International Journal of Health Sciences and Research
www.ijhsr.org ISSN: 2249-9571

Original Research Article

Awareness Implications on Adverse Drug Reactions: Findings from A Cross-Sectional Study among Outpatients Attending a Public Hospital in Malaysia

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ABSTRACT

Introduction: Adverse drug reactions (ADRs) is a growing concern worldwide as the risk of the ADR is underrated. Spontaneous or voluntary reporting of suspected adverse drug reactions (ADRs) provides input for medication without harm initiatives as to reduce medication related adversities.
Objectives: To assess the knowledge, beliefs, and behaviour of outpatients and its association in addressing adverse drug reactions.
Methods: A cross-sectional study was conducted among voluntary participation of 400 outpatients attending Penang General Hospital, Malaysia. The targeted respondents were long-term medications dependant, whom was waiting for their prescriptions at the department of pharmacy.
Results: There was a significant difference between knowledge and attitude in addressing ADRs ($p<0.05$) among the respondents. Respondents agreed that western medicine solely causes side effects (84.5%). In addition, doctors and pharmacist (95.5% and 94.0%, respectively) needed to inform patients about possible side effects of the prescribed medicine. Majority of respondents would inform their physician if they were consuming traditional medications (70.8%) and were using non-prescribed medicines bought at pharmacy (78.3%) at the same time the Western medicines prescribed. However, only a lesser percentage of the respondents would seek information about the side effects of the medicine before taking those (56.5%). Overall, the majority have indicated that medicines' side effects can be prevented ($p<0.05$).
Conclusion: There is a general misconception in addition to low levels of awareness and understanding among the public toward ADRs. It is anticipated that this study would be useful in designing public educational interventions to enhance the identification and reporting of ADRs.

Keywords: Adverse Drug Reactions; Pharmacovigilance; Knowledge; Beliefs; Attitude

INTRODUCTION

Adverse Drug Reactions (ADRs) defined as "an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product". [1,2]

Adverse drug reactions (ADRs) account for 3.2-7% of acute hospital admissions worldwide. [3] ADRs are associated with prolonged length of hospital

stay, increased economic burden and increased number of death. [4-6] In the United States, it had been reported that more than 100,000 deaths were attributed annually to serious adverse drug reactions. [7] In addition, there have been several studies which highlighted on the ever-increasing socioeconomic and health consequences of ADRs. [8]

In Malaysia, ADR reporting adheres to spontaneous reporting to Malaysian Adverse Drug Reactions Advisory Committee (MADRAC). [9] A total of 10,102 incidences have been reported to MADRAC in year2012. [10] However, the major disadvantage of the spontaneous reporting is the underreporting of ADR incidence. [11]

In an event of a drug-related problem, the majority of patients are unsure what should be their course of action. [12] As reported by Cullen et al (2006), patients' knowledge on the risks associated with medications is frequently inaccurate and inconsistent. Furthermore, poor knowledge on prescribed, over-the-counter (OTC) and complementary/alternative medicine (CAM) has been widely reported among patients. [13] The patients' knowledge and behaviourinfluence usage of the drugs appropriately and in a safe manner. In addition, patients' misconceptions on ADR can adversely affect the drug treatment process. [14] Accurate information and advice from healthcare professionals are essential to reassure patients thus ensuring patients are well informed about their medicines uptake. [15]

Patients who are better informed on their mediations are more likely to avoid adverse drug-related reactions, have a better coping mechanism with predictable side-effects, and are able to predict the likelihood of the potential non-dose-related side-effects. [14] Tailored communications in understanding the probability of experiencing ADR by the healthcare providers to the patients help in avoiding and minimalizing the effects of ADR. [16] Therefore, this study is an important platform for assessing the knowledge, belief, and behaviour regarding adverse drug reactions among the public.

METHODOLOGY

Participants: A cross-sectional study assessing knowledge, beliefs, and attitudes utilizing questionnaire-based study was conducted by voluntary participation of 400outpatients attending Penang General Hospital, Malaysia. Respondents aged 18 and above who were able to communicate in either Bahasa Malaysia or English were included in this study. Written informed consent was obtained and a brief respondent explanatory note was read out to the participants before they answered the questionnaire. The study was carried out after obtaining the approval from the Malaysia Research Ethics Committee (MREC) (Approval number: NMRR-15-2370-27572 (IIR).

Validity and Reliability: The questionnaire was adopted with written permission from Jose et al (2011). The Cronbach alpha of different sections of the questionnaire were 0.625 (knowledge), 0.615 (belief) and 0.648 (behaviour) indicating a good reliability. The questionnaire was prepared in the English language. The survey instrument was 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 20 pharmacists and 20 general public at Hospital Pulau Pinang, Malaysia to test the appropriateness of the questions and their comprehension. Some minor revisions were made based on the comments during the pilot study. It revealed that, after minor modification, the questions seemed to be readily understood by those participants of the pilot study.

Statistical Methods: The data were entered and analyzed using computer software, Statistical Package for Social Sciences (SPSS) base version 21.0. The study included descriptive and bivariate analysis. Descriptive data were tabulated and presented in N (%) accordingly.For all

statistical analysis, $p < 0.05$ was considered as significant.

RESULTS

A total of 400 respondents participated in this study (Table 1). Most of the respondents (n=178; 44.5%) were from the age group of 18-35 years old. The number of male respondents (n=213; 53.2%) was slightly more than female respondents (n=187; 46.8%). More than half of the subjects (n=219; 54.7%) are of tertiary education level. Many of the subjects have no history of long term medicine usage (n=218; 54.5%) and had never experienced side effects from medications (n=271; 67.7%).

Table 1: Respondents demographics (n=400)

Characteristics	n (%)
Age group (years)	
18-35	178 (44.5)
36-50	101(25.2)
51-65	95 (23.8)
>65	26 (6.5)
Gender	
Male	213 (53.2)
Female	187 (46.8)
Educational qualification	
Primary	21 (5.3)
Secondary	160 (40.0)
Tertiary	219 (54.7)
History of long term medicine use	
Yes	182 (45.5)
No	218 (54.5)
Experience of side effects	
Yes	129 (32.3)
No	271 (67.7)

Footnote: Descriptive data was tabulated and presented in N (%) accordingly

In assessing the outpatients' knowledge on adverse effects of medicine (Table 2a), most of the respondents (n=338, 84.5%) agree that Western medicine solely causes side effects. The listed reason for their response are Western medicine contains chemical substances (n=279; 29.6%), Western medicines is potent (n=253; 26.9%), incorporated with impure or strong chemical (n=229; 24.3%) and it's not easily eliminated from the body (n=181; 19.2%). Less than half of the total respondents agree that 'Over-The-Counter' (OTC) medicines, which are easily purchased from the pharmacies, have absolutely no side effects (n=157; 39.3%). This is because OTC medicines are safe therefore are freely available without doctor's instruction (n=59; 36.9%), OTC medicines are used in common or minor illness are safe (n=57; 36.3%) and OTC medicines are less likely to cause side effects (n=50; 31.8%). Only a small number of the respondents (n= 99; 24.8%) agree that traditional medicine causes no side effects. Those agreed to the former statement responded that traditional medicines derived from natural medicines (n=85; 85.9%), free from additives (n=64; 64.6%) and it is likely to cause side effects (n=57; 57.6%). However, only about 30% of the respondents agree that medicines' side effects can be prevented.

In term of respondents' beliefs about adverse drug effects of medicine (Table 2b), the majority of respondents believe that doctors (n=382; 95.5%) and pharmacist (n=376; 94.0%) are responsible for informing the patients about possible side effects of the prescribed medicine. In addition, respondents believe that doctor is always responsible for side effects of the prescribed medicine if they occur. Finally, about 41% of the respondents' belief that doctors will only prescribe medicines which are safe.

On assessing the attitudes (Table 2c) toward adverse drug effects of medicines, over 77% of the respondents indicated that they would seek information on the prescribed medicine form the doctor. In addition, about 283 (70.8%) respondents would inform doctors if they are using the traditional medicine once Western medicines are prescribed. Respondents whom would not inform the doctors stated that there is no need to inform the doctor (n=48; 33.0%) and it's safe to use both traditional and prescribed medicines together (n=37; 26.0%). About 31% of the respondents would think that doctors' response would be worrisome if they inform about their traditional medicine intake. In addition, 19% of the respondents indicated that doctors have limited knowledge on the traditional medicine.

On the other hand, in terms of usage of non-prescribed medicines bought from pharmacy concurrently with medicines prescribed by doctors many respondents indicated that they would inform (n=313; 78.3%). Respondents whom would not inform the doctor indicated the following reasons; doctors needed not to be informed as these medicines are used for short periods or occasionally (n=46; 29.0%), there is no need to inform the doctors (n=46; 29.0%), not necessary to inform about medicines used for other condition or purposes (n=39; 25.0%) and it is safe to use both medicines together (n=27; 17.0%). Less than 605 of the total respondents have answered that they would obtain information about the medicine's side effects before taking it.

Table 2: Respondents Knowledge, Beliefs and Attitude on Adverse Drug Effects of Medicine (n=400) in Hospital Pulau Pinang, Malaysia

2a) Knowledge on Adverse Drug Effects of Medicine		**No. of Respondents Agreedn (%)**
Q1	Western medicine solely causes side effects	338 (84.5)
	Agreed respondents answers the follows;	
	Western medicine contains chemical substances	279 (29.6)
	Western medicines are potent	253 (26.9)
	Western medicines incorporated with impure or strong chemical	229 (24.3)
	Western medicines are not easily eliminated from body	181 (19.2)
Q2	OTC medicines contributes absolutely no side effects	157 (39.3)
	Agreed respondents answers the follows;	
	OTC medicines are considered safe therefore available without doctor's instructions	58 (36.9)
	OTC medicines used in common or minor illness are safe	57 (36.3)
	OTC medicines are less likely to cause side effects	50 (31.8)
Q3	Traditional medicines contributes absolutely no side effects	99 (24.8)
	Agreed respondents answers the follows;	
	Traditional medicines derived from natural sources	85 (85.9)
	Traditional medicines are free from additives	64 (64.6)
	Traditional medicines are less likely to cause side effects	57 (57.6)
Q4	Medicine side effects can be prevented	125 (31.3)
2b) Beliefs on Adverse Drug Effects of Medicine		**No. of Respondents Agreed n (%)**
Q1	Doctor are responsible to inform the patients about possible side effects of the prescribed medicine	382 (95.5)
Q2	Pharmacist recommending medicine should inform the consumer about the possible side effects	376 (94.0)
Q3	Doctor is always responsible for side effects of the prescribed medicine	294 (73.5)
Q4	Doctors only prescribed medicine that are completely safe	164 (41.0)
2c) Attitude on Adverse Drug Effects of Medicine		**No. of Respondents Agreed n (%)**
Q1	I would seek information of the prescribed medicine side effects from the doctor	309 (77.3)
Q2	I would inform the doctor if uptaking traditional medicine at the same time as western medicines prescribed	283 (70.8)
	Disagreed respondents chooses the follows;	
	Doctors needed not to be informed	48 (33.0)
	Safe to use both medicines together	37 (26.0)
	Doctor's responses are worrisome	31 (22.0)
	Doctors have limited knowledge about these traditional medicines	28 (19.0)
Q3	I would inform the doctor on usage of non-prescribed medicines bought at pharmacy concurrently with the medicines prescribed by the doctor	313 (78.3)
	Disagreed respondents chooses the follows;	
	Doctors needed not to be informed as these medicines are used for short periods or occasionally	46 (29.0)
	Doctors needed not to be informed	46 (29.0)
	Doctors needed not to be informed about medicines used for other conditions or purposes	39 (25.0)
	Safe to use both medicines together	27 (17.0)
Q4	I get information about a medicines side effects before taking the medicine	226 (56.5)
Q5	If I suspect that myself or the person I am looking after is experiencing a side effect, I would	
	Stop using the medicine and inform at next appointment	272 (21.4)
	Stop using the medicine and inform a doctor immediately	241 (18.9)
	Inform or consult a pharmacist	212 (16.6)
	Reduce the dose ownself	165 (13.0)
	Try some self- medications	145 (11.4)
	Stop using the medicine and not inform a doctor	143 (11.2)
	Wait and see	96 (7.5)
Q6	I will inform the doctor if allergic to certain medicine or if had experienced allergic side effects	384 (96.0)

Table 3: Association of respondents whom had experienced medicine side effects and their associated responses (n=400)

Traditional medicines contributes absolutely no side effects				
Response	N (%)	Adjusted OR	(95%CI)	(p-value)
				<0.001
Agree	99 (24.8)	2.42	(1.01,5.82)	0.048
Disagree	230 (57.5)	6.14	(2.76,13.66)	<0.001
Unsure	71 (17.8)	1.00(ref.)		
Medicine side effects can be prevented				
Response	N (%)	Adjusted OR	(95%CI)	(p-value)
				0.018
Agree	125 (31.3)	0.51	(0.31,0.86)	0.011
Disagree	100 (25.0)	0.57	(0.33,0.98)	0.041
Unsure	175 (43.8)	1.00(ref.)		
Doctors only prescribed medicine that are completely safe				
Response	N (%)	Adjusted OR	(95%CI)	(p-value)
				0.069
Agree	164 (41.0)	2.39	(1.14,5.03)	0.021
Disagree	183 (45.8)	1.95	(0.92,4.12)	0.081
Unsure	53 (13.3)	1.00(ref.)		

Footnote: Adjusted OR= adjusted by age and gender

Table 4: Influence of Patients' Knowledge Regarding Adverse Effects of Medicine (n=400)

Score		***Median (IQR)***	**Z value**	**p Value**	**r value**
Gender	Male Female	12 (10-13) 11 (9-13)	-1.185	0.236	
Age	-	-	-	0.002*	-0.154
Educational Level	Primary Secondary Tertiary	12 (9.5-13) 11 (7.25-13) 12 (10-13)	X^2 6.825	0.033*	
On long-term medicine?	Yes No	11 (9-13) 12 (10-13)	-1.698	0.09	
Ever experienced side effects?	Yes No	12 (10-13) 11 (9-13)	-1.581	0.114	

* p< 0.05 = significant; Z= Mann-Whitney test; X^2 = Kruskall-Wallis test; r = Spearman correlation

Table 5: Influence of Patients' Behaviour Regarding Adverse Effects of Medicine(n=400)

Score		***Mean ± SD***	**t value**	**p Value**	**r value**
Gender	Male Female	16.79 ± 4.25 16.79 ± 3.74	0.005	0.996	
Age	-	-	-	0.023*	-0.113
Educational Level	Primary Secondary Tertiary	17.05 ± 3.51 15.96 ± 4.51 17.38 ± 3.56	F value 5.99	0.003*	
On long-term medicine?	Yes No	16.44 ± 4.18 17.10 ± 3.88	-1.638	0.102	
Ever experienced side effects?	Yes No	16.55 ± 3.71 16.91 ± 4.16	0.406	0.831	

* p< 0.05 = significant; t= Independent t-test; F= One-Way Anova; r = Spearman correlation

In an event of suspected ADR, respondents or by the person taken care by the respondents, would both stop the medicine intake and inform the doctor in the next appointment (n=272 ; 21.4%) or inform the doctor immediately (n=241; 18.9%). Other courses of action that were indicated was informing and consulting a pharmacist (n=212; 16.6%), reducing the dose by their own (n=165, 13.0%), trying some self-medications (n=145, 11.4%), stop using the medication and not informing the doctor (n=143; 11.2%) and wait and see (n=96; 7.5%). The majority of the respondents (n=384; 96.0%) have indicated that they would inform the doctor if they are allergic to certain medicine or if they had experienced allergic side effects.

There was a significant association between the respondents (Table 3) whom had experienced medicine side effects and the respondents whom had disagreed (p<0.001) with traditional medicine being with no side effects (OR:6.14 ; 95% CI 2.76-13.66) compared to the respondents whom agreed (p=0.048) with traditional

medicine being with no side (OR:2.42 ; 95% CI 1.01-5.82).

In addition, there were overall significant value (p=0.018) among respondents experienced medicine side effects and their response for medicine side effects can be prevented. A Higher level of association was found among respondents group who agreed (p=0.011) with that medication side effects can be prevented (OR: 0.51; 95% CI 0.31-0.86) compared to the disagreed (p= 0.041) group (OR: 0.57; 95% CI 0.33-0.98).

In this study, there is a significant difference between the age of the respondents and their knowledge (p=0.002) (Table 4) and behaviour (p=0.023) (Table 5). In addition, there is a significant difference between educational level of the respondents' knowledge (p=0.033) (Table 4) and behaviour (p=0.003) (Table 5).

However, no significant (p= 0.069) association was found among the different groups of respondents for doctors only prescribed medicine that is completely safe and has experienced medicine side effects.

DISCUSSION

Knowledge, attitude, and practice (KAP) analysis provides an insight into the intrinsic factors and helps in understanding the reasons for under-reporting [17] in the ADRs reporting. Several studies carried out in Malaysia have shown poor knowledge, attitude, and deficient practices of ADR reporting among the health professionals. [3,18,19] Similar findings have also been reported among medical students in India. [20] In terms of public perception, a study conducted in Kuala Lumpur, Malaysia reported that81.4% of 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 Malaysian national reporting system. [21] The major reason for under-reporting is complacency of that only safe drug being marketed, thus contributing for the non-detection of ADR. [22]

In this study, statistical significance was found between age of the respondents and their knowledge level (p<0.05). Further analysis using Spearman correlation, revealed that younger respondents (18 – 35 years old) tend to have better knowledge on ADR compared to older respondents (r-value = - 0.154) (Table 4). This finding supported by similar studies done by Shahin et al (1999) and Gazmarian et al (1999) who reported on knowledge score decreases with increasing age. [23,24] This is attributed to the fact that younger generation being more exposed to new information. [25] Therefore, they have a higher chance of obtaining medical information including information on ADR as they would be more anxious and keen from the online databases. [26,27] This behaviour contradicts in the elderly as self-education in form of informal learning is not common. In addition, sense of embarrassment by the elderly causes them to ask fewer questions and defer to physicians' advice. [26]

In addition, statistical significance as was also noted between the educational level of the respondents and their knowledge (p<0.05) (Table 4). Respondents with higher education level have higher level of awareness. [23,28] Respondents with higher level of education are more likely to ask more questions and are more expressive in the responses. This attitude paves ways to more effective two-way communication between them and the healthcare providers. Moreover, respondents with high level of education are more willing to share information on their health related issues which includes concurrent, traditional or OTC medicines usage. They have expressed immense interest in obtaining new information from the healthcare providers. [4] As reported in Shahin et al (1999) and Perera et al (2012), respondents with lower level of education showed poor knowledge about their medications. In addition, as reported in Aelbrecht et al (2015), respondents with a lower level of education communicated lesser, thus causing one-way communication dominated by the study

physician. [4] These findings were further supported by Verlinde (2012) who reported that due to the social gradient, there were less counseling and chatting session between lower educated patients and doctor. This may be the reason that the lower educated patients are less likely to approach doctors frequently in getting information about their medications. [29]

The knowledge level of the public on ADR is influenced by certain demographic characteristics as well as previous experience of side effects. [30] The difference in the knowledge score between genders was not significantly different, in contrast to the results published by Cham et al (2002) in which women were reported to be more aware of the toxic effects of medication. [31] Furthermore, knowledge of patients on ADR is associated with gender and educational status. [5]

In this study, the majority of the respondents indicated that doctors and pharmacists should inform the patients about possible side effects of the medication. Overall, it is the accountability of the prescribers if there would be any occurring side-effects. Similar finding has been reported by Jose et al (2011). [30] A study done in Omani, reported that the study respondents believed that physician will only prescribe medicines which are completely safe, thus suggesting a high level of confidence in the medical therapy obtained. [27]

The majority of this study respondent has indicated that they would inform the doctor if consuming traditional medicine (70.8%) and using non-prescribed medicines bought at the pharmacy (78.3%) at the same time as western medicines prescribed. This finding is similar to Omani public that they are aware of the importance of informing doctors about their allergy status, medicine side effect history and concomitant use of traditional and/or OTC medicines. However, studies conducted in Taiwan and Saudi Arabia reported that majority of participants did not inform their doctors or pharmacist about their current medication. [32,27,33,34] This possesses as a serious concern because of the widespread and increasing use of alternative and OTC medicines among the public, as possible drug interactions and possibilities of the occurrence of ADRs are unknown. Thus, this calls for effective medication history taking [25,35] before the prescription of certain medication which would likely to contribute to ADRs.

The majority of respondents expects doctors to provide information on side effects and perceived that doctors are responsible for putting patients at risk. This may be due to the beliefs that the side effect occurred because of wrong prescribing, inadequate monitoring or inappropriate sharing of information by the health providers. This concurs with earlier studies in which patients reported they had been given insufficient information about their drugs and inadequate monitoring by the physicians thus contributing to ADRs. [4,36]

Participants revealed their willingness to learn and to improve their pharmacovigilance knowledge in order to improve ADR reporting. [37] Education is known to serve as the leading factor to empowerment. In Malaysia, a study conducted by Elkalmi et al (2011) had shown the positive impact of educational intervention in improving the pharmacists' perception on pharmacovigilance. [38] Thus, it was suggested that pharmacovigilance should be included into undergraduate curriculum and trainings [18,37,39] The educational intervention had been found to improve ADR reporting in Portugal and Rhode Island in USA. [40,41] Lack of knowledge on ADR causes failure in detection of ADR. [42]

Public education on drug use should focus on effective communications in disseminating appropriate and timely information on the prescribed and non-prescribed medications. In addition, during the event of an ADR, many of the respondents discontinued the medication and informed their doctor either immediately, at the next visit or consulted a

pharmacist. This suggests that the public is aware of the importance of seeking advice from healthcare professionals in the event of an ADR.

CONCLUSION

The survey has shown that there is a moderate level of public knowledge regarding safety of medications and from this study it is evident that the public underestimates the risk of the medications. It is of concern drug safety is being taken lightly. This has to be urgently addressed primarily by educational interventions. Thus, the present study would be useful in designing public educational interventions in improving drug safety, addressing the misconceptions and designing effective communication between healthcare professionals and the public so the appropriate sharing of information on side effects of prescribed alternative and OTC medications can be appropriately disseminated. In addition, healthcare professional's knowledge and attitude play a pivotal role in identifying the occurrence and incidence of ADRs.

Study Limitation

The results of this study were discussed with the acknowledgment of certain study limitations. One major study limitation would be the method of the sampling where convenience sampling method approach was adopted. In addition, this is a single site study. Therefore, the study might be performed in many other sites for better generalizability for the Malaysian population.

ACKNOWLEDGEMENT

The authors would like to thank the Director General of Health, Malaysia for the permission to publish this paper. Sincere thanks and appreciation to Dr Jimmy Jose from School of Pharmacy, University of Nizwa, Oman for providing the study validated questionnaire and the permission for use the questionnaire for this study.

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How to cite this article: Anantham SC, Seow YY, Zakaria MF et. al. Awareness implications on adverse drug reactions: findings from a cross-sectional study among outpatients attending a public hospital in Malaysia. Int J Health Sci Res. 2018; 8(8):141-150.

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