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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.

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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 RAOSOF 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, <i>n</i>	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

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