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ORIGINAL ARTICLE

Pharmacy students' knowledge and perceptions about adverse drug reactions reporting and pharmacovigilance

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Abstract Pharmacy students' knowledge about adverse drug reaction reporting can impact their attitude towards patient care and issues on patient safety. The aim of this study was to investigate the knowledge and perception of pharmacy students about adverse drug reaction reporting and pharmacovigilance and to study their willingness to report. A cross-sectional study using a validated questionnaire was conducted among the university students. The demographic details of the respondents were studied. The number of female respondents was comparatively higher than the male respondents. There were no significant differences by gender regarding the knowledge on adverse drug reaction reporting and pharmacovigilance except with the knowledge of post-marketing surveillance for which male students appeared to be more knowledgeable than female students. The results showed that the pharmacy students had sufficient knowledge and there are significant differences in perception among the students on adverse drug reaction reporting.

1. Introduction

A little is known about serious and rare adverse effects associated with a drug at the time of approval by the Food and Drug Administration. Voluntary reporting of adverse drug reaction (ADR) of a drug is an important source of information to the health care professionals (Gavaza et al., 2012). It helps to utilize the available drugs in a better way and reduce the drug related problems in patients. Knowledge of health care providers about ADR reporting can impact their attitude towards patient care and issues on patient safety. In Malaysia, Malaysian Adverse Drug Reactions Advisory Committee (MADRAC) is the pharmacovigilance centre to monitor ADR, which promotes ADR reporting and also circulates drug safety information to all the healthcare professionals (Elkalmi et al., 2014). The healthcare professionals can report an ADR directly to MADRAC through email, Fax and online. The World Health Organization recommends that 200 or more reports are to be submitted per million populations per year,

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which sets a target of about 6000 reports for Malaysia's population of 28.9 million (Norén, 2014). However, compared to other countries, which use the spontaneous reporting systems, the reporting rate in Malaysia is very low (Agarwal et al., 2013).

Pharmacists are primary providers of medications to the public and their significant role in dispensing and counselling is well suited to promote effective use of medications and patient safety. Their pharmacological knowledge and exposure to patient medication records enable them to make a significant contribution towards pharmacovigilance and ADR reporting (Ahmad et al., 2013; Rutter et al., 2014; Wilbur, 2013; Singh and Bhatt, 2012; Attlee et al., 2014; Jose et al., 2014; Gavaza et al., 2011). Students' perception of their preparedness and ability is the initiated measure in making any process into regular practice is an important aspect of any new implementations in healthcare education (Bojanić et al., 2009). As drug related problems are growing as a potential threat for patient safety and the obligation of a pharmacist in the hospital set up and community practice to report ADR is growing more intense (Elkalmi et al., 2013a), proper assessment and discussion must be possessed in order to determine whether pharmacy graduates who are leaving school feeling trained to carry on this new role or not. A lack of knowledge about ADR reporting process has also been associated with negative attitudes towards the pharmacovigilance. Moreover, the pharmacists' decision making skills on ADR reporting are an understudied area in Malaysia (Savage, 2013). The aim of the study was to gain understanding of the students' awareness of the process involved in reporting ADR to MADRAC, so as to enable the design and implementation of more effective training in ADR reporting for undergraduates. Ethics approval for the study was obtained from The International Medical University Joint-Committee of the Research and Ethics Committee, International Medical University, Kuala Lumpur Malaysia (Reference Number: BP I-01/11(27)2014).

2. Methods

We conducted a cross-sectional study enrolling among Pharmacy undergraduate students from July to October 2014, in a private medical University in Kuala Lumpur, Malaysia. The study population was a convenient sample of students studying final year BPharm (Hons). A questionnaire was designed after a detailed review of relevant literature. It was written in English, as the medium of instruction in Malaysian universities is English. The survey questionnaire consisted of 24 structured questions that covered 3 main areas includes pharmacy students' demographic data, their knowledge on ADR reporting and pharmacovigilance and their perception towards the ADR reporting procedures. The reliability of questionnaire was evaluated by using 20 students from pharmacy course in this university and the Cronbach's alpha value obtained was 0.82. This data were not included in the actual study. Content validity was done by using two pharmacists with experience in drug related studies and ADR reportage to appraise the applicability, precision, and shortness of the items included in the questionnaire. The remarks and explanations of them were implemented in the questionnaire.

The sample size required for this study was calculated using a RAOSOFT calculator with a 5% margin of error and 95% confidence level. According to this calculation 105 respondents were needed for this study. The hard copy of the survey questionnaire was handed personally to the students. The students were informed about the objectives and purpose of conducting the research on the first page of the survey questionnaire. The students were also given a written consent form for approval of their participation in this study. The students' confidentiality and anonymity were ensured. 108 students gave their consent to participate in the survey and completed the survey questionnaire.

Data were analysed using the Statistical Package for Social Sciences (SPSS) version 22. Participants who responded 'Yes' for knowledge questions were tabulated as percentages of correct answers. Participants' response to perception questions was presented as percentages of agreement. Within the sample, these responses were compared with gender and ethnicity differences. A chi-square test was conducted for this purpose and a 'p value' ($p < 0.05$) was established to measure significant differences between responses.

3. Results

The response rate for this study was more, compared to other studies on ADR reporting in public universities and practicing pharmacists from Malaysia (Gavaza et al., 2011; Bojanić et al., 2009; Elkalmi et al., 2013). The demographic details of the respondents participated in the study are presented in Table 1.

The number of female respondents was comparatively higher than the male respondents. The mean age value obtained was 22.9 years. The majority of the respondents were Chinese ethnic which consisted of 76.9% ($n = 83$) of the total respondents.

Ten questions were used to assess the basic knowledge of students on ADR reporting and pharmacovigilance. A score of 1 was given for the answer 'yes' and a score of 0 was given for the answer 'no' (cut off score: 0–4 = no or little knowledge; 5–10 = sufficient knowledge). Overall, there were no significant differences by gender regarding the knowledge on ADR reporting and pharmacovigilance except with the knowledge of post-marketing surveillance for which male students

Table 1 Demographic details of respondents ($N = 108$).

Demographics		Frequency, n	Percentage (%)
Gender	Male	27	25.0
	Female	81	75.0
Age (years)	22	43	39.8
	23	53	49.1
	24	3	2.8
	25	4	3.7
	26	3	2.8
	27	1	0.9
	28	1	0.9
Ethnicity	Malay	10	9.3
	Chinese	83	76.9
	Indian	15	13.9
	Others	0	0

appeared to be more knowledgeable than female students ($p = 0.003$) (Table 2).

Table 2 Respondents' knowledge on ADR reporting and pharmacovigilance.

Questions	Answers (%)		*P*-value (percentage of correct answers)	
	Yes	No	Gender	Ethnicity
I have an idea of how to report ADRs to the relevant authorities in Malaysia	68.5	31.5	0.478	0.047*
Students can perform adverse drug reactions reporting during their clerkship	80.6	19.4	0.210	0.759
The topic of Pharmacovigilance is well covered in my curriculum	55.6	44.4	0.658	0.689
Reporting of known ADRs makes a significant contribution to the reporting system	92.6	7.4	0.401	0.742
I know the different classifications of ADR	64.8	35.2	0.105	0.001**
Hypersensitivity reactions are related to ADR	90.7	9.3	0.705	0.687
There is a difference between ADR and the adverse event	75.0	25.0	0.161	0.469
I know the different types of hypersensitivity reactions	71.3	28.7	0.903	0.997
I know what Post-Marketing Surveillance is	88.0	12.0	0.003**	0.643
I know how Causality Assessment of ADR is done in Malaysia	12.0	88.0	0.045*	0.032*

* *P* value < 0.05 level of significance.
** *P* value < 0.005 level of significance.

For the questions on the knowledge of how causality assessment of ADR is done, female students were more knowledgeable than male students ($p = 0.045$). Chinese ethnic students had better idea on how to report ADRs to the relevant authorities ($p = 0.047$). Malay ethnic students can differentiate the classes of ADR ($p = 0.001$). Indian ethnic students knew better how causality assessment of ADR is done in Malaysia ($p = 0.032$) than their counterparts. Ten questions were used to explore the perception of pharmacy students on ADR reporting and pharmacovigilance. These questions were in the form of a 5-pointer Likert scale. A score of 5 was given for strongly agree, 4 for agree, 3 for not sure, 2 for disagree and 1 for strongly disagree (cutoff score: 10–30 = negative perception; 31–50 = positive perception).

Data revealed that the overall perception towards ADR reporting and pharmacovigilance was positive. Male students had a positive perception than female students regarding their preparedness to report any ADRs noticeable in their future practice ($p = 0.040$). Female students had an impression that, the reasons for not reporting a suspected ADR are due to the uncertainty of its association with drugs ($p = 0.038$) which is a positive perception. Students belong to Malay ethnicity preferred to report any ADR (serious or non-serious) spontaneously ($p = 0.003$) compared to the Chinese and Indian ethnic students. More Indian ethnic students have an impression that female patients should be asked if she is pregnant when dispensing medications to them ($p = 0.012$) (Table 3).

4. Discussion

This is the first study among private university students in Malaysia that evaluates their knowledge of ADR and perception towards ADR reporting and pharmacovigilance. The results of this study among pharmacy students revealed several

Table 3 Respondents' perception on ADR reporting and pharmacovigilance.

Questions	Answers (%)					*P*-value (% of agreement)	
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Gender	Ethnicity
ADR reporting should be made compulsory for healthcare professionals	50.0	39.8	9.3	0.9	–	0.874	0.267
Information on how to report ADRs should be taught to students	65.7	30.6	2.8	0.9	–	0.351	0.602
With my present knowledge, I am very well prepared to report any ADRs noticeable in my future practice	3.7	26.9	56.5	11.1	1.9	0.040*	0.770
Healthcare is one of the most important professions to report adverse drug reactions	65.7	25.9	3.7	3.7	0.9	0.588	0.562
Serious and unexpected reactions that are not fatal or life-threatening during clinical trials must not be reported	2.8	1.9	5.6	38.0	51.9	0.610	0.361
The purpose of ADR spontaneous reporting system is to measure the incidence of ADR	16.7	59.3	18.5	5.6	–	0.659	0.4268
Any ADR (serious or non-serious) should be reported spontaneously	43.5	44.4	7.4	3.7	0.9	0.421	0.003
Reason for not reporting a suspected ADR is due to the uncertainty of its association with drugs	13.9	50.9	23.1	7.4	4.6	0.038*	0.804
Patients should be counselled about ADR every time their medications are dispensed	31.5	55.6	8.3	4.6	–	0.341	0.807
Female patients should be asked if she is pregnant when dispensing medications to them	75.0	21.3	2.8	0.9	–	0.437	0.012

* *P* value < 0.05 level of significance.

interesting findings about their knowledge and perceptions about ADR reporting and pharmacovigilance. Female respondents in this study were high since the female population among final year pharmacy students in this university was high. Previous studies have linked a lack of knowledge of ADR among pharmacists to an unwillingness to report the adverse events related to drugs (Al-Arifi, 2014; Oshikoya and Awobusuyi, 2009). Although we did not find an unwillingness to report an ADR in pharmacy students, it did uncover some areas where pharmacy students were less knowledgeable.

Understanding the procedure of reporting an ADR reflects the knowledge and attitudes towards the ADR reporting. It is an important part of pharmacovigilance and improving the way the students deal the drug related problems in the future. Based on the results, the pharmacy students had sufficient knowledge regarding ADR reporting. This finding is similar to the report of a previous study conducted on healthcare professionals (Al-Arifi, 2014; Oshikoya and Awobusuyi, 2009). However, 88% of the students do not know how causality assessment of ADR is done in Malaysia and it is reflected that the students are not fully prepared to contribute towards ADR reporting in future practice. Educational training programmes can clarify and enhance the knowledge of ADR reporting and how causality assessment of ADR is done (Granas et al., 2007; Li et al., 2014; Rehan et al., 2002). Hence, hands on workshops and training programmes can be given to improve the students' knowledge on causality assessment of ADR. The topics on pharmacovigilance can explain more about the techniques of identifying, averting, and reporting ADRs. This will enable the students to play a prominent role in reporting ADRs and patient safety in the future.

Only about 50% of the students revealed that the pharmacovigilance topic was well covered in the curriculum. Various factors such as presence of students during lecture (Miller and Metz, 2014) and students' concentration during the lecture (Stuart and Rutherford, 1978) have proven to be influential. The students' feedback on the pharmacovigilance topic is directly opposite to another study from the public universities in Malaysia, where almost all pharmacy students had indicated that the topic of pharmacovigilance is well covered in the curriculum. However, their knowledge level on pharmacovigilance was reported as limited (Elkalmi et al., 2011). The respondents in this study showed a better knowledge level on pharmacovigilance though only 58% of them felt the pharmacovigilance related topic had been covered completely in their curriculum. This shows that the pharmacy students are expecting more on pharmacovigilance related topics from their curriculum. We could not compare this result with the previous studies as the objectives and study period of the previous studies were different from each other. It would be logical to design such kind of study in the future to compare the students from all universities in Malaysia to obtain more generalized results.

The demographic data revealed that all the students were under the same age group as the student population who participated in this study was from the same cohort. Male respondents knew more about post-marketing surveillance and female students knew more about the causality assessment of ADR. The difference in these responses might be attributable to their interest in particular subjects. There are significant differences in knowledge among the students belonging to different ethnicity (Malay, Chinese and Indian). The results revealed that the students belong to Chines ethnicity have a better idea on how to report ADRs to the relevant authorities. The students belong to Malay ethnicity can differentiate the classes of ADR in a better way. The questions on the causality assessment were answered better by the Indian ethnic students. Previous study revealed that other than cultural values, information sharing, effective knowledge transfer within their ethnic group subsequently help knowledge acquiring process (Thumboo et al., 2003). The cultural, social and religious backgrounds of each ethnic group may have influences in their knowledge.

The perception of the study population towards ADR reporting and pharmacovigilance was positive. It revealed that the pharmacy students reflected their willingness to report an ADR voluntarily. Half of the study population strongly agreed that ADR reporting should be made compulsory for healthcare professionals. This indicates that the students have positive perception towards ADR reporting and pharmacovigilance. The majority of the study population strongly agreed that pharmacovigilance should be taught to them as they were not sure about their preparedness to report an ADR in future practice. However, the uniformity and comprehensiveness of the topic on pharmacovigilance in various universities in Malaysia is yet to be compared. The findings of the study showed that education and training programmes on pharmacovigilance can be provided in order to train the students to perform their responsibilities as better healthcare professionals in the future. The study found no significant differences between male and female students' perception except knowledge of post-marketing surveillance and knowledge of how causality assessment of ADR is done. These gender differences may be attributed to the relatively higher social responsibilities between men and women, which increase their understanding of the causes and consequences (Nigatu et al., 2014).

The results of students' strong disagreement on reporting a non-life threatening serious ADR obtained are compatible with the content of the MADRAC guidelines (Biswas, 2013). Similar results were reported by previous study on the same topic (Palaian et al., 2010). The causal association between the drug and its ADR was one of the reasons which created uncertainty in their mind and lead to non-reporting of ADR (Khan, 2013). The majority of the students agreed that patients should be counselled about ADR during dispensing of medications and may avoid their non-compliance. This is necessary to ensure that the patients are well informed of the adverse reactions caused by the drugs taken. The study found that there are significant differences in perception among the students belonging to different ethnicity about basic knowledge of the classification of ADR and the perception while dispensing a medicine to the pregnant women. The results of this survey also may provide an opportunity for future research into curricular planning and teaching of topics such as pharmacovigilance and ADR reporting where misconceptions or stigmata exist.

5. Limitations

Limitations of the study are the number of students who participated in this study was relatively small considering the number of students currently enrolled in various pharmacy schools in Malaysia. Additionally, this study was conducted

in a university located in an urban area. Knowledge and perception may vary based on the other localities such as semi-urban and rural areas. Hence, this study may not generalize the data for all pharmacy students in Malaysia. Another limitation to this study is that it only surveyed pharmacy students instead of those of other health professions.

6. Conclusions

The results showed that the pharmacy students had sufficient knowledge on ADR reporting and pharmacovigilance. Studies have shown that improvement in educational programmes is warranted in order to optimize patient safety. The students' perception towards ADR reporting can be amplified by providing more workshops and hands on training during their clinical placements. It will enable them to play a significant role in ADR reporting in future practices and reduce the incidences of ADR related hospital admissions in Malaysia.

Authors' contribution

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work-MMK, KR.
- Drafting the work or revising it critically for important intellectual content-SN, KR.
- Final approval of the version to be published-MMK, KR.
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved-MMK.

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