

*Full length research paper*

## Pakistani physicians' knowledge and attitude towards reporting adverse drug reactions

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Received 21 October, 2013; Accepted 7 April, 2014

The present study was designed to investigate the knowledge and attitude of Pakistani physicians towards adverse drug reaction (ADR) reporting. In this study, five hundred and fifty survey forms were distributed among the physicians belonging to different private and public sector clinics and hospitals of Karachi through email or direct correspondence. Two hundred and twenty five physicians provided consent to show their responses for research purposes. Hence, the response rate for filling the questionnaire was 40.9%. Most of the doctors that participated in the study were consultants. The previously validated questionnaire was adopted that sought the demographics of the physicians, their knowledge and attitudes towards ADR reporting. Descriptive statistics were employed to report the response of respondents to questionnaire items. The association of the position and organization on the responses of participants towards ADR reporting was determined by using a chi-square. Majority of the participants (88%) were aware about the ADRs; 31.5% were aware of pharmacovigilance; 7.5% had an access to ADR reporting system; and only 9.7% were informed about the availability of ADR reporting system. Physicians (64%) were considered to be the most qualified health professionals to report ADRs. The knowledge of ADRs among physicians working in different hospitals of Karachi was quite sufficient, but their attitude toward ADR reporting was lacking. Physicians strongly suggested the need of training through frequent continuous medical education sessions to improve reporting.

**Key words:** ADR reporting, knowledge, attitude, physicians.

### INTRODUCTION

Adverse drug reaction (ADR) can be 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" (Edwards and Aronson, 2000). Trend concerning ADR as an area of major health concern was developed after

thalidomide disaster in 1960s (D'arcy and Griffin, 1994). ADRs are the major health tribulations considered globally since every drug provides evidence to have adverse effects, even if utilized appropriately. Drug related morbidity and mortality are the major causes of patient hospitalization affecting the status of public health (Lazarou et al., 1998). It also imposes a considerable fiscal burden on the health care systems of society

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(Ayani et al., 1999; Wu and Pantaleo, 2003) Healthcare professionals can play a vital role in detecting and reporting of ADR if they are encouraged to execute it appropriately (DACA, 2008). It is anticipated that the ratio of ADRs that are reported is only 6 to 10% (Smith et al., 1996; Edwards and Aronson, 2000). Different factors including medical professionals' knowledge and attitudes to reporting are associated with ADRs under-reporting which consequently impart negative impact on the public health (Lopez-Gonzalez et al., 2009). Initially, the 20th world's assembly adopted a resolution to begin a project on the feasibility of global system of monitoring adverse reaction of drugs. For the first time, an international data base was established at WHO head quarter in Geneva in 1971 which later shifted to Uppsala, Sweden in 1978 (WHO, 2000, 2001). Since then, Uppsala Monitoring Centre (UMC) located in Sweden is carrying out this imperative job for managing of the WHO-PIDM which is a collaborating centre for maintaining international ADR database, Vigibase. The major focus of UMCs is to support high-quality decision-making concerning the benefits and risks associated with medicines. WHO Programme has 105 countries as an official member and 35 countries as associate member. Pakistan was also one of an associate member of WHO program (Waller, 2006; WHO, 2001, 2000; Wiffen, 2002). Numerous countries of the world have well-developed drug safety surveillance program owing to the recognition of the importance of this program (Yadav, 2008). ADR reporting system focuses on the ways to decrease ADR risks associated with FDA approved medications (Wiffen, 2002). Spontaneous and voluntary reporting is the most effective methods of acquiring ADR information (Waller, 2006). The medical professionals can play a very significant role in reporting suspected ADRs that they encountered in their clinical practice. But still, there is substantial divergence in the patterns of ADR reporting phenomena in some countries (Kharkar and Bowalekar, 2012).

It is realized that creating awareness on the relevance and importance of ADR monitoring is an assurance for establishing and sustaining sound ADRs reporting program (Ernst and Grizzle, 2001). Physicians are the key components of healthcare system encountering ADRs in their daily practice. Several studies have been conducted with an aim of recognizing physician's attitude and perception about ADR reporting worldwide (Gupta and Udupa, 2011; Okezio, 2008; Aziz et al., 2007). ADR reporting system has yet not received the deserving importance in Pakistan owing to the lack of its basic knowledge among the health professionals. Ghulam et al. (2013) conducted a study in Lahore, Pakistan to investigate the factors contributing to ADR under reporting among different healthcare professionals (Ghulam et al., 2013). Therefore, the present study was designed to explore their knowledge and attitudes towards ADR reporting in different hospitals of Karachi, the largest city of Pakistan and also to find out the ways of improving

spontaneous reporting.

## MATERIALS AND METHODS

### Study design and study period

The present study was cross-sectional study and was conducted from September, 2012 till February, 2013.

### Study population

The study population comprised of physicians working in different public and private sector hospitals and clinics of Karachi selected by non probability convenience sampling technique. Physicians were surveyed with a 31 items questionnaire to assess attitudes and perception of medical practitioners towards ADR reporting.

### Study tool

A prevalidated questionnaire was adapted from previous studies to assess attitudes of medical practitioners to ADR reporting (Bateman et al., 1992; Belton, 1997). In addition to the demographic information of the physicians, the questionnaire consisted of two parts. The first part consisted of thirteen questions that explored the perception of physicians towards ADR, the most qualified healthcare professional to whom ADR should be reported, the frequency of ADR encountered in daily practice and the purpose of reporting ADR from physicians point of view. Part two comprises eighteen questions; exploring the attitude and the factors that hinder physicians to report ADR, the most appropriate method of improving ADR reporting, training on ADR reporting and the most reliable source of information about ADRs.

### Ethical approval

Prior permission was taken from the various heads of departments in the hospitals and clinics before initiating the study. The questionnaires were distributed to the physicians after explaining them the purpose of the study. Their verbal consent was taken and the questionnaires were left with them for a period of 1 week. After the given time period the filled questionnaires were collected back.

### Data analysis

The retrieved questionnaires were entered into Statistical Package for Social Sciences (SPSS 20.0, Chicago, IL) for analysis. The demographic data of the participants was estimated in frequencies and percentages. Descriptive statistics were employed to report the response of respondents to questionnaire items. The association of the position and organization with the responses of participants towards ADR reporting was determined using a chi-square at 0.05 significant level.

## RESULTS

In the present study, five hundred and fifty survey forms were distributed among the physicians belonging to different private and public sector clinics and hospitals of Karachi through email or direct correspondence. Two hundred and twenty five physicians provided consent to

**Table 1.** Characteristics of the physicians participated in the study.

Characteristic	Number (%)
<b>Gender</b>	
Male	86 (38.2)
Female	139 (61.7)
<b>Age (Years)</b>	
25-30	81 (36)
31-35	51 (22.6)
36-40	27 (12)
41-50	33 (14.6)
51 and above	33 (14.6)
<b>Organization</b>	
Private	150 (66.6)
Public sector	75 (33.3)
<b>Position</b>	
Consultant	116 (51.5)
Chief medical officer	18 (8)
Medical officer	29 (12.8)
Resident medical officer	38 (16.8)
Head of department	24 (10.6)

show their responses for research purposes. Hence, the response rate for filling the questionnaire was 40.9%. Majority of the respondents were female 61.7%, while 38.2% were male. Most of the respondents (66.6%) who participated were rendering their services privately and 33.3% were employed in public sector hospitals. Most of the doctors (51.5%) who participated in the study were consultants (Table 1).

Perception of physicians regarding ADRs is recorded in Table 2. Majority of the participants (88%) were aware about the ADRs. Almost all physicians (90.6%) considered that reporting ADRs to ministry of health is necessary. Physicians (85.7%) also agreed that all ADRs should be reported for newly marketed as well as for established drugs. In view of respondents (74.6%), ADR reporting system should be improved in Pakistan. On the other hand, only 31.5% of the participants were aware of the term pharmacovigilance and 9.7% were informed about the availability of ADR reporting system. 29.6% of the participants encounter 0 to 5 ADRs/week, while 65.6% did not encounter a single ADR in their daily practice.

Most of the participants (83.5%) considered that they should report a recognized ADR. About 80% agreed that ADR reporting is a professional obligation; 70.4% opined that managing patient is more important than reporting

ADR. 70.6% agreed that they can confidently discuss an ADR with other colleagues. Only 15.5 and 16% knew where to report and how to report, respectively. Only 7.5% have an access to ADR reporting system; 48% thought that ADR reporting generates an extra work. About 20% of the respondents considered that reporting of a single ADR makes no significant contribution to the ADR reporting system. A small number of participants (7.5%) had ever been trained on how to report an ADR (Table 3).

The prime purpose of ADR reporting from physicians' point of view is to improve patient safety (69.6%), and to identify safe drugs (20%) (Figure 1). Respondents (68.8%) agreed that they will be encouraged to report ADR if the reaction is serious. Mostly physicians (80%) considered that ADR reporting should be compulsory. Continuous Medical Education (CME) was considered as the most appropriate method for the improvement of ADR reporting by physicians (52%), while increased collaboration with other health care professionals (11.2%) and having an ADR specialist in every department (10.4%) were considered next to CME (Figure 2). The reliable sources of information about ADR reporting as considered by physicians included seminars (33.6%), internet (24%), journals (18.4%) and drug advertisement (10.4%).

The influence of position and organization on physicians' response was analyzed statistically by Chi square. Results showed that the position of participant had a significant impact on their responses, that is, it was difficult for them to decide whether an ADR has occurred or not ( $\chi^2 = 11.075$ ,  $p = 0.004$ ); reporting of a single ADR makes no significant contribution to the ADR reporting system ( $\chi^2 = 12.174$ ,  $p = 0.002$ ) and ADR reporting system should improve in Pakistan ( $\chi^2 = 14.291$ ,  $p = 0.001$ ).

The influence of participants' organization also had a significant impact on their responses. Knowledge about Drug Regulatory Authority of Pakistan (DRAP) form of ADR reporting ( $\chi^2 = 20.594$ ,  $p < 0.0001$ ) their perception that ADR reporting generates an extra work ( $\chi^2 = 17.905$ ,  $p < 0.0001$ ) and time to actively look for ADR at work ( $\chi^2 = 21.765$ ,  $p < 0.0001$ ) were the most significant reasons of ADR under reporting.

## DISCUSSION

Adverse reactions are predictable risk of drug remedy. Some ADRs are negligible which may be resolved without any significant sequel, while some ADRs can be fatal or may be the cause of enduring disability. Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. It encompasses recognizing, reporting, and responding to risk-benefit issues associated with marketed drugs (WHO, 2002). The information generated in this post-marketing

**Table 2.** Physicians' perception about ADRs.

Statement	Yes	No	Don't know
Awareness about ADRs	198 (88)	18 (8)	9 (4)
Knowledge about pharmacovigilance	71 (31.5)	92 (40.8)	62 (27.5)
Knowledge about any drug that has been banned due to ADR	115 (51.1)	72 (32)	38 (16.8)
All ADRs should be reported	193 (85.7)	6 (2.6)	26 (11.5)
Serious ADRs should be reported	193 (85.7)	11 (4.8)	21 (9.3)
Availability of ADR reporting system	22 (9.7)	67 (29.7)	136 (60.4)
Reporting ADRs to ministry of health is necessary	204 (90.6)	2 (0.8)	19 (8.4)
Knowledge about DRAP form of ADR reporting	63 (28)	74 (32.8)	88 (39.1)
Should ADR reporting system improve in Pakistan	168 (74.6)	17 (7.5)	40 (17.7)

**Table 3.** Physicians' attitude towards reporting ADRs.

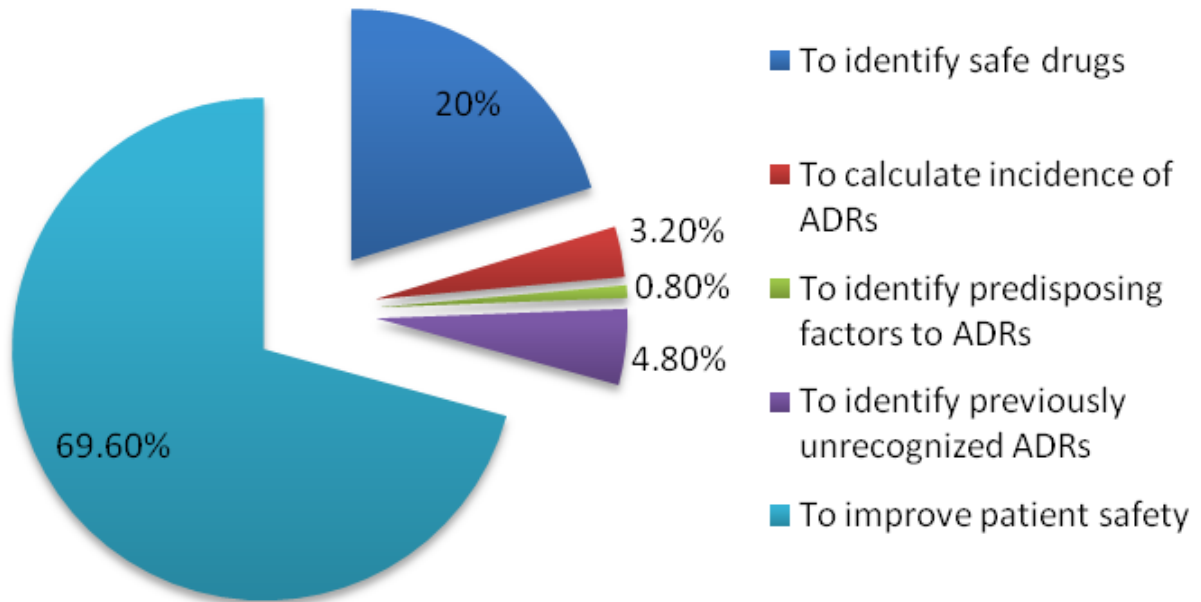
Statement	Yes	No	Don't know
Know where to report ADR	35 (15.5)	108 (48)	82 (36.4)
Know how to report ADR	36 (16)	108 (48)	81 (36)
Have an access to ADR reporting system	17 (7.5)	170 (75.5)	38 (16.8)
Have time to fill ADR form	101 (44.8)	105 (46.6)	19 (8.4)
Managing patient is more important than reporting ADR	159 (70.6)	40 (17.7)	27 (12)
ADR reporting generates an extra work	108 (48)	89 (39.5)	28 (12.4)
Have time to actively look for ADR at work	76 (33.7)	125 (55.5)	24 (10.6)
Is it difficult to decide whether an ADR has occurred or not	90 (40)	92 (40.8)	43 (19.1)
Can confidently discuss an ADR with other colleagues	159 (70.6)	56 (24.8)	10 (4.4)
Should report a recognized ADR	188 (83.5)	11 (4.8)	26 (11.5)
ADR reporting may have negative impact on the company that marketed drug	24 (10.6)	162 (72)	39 (17.3)
ADR reporting is professional obligation	180 (80)	18 (8)	27 (12)
Reporting of a single ADR makes no significant contribution to the ADR reporting system	45 (20)	146 (64.8)	34 (15.1)
Have ever been trained on how to report an ADR	17 (7.5)	162 (72)	46 (20.4)

surveillance can be used to revise products' labels and to reconsider the approval decision of such drug. Even the information provided can be the indication of probable harms related with the utilization of certain drugs. Therefore, the transmission of this information is also a critical aspect of pharmacovigilance, needed for safe prescribing of drugs (Brewer and Colditz, 1999). Every healthcare professional can play his/her role in upgrading patients' safety particularly medical practitioners, who are the primary component of ADR reporting system depending on their knowledge, attitudes and perceptions about ADR (Vallano et al., 2005; Vessal et al., 2009; Rawlins, 1994). Several studies have been conducted regarding the knowledge and attitude of physicians in different countries of the world which showed the inadequate knowledge of physicians about ADR reporting (Bateman et al., 1992; Belton, 1997; Enwere and Fawole, 2008; Milstein, 1986; Rogers, 1998). Therefore, the present study was conducted with the objective of investigating the knowledge and attitudes of physicians to ADR reporting in different hospitals of Karachi. It was observed in our

study that only some participants were aware of ADR reporting and its availability in Pakistan.

Response rate was very low in the present study. This outcome could be a reflection of the importance attached to the problem of ADRs by this category of medical personnel and this is not very encouraging. Similar behavior of physician was also observed in other studies (Fadare et al., 2011). The considerable numbers of physicians in the present study never reported an ADR; majority of the participants did not encounter a single ADR in their daily practice, that is comparable with other studies (Cosentino et al., 1997; Figueiras et al., 1999; Vallano et al., 2005). A study performed in Barcelona/Spain showed that lack of time to report an ADR, unavailability of ADR reporting system in hospitals and lack of information about the spontaneous reporting system were the main reasons of under reporting ADRs (Evans et al., 2006). Similar trends were also observed in our studies which were the prime reasons of under reporting of ADRs in the view point of the physicians.

Our study revealed that only 15.5 and 16% knew where



**Figure 1.** Purpose of reporting ADR in physicians' point of view.

to report and how to report, respectively. Merely 7.5% have an access to ADR reporting system; 48% thought that ADR reporting generates an extra work. A small number of participants 7.5% had ever been trained on how to report an ADR. Previous studies reveals that under-reporting of ADRs is a worldwide phenomenon (Williams and Feely, 1999; Hazell and Shakir, 2006; Lopez-Gonzalez et al., 2009; Nichols et al., 2009). The major factors contributing to under-reporting ADR includes lack of knowledge of the forms for reporting, ignorance of the rules and procedure for reporting, and not being sure of the type of reactions to be reported. The results are similar to the studies carried out in China, Nigeria, and Malaysia (Li et al., 2004; Aziz et al., 2007; Okezie, 2008).

A study conducted in Lagos, Nigeria on physicians' perceptions to ADR reporting documented that 89.9% of them considered physicians as the most qualified health professionals to report ADR (Oshikoya and Awobusuyi, 2009). Analogous trend was observed in our study that 64% of participants considered physicians to be the most appropriate person to report an ADR, while 31.2% considered pharmacist as more suitable person to report an ADR. Physicians' attitude showed that 83.5% considered that they should report a recognized ADR. This study showed an overwhelming result that 80% agreed that ADR reporting is a professional obligation; these results are nearly similar to study conducted in India (Gupta and Udupa, 2011).

Different educational platforms like pharmacovigilance training and workshops conducted for healthcare professionals are essential for improving physicians' knowledge, attitudes and perceptions about ADRs

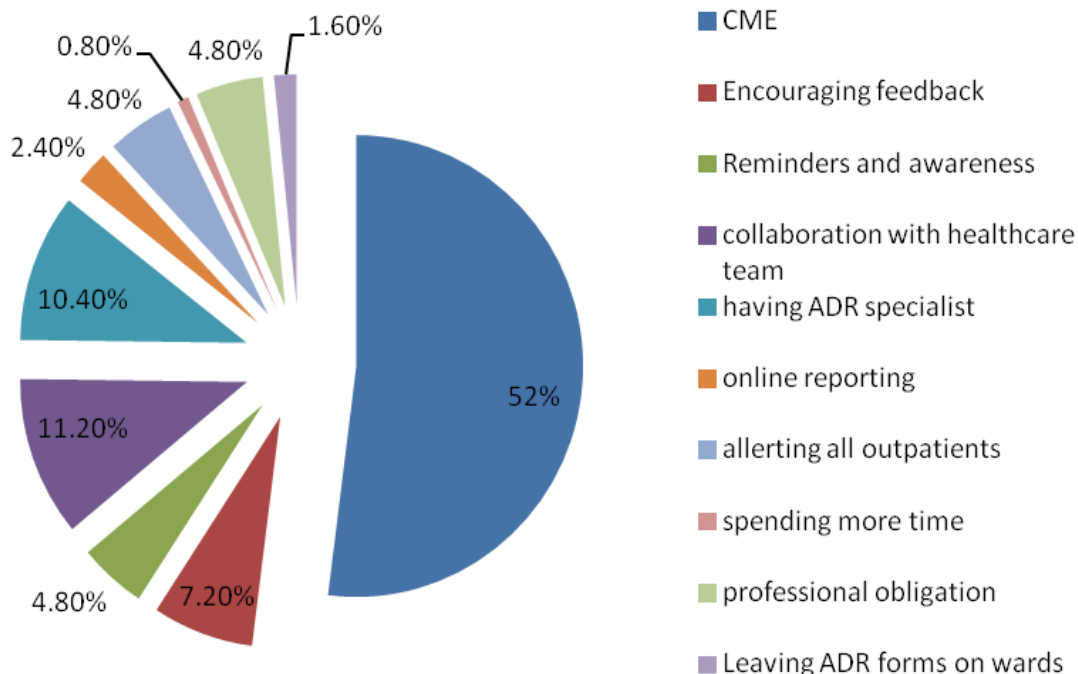
(Salehifar et al., 2007). The present study revealed that CME was considered the most appropriate method for the improvement of ADR reporting. Other considerable ways to improve such reporting system in view of physicians included increased collaboration with other health care professionals and having an ADR specialist in every department.

Limitation of the present study included that the physicians who participated in the present study were only from Karachi. Therefore, the present data did not provide us the comprehensive picture of ADR reporting attitude among physicians of the entire country. It is strongly recommended to conduct a nationwide survey to gather baseline physicians' knowledge and attitude about ADRs.

ADR reporting system has not been flourished in most of the under developing countries like Pakistan. In order to implement such system in its full form, an initial step has to be taken, that is, gather information about physicians' knowledge and attitude of the community. Such information will help the government of Pakistan to successfully implement the ADR reporting system; thereby achieving reduced hospitalization and morbidity/mortality due to ADRs. In such a way, healthcare system of Pakistan will get a new revival.

## Conclusion

The current study provided the information that the knowledge of ADRs among physicians working in different hospitals of Karachi is quite sufficient, but their perception toward ADR reporting was lacking and reflected



**Figure 2.** Appropriate method of improving ADR reporting in physicians' point of view.

when it comes to the actively reporting of ADRs. Healthcare professionals should be meticulously involved in pharmacovigilance activities in their daily practice which will set a concrete foundation in healthcare system of Pakistan. Physicians who participated in the study also suggested for the need for training through frequent CME lectures and integration of ADR reporting into the clinical activities of the physicians that would improve reporting.

## ACKNOWLEDGEMENT

The authors wish to acknowledge Dr. Saima Naseem for her support in compiling the data.

## Conflict of interest

Authors declare no conflict of interest.

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