

Pharmacy students' knowledge and perceptions of adverse drug reactions and reporting.

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Abstract

Adverse Drug Reactions (ADRs) have medical as well as economic consequences, leading to increased patient morbidity and mortality. Under reporting of ADRs is a huge health problem globally. Malaysia like many other countries worldwide uses spontaneous reporting systems as a means of collecting data on suspected adverse drug reactions. However, compared to other countries, which use the system, the reporting rate in Malaysia is very low.

The aim of this study is to evaluate the knowledge and perception of pharmacy students at Management and Science University, Selangor, Malaysia in pharmacovigilance system and ADR reporting. This was a descriptive cross-sectional study. Pharmacy students have high understanding and are knowledgeable about the ADR reporting process and the current pharmacovigilance system. However, skill on reporting ADR is poor among pharmacy students and promoting on ADR reporting is also poor in Malaysia. Pharmacy curriculum should include skill related topics related to the methods of detecting, preventing, and reporting ADRs.

Competency in the skill of ADRs reporting may be assessed by using of an Objective Structured Clinical Examination (OSCE). Policy makers and responsible government bodies should take initiatives to promote ADR reporting among health professionals, including pharmacists, in order to improve the reporting system. Interactive interventional programs could be conducted among pharmacists to improve and promote spontaneous reporting of ADRs both in the hospital and community pharmacy practice settings.

Keywords: Adverse drug reaction, Pharmacovigilance, Pharmacy students

Introduction

An Adverse Drug Reaction (ADR) is defined as an unintended and noxious response to a drug that occurs at doses normally used for the prophylaxis, diagnosis, or therapy of diseases, or for the modification of physiological function. ADRs have medical as well as economic consequences, leading to increased patient morbidity and mortality¹. ADRs occur frequently, leading to a high burden of patient harm in the hospital setting.

Spontaneous reporting of ADRs remains the cornerstone of pharmacovigilance and is important in maintaining patient safety². ADR reporting is considered a professional obligation of healthcare providers, however under reporting by healthcare professionals is common problem and it is estimated that only 6% of all ADRs are reported globally³.

In the United States of America (USA), it has been estimated that around 2.9-5.6% of all hospital admissions are due to ADRs and as many as 35% of hospitalized patients experience an ADR during their hospitalization⁴. Fatal ADRs rank among the most common causes of death in the USA⁵. The economic burden of ADRs is also considerable; for example in the USA, an annual total cost of \$47.4 billion for 8.7 million drug related admissions were reported⁵.

Malaysia like many other countries worldwide uses a spontaneous reporting system as a means of collecting suspected ADRs. Malaysia is one of the developing countries in South East Asia with a national pharmacovigilance program. The Malaysian Adverse Drug Reaction Advisory Committee (MADRAC) is responsible for collecting ADRs reports in the country. The monitoring system was established in 1987. A postage-paid "Blue Card" is used to document and report ADRs. The blue card is accepted as the best method to capture maximum data due to its ease of use⁶.

Historically, underreporting of ADRs has been a serious problem in Malaysia and while reporting has increased gradually over the years, reporting is frequently only conducted by certain health professionals

and the number of reports received by MADRAC remains low compared to other countries⁷.

Pharmacists play an important role in the detection and reporting of ADRs. They have the both the expertise and professional responsibility to report of ADRs. Clinical pharmacists may participate in all stages of the medication use process, including drug ordering, transcribing, dispensing, administering, and monitoring. Studies reveal that pharmacists' retrospective review of medication orders prevent errors⁸. The presence of a clinical pharmacist on rounds as a full member of the patient care team in a medical intensive care unit (ICU) is associated with a substantially lower rate of ADRs caused by prescription error^{8a}. A study on ward pharmacy service concluded that, it led to a 40-50% reduction in errors and ambiguities of prescribing, assisted in the safe and more effective use of medicines in hospitals⁹. Therefore, it is vital that pharmacists have comprehensive knowledge and understanding on ADRs and the ADR reporting system. Local attitudinal issues including pharmacists' attitude towards ADR reporting were described as possible contributing factors for low level of ADR reporting activities¹⁰. Under-reporting of ADRs is a major limitation in Malaysia^{7c}.

Underreporting of ADRs by pharmacists is a major hindrance to successful pharmacovigilance. As future pharmacy practitioners, pharmacy students need to be well trained on how to recognize, prevent, and report ADRs. In addition, it is important they understand the impact of ADRs reporting on pharmaceutical health care and drug safety. Therefore it is vital to

understand if pharmacy students receive sufficient knowledge and training during their undergraduate pharmacy education on ADRs and reporting system.

The aim of this study was to evaluate the effectiveness of pharmacy education related to ADRs reporting among Pharmacy students at Management and Science University, Selangor, Malaysia.

Methodology

Study design, sampling and data collection procedure

It was a cross-sectional study among final year pharmacy students at Management and Science University Malaysia. Participants were recruited through face-to-face interviews. Simple random sampling method was applied. The expected sample size was 95 and total recruited sample was 80 respondents.

Participants were invited to complete a self-administered questionnaire which took approximately 10 minutes to complete. Respondents were instructed to complete the survey in a private area to ensure privacy and return it to the researcher in person to maintain confidentiality. Oral informed consent was obtained from the participants prior to the survey. The response rate was 76% consisting of 80 participants, the response rate is very close to the accepted range for survey research intended to represent schools and faculties of pharmacy ($\geq 80\%$) and for a postal mail survey¹¹.

Questionnaire

A validated pre tested questionnaire was used to assess the knowledge and perception of pharmacy students. The questionnaire consisted of four sections; socio-demography, knowledge, attitude and perception of ADRs and ADR reporting. Knowledge measures assessed included ADR definition, goals and importance of pharmacovigilance, and types of drug-induced reactions that must be reported. Participant perceptions of ADR reporting was measured using questions such as the importance of ADR reporting, information needed for reporting, how to and to whom ADRs are reported in Malaysia. The respondents knowledge and perception were considered to be high if the each and every variable was scored $>70\%$.

Data analysis

Overall, 80 participants were included from the School of Pharmacy, Management and Science University in the baseline descriptive analysis. Point estimates (e.g., frequency and means) were computed. Data were analyzed using t-test, chi-square tests to examine the relationship among socio demographic characteristics and clinical attachment exposure variables with knowledge and perception of pharmacovigilance and ADR reporting. Significance level was set at $p < .05$. SPSS 18 was used for all analyses.

Results

Socio-demography and clinical attachment exposure

As shown in Table 1, most of the respondents (36.2%) were second year Bachelor of Pharmacy students. The majority of respondents (75%) were females. The mean of respondents' age was

22 (SD 1.64). About one fourth of the respondents were exposed to clinical attachment experience (20%). During their clinical attachment about 16.3% had experienced ADRs during clinical exposure

Table 1: Socio-demography and clinical attachment exposure of respondents.

Variables	Frequency (%)
Years of studies	N = 80
First year	20 (25)
Second year	29 (36.2)
Third year	15 (18.8)
Fourth year	16 (20)
Gender	N = 80
Male	20 (25)
Female	60 (75)
Age	N = 80
Mean (SD)*	22.5 (1.6)
Clinical attachment exposure	
No	64 (80)
Yes	16 (20)
Clinical experiences	
None	64 (80)
4-8 weeks	16 (20)
Experiences ADRs during clinical attachment	
No	67 (83.8)
Yes	13 (16.3)

* standard deviation, N – total number of respondents.

Table 2: Knowledge about pharmacovigilance and ADR reporting among the respondents.

Variables	Frequency (%)
ADR reporting Pharmacist's duty	N = 80
No	1 (1.2)
Yes	79 (98.8)
Confirmation of ADRs related to drug before reporting is important	N = 80
No	8 (10)
Yes	72 (90)
ADR definition	N = 80
Wrong	22 (27.5)
Correct	58 (72.5)
Pharmacovigilance definition	N= 80
Wrong	18 (22.5)
Correct	62 (77.5)
Pharmacovigilance is aspect of Pharmacoepidemiology	N = 80
No	12 (15)
Yes	68 (85)
ADRs enable safe drug to be identified	N = 80
No	11 (13.8)
Yes	69 (86.3)
Reporting ADR helps measure incidence of ADR	N = 80
No	6 (7.5)
Yes	74 (92.5)
ADR reporting helps to identify factors predispose to ADR	N= 80
No	4 (5)
Yes	76 (95)
ADR reporting helps to identify previously unrecognized ADR	N = 80
No	12 (15)
Yes	68 (85)
ADR reporting helps to compare ADRs for drugs in similar therapeutic classes	N = 80
No	12 (15)
Yes	68 (85)
ADR reporting helps to compare ADRs for same drug from different companies	N = 80
No	22 (27.5)
Yes	58 (72.5)
Herbal products should be reported	N = 80
No	33 (41.2)
Yes	47 (58.8)
Minimum requirement of an initial report	N = 80
False	15 (18.8)
True	65 (81.2)

N – total number of respondents.

Knowledge about pharmacovigilance and ADR reporting

Table 2 describes the knowledge about ADR and spontaneous reporting system among pharmacy students; almost all the respondents (98.8%) were knowledgeable that the role of pharmacist included ADR reporting. The majority of students were knowledgeable about the definition of ADR (73%) and Pharmacovigilance (78%). All other knowledge and understanding questions eliciting the importance of ADR reporting related responses were high among students, however about 59% of the students believed that ADR related to herbal products should be reported.

Perception of pharmacovigilance and ADR reporting

As shown in Table 3, most of the respondents (93.8%) believed that ADR reporting is necessary and basic information required for reporting (95%). However, only

one third of the respondents (31.2%) knew how to report an ADR and only 31% of the respondents had had sufficient exposure on the importance of ADR reporting. Two thirds of the study population (66%) believed that ADR reporting is not widely promoted in Malaysia.

From independent t-test and one way ANOVA test it was revealed that sub groups of socio-demographic and clinical attachment exposure variables, such as gender, age group, academic year of study program, clinical attachment training in the hospitals during undergraduate program, experiences ADRs during clinical attachment and familiarity with MADRAC were not significantly different on knowledge about pharmacovigilance and ADR reporting. The $p > 0.05$ in all tests.

Socio-demographic and clinical attachment exposure variables also have no significant influence on perception of pharmacovigilance and ADR reporting.

Table 3: Perception of pharmacovigilance and ADR reporting among respondents.

Variables	Frequency (%)
I know how to report an ADR	N = 80
No	55 (68.8)
Yes	25 (31.2)
I think ADR reporting is necessary	N = 80
No	5 (6.2)
Yes	75 (93.8)
ADR reporting is widely promoted	N = 80
No	53 (66.2)
Yes	27 (33.8)
Know all the information needed to report ADRs	N = 80
No	4 (5)
Yes	76 (95)
Sufficient exposure on importance of ADR reporting	N = 80
No	55 (68.8)
Yes	25 (31.2)

N – total number of respondents

Discussion

This pilot study, conducted at a Private Malaysian university, examines pharmacy students' knowledge and perception on ADRs and their ability to execute the skills required to complete an ADR appropriately. Findings from this study may provide insight into how pharmacy students will practice and the importance they will place on ADR reporting when they are registered pharmacy professionals.

These findings show that the students at this University have high baseline knowledge of pharmacovigilance and ADR reporting. Multiple-choice questions about ADR definition, goals and importance of pharmacovigilance and types of drug-induced reactions that must be reported was used to evaluate students' knowledge.

However, the skill of how to report an ADR (31%), the perception that ADR reporting is widely promoted (34%) and sufficient exposure on ADR reporting (31%) were very low among the respondents.

It should be noted that while pharmacy students have sufficient knowledge about pharmacovigilance and ADR reporting, skills on how to report and sufficient training on reporting ADR were not satisfactory. This could be one of the factors contributing to the low rate of ADR reporting among Pharmacists⁷. Therefore, 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^{11a}.

It is important to note that many pharmacy students believed that ADR reporting is not widely promoted in Malaysia. Though undergraduate Pharmacy education in Malaysia is providing sufficient knowledge and a positive perception on pharmacovigilance system and ADR reporting, in the real life practice setting, ADR reporting rate is limited⁷. One of the main factors for this drawback might be lack of promotion on ADR reporting in Malaysia. Pharmacists who receive more education and training on ADR reporting are more likely to report ADRs¹².

It is important that pharmacy education incorporates skill related topics, such as how to report an ADR and the teaching should be practical oriented. Competency in the skill of ADRs reporting can be assessed by using of an Objective Structured Clinical Examination (OSCE). Policy makers, responsible government bodies should take initiatives to promote ADR reporting among health professionals including pharmacists in order to improve the reporting system. Interactive interventional programs could be conducted among pharmacists to improve and promote consistent reporting of ADRs in the hospital and community pharmacy practice settings.

Limitation

This study has several limitations. Pharmacy student participants were from only one university. Our participants were only from a private institution, it may be appropriate to have a mixed sample with participants from public institutions as well. We have applied simple random sampling technique to select

the respondents but there might be some errors in selection of the samples. This was a descriptive type study, therefore the conclusions derived may not be robust, however these findings could be used as preliminary data to plan future in depth studies related to the ADR reporting and education system.

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