$  ( $n = 39$ ) who disagreed. Most ( $n = 20, 16.3\%$ ) of the students who strongly agreed or agreed with the question statement were from university number 5. Only  $7\%$  ( $n = 18$ ) of the students who indicated that they had previously taken a course related to pharmacovigilance either strongly agreed or agreed with this statement. There was a significant difference ( $P < 0.001$ ) in responses to this question by gender. Responses to questions exploring the final-year pharmacy students' perceptions about pharmacovigilance and ADR reporting are shown in Table 3.

## DISCUSSION

To the best of our knowledge, this is the first study in Malaysia that evaluates the knowledge and perception of final-year (fourth -year) public university pharmacy students toward pharmacovigilance and ADR reporting. In the present study, an overall response rate of  $84\%$  was recorded. This figure can be regarded as extremely high, especially when compared with those of other studies on the same topic carried out among pharmacy<sup>5,12,18</sup> or medical students.<sup>29,30</sup> The response rate is within the accepted

range for survey research intended to represent schools and faculties of pharmacy ( $\geq 80\%$ ) and for a postal mail survey.<sup>31,32</sup> In order to maximize the response rate and minimize response bias, the questionnaire was administered personally to students by the course coordinators at the respective schools.<sup>33,34</sup>

Because this study was conducted with final-year pharmacy students in 5 schools of pharmacy in Malaysian public universities that were accessible to the researcher, the findings may not be confidently extrapolated to the pharmacy students in other public universities. It was also unknown which schools' curricula offered subjects related to pharmacovigilance. It would be logical to extend this type of study to other universities in Malaysia to obtain more generalizable results.

During the study period, there was a lack of data regarding which universities' curricula offered courses related to pharmacovigilance and ADR reporting. All the 5 faculties and schools of pharmacy were selected for the study sample. There were 501 final-year students enrolled in these schools. Our findings confirmed previous reports indicating that a deficiency in knowledge and perceptions about pharmacovigilance and ADR reporting is accountable for ADR underreporting in both developed and developing countries.<sup>5,35,36</sup>

Although two-thirds of the students expressed a positive attitude toward pharmacovigilance and ADR issues, this survey revealed they were only moderately aware of and knowledgeable about pharmacovigilance. The training that undergraduate pharmacy students' receive may be improperly delivered or otherwise insufficient to adequately prepare them for the task of ADR monitoring and reporting in their future careers. This is not surprising, considering that only about  $50\%$  of the students indicated that they had taken a pharmacovigilance course. It would be beneficial to emphasize to undergraduate pharmacy students the importance of pharmacovigilance and ADRs

Table 3. Perception About Pharmacovigilance Activities and ADR Reporting Among Final-Year Pharmacy Students

Survey Question/Statement	Responses						P		
	SD, No. (%)	D, No. (%)	N, No. (%)	A, No. (%)	SA, No. (%)	Gender	University	Previous Exposure to PV Subject	
Pharmacovigilance should be included as a core topic in pharmacy education.	8 (1.9)	9 (2.2)	79 (23.3)	288 (54.7)	75 (18.0)	0.826	0.374	0.002	
I believe that the topic of pharmacovigilance is well covered in my pharmacy school curriculum.	13 (3.1)	59 (14.1)	209 (50.1)	120 (28.8)	16 (3.8)	0.346 <sup>a</sup>	0.256	0.002 <sup>a</sup>	
I do not have any idea of how to report ADRs to the relevant authorities in Malaysia.	70 (16.8)	196 (47.0)	96 (23.0)	49 (11.8)	6 (1.40)	0.225	0.000	0.172	
Pharmacy students can perform adverse drug reactions reporting during their clerkship.	7 (1.7)	52 (52)	117 (28.1)	190 (45.6)	51 (12.2)	0.417	0.000	0.685	
ADR reporting should be made compulsory for pharmacists.	4 (1.0)	11 (2.6)	87 (20.9)	205 (49.2)	110 (26.4)	0.179	0.117	0.695	
Information on how to report ADRs should be taught to senior pharmacy students.	4 (1.0)	9 (2.2)	41 (9.8)	202 (48.4)	161 (38.6)	0.320	0.488	0.268	
Reporting of known ADRs makes no significant contribution to the reporting system.	115 (27.6)	186 (44.6)	63 (15.1)	43 (10.3)	10 (2.4)	0.000 <sup>a</sup>	0.011	0.211 <sup>a</sup>	
With my present knowledge, I am very well prepared to report any ADRs notice in my future practice.	12 (2.9)	61 (14.6)	188 (45.1)	133 (31.9)	23 (5.5)	0.234	0.001	0.056	
I believe a pharmacist is one of the most important healthcare professionals to report adverse drug reactions.	2 (0.5)	6 (1.4)	32 (7.7)	178 (42.7)	199 (47.7)	0.145 <sup>a</sup>	0.020	0.241 <sup>a</sup>	
I believe serious and unexpected reactions that are not fatal or life-threatening during clinical trials must not be reported.	165 (39.6)	168 (40.3)	45 (10.8)	22 (5.3)	17 (4.1)	0.000	0.122	0.182	

Scale: SA = strongly agree; A = agree; N = neutral; D = disagree; SD = strongly disagree

Abbreviations: ADR = adverse drug reaction; PV = pharmacovigilance

\* Chi square test.

reporting and encourage them to be involved in advocating ADR reporting for both pharmacists and other healthcare professionals. By promoting an ADR reporting culture among these professionals, the problem of underreporting could be reduced.<sup>37</sup> Unfortunately, only a few students were able to correctly answer questions relating to Malaysian ADR reporting guidelines, suggesting that this topic is either not covered sufficiently or not covered at all in the curricula of the study institutes. The current survey clearly shows that the majority of the pharmacy students, regardless of which university they attend, do not understand the concept of pharmacovigilance. Educational training programs, however, can clarify and enhance the knowledge of healthcare professionals regarding ADR reporting requirements.<sup>38-40</sup>

About 18% of the pharmacy students correctly answered the survey question related to uncertainty about the causal relationship between the suspected ADR and the drug being a barrier to ADR reporting. This finding is consistent with those of similar reports about healthcare professionals elsewhere.<sup>41-43</sup>

About 70% of the respondents believed that ADRs associated with herbal products should be reported. The responses to this question show that pharmacy students do not know the requirements for reporting ADRs associated with herbal medication, which further suggests a lack of education about pharmacovigilance and ADR reporting guidelines. Responses to the question pertaining to the reporting of herbal medication were positively and significantly associated with the university of enrollment ( $P = 0.008$ ) but not with gender or whether the students had previously taken a course on pharmacovigilance ( $P = 0.604$  and  $P = 0.958$ , respectively). This may be a positive finding as it shows that students are concerned about reporting even though they are not familiar with the reporting guidelines of ADRs associated with herbal medications. Still, there is evidence of a difference in coverage of herbal medicines in the universities' curricula, and this is an issue that needs to be addressed by school administrations. The study results showed that attending courses on pharmacovigilance and ADR reporting was associated with an increase in pharmacy students' level of knowledge and awareness about ADR reporting ( $P = 0.003$ ). There also was a significant difference in the mean total score of knowledge about pharmacovigilance according to which university the student attended. This finding may be explained by the differences and diversity in the curricula of the faculties and schools of pharmacy in the Malaysian universities or by students having been exposed to the practice of ADR reporting in the hospitals where they were trained. These weaknesses can be addressed by intensive training and workshops on pharmacovigilance and

the structure of the ADR reporting system in this country.<sup>23,44</sup> Knowledge, skills, and positive perceptions regarding pharmacovigilance and ADR reporting activities can be cultivated during undergraduate education and service training. This study shows that universities provide inadequate information about pharmacovigilance and ADR reporting in their undergraduate curricula, suggesting that a customized and comprehensive curriculum related to pharmacovigilance should be designed and implemented in pharmacy faculties and schools.

Beliefs regarding pharmacovigilance and ADR reporting activities in Malaysia were explored by asking pharmacy students to respond to 5 statements using a 5-point Likert scale. The majority of the pharmacy students agreed with the statement that pharmacovigilance should be included as a core topic in pharmacy education. This indicated their positive perception of the importance of pharmacovigilance. This statement was significantly associated with the variable of whether the student had previously taken a pharmacovigilance course. This finding is similar to that of previous reports involving healthcare professionals.<sup>11,38</sup>

Whether the students had taken a course related to pharmacovigilance was significantly associated with the belief that the pharmacovigilance topic was not well covered in the schools' curricula. More than half of the students indicated that they had attended pharmacovigilance courses previously, reflecting a possible lack of uniformity and comprehensiveness in the curricula related to the teaching of pharmacovigilance in the faculties of pharmacy throughout Malaysia. Strategic plans in cooperation with other relevant authorities are needed to address this issue and improve the basic knowledge, which, in turn, will promote a culture of ADR reporting among future pharmacy practitioners.

More than half of the students agreed with the statement regarding whether pharmacy students are capable of reporting ADRs during their clerkships. This statement was significantly associated with the university attended ( $P < 0.001$ ). The difference in these responses might be attributable to differences in the universities' curricula with respect to teaching pharmacovigilance. The findings indicating a positive attitude of pharmacy students toward ADR reporting are similar to the results reported for healthcare professionals in previous studies.<sup>45,46</sup>

The vast majority of students (87%) agreed that there is a need to teach and provide pharmacy students with information on pharmacovigilance and how to report ADRs. Meeting this need will require pharmacy faculties and schools to provide education and training programs on ADR reporting to prepare pharmacy students for performing their responsibilities as healthcare providers.

Pharmacists who receive more education and training on ADR reporting are more likely to report ADRs.<sup>9</sup> Almost all of the students (90.4%) agreed that the pharmacist is one of the most important healthcare professionals to report ADRs. These findings are similar to results for healthcare professionals in other studies.<sup>5,6,47-50</sup> The majority of students (80%) believed that serious and unexpected ADRs, including those that are neither fatal nor life threatening, must be reported. These study findings are consistent with Malaysian guidelines for reporting ADRs.<sup>51</sup> The responses to this statement were significantly associated with gender ( $P < 0.001$ ) and are consistent with the results of previous studies involving pharmacists and other healthcare professionals.<sup>11</sup>

The number of students who participated in this study was relatively small considering the number of students currently enrolled in Malaysian faculties and schools. Therefore, these results may not necessarily be extrapolated to all pharmacy students.

## CONCLUSION

This first national survey on pharmacovigilance activities and ADR reporting among pharmacy students in Malaysia suggests that pharmacy students in this country may lack in-depth understanding of the facts about ADR reporting and may need more information on the national pharmacovigilance system and the ADR reporting process. Pharmacy students' education should include topics related to the methods of detecting, preventing, and reporting ADRs to enable pharmacists to play a vital role in the prevention and reporting of ADRs through their interactions with both prescribers and patients.

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