Original Article

Knowledge, Practices and Attitudes Towards Adverse Drug Reaction Reporting by Private Practitioners from Klang Valley in Malaysia

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Abstract

Objectives: **The study aimed to determine current status of Knowledge, practices and attitudes towards adverse drug reaction (ADR) reporting among private practitioners in Klang region of Malaysia.**

Methods: **A total of 238 private practitioners in Klang valley were distributed a questionnaire consisting of seven questions, two knowledge-related, two practice-related and three attitude-related. Each favourable and unfavourable response was given a score of 1 and 0 respectively. Total score of 70% or more for each domain was considered "satisfactory" whereas less than 70% as "unsatisfactory".**

Results: **One hundred forty-five participants completed questionnaire. Knowledge assessment showed 83.4% responses stating that ADR reporting helps to identify safe drugs and 91.7% responded that it measures ADR incidence. Regarding practices, 76.6% respondents were willing to report only if confident that reaction is an ADR. Regarding attitudes, 81.9%, 66.9% and 23.5% participants showed complacency, ignorance, and indifference respectively. Unsatisfactory knowledge, practices, and attitudes were observed in 57.2%, 56.6%, and 73.1% respondents respectively. Satisfactory knowledge was significantly higher in respondent with higher qualification with odds ratio of 2.96 with 95% confidence interval of 1.48–5.93.**

Conclusion: **The study showed unsatisfactory level of knowledge, practices and attitudes towards ADR reporting among high proportion of private practitioners in Klang valley, Malaysia.**

Keywords: *adverse drug reaction reporting systems, attitudes, knowledge, pharmacovigilance, practice*

Introduction

The field of drug safety has become a focus of serious attention especially over the past decade as indicated by frequent publication of post-marketing drug related events in several scientific journals. Systematic analysis of the post-marketing adverse drug reaction (ADR) reports in the past has raised serious concern among healthcare professionals and regulatory agencies, and has resulted in withdrawal of drugs like rofecoxib, rosiglitazone, and aprotinin. Since long, ADR related health problems are known to contribute significantly to morbidity and mortality among children, adults, and elderly (1–3). Moreover, ADRs impose considerable economic burden on society especially in developing countries with already overworked healthcare systems (4).

The international system of monitoring ADRs based on the information derived from member countries was initiated by World Health Organization (WHO) in 1971 and initially 10 countries contributed the information. Today, more than 100 countries are the member states of WHO drug monitoring center and Malaysia is one of them. The member countries are required to collect, collate, evaluate and report individual case safety reports (ICSRs) from healthcare providers and patients. The drug monitoring authorities in member countries have adapted different approaches to receive ICSRs.

Spontaneous, voluntary ADR reporting is one of the most commonly used method of collecting ICSRs in several WHO member countries including Malaysia. Therefore, this system forms the backbone of the national and international drug safety monitoring in post-marketing phase. Significant under-reporting by healthcare professionals is a serious drawback of voluntary reporting system. Since the under-reporting of ADRs is widely prevalent among various countries, several studies have been undertaken to identify the causes of under-reporting and accordingly corrective measures have been implemented. Similar initiatives, however, have not been taken so far in Malaysia.

According to Malaysian Adverse Drug Reaction Advisory Committee (MADRAC), there

were a total of 7079 ADR reports received in the year 2010. Of the 7079 ADR reports, only 15.6% (248) reports were from private practitioners (5). Although one study, which is also the only study from Malaysia listed in Pubmed, has shown that significantly high proportion of doctors in a University Hospital did not report ADRs, the extent of under-reporting of ADRs by private practitioners is even more alarming because a substantial number of Malaysian population (41%) is attended by private practitioners for their healthcare needs (6,7). Therefore, in order to undertake corrective measures for improvement in ADR reporting, it is of crucial importance to determine the possible causes of under-reporting by private practitioners in Malaysia. The aim of the current study was to determine the current status of knowledge, practices and attitudes towards ADR reporting among private practitioners from Klang Valley in Malaysia.

Materials and methods

The ethical issues were considered by the Research Committee, Faculty of Medicine, Universiti Teknologi MARA and the study was approved. This was a questionnaire-based survey that included private practitioners from various fields of practice working at their private clinic, or private hospitals in Kuala Lumpur and adjacent areas in Klang Valley. According to Malaysian private health care facilities and services act 1998 (amendment 2006) a "private hospital" means any premises, other than a government hospital or institution, used or intended to be used for the reception, lodging, treatment and care of persons who require medical treatment. A "private medical clinic" means any premises, other than a Government healthcare facility, used or intended to be used for the practice of medicine on an outpatient basis. A "clinician" means any person who is registered under the Medical Act 1971 [Act 50] and who holds a valid practicing certificate.

We adopted a simple random sampling method. Using Statistical Package for Social Sciences (SPSS) program version 19. A sampling frame of 60 clinics and hospitals was obtained from the list of 78 private clinics and hospitals in Klang Valley registered with Ministry of Health, Malaysia. A maximum of 4 private practitioners were selected randomly at each clinic/hospital and a total of 238 private practitioners were distributed the questionnaire. A validated structured questionnaire used in this study was based on previously done study (8). The internal consistency was assessed by Cronbach's alpha from data of 30 subjects as pre-testing technique. The questionnaire consisted of two parts. Part 1 collected the demographic data and part 2 consisted of two questions with 11 sub-items to assess knowledge, two questions with seven sub-items to assess practices and three questions with 22 sub-items to assess attitudes towards ADR reporting. The questions in knowledge domain referred to the type of ADRs to be reported and the purpose of ADR reporting. In practice domain participants were asked whether they have ever reported an ADR and when they are likely to report ADRs. To assess attitudes towards ADR reporting questions referred to the availability of blue card, issues related to filling it and sending to responsible authorities, and practitioner's concerns related to confidentiality and legal responsibilities. They were also asked about their interest in publications rather than reporting and concerns related to causal relationship of the event, with drug administration and possibly risk to their career. A total of 238 participants including 140 males and 98 females were contacted personally. Questionnaire was self-administered following a face-to-face briefing with regards to the purpose of study. Second visit was made one week later to collect the completed questionnaire. A third and final visit was made one week after the second visit to collect questionnaire from participants with delayed response.

Categorical variables were described by frequency and percentage and numerical variable with mean ± SD. Score of the three domains, knowledge, practice and attitudes, was computed by summing all favourable answers which were given a score of 1. To further categorize each domain score, we used a cut off value of 70% and above. Accordingly, scores above 70% of the total domain score were considered satisfactory, and below 70% were considered unsatisfactory (9). Backward multiple logistic regression was performed to control for confounding effect and results were presented as odds ratio (OR) and its 95% confidence interval (CI).

Results

The characteristics of the study sample are presented in table 1. A total of 145 private practitioners; 90 males and 55 females, completed the questionnaire with a response rate of about 61%. The mean age of the participants was 43.96 years (SD 11.52). Participating practitioners had mean 17.32 years (SD 9.84) of experience in their field of practice. Among all, 64.8% (94) were from

medical specialty while remaining were from surgical and other specialties. For about three fourth (76.6%) of the participants, the workplace was clinic and the remaining were from hospital set up. Not more than four participants were from the same hospital or clinic. The internal consistency analysis of questionnaire showed Cronbach's alpha amounting to 0.686, 0.857 and 0.701 for knowledge, practice and attitude domains respectively.

Knowledge

The type of ADR to be reported

Nearly half (46.2%) of the participants responded that only proven reactions need to be reported and only 58.6% correctly responded that all suspected reactions to established drugs in new combination or for new indication should be reported. Regarding the new products, 45.5% were of the opinion that only serious reactions need to be reported and 89.7% responded that all serious reactions to new and old products should be reported (Table 2).

The purpose of ADR reporting

Majority (83.4%) of respondents were of the opinion that ADR reporting helps to identify safe drugs and up to 91.7% were in agreement that ADR reporting helps in measuring the ADR incidence. However, participants also correctly responded that ADR reporting helps in identification of previously unrecognized ADR (75.2%), identification of predisposing factors (63.4%) and characterization of ADR (83.4%). Among all 91.7% responded that ADR reporting helps in comparing drugs of similar therapeutic classes (Table 2).

Practices

Among all, 49.7% responded that they will report ADR only if they have observed similar reaction to other drugs of the same class, and up to 76.6% said that they will report only if they are confident that the reaction is an ADR. More than half of the participants said that they will report an ADR only if it is serious (63.4%), unusual (66.9%), and to a new product (59.3%). Although, 76 participants had encountered an ADR, only four have ever reported. Therefore, this translates into a reporting rate of 5.26% (4 out of 76) (Table 3).

Attitudes

Familiarity with the methods of ADR reporting

More than half of the practitioners were not sure of the whereabouts of the agency to which report must be sent (57%) and how the report should be sent (55.6%). Up to 66.7% of the participants said that they did not have the relevant phone numbers.

More than half (69%) of the participants said that the card is not available and they do not know from where they can get the ADR reporting card. Although, 60.9% of the participants disagreed that the card is difficult to fill up, 47.8% responded that the space provided is inadequate (Table 4).

Table 1: Characteristics of the study participants

Variable		Frequency	Percent (%)
Sex	Male	90	62.1
	Female	55	37.9
Area of specialization	Medical	94	64.8
	Surgical	12	8.3
	Others	39	26.9
Number of patient seen per day	< 10	10	6.9
	10–20	28	19.3
	> 20	107	73.8
Workplace	Hospital	34	23.4
	Clinic	111	76.6
Qualifications	Basic medical degree	89	61.4
	Higher	56	38.6

Practitioner's concerns about ADR reporting

Majority (81.9%) of the participants were of the opinion that really serious ADRs are documented before the drug is marketed. Up to three-fourth (74.5%) of the respondents disagreed that one case an individual physician sees cannot contribute to medical knowledge. Among the respondents, there was concern about revealing

Table 2: Responses to questions regarding knowledge about the type of ADR to be reported and purpose of ADR reporting

	Frequency (%)	
	Yes	No
Regarding type of ADR to be reported		
1. All suspected reactions to established drugs in new combination or for new indication should be reported	85 (58.6)	60 (41.4)
2. All suspected reactions to new products should be reported	106 (73.1)	39 (26.9)
3. Only serious reactions to new products should be reported	66 (45.5)	79 (54.5)
4. All serious reactions to old & new products should be reported	130 (89.7)	15 (10.3)
5. Only proven reactions should be reported	67 (46.2)	78 (53.8)
Following is/are the purpose(s) of the national ADR reporting scheme in Malaysia		
1. For identification of previously unrecognized ADRs	109 (75.2)	36 (24.8)
2. To recognize factors predisposing to ADRs	92 (63.4)	53 (36.6)
3. To characterize ADRs	121 (83.4)	24 (16.6)
4. To enable toxicity of drugs in similar therapeutic classes to be compared	133 (91.7)	12 (8.3)
5. To identify safe drugs	121 (83.4)	24 (16.6)
6. To measure the incidence of ADRs	133 (91.7)	12 (8.3)

Table 3: Responses to questions regarding practices among private practitioners with regards to ADR reporting

	Frequency (%)	
	Yes	No
Have you ever		
1. sent an adverse drug reaction report to your national reporting agency or a pharmaceutical company	4 (2.8)	141 (97.2)
2. suspected an ADR	76 (52.4)	69 (47.6)
I will report an ADR, only if		
1. The reaction is serious	92 (63.4)	53 (36.6)
2. The reaction is unusual	97 (66.9)	48 (33.1)
3. I have observed similar reactions to the drug class before	72 (49.7)	73 (50.3)
4. The reaction is to a new product	86 (59.3)	59 (40.7)
5. I am confident that the reaction is an adverse reaction to the drug	111 (76.6)	34 (23.4)

their own identity and that of the patient's identity. More than half (63%) of the practitioners were not sure whether the patient's confidentiality will be maintained and one-fourth of them strongly agreed about the concern. More than one third (38.5%) of the participants were worried that providing information will hold them responsible for causing harm to the

Table 4: Responses to questions regarding attitudes of private practitioners towards ADR reporting

		Frequency (%)	
		Strongly agree-Agree	Disagree - Strongly disagree
1.	The blue card is not available and I do not know from where I can get the card	100 (68.9)	45 (31.1)
2.	The card is too difficult to fill up.	45 (39.1)	70 (60.9)
3.	The space provided in the card to describe the ADR is too little – or inadequate/insufficient	55 (47.8)	60 (52.1)
4.	It requires stating my identity, which I do not wish to provide	42 (36.6)	73 (63.5)
5.	It requires stating patient's identity, which I do not wish to provide	54 (46.9)	61 (53.1)
6.	Filling this card will hold me responsible for ADR related harm to the patient	45 (38.5)	72 (61.5)
7.	I do not know the relevant phone numbers	96 (66.7)	48 (33.3)
8.	I do not know the address of the agency to which I should report	82 (56.9)	62 (43.1)
9.	I am not sure about how to report	79 (55.6)	63 (44.4)
10.	I am not sure whether the patient's confidentiality will be maintained	90 (62.9)	53 (37.1)
11.	I feel I will appear foolish	11 (7.8)	131 (92.2)
12.	I am worried about legal liabilities	54 (37.5)	90 (62.5)
13.	I am too busy to report	58 (40.6)	85 (59.4)
14.	I wish to publish a personal series of cases rather than reporting ADRs	15 (10.6)	126 (89.4)
15.	Really serious ADRs are well documented by the time a drug is marketed	120 (81.9)	26 (18.1)
16.	It is nearly impossible to determine if a drug is responsible for a particular adverse event	74 (52.1)	68 (47.9)
17.	The one case an individual physician might see cannot contribute to medical knowledge	34 (23.5)	108 (74.5)
18.	I should be financially reimbursed for providing the reports of ADRs	29 (20.6)	112 (79.4)
19.	I have a professional obligation to report ADRs	116 (80.6)	28 (19.4)
20.	Reporting ADRs puts my career at risk	29 (20.4)	113 (79.6)
21.	It takes too much time to report ADRs	65 (47.4)	72 (52.6)
22.	I will be asked to provide more information which I don't want to do because I am busy, it will take too much time (or other reasons)	77 (54.6)	64 (45.4)

patient, however, 79.6% of them disagreed that ADR reporting can put their career at risk. Moreover, 37.5% of the participants were worried about possible legal liabilities due to ADR reporting against 62.5% who did not agree with such concerns. Majority of participants (89.4%) did not agree that they will not report ADRs because they would prefer to publish a case series.

Among all respondent, 80.6% acknowledged that they have professional obligation to report ADRs, but 47.4% of the practitioners responded that it takes too much time to report ADR and 40.6% said that they are too busy to report. In addition, 54.6% were concerned that they will be asked for more information and this will take more of their time. Only 20.5% of respondents expected financial reimbursement for ADR reporting (Table 4).

Frequency of responses as "satisfactory" or "unsatisfactory"

The knowledge and practices were of unsatisfactory level among more than half of the respondents (57.2%, 56.6% respectively), and even more alarming was the observation that about three-fourth (73.1%) of the respondents had unsatisfactory attitudes towards ADR reporting.

Factors associated with satisfactory knowledge practice and attitude

Backward Multivariable logistic regression showed that only qualification associated with satisfactory knowledge among private practitioners. Those with higher degree were 2.96 (95% CI: 1.48, 5.93) times more likely to have satisfactory knowledge compared to those with basic medical degree. None of the other personal or professional characteristics were found to be associated with knowledge, practices, and attitudes of practitioners regarding ADR reporting (Table 5).

Discussion

According to Malaysian guidelines for ADR reporting and monitoring, the purpose of ADR monitoring is to allow detection of ADRs as early as possible especially the serious, rare, and unknown reactions. ADR monitoring helps in characterizing the ADRs and identifying the associated risk factors besides establishing the

Table 5: Factors associated with satisfactory knowledge practice and attitude

		Knowledge		Practice		Attitude	
		OR (95%CI)	*P*	OR (95%CI)	*P*	OR (95%CI)	*P*
Sex	Male	1		1		1	
	Female	0.593 (0.28–1.256)	0.172	0.969 (0.480–1.955)	0.930	1.159 (0.525–2.558)	0.714
Qualifications	MBBS	1		1		1	
	Postgraduate	2.667 (1.275–5.578)	0.009	0.811 (0.396–1.660)	0.566	0.841 (0.372–1.901)	0.678
Specialization	Medical	1		1		1	
	Surgical	0.681 (0.155–3.004)	0.612	2.230 (0.547–9.091)	0.263	0.243 (0.025–2.325)	0.220
	Others	1.285 (0.564–2.927)	0.550	1.337 (0.603–2.965)	0.475	2.042 (0.863–4.828)	0.104
Number of patients seen per day	< 10	1		1		1	
	10–20	2.484 (0.487–12.674)	0.274	0.950 (0.199–4.528)	0.948	1.317 (0.196–8.846)	0.777
	> 20	1.556 (0.324–7.478)	0.581	1.085 (0.240–4.896)	0.916	1.091 (0.175–6.793)	0.926
Workplace	Hospital	1		1		1	
	Clinic	0.511 (0.210–1.245)	0.139	0.971 (0.409–2.304)	0.947	0.590 (0.224–1.554)	0.286

Results are of univariable simple logistic regression.

frequency of new and established ADRs. ADR reporting helps in comparing drugs in the same therapeutic class but the purpose is not to identify the safe drugs. All suspected reactions to new drugs must be reported. All suspected reactions to established drugs in new combination or for new indication should be reported and all serious and unusual reactions to old and new products must be reported. Agreement to statements such as "only serious reactions to new products should be reported" or "only proven reactions should be reported" is unfavourable. Accordingly, the practice of reporting ADRs by practitioners only when they have observed similar reactions to the drug class before or only if they are confident that the reaction is an adverse reaction to the drug are unfavourable.

In several countries, spontaneous and voluntary reporting of suspected drug-related events to a central agency is the mainstay of National Pharmacovigilance Programme (10–12). The strengths and weaknesses of spontaneous and voluntary reporting system have been debated extensively (13–15), and according to general agreement the system has been favoured and implemented in various WHO member countries including Malaysia.

Several studies done previously in Asia, Europe, America, and Africa have shown lack of sufficient knowledge among healthcare professionals about ADR reporting (16–26). According to the previously done studies in Malaysia, 40% of doctors (6) and majority of community pharmacists (26) were found to be unaware of the existence of the national reporting system in Malaysia. It was also shown that 'ADR considered to be too trivial or too well known to report' as the strongest predictor of not reporting (6). Other studies have also revealed that ADR under-reporting by health professionals is commonly attributed to reasons such as ADR is not serious, ADR is well known, uncertainty about causal relationship and lack of time (28,29). In agreement with these studies, our study also demonstrated lack of sufficient knowledge among the private practitioners with regards to the type of ADRs to be reported and the purpose of ADR reporting system in Malaysia. The extent of insufficient knowledge appears to be rather high in Malaysia as compared to doctors contributing to ADR reporting in other countries. In one of the studies in Canada only 19.6% of participants said that a well known ADR need not be reported, in Netherlands only 18% were not aware of the need for ADR reporting and in United Kingdom most of the doctors know the type of the ADR to be reported (23,30,31).

Current study also revealed prevalence of unsatisfactory practices for ADR reporting among private practitioners as only four doctors reported ADRs out of 76 who encountered the ADRs giving a reporting rate of 5.26%. Similar results have been reported by a previously done study at a University Hospital in Malaysia, which showed that 81.4% doctors suspected an ADR but did not report (6). More than three-fourth of the participants in our study responded that they will report only when they are confident that the reaction is an adverse effect of a drug. Moreover, a higher proportion of practitioners are likely to report only when the ADR is serious, unusual, and to a new product. Similar observations have been made by other investigators (29,30).

Besides knowledge and practices, strong correlation has also been observed between the attitude of healthcare professionals and ADR reporting (31). The current study also evaluated the attitudes of Malaysian private practitioners towards ADR reporting. We analyzed the attitudinal causes of ADR under-reporting according to Inman's criteria of seven deadly sins (32). According to Inman, the causes of under-reporting can broadly be classified in two categories: i) failure to recognize an ADR ii) failure to report a recognized ADR. Inman's proposal made in 1976 was amended in 1986 and was re-amended in 1996 (33,34). Accordingly, the list of seven attitudinal characteristics that lead to under-reporting and described as "seven deadly sins" includes the following.

1. *Complacency*: The belief that really serious ADRs are well documented and only safe drugs are allowed on to the market. An overwhelming 81.9% of the participants in our study showed complacency.
2. *Fear and guilt*: The belief that reporting may cause their involvement in further investigation and litigation by health departments. In our study, up to 54.6% respondents had fear of getting involved in further investigations and 37.5% had fear of legal liabilities. The guilt of harming the patient by administering treatment was shown by 38.5% of the participants.
3. *Diffidence*: Due to possibility of appearing foolish by reporting ADR merely based on suspicion. In our study majority of participants did not show diffidence.

4. *Indifference*: As to the individual's role in contributing essential knowledge. In our study nearly one-fourth of the participants showed indifference.
5. *Lethargy*: As shown by lack of effort to find the relevant card, phone numbers, addresses and time. Significant proportion of participants in our study showed lethargy by agreeing that they do not know from where to get the card, they do not know the relevant phone numbers and addresses and are too busy to report.
6. *Ignorance*: Due to belief that only serious (63.4%) and unusual (66.9%) ADRs must be reported was shown by a significant proportion of respondents.
7. *The belief that they should be financially reimbursed* was shown by only 20.5% of the study participants.

In addition to the factors described by Inman, our study also showed insecurity among participants as exhibited by agreement with statement such as "It is nearly impossible to determine if a drug is responsible for a particular adverse event" and by exhibiting concerns regarding the confidentiality of patient's and their own identity. A previous study involving community pharmacists in Malaysia showed that although, majority of participants considered reporting ADRs as an integral part of their professional responsibilities and acknowledged the importance of ADR reporting, there was lack of knowledge with regards to the whereabouts of the card and concerns regarding the possible legal action (26).

Practitioners possessing postgraduate degree showed higher knowledge as compared to those with only basic medical degree. Unsatisfactory knowledge among those with basic medical degree in our study is probably an outcome of the absence of the details of pharmacovigilance programme in the undergraduate curriculum in Malaysia. More clinical experience of postgraduates seems to enhance their knowledge with regards to ADR reporting. However, despite better knowledge among postgraduate practitioners, no differences were observed in practices and attitudes towards ADR reporting among these private practitioners and this has possibly resulted in an extremely poor reporting rate of 5.26%.

Importantly, our study demonstrates that firstly, among the practitioners there is uncertainty about the type of ADR to be reported. Secondly, up to three-fourth of the participants are willing to report only if they are confident that it is an ADR. Thirdly, a significant number agrees that it is nearly impossible to determine if it is an ADR. In addition to this, inadequate knowledge about the purpose of ADR reporting and other unsatisfactory practices, and attitudinal characteristics seem to contribute to significant underreporting of ADRs by private practitioners in Klang valley, Malaysia.

Conclusion

To summarize, our study showed general lack of knowledge among private practitioners from Klang valley in Malaysia, which seems to contribute to failure of recognition of the type of ADRs to be reported. Secondly, the study showed prevalence of unsatisfactory practices and attitudes among these private practitioners contributing to failure to report even if the ADR was identified.

We propose that educational intervention strategies either by introducing details of pharmacovigilance in undergraduate curriculum at medical schools or organized by National Drug Control Authority and MADRAC will help in improving ADR reporting. As this study has for the first time evaluated the causes of ADR underreporting among private practitioners in Malaysia, the findings will be of value in determining the objectives of the educational strategies.

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Conflict of interest

The authors declare that they have no competing interests.

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Authors' Contributions

Conception and design, provision of study materials or patient and administrative, technical or logistic support: RA, NMI
Analysis and interpretation of the data and collection and assembly of data: RA, AMD
Critical revision of the article for the important intellectual content and final approval of the article: RA, AMD, NMI
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