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## Assessment of Knowledge, Attitude and Practices of Adverse Drug Reaction Reporting among Doctors and Pharmacists in Primary Healthcare



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### ABSTRACT

**Background:** Adverse drug reactions (ADRs) are global problems of major concern. Healthcare professional's knowledge and attitudes to ADR and ADR reporting play vital role to report any cases of ADR. Positive attitudes may favour ADR reporting practices by healthcare professionals. **Objective:** This study was aimed to investigate the knowledge, attitudes, and practices towards ADR reporting among healthcare professionals working at primary outpatient care in Kuala Muda District Health Office, Kedah, Malaysia. **Methodology:** A cross-sectional study was done by survey using a self-administered structured questionnaire. The questionnaire was distributed to all healthcare professionals working at primary outpatient care in Kuala Muda District Health Office, Kedah, Malaysia. **Result & Discussion:** The overall response rate was 87.4%. The mean knowledge score was  $66.9\% \pm 19.86$  for doctors and  $76.9\% \pm 13.87$  for pharmacists ( $p=0.03$ ). 43.8% of the healthcare professionals did not aware of the blue card reporting system in Malaysia. Almost all of the respondents agreed that ADR reporting should be made mandatory and they recognized that it's their professional obligation to report any ADR. However, only 51.9% of doctors and 70.8 % of pharmacist had reported. Half of the respondents professed that ADR forms are too complex to fill and almost all of the respondents (90.4% doctors and 87.5% pharmacists) declared that they are lacking time to fill in the report. 69.2% of doctors expressed that they have not been trained on ADR reporting which was contradicting with the pharmacists (12.5%) ( $p<0.001$ ). Almost all respondents (82.7 % doctors and 95.8 pharmacists) concurred that ADR reporting should be taught in details to them. **Conclusion:** Respondents reflected inadequate knowledge on ADR reporting. The prevalence of unsatisfactory practices and attitudes among these primary health care doctors and pharmacists contributed to the failure to report ADR even if the ADR was identified. Educational intervention strategies can be introduced in order to promote ADR reporting.

## INTRODUCTION

Adverse drug reactions (ADRs) are global problems of major concern. They are one of the common causes of morbidity and mortality in both hospital and community settings and affecting many with varying magnitudes; as well as leading to morbidity and mortality [1-3]. World Health Organization (WHO) defines ADR as “any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function” [4].

When a drug is being approved by the Food and Drug Administration, there is a little known about serious and rare adverse effects associated with that drug while a post-marketing surveillance is important and it relies much upon the spontaneous and voluntary reporting of ADR by the health care professionals [5]. The spontaneous and voluntary reporting of ADR is inexpensive and easy to operate. It encompasses all drugs and patient populations, including special groups. However, under-reporting and an inability to calculate the incidence of ADRs are the inherent disadvantages of this method [6-8]. Worldwide, 95% of serious ADRs do not get reported to the health authorities [9].

In Malaysia, ADR reporting also adhered to spontaneous reporting and it is done via Malaysian Adverse Drug Reactions Advisory Committee (MADRAC) [10]. According to MADRAC annual report 2012, there were a total of 10,102 ADR reports received in the year 2012 [11]. Out of this, only 342 reports were from Kedah state and only 10 reports were done by Kuala Muda District Health Office in the year 2012.

Healthcare professional's knowledge and attitudes towards ADRs and ADRs reporting play vital role to report any cases of ADRs. Knowledge of health care providers about ADRs reporting can impact their attitude towards patient care and issues on patient safety. Positive attitudes may favour ADRs reporting practices by healthcare professionals. Since ADRs reporting is spontaneous and is done voluntarily by health professionals, to improve the participation of health professionals in spontaneous reporting, it might be necessary to design strategies that modify both the intrinsic (knowledge, attitude and practices) and extrinsic (relationship between health professionals and their patients, the health system and the regulators) factors. The operational definition of knowledge means a theoretical or practical understanding of the subject matter. Attitude means predisposition or a tendency to respond positively or negatively towards a certain idea, object, person, or situation while practice

means the application of knowledge or practical approach to the subject matter. A “KAP” study will be able to measure the Knowledge, Attitude and Practices of a community where it will serve as an educational diagnosis of the community. Thus, a knowledge, attitude and practice (KAP) analysis may provide an insight into the intrinsic factors and help understand the reasons for under-reporting [12].

Knowledge, attitude, and practice regarding ADR reporting have not been studied extensively in Malaysia, especially in primary care in Kedah state. A few studies carried out in Malaysia have shown poor knowledge, attitude, and deficient practices of ADR reporting among the doctors [13–15]. A study in Kuala Lumpur Malaysia reported that 81.4% out of 350 respondents indicated that they had suspected an ADR but did not report it, while about 40% of the respondents were not aware of the existence of the national reporting system in Malaysia [16].

### **General Objective**

To provide a current profile of knowledge, attitude, and practices of ADR reporting among primary outpatient care pharmacists and doctors in Kuala Muda District Health Office, Kedah, Malaysia.

### **Specific Objective**

1. To assess primary outpatient care pharmacists and doctors’ knowledge of ADR reporting at their workplace.
2. To assess primary outpatient care pharmacists and doctors’ attitude towards ADR reporting.
3. To assess primary outpatient care pharmacists and doctors’ practices of ADR reporting.

## **MATERIALS AND METHODS**

### **Study Design**

This is a cross-sectional questionnaire-based survey.

### **Questionnaires development**

The survey instrument was developed based on existing literature on medication safety [14, 17-19]. Modification was made to suit the local situation such as we modified the questions

to test the respondent's knowledge towards the Malaysian ADR reporting system. The survey instrument consisted of 2 parts, part 1 involves the collection of participant demographic data, while part 2 consisted of 3 domains which included respondent's knowledge, attitude and practices towards ADR reporting. The domain which assesses knowledge of respondents in ADR reporting will be in true and false and the other two domains (attitude and practices) will be in 4 point likert scale. (1 - Strongly Disagree, 2 - Disagree, 3 - Agree and 4- Strongly Agree). The survey instructions stated that there are no correct or incorrect responses and instructed participants to rate the response that best reflects their perceptions. The questionnaire was prepared in English language. The survey instrument will be reviewed for its face and content validity by a group of experts in the field of medication safety. Moreover, a pilot study was conducted with 15 pharmacists and 15 physicians from outpatient care clinics, Hospital Sultan Abdul Halim, Kedah, Malaysia. Some minor revisions were made based on the comments during the pilot study. The study had been approved by the local medical research ethical committee (MREC).

### **Study setting, population and sampling**

All 9 primary outpatient care clinics under Kuala Muda District Health Office, Kedah, Malaysia were included in this study. The targeted population was all pharmacists and doctors working under primary outpatient care of Kuala Muda District Health Office. This is a census study as data is gathered on every member of the population. This study included all registered pharmacists and doctors working in primary outpatient care clinics in Kuala Muda District Health Office. The exclusion criteria were provisional registered pharmacists (PRP), pharmacy students attached to the relevant health facilities, doctors under housemanship and doctors or pharmacists on long leave/sick leave.

### **Survey administration**

A mail containing the questionnaires was sent in November 2015 to all the participants. Before sending the mail, a meeting with all the head of department of each clinic will be held to inform the relevant study. The survey instrument was accompanied by an addressed envelope (for returning the completed questionnaire) and a cover letter explaining the aim of the study, definition of ADR reporting and confidentiality of all responses from participants. The participants were asked to complete the questionnaires and return them in two weeks

time. The first reminder was sent to each pharmacist and doctor approximately after first week. The second reminder was sent after one week of the first reminder.

### Data analysis

All the data received from this survey were entered in the SPSS version 20 for statistical analysis. Appropriate descriptive and inferential statistics were used for data analysis. Descriptive analysis was used to analyse the demographic data, attitude and practice domain of the survey. Independent t-test was used to analyse the knowledge between doctors and pharmacists towards ADR reporting.

## RESULTS AND DISCUSSION

A total of 76 respondents have answered the questionnaires. The response rate was 87.4%. They were 52 doctors and 24 pharmacists involved in the study. Out of the 76 respondents, 17 were male and 59 were female. The mean working experience for doctors was 7.9±5.14 years while pharmacists recorded 5.2 ± 2.51 years. The mean age for the doctors was 34.7±5.86 while the mean age for the pharmacist was 29.2±3.13 years old.

**Table 1: Demographic Data**

<b>Variables</b>	<b>n[%]</b>	<b>Mean[SD]</b>
<b>Occupation</b>		
<i>Doctors</i>	52[68.4]	
<i>Pharmacists</i>	24[31.6]	
<b>Gender</b>		
<i>Male</i>	17[22.4]	
<i>Female</i>	59[77.6]	
<b>Working Experience</b>		
<i>Doctors</i>		7.9[5.14]
<i>Pharmacists</i>		5.2[2.51]
<b>Age</b>		
<i>Doctors</i>		34.7[5.86]
<i>Pharmacists</i>		29.2[3.13]

SD= standard deviation

Pharmacist has higher mean score  $76.9 \pm 13.87$  compare to doctors  $66.9 \pm 19.86$  for knowledge of ADR reporting,  $p=0.03$ . (Refer table 2) Most respondents (43.8%) do not aware of the blue card reporting system in Malaysia. Among this, 46.9% of doctors do not aware of the system while 37.5% pharmacists do not aware about this system. 37.3 % of the total respondents felt that only doctors and pharmacists are responsible for ADR reporting. Among this, 43.1 % of doctors and 25 % of pharmacists has the same thought. The existing system of ADR monitoring in Malaysia, similar to other country rely upon the spontaneous reporting of health professionals as a main source for information and it requires a good knowledge of health care professionals to report.

**Table 2: Comparing mean knowledge score between doctors and pharmacists using independent t-test**

	Knowledge Score Mean [SD]	Std Error	P value <sup>a</sup>
Doctors	66.9 [19.86]	2.755	0.03
Pharmacists	76.9 [13.87]	2.831	

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

SD=Standard deviation

### Results on Attitude of ADR Reporting

In a review article by Lopez-Gonzalez *et al*, attitude of HCPs was concluded to be one of the major determinants to ADR reporting [20]. By understanding attitudes, proper remedial action can be taken to rectify and subsequently to improve participation of HCPs in pharmacovigilance. In our study, almost all doctors and pharmacists felt that ADR reporting is necessary and is part of their professional obligation. Similar finding has been cited in various studies [13, 19, 22]. However, in a study in India, only 40% of pharmacists agreed that ADR reporting is their professional obligation as compared to 83% of doctors [18]. In the field of healthcare industry, medication safety is always the utmost emphasis. Thus, all healthcare providers must integrate pharmacovigilance into their daily practice and aware that ADR reporting is an important source of information contributing to drug safety database.

Currently, Malaysia is practising voluntary ADR reporting system as many countries in the world. As defined earlier, a major and well-recognized setback associated with this system is the underreporting of ADR [21]. An interesting finding in our study was almost all study participants agreed that ADR reporting should be made mandatory. This was found to be much higher as compared to other studies, where only 60% doctors, 40% of pharmacists and 53% of physicians agreed on the mandatory ADR reporting [18, 23]. Despite the positive attitude of our study population towards ADR reporting, the reporting rate remains low. Thus, the reasons for underreporting or non-reporting reserve further investigation.

More pharmacists than doctors (50% pharmacists and 30.7% doctors) in this study assumed that reporting of just one ADR makes no significant contribution to the ADR reporting scheme. One study in Malaysia illustrated that 25.5% of private practitioners in Klang Valley was being indifference in assuming that one ADR reported did not contribute to medical knowledge [13]. This assumption among the HCPs is possibly one of the obstacles to the low reporting of ADR in Kuala Muda District Health Office. It is important to raise the awareness that the occurrence of ADR from a drug might differ in different populations and ethnicities. Thus, every single ADR reported to MADRAC does contribute to the local database of ADR in Malaysian population.

Majority of doctors and pharmacists in this study agreed that pharmacovigilance should be taught in detail to HCPs. This finding is consistent with another same study in which the participants revealed their willingness to learn and to improve their pharmacovigilance knowledge in order to improve ADR reporting [23]. Education is known to serve as the leading factor to empowerment. In Malaysia, a study conducted by Elkalmi *et al.* had shown the positive impact of educational intervention in improving the pharmacists' perception on pharmacovigilance [24]. Thus, it was suggested that pharmacovigilance should be included into undergraduate curriculum [13, 23].

Almost half of the study population (48.1% of doctors and 50% of pharmacists) felt that the ADR form is too complex to fill. This finding is slightly higher compared to another study in Malaysia with only 39.1% of the doctors agreed that the ADR form is difficult to fill [13]. Further investigation is needed to explore the difficulties in filling ADR form so that feedback can be channelled to MADRAC for the improvement of the form.

Larger proportion of pharmacists and doctors (70.8% vs 52.0%) felt that ADR reporting should hide the identity of HCPs. This is agreeable to the finding by another study in Malaysia where the private practitioners in Klang Valley, Malaysia preferred to keep their identity anonymous due to the fear of any untoward investigation and legal liabilities which might jeopardous their career [13]. Similar result has also been reported in India [18]. In fact, the identity of reporters is important for MADRAC to secure traceability of missing information ensuring the quality of the reports received.

Majority of the participants agreed that lack of time to fill in ADR report and to actively look for ADR while at work resulting in low reporting rate of ADR. Similar finding has been reported by other studies where the respondents revealed that ADR reporting is time consuming and busyness is the barrier to ADR reporting [13, 25]. In Malaysia, in the effort to encourage pharmacists to report ADR, Pharmacy Board has offered the incentive whereby for every ADR accepted and approved by MADRAC, the pharmacist will be entitled for one CPD credit point up to a maximum of 10 points per year (a minimum of 40 CPD point is prerequisite to renew annual practice certificate).

Table 3 showed the comparison of attitude of ADR reporting among doctors and pharmacists in the Kuala Muda District Health Office, Kedah, Malaysia.



**Table 3: Comparing attitude on ADR reporting among doctors and pharmacists.**

	Questions	Doctors		Pharmacists		Chi Sq	p value <sup>a</sup>
		Disagree n[%]	Agree n[%]	Disagree n[%]	Agree n[%]		
1	Reporting ADR is necessary	0 (0.0)	52 (100.0)	1 (4.2)	23 (95.8)	2.334	0.311
2	ADR reporting should be made mandatory	5 (9.6)	47 (90.4)	0 (0.0)	24 (100.0)	5.293	0.071
3	ADR reporting is our professional obligation	2 (3.8)	50 (96.2)	1 (4.2)	23 (95.8)	0.996	0.608
4	ADR form is too Complex to fill	27 (51.9)	25 (48.1)	12 (50.0)	12 (50.0)	0.178	0.915
5	Pharmacovigilance should be taught in detail to healthcare professionals	9 (17.3)	43 (82.7)	1 (4.2)	23 (95.8)	2.568	0.463
6	ADR reporting should hide the identity of health care professionals	25 (48.0)	27 (52.0)	7 (29.2)	17 (70.8)	3.007	0.391
7	Lack of time to fill in report resulting in low reporting rate of ADR	5 (9.6)	47 (90.4)	3 (12.5)	21 (87.5)	6.586	0.086
8	Lack of time to actively look for ADR while at work leading to non reporting of ADR	11 (21.2)	47 (78.8)	4 (16.7)	20 (83.3)	3.935	0.269
9	I assume that reporting of only one ADR makes no significant contribution to the ADR reporting scheme	36 (69.2)	16 (30.7)	12 (50.0)	12 (50.0)	2.709	0.439

<sup>a</sup> Chi Square Test

## **Results on Practices of ADR Reporting**

Both Doctors (75.0%) and Pharmacist (91.7%) in Kuala Muda District Health Office disagreed that they only report life threatening or serious ADR which in contradict with other study carried out in a tertiary hospital where the respondents mentioned that they were encouraged to report ADR if only the reaction was serious [23]. The same study also revealed that 73.7% from their respondents reported ADR if only the reaction was serious [23]. Thus, healthcare professionals in the Kuala Muda District Health Office have higher awareness on the need to report for ADR despite on its severity.

Education and training on ADR reporting is fundamental to improve the overall ADR reporting rate [15, 23]. Educational intervention had been found to improve ADR reporting in Portugal [26] and Rhode Island [27] in USA. One study reported that an initial 148% increase in the number of ADR reports was observed immediately after the educational intervention [26]. In our study, we found a significant different in term of education in training received by Doctors and Pharmacists in Kuala Muda District Health Office. 69.2% of Doctors in Kuala Muda District Health Office had never being trained on how to report an ADR while only 12.5% Pharmacists claimed not being trained. The differences found might be due to an early introduction of pharmacovigilance in the undergraduate curriculum study in pharmacy courses which contradictory to the doctor population. Thus, educational intervention is mandatory to be introduced in the undergraduate curriculum of HCPs or during their practice in the health care setting. A study in Nepal also convinced that the knowledge of healthcare profession regarding ADR monitoring and pharmacovigilance programme shall be increased via educational intervention as it is one of better means of overcoming under reporting [28].

In our study, although we found that the mean working experience was 8 years for doctors and 5 years for pharmacists, there were still small populations of respondents (26.9% of doctors and 4.2% of pharmacists) have never come across with any ADR cases. Lack of knowledge [29] might lead to failure to detect the ADR even when it is occurring. Inman has summarized a major reason for under-reporting which is complacency (only safe drug are marketed), this may be one of the reason for the undetected ADR during practices [30].

Our study illustrated that most of the doctors did come across with ADR (73.1%) but did not take action as majority of them (48.1%) admitted that they had never been done at least 1

ADR reporting for past the 1 year. The lack of practices on ADR among doctors also been reported in various studies across different countries and regions [13, 31-33].

**Table 4. Comparison of practices on of ADR reporting among doctors and pharmacists**

	Questions	Doctors		Pharmacists		Chi Sq	P value <sup>a</sup>
		Disagree n[%]	Agree n[%]	Disagree n[%]	Agree n[%]		
1	I have came across with an ADR	14 (26.9)	38 (73.1)	1 (4.2)	23 (95.8)	5.784	0.123
2	I have been trained on how to report ADR.	36 (69.2)	16 (30.8)	3 (12.5)	21(87.5)	22.794	<0.001
3	I am following approaches in preventing ADRs / prevented ADRs during my practise	10 (19.2)	42 (80.8)	3 (12.5)	21 (87.5)	0.865	0.834
4	I only report severe or life threatening ADR.	39 (75.0)	12 (25.0)	22 (91.7)	2 (8.3)	3.26	0.353
5	I mention the ADR on patients' record	9 (17.3)	43 (82.7)	8 (33.3)	16 (66.7)	5.579	0.061
6	I have done ADR reporting at least once for the past 1 year	25 (48.1)	27 (51.9)	7 (29.2)	17 (70.8)	4.384	0.223
7	I have seen ADR reporting form	8 (15.4)	44 (84.6)	0 (0.0)	24 (100.0)	5.204	0.157

Table 4 showed the comparison of practices on of ADR reporting among doctors and pharmacists in the Kuala Muda District Health Office. Table 4: Comparing practices on ADR reporting among doctors and pharmacists.

**CONCLUSION**

Spontaneous reporting required good knowledge among the key personnel to make the report and in this study, the knowledge among the health care professionals in the current setting is however still moderate. The prevalence of unsatisfactory practices and attitudes among these

primary health care doctors and pharmacists contributed to failure to report ADR even if the ADR was identified.

Educational intervention strategies either introduce from the undergraduate levels or to have more campaign on ADR reporting organized by the regulatory authorities will help to improve ADR reporting. A most recent implementation of CPD point awarded to those pharmacist we has reported an ADR may be one of the strategy to improve the number of ADR reporting in the country. More similar rewarding practice can be implemented in different health care setting for the overall improvement of the reporting system.

### **Study Limitation**

The limitation of this study rely upon the single centre of result may not represent to the whole nation. Therefore, its findings cannot be generalized to the whole country. However, given the paucity of data regarding adverse drug reaction reporting in primary care in Malaysia, we believe these preliminary findings are useful for future guidance for health authorities. Moreover, the current findings warrant a large scale study to further study this adverse drug reaction reporting practices in primary care.

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### **List of abbreviation**

ADR: Adverse drug reaction

KAP: Knowledge, attitude, practice

HCPs: Healthcare professionals

MADRAC: Malaysian Adverse Drug Reactions Advisory Committee

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