



## Original article

# Assessment of knowledge, attitude and practice of adverse drug reaction reporting among healthcare professionals in secondary and tertiary hospitals in the capital of Pakistan

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## ABSTRACT

Adverse Drug Reactions (ADRs) underreporting is a great challenge to pharmacovigilance. Healthcare professionals should consider ADR reporting as their professional obligation because the effective system of ADR reporting is important to improve patient care and safety. This study was designed to assess the knowledge, attitude, practice and factors associated with ADR reporting by healthcare professionals (physicians and pharmacists) in secondary and tertiary hospitals of Islamabad. A pretested questionnaire comprising of 27 questions (knowledge 12, attitude 4, practice 9 and factors influencing ADR reporting 2) was administered to 384 physicians and pharmacists in public and private hospitals. Respondents were evaluated for their knowledge, attitude and practice related to ADR reporting. Additionally, the factors which encourage and discourage respondents to report ADRs were also determined. The data was analysed by using SPSS statistical software. Among 384 respondents, 367 provided responses to questionnaire, giving a response rate of 95.5%. The mean age was 28.3 (SD = 6.7). Most of the respondents indicated poor ADR reporting knowledge (83.1%). The majority of respondents (78.2%) presented a positive attitude towards ADR reporting and only a few (12.3%) hospitals have good ADR reporting practice. The seriousness of ADR, unusualness of reaction, new drug involvement and confidence in the diagnosis of ADR are the factors which encourage respondents to report ADR whereas lack of knowledge regarding where and how to report ADR, lack of access to ADR reporting form, managing patient is more important than reporting ADR legal liability issues were the major factors which discourage respondents to report ADR. The study reveals poor knowledge and practice regarding ADR reporting. However, most of the respondents have shown a positive attitude towards ADR reporting. There is a serious need for educational training as well as sincere and sustained efforts should be made by Government and Hospital Authorities to ensure proper implementation of ADR reporting system in all of the hospitals.

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## 1. Introduction

Adverse drug reaction (ADR) is defined by World Health Organisation (WHO) as 'Any reaction to a drug that is noxious, unintended and occurs at doses used for prophylaxis, diagnosis and therapy excluding failure to accomplish the intended response'

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(Ahmad et al., 2013). ADR is a major problem that occurs worldwide. Health professionals played a very vital role in reporting of ADR around the world which has led to the detection of serious and unusual ADR that were previously undetectable and many drugs like "rofecoxib" were withdrawn in the past, therefore, enhancing the safety of patients (Wysowski and Swartz, 2005). It has been noticed in the past that ADR reporting has provided early warning signs and therefore increases patient safety. Pharmacovigilance and report of adverse drug reaction were started after the thalidomide disaster in the mid-20th century (Canto, 2010). Thalidomide was the drug which was prescribed in many countries to alleviate morning sickness in pregnant women and this drug was teratogen and caused congenital disorder in newborns. After the disaster, National Pharmacovigilance Centres were established in a number of countries around the world.

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Adverse drug reactions are the 4–6th leading cause of death. Patients who experienced adverse drug reaction are hospitalised 8–12 days longer than those who did not experience adverse drug events and their hospitalised cost is between \$16,000–24,000 or more (Lazarou et al., 1998). Countries with lack of ADR reporting system are not able to protect their population from the harmful effect of medicines, therefore, an effective system of ADR reporting is very important to improve patient care and safety and in turn improving overall health. According to WHO best reporting rate include more than 200 reports/1000,000 people per year. However, reporting of ADR which is serious did not exceed 10% (Belton et al., 1995). Uppsala Monitoring Centre (UMC) is a collaborating centre for monitoring Global ADR database Vigibase. According to 2011 report WHO program has 105 countries as official members and 35 as associate members which include Pakistan as well (Kumar et al., Taneja and Ahuja, 2011, Shamim et al., 2016).

With the passage of time use of drugs is also increased which in turn leads to more adverse drug reaction occurrence. The financial burden on patients also reduces by ADR reporting because ADR causes additional treatment (Ramachandudu, 2015). Reporting of ADR can result in detection of serious and unusual ADR which was remained undetected during a clinical trial. Rational use of medicines not only decreases morbidity and mortality but also increases the quality of life (Gustafsson et al., 2011), so in order to improve rational use of medicines the safety efficacy and quality of medicine should be ensured, on the other hand irrational use of medicines can be life threatening because it could be the reason for serious adverse drug reaction (Mahmood et al., 2011). An efficient system of ADR reporting is very important for pharmacovigilance program (McBride, 1961, Ramesh et al., 2003, Khan et al., 2006). In developed countries like Europe, USA and Canada it is stated that every single ADR is important to report. Some developing countries such as India, Malaysia and some African countries are also making efforts to develop proper ADR reporting system.

Pakistan is a country which extends from mountains of the Himalayas to the Arabian sea bordering with China, India, Iran and Afghanistan. It is located along the ancient trade route between Asia and Europe (Azhar et al., 2009). Private sector serves 70% of the population whereas 10,000 public health facilities are present which range from basic health unit to tertiary care health facilities (Ghaffar et al., 2000). National Health Policy (NHP) exists in Pakistan (Su et al., 2010) but pharmacovigilance is not included in the National drug policy of Pakistan. There is no proper system or institution for monitoring of ADR. Laws also exist regarding ADR monitoring but the National Pharmacovigilance Centre that is linked to Medicines Regulatory Authority (MRA) does not exist (WHO, 2010). For ADR reporting official form is used which is available at the website of Ministry of Health, Pakistan.

National ADR database does not exist in Pakistan. In previous years, no ADR was reported to WHO database. Monitoring of ADR is not conducted in public health programs (Raza and Jamal, 2015). Pharmacovigilance system in Pakistan is still in its initial stages of development, this is due to the lack of knowledge, ignorance or lack of training as very few studies have been conducted on ADR system in the past (Shakeel et al., 2014). Therefore, the present study is undertaken to determine the current status of ADR reporting system in the capital of Pakistan, to investigate knowledge and attitude of physicians and pharmacists towards ADR reporting in secondary and tertiary hospitals.

## 2. Methodology

### 2.1. Study design and sampling strategy

This cross-sectional study was conducted in Islamabad the capital city of Pakistan. The study was commenced from January to

June 2017 for the period of six months. A survey involving three hundred and eighty-four physicians and pharmacists from six public and thirteen private hospitals was carried out. These numbers were selected by non-probability convenience sampling technique. The sample size was calculated by using the proportional formula of OpenEpi by assuming the population size of 100,000 and anticipated frequency of 50%. Sample size came out to be 384 at confidence interval 95%. A validated structured questionnaire was delivered to each participant by hand and was asked to fill it.

### 2.2. Questionnaire

Information regarding knowledge attitude and practice of ADR reporting in different countries around the world was collected. Different structured questionnaires which were used for various knowledge, attitude, practice (KAP) studies around the world were also examined and initial draft of the questionnaire was designed as multiple choice questions (Desai et al., 2011, Kamtane and Jayawardhani, 2012, Upadhyaya et al., 2012, Gupta et al., 2015). The questionnaire was developed in English as most of the participants were fluent in the English language. The validity of the questionnaire was assessed by pretesting the questionnaire with 40 healthcare professionals working in 4 different hospitals. The cronbach alpha was calculated which was 0.72 and after that, no modifications were carried out. After pilot-scale testing, the questionnaire was distributed to final respondents of the study. The questionnaire consisted of four sections. The first section included demographic information such as age, gender, hospital category and speciality whether a person is a physician or pharmacist. The second section was having twelve questions that were used to measure the knowledge of pharmacists and physicians related to ADR reporting. The third section was comprised of four questions with the help of which participants' attitude towards ADR reporting was assessed. The fourth section included nine questions with the help of which practice of ADR reporting by pharmacists and physicians in hospitals were determined. Finally, the fifth section was limited to two questions with the help of which factors encouraging and discouraging to physicians and pharmacists to report ADR were determined.

### 2.3. Ethical approval

Ethical approval was taken from ethics committee present at Quaid-i-Azam University in Islamabad, Pakistan. Written informed consent was also taken from every respondent who was willing to participate in the study. Written ethical approval was taken from some private hospitals where the ethical committee was present and functional. The physicians and pharmacists were briefed about the rationale of the study and participants were assured of the privacy and confidentiality.

### 2.4. Data collection and statistical analysis

Survey of various hospitals was carried out the physicians and pharmacists were contacted directly in their department and questionnaires were distributed to them. Participants were explained about the purpose of the study. Any clarification needed in the understanding questionnaire was provided. Informed consent was also attached with the distributed questionnaire. Those physicians and pharmacist who were agreed to participate in the study were requested to fill the questionnaire in 30 min. The questionnaires were left to those participants who were busy at that time and were collected after 2–3 days. Some questionnaires were distributed via hospital directors, such as Shifa International Hospital. Some questionnaires were distributed via Email or social networking sites like Facebook. The collected data was analysed using

statistical package for social sciences (SPSS) version 16 through a special coding system. The coded data were systematically verified and checked for errors. Descriptive and inferential statistics were applied for data analysis. Arithmetic Mean (Average) was calculated for quantitative variables, while for qualitative variables, frequencies and percentages were measured.

### 3. Results

#### 3.1. Demographic characteristics

In present study total, 384 questionnaires were distributed among physicians and pharmacists to different public and private hospitals of Islamabad. Out of 384 questionnaires, 367 were duly filled giving a response rate of 95.5%. 58.6% of the respondents were males and 41.4% were females. The average age of all respondents was 28.3 years. Out of all respondents, 90.7% were physicians and 9.3% were pharmacists. Among the hospitals which were surveyed 60.5% were public and 39.5% were private (Table 1).

#### 3.2. Description of knowledge regarding ADR

There were 12 questions assessing knowledge regarding ADR. As shown in Table 2, 26.4% and 34.6% knew about the term pharmacovigilance and ADRs respectively, 34.6% knew about the types of ADR. Among respondents, 23.7% knew where the International Centre for adverse drug reaction monitoring is located. Only 24.3% were aware of the drugs that are banned due to ADR whereas 43.3% knew the major side effect for the occurrence of ADR. A small proportion of respondent 20.2% knew where to report ADR in Pakistan and only 13.1% knew about the formal reporting system in other countries. The majority of respondents 83.4% did not share information regarding ADR to anyone, whereas 33.5% respondents gathered information about ADR through the internet, 24.0% from textbooks, journals, medical representative, seminars and direct mail brochures, 19.3% and 13.4% collected information from textbooks and journals respectively. Among respondents, 37.1% believed that side effects like a headache, vomiting and fever should be reported. Only a small proportion of the respondents were aware of WHO online database for reporting ADR 17.6% (Table 2).

#### 3.3. Description of attitude regarding ADR

The majority of respondents 70.6% strongly agreed that ADR reporting is necessary, 71.7% respondents strongly agreed that ADR reporting should be mandatory, 66.8% physicians and pharmacists strongly agreed that ADR reporting increase patient safety and 70.3% respondents think that ADR reporting is time-consuming (Table 3).

**Table 1**  
Demographic characteristics.

Demographic features	Categories	Total n (%)
Age	Mean age in years	28.3 ± 6.7
Gender	Male	215 (58.6)
	Female	152 (41.4)
Specialty	Physician	333 (90.7)
	Pharmacist	34 (9.3)
Nature of job	Permanent	132 (36.0)
	Temporary	235 (64.0)
Hospital category	Public	222 (60.5)
	Private	145 (39.5)

#### 3.4. Description of practice regarding ADR reporting

The majority of respondents reported that ADR reporting system is not present at their workplace 53.4% (n = 196). About 33.2% (n = 122) of respondents stated that ADR reporting system present at their workplace, whereas 13.4% (n = 49) did not know whether ADR reporting system is present at their workplace or not. Only 33.2% (n = 122) have free access to ADR reporting form whereas 66.8% (n = 245) stated that they do not have free access to ADR reporting form at their workplace. Most of the respondents stated that their workplace does not encourage them to practice ADR reporting 55.6% (n = 204), however, 44.4% (n = 163) stated that their work place encourages them to report ADR.

Among the physicians and pharmacists who have filled the questionnaire 56.1% (n = 206) stated that their workplace does not provide information regarding ADR reporting and 43.9% (n = 161) stated that information regarding ADR provided to them in hospitals where they are working. The majority of the respondents 86.9% (n = 319) agreed that they did not get any training regarding ADR. More than half respondents 54.5% (n = 200) stated that they encountered 0–5 ADR per week, 30.5% (n = 112) respondents encountered 5–10 per week and 15% (n = 55) encounter more than 10 per week (Fig. 1). A large number of respondents never reported ADR 88.3% (n = 324), whereas only 11.7% (n = 43) reported ADR in their professional life. Among those who have ever reported ADR 9.3% (n = 4) reported at ADR reporting centre, 11.6% (n = 5) reported to concerned pharmaceutical industry, 62.8% (n = 27) reported to head of the department and 16.3% (n = 7) reported ADR to Ministry of Health (Fig. 2).

Among the respondents who reported ADR 53.5% (n = 23) reported only severe 23.3% (n = 10) reported moderate 11.6% (n = 5) reported mild whereas 11.6% (n = 5) reported all types of ADR (Fig. 3). Majority of the respondents preferred direct contact to report ADR 62.1% (n = 228), 23.2% (n = 85) use email to report ADR which they encountered. Some respondents 10.9% (n = 40) preferred telephone as reporting tool of ADR as shown in Fig. 4.

Most of the respondent agreed that both physicians and pharmacists are responsible for reporting ADR 63.2% (n = 232) while 21.8% (n = 80) stated that physicians should report ADR and 15.0% (n = 55) stated that it is a duty of pharmacist to report ADR (Fig. 5).

#### 3.5. Knowledge scoring regarding ADR

An attempt was made to find out the overall knowledge of respondents. There were 12 questions related to knowledge and each right answer was given the score of '1' and each wrong answer was given the score of '0' mean knowledge score was calculated for each individual and on the basis of individual score respondent knowledge was categorised as good and poor knowledge. As shown in Fig. 6., 16.9% (n = 62) of the respondents have good knowledge while 83.1% (n = 305) respondents showed poor knowledge regarding ADR reporting.

#### 3.6. Attitude scoring regarding ADR

There were four questions regarding attitude, the answer of strongly agree was assigned with the score of 4, agree with 3, disagree with 2 and strongly disagreed with 1 for each type of question. Reverse scoring was done for the negatively worded question and mean attitude score was calculated for each respondent on the basis of which respondent attitude was categorised as positive and negative. Among total respondents, 78.2% (n = 287) showed a positive attitude towards ADR reporting while 21.8% (n = 80) showed negative attitude (Fig. 7).

**Table 2**  
Respondent's knowledge about ADRs.

Questions regarding knowledge	Respondents response n (%)
1 Define pharmacovigilance?	
(a) The science of monitoring ADR's happening in a hospital	126 (34.3%)
(b) The process of improving the safety of drugs	98 (26.7%)
(c) The detection, assessment, understanding and prevention of adverse effects	97 (26.4%)
(d) The science detecting the type and incidence of ADR after the drug is marketed	44 (12.1%)
(e) Do not know	2 (0.5%)
2 Define ADR?	
(a) Noxious and unintended response to drug and occurs at doses normally used in man or animal for prophylaxis, diagnosis or therapy of disease	111 (30.2%)
(b) Noxious and unintended response to drug and occurs at doses normally used in man for prophylaxis, diagnosis and therapy of disease	127 (34.6%)
(c) Any untoward medical occurrence that may present during treatment with a medicine but which does not necessarily have a causal relationship with this treatment	89 (24.3%)
(d) Any adverse reaction identified in regulatory documents such as investigators brochures or product monograph occurring within the expected frequency	40 (10.9%)
(e) Do not know	0 (0.0%)
3 Are you aware of any formal reporting system available in other countries	
(a) Yes	48 (13.1%)
(b) NO	319 (86.9%)
4 Are you aware of any drug that has been banned in the world due to ADR?	
(a) Yes	89 (24.3%)
(b) No	180 (49.0%)
(c) Do not know	98 (26.7%)
5 Have you ever shared information about ADRs with anyone?	
(a) Yes	61 (16.6%)
(b) No	306 (83.4%)
6 Where is an international centre for adverse effect reaction monitoring located?	
(a) Sweden	87 (23.7%)
(b) Germany	50 (13.6%)
(c) USA	76 (20.7%)
(d) Do not know	154 (42.0%)
7 Which of the following is a major risk factor for the occurrence of maximum adverse drug reactions?	
(a) Arthritis	27 (7.4%)
(b) Renal failure	159 (43.3%)
(c) Visual impairment	25 (6.8%)
(d) All of these	84 (22.9%)
(e) Do not know	72 (19.6%)
8 In case a serious adverse event in Pakistan is observed where it should be reported?	
(a) Pakistan medical and dental association	42 (11.4%)
(b) Pharmacy Council of Pakistan	141 (38.4%)
(c) Ministry of health	74 (20.2%)
(d) No centre for reporting	65 (17.7%)
(e) Do not know	45 (12.3%)
9 Identify the types of ADR's?	
(a) Type A, B, C, D, E, F and G	127 (34.6%)
(b) Type 1, 2, 3, 4, 5, 6 and 7	21 (5.7%)
(c) Known, unknown and common, uncommon	96 (26.2%)
(d) Reversible and irreversible	90 (24.5%)
(e) Do not know	33 (9.0%)
10 Which one of the following is the WHO online database for reporting ADR's?	
(a) ADR advisory committee	45 (12.3%)
(b) Med safe	49 (13.4%)
(c) Vigibase	65 (17.6%)
(d) Med watch	21 (5.7%)
(e) Do not know	187 (51.0%)
11 From which sources do you gather information about ADRs to new drugs?	
(a)Textbooks	71 (19.3%)
(b) Journals	49 (13.4%)
(c) Internet	123 (33.5%)
(d) Medical representatives	3 (0.8%)
(e) Seminars/conferences	18 (4.9%)
(f) Direct mail brochures	15 (4.1%)
(g) All of the above	88 (24.0%)
12 Side effects like headache fever and vomiting should not be reported?	
(a) Strongly agree	65 (17.7%)
(b) Agree	71 (19.4%)
(c) Disagree	102 (27.8%)
(d) Strongly disagree	129 (35.1%)

**Table 3**  
Respondents' attitude towards ADR reporting.

	ADR reporting necessary n (%)	ADR reporting should be mandatory n (%)	ADR reporting increase patient safety n (%)	ADR is time consuming n (%)
Strongly agreed	259 (70.6)	263 (71.7)	245 (66.8)	148 (40.3)
Agreed	96 (26.2)	95 (25.9)	110 (30.0)	110 (30.0)
Disagreed	6 (1.6)	7 (1.9)	5 (1.4)	88 (24.0)
Strongly disagreed	6 (1.6)	2 (0.5)	7 (1.8)	21 (5.7)

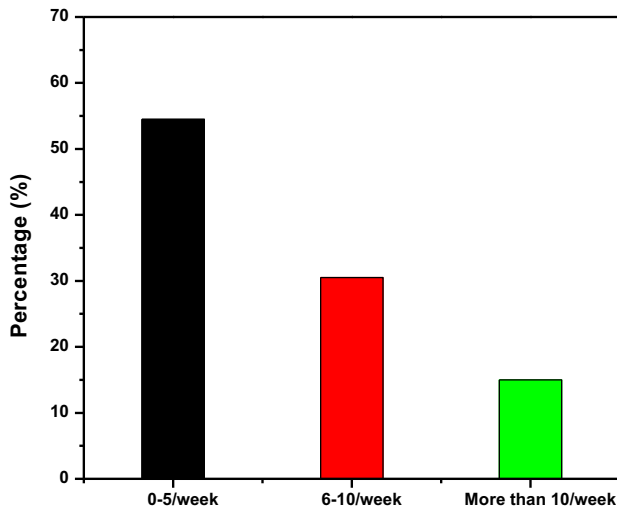


Fig. 1. ADR reported per week.

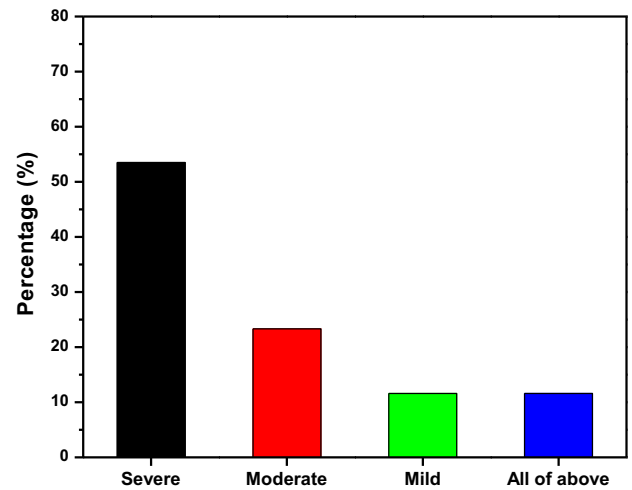


Fig. 3. Nature of ADR reported by respondents.

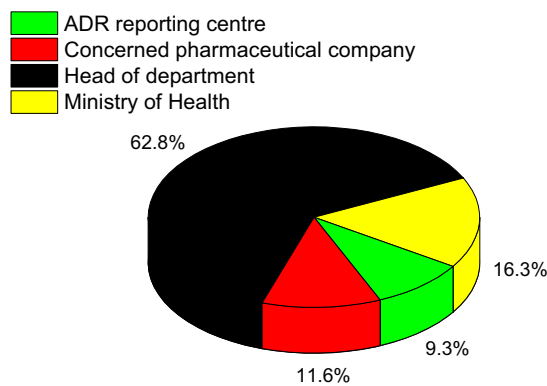


Fig. 2. Place where respondents report ADR.

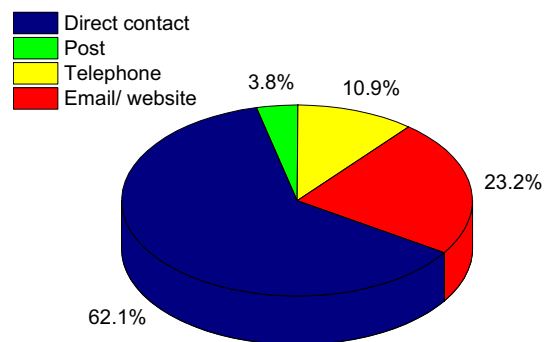


Fig. 4. Preferred methods to report ADR.

3.7. Practice scoring regarding ADR

There were 9 questions regarding practice, A score '1' was given to good practice and score '0' was given to poor practice and on the basis of individual mean score practice was categorised as good practice and poor practice. As shown in Fig. 8, ADR reporting was practised in only 12.3% (n = 45) hospitals whereas 87.7% (n = 322) hospitals have poor ADR reporting practice.

3.8. Factors affecting ADR reporting in the hospitals

Physicians and pharmacists claimed that they are more likely to report ADRs if the reaction is serious 63.8% (n = 234), unusual or unexpected 12.5% (n = 46) new drug involvement 8.4% (n = 31) confidence in diagnosing ADR 9.0% (n = 33). A small proportion of respondents 6.3% (n = 23) stated that seriousness, unusualness/

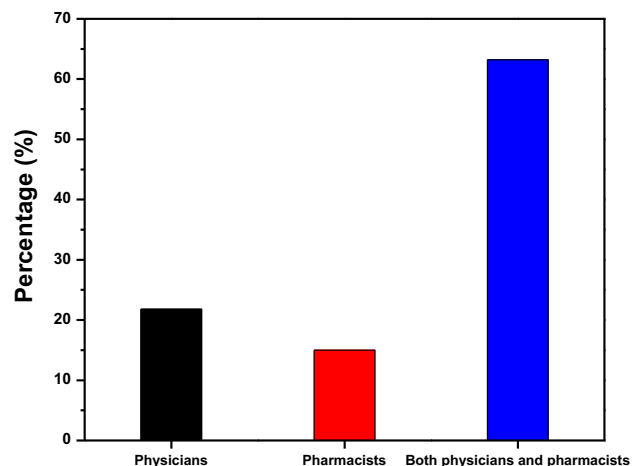


Fig. 5. Professionals responsible to report ADR.

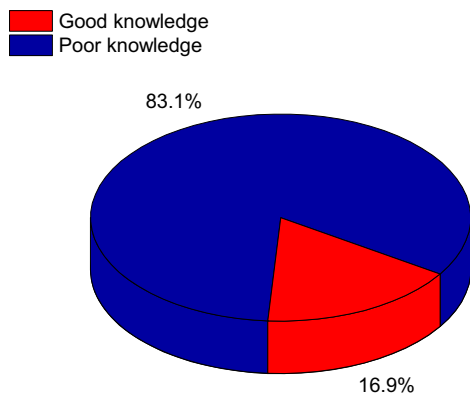


Fig. 6. Overall knowledge of respondents regarding ADR.

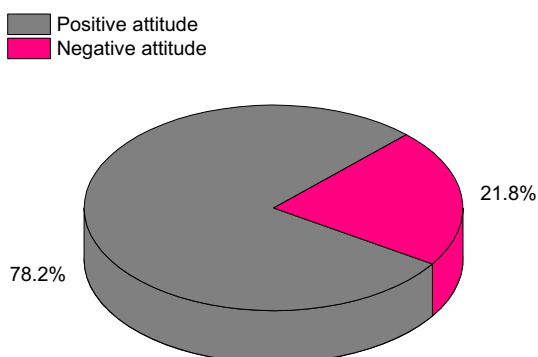


Fig. 7. Overall attitude of respondents regarding ADR.

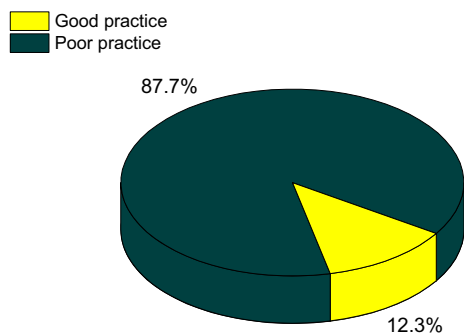


Fig. 8. Overall practice of respondents regarding ADR.

unexpected reaction, new drug involvement and confidence in diagnosing ADR, all are important factors and encourage them to report ADR (Fig. 9). Factors that discourage respondents to report ADR include not knowing where and how to report ADR 20.2% ( $n = 74$ ) and 10.4% ( $n = 38$ ) respectively. Some stated that reporting ADR is not important 12.3% ( $n = 45$ ), lack of access to ADR reporting form 6.3% ( $n = 23$ ), managing patient is more important 12.8% ( $n = 47$ ). Other factors like patient confidentiality issues 2.2% ( $n = 8$ ), legal liability issue 2.7% ( $n = 10$ ) also discourage physicians and pharmacists to report ADR respectively, whereas 33.1% ( $n = 122$ ) respondents stated that all the above factors discourage them to report ADR (Fig. 10).

#### 4. Discussion

The present study is a survey based which included public and private hospitals of Islamabad city. Previously no study was

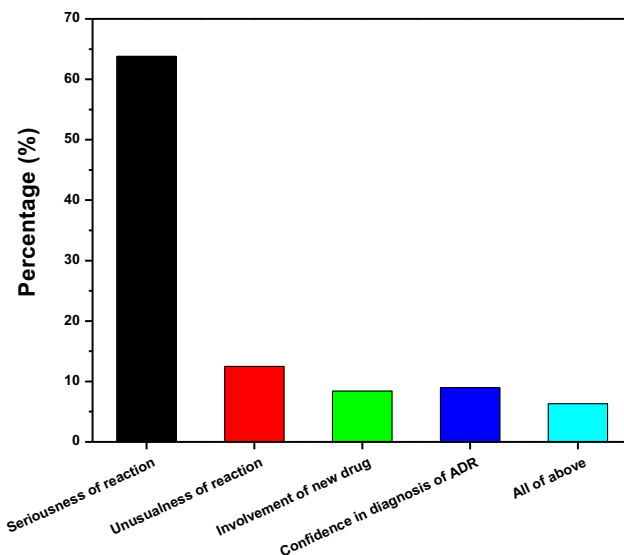


Fig. 9. Factors that encourage respondents to report ADRs.

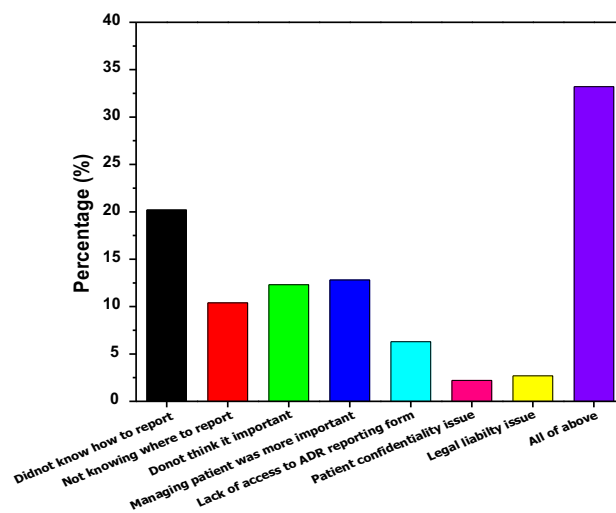


Fig. 10. Factors that discourage respondents to report ADRs.

conducted in the capital of Pakistan regarding ADR reporting, therefore this study carried out to assess the knowledge, attitude and practice of ADR reporting among physicians and pharmacists in these hospitals, also the factors which influence ADR reporting are also discussed. The study includes both pharmacists and physicians in public and private hospitals. The interesting findings show that only 3.6% pharmacists in public hospitals and 17.9% in private hospitals participated in present study, this shows that role of pharmacists in the clinical setup is still under question. The previous studies carried out in Pakistan also showed that a number of pharmacists in both public and private sector are small (Azhar et al., 2011). Not only Pakistan but other developing countries also facing a shortage of pharmacists. Countries like Malaysia also facing acute shortage of pharmacists, their data shows that the ratio of pharmacists to population is 1:62 which is low (Azhar et al., 2009). In African countries like Ghana, there is a huge shortage of pharmacists. According to one report, only 619 pharmacists are present for 2.9 million people (Owusu-Daaku et al., 2008). According to one report, 8102 pharmacists are present in Pakistan, of whom only 15% are working in the hospitals at federal and provin-

cial level (Ahsan, 2005). It has been suggested that health system of Pakistan should recognize the role of pharmacists in a clinical setup.

Knowledge regarding ADR is very important when it comes to reporting ADR. It is very important for physicians as well as pharmacists to possess great knowledge of ADR and procedure of reporting ADR. The results showed that physicians and pharmacists have poor knowledge regarding ADR reporting which is in correspondence with studies conducted in other different cities of Pakistan which include Lahore, Abbottabad and Hyderabad, all these studies show poor knowledge of physicians and pharmacists regarding ADR reporting (Nazir, 2014, Raza and Jamal, 2015). In contrast, according to a study conducted in Karachi Pakistan shows that physicians have sufficient knowledge regarding ADR (Iffat et al., 2014), the possible reason behind this could be the selected hospitals in the study were having proper functional ADR reporting system. Similar studies carried out in other countries of the world such as India also show poor knowledge of physicians and pharmacists regarding ADR (Khan et al., 2013). Findings regarding knowledge in the present study are reasonably similar to the findings in both developed and developing countries as other studies showed that 71% of the healthcare professional in China and 40% in Malaysia do not have significant knowledge of ADR reporting. Furthermore, many healthcare professionals even in the European Union (EU) do not know how to report ADR (Belton et al., 1995). Lack of knowledge regarding ADR reporting among physicians and pharmacists is also reported in Saudi Arabia (Abdel-Latif and Abdel-Wahab, 2015).

The present study reveals that only 22% physicians and pharmacists know about the international centre for reporting ADR and 19.2% know where to report ADR in Pakistan which is very crucial and indicates that there is much more need to be done to educate physicians and pharmacists about ADR reporting. A similar study was conducted in Pakistan which shows that only 15.5% of physicians know about the ADR reporting centre. A study carried out in India reveals that 41.6% were aware of the International Centre for ADR monitoring (Gupta et al., 2015). Many respondents could not identify the most appropriate source of information on ADR. According to the present study, 31.9% physicians and pharmacists refer to the internet, 18.4% textbooks, 12.7% journals and 4.7% to seminars. Similar results were obtained from a study conducted in Pakistan which shows 24% refers to the internet, 33.6% seminars and 18.4% journals (Abubakar et al., 2014).

Previous studies around the world emphasised great importance in providing awareness regarding ADR reporting and education interventions have a positive impact on increasing awareness regarding ADR reporting among healthcare professionals (Adhikary et al., 2013, Abubakar et al., 2014). Therefore it is very important to provide education and training to improve ADR reporting system. Educational interventions have been found to improve ADR reporting in many countries such as USA and Portugal (Figueiras et al., 2006), it was proved that there was an increase of 148% in the number of reports of ADR soon after the educational interventions (Figueiras et al., 2006).

According to a study in India, the healthcare professionals who have received educational training regarding ADR reporting had adequate knowledge of pharmacovigilance and improved awareness regarding ADR (Bisht et al., 2014). Proper education and training should be provided to healthcare professionals at regular interval to increase their knowledge regarding ADR reporting. Some other studies also confirmed that educational interventions lead to an increased awareness about ADR reporting (Li et al., 2004, Rajesh et al., 2011). A recent study in Nepal showed that knowledge regarding ADR reporting shall be increased through educational intervention (Palaian et al., 2011). Therefore continuous efforts are required for increasing awareness of ADR reporting through provision of education and training program at regular

interval because many healthcare professionals had encountered ADR during their clinical practice but they do not have proper awareness where and how to report ADR. This reflects that there is a need to enhance healthcare professionals knowledge regarding ADR. The present study results also reveal a lack of knowledge is also the main reason for the poor practice of ADR reporting in Pakistan. On the other hand, the studies conducted in India showed that the healthcare professionals have high knowledge regarding ADR reporting but still the poor practice of ADR (Ramesh and Parthasarathi, 2009, Ghosh et al., 2010, Gupta and Udupa, 2011).

The attitude of the physicians, as well as pharmacists were quite encouraging. The survey disclosed that a large number of respondents believed that ADR reporting is necessary and increase patient safety. Since most of the physicians and pharmacists consider ADR reporting is necessary, they should overcome the obstacles in reporting ADR and report ADR voluntarily, whenever they encountered and should consider ADR reporting as their professional obligation. About 93% respondents agreed that ADR reporting should be mandatory and it is also confirmed by previous studies. In developed countries like UK, France, Sweden and Netherland ADR reporting rate is high ranging from 40 to 70% (Belton et al., 1995, Ekman and Bäckström, 2009). The main reason behind this is that the ADR monitoring system is well established, as well as ADR reporting is mandatory in those countries. The positive attitude of respondents towards ADR reporting is an important factor as by understanding the attitude of healthcare professionals, proper action can be taken to improve participation of healthcare professionals in ADR reporting. 92% respondents in the present study believed that ADR reporting will increase patient safety. A similar outcome was reported from Netherland and India 90% of healthcare professionals in Netherland and 97.3% in India believe that ADR reporting increase patient safety (Passier et al., 2009, Desai et al., 2011).

The ADR reporting practice among physicians and pharmacists was far below than expectations. ADR has not been reported despite encountering ADR in their daily practice. One of the important findings of this study is the majority of respondents 88.3% never reported ADR. Only 11.7% reported ADR and those who have reported ADR did not report to the proper place, only 9.1% respondents report ADR to the Ministry of Health. These results are in contrast with a study conducted in Sweden where 60% of healthcare professionals report ADR to appropriate authority, the possible reason behind this could be the Sweden's healthcare professionals have greater knowledge and ADR better established reporting system (Rishi et al., 2012, Mulatu and Worku, 2014). It is evident from the study that physicians and pharmacists are not encouraged by their workplace to report ADR. The majority stated that their workplace does not encourage them to report ADR and does not provide any information regarding ADR reporting. A large proportion of respondent stated that they have never been trained for reporting ADR. Similar results were found in a study conducted in Quetta, Pakistan where 89% healthcare professionals felt that they are never been trained on ADR reporting (Anwar and Haq). Furthermore, about 7.5% of healthcare professionals are trained on ADR reporting in Karachi (Iffat et al., 2014). According to a study in UAE reveals that 94.5% of physicians did not receive any training regarding ADR reporting (John et al., 2012). Its mean hospital management and drug regulatory agencies are also neglecting towards ADR reporting. There is an urgent need to make an effort to improve ADR reporting system in those countries including Pakistan.

About 63.8% of the respondent stated that serious ADR should be considered, more important to be reported while only 12.5% believed that unusual and unexpected reaction should also be reported. It is a very serious issue that physicians and pharmacists do not even know which type of ADR should be reported. It is

significant to note that less serious, unusual and unexpected ADR should also be considered important to report as in future they might serve as a cause of fatal ADR. One of the findings of this study is that lack of knowledge on how, where and whom to report ADR is one of the main reasons which discourages physicians and pharmacists to report ADR which is inconsistent with the other studies carried out in West Ethiopia and Nigeria where lack of knowledge is the main reason for not reporting ADR (Oshikoya and Awobusuyi, 2009, Gurmesa and Dedefo, 2016). Whereas studies carried out in India revealed that lack of time is the main reason that discourages healthcare professionals to report ADR (Shah et al., 2016). Unlike other studies carried out in the developed countries, lack of knowledge is the main factor which discourages physicians and pharmacists to ADR reporting rather than professional and personal characteristics (Scott et al., 1990, Bateman et al., 1992, Lee et al., 1994, Belton et al., 1995).

A study conducted in Nigeria states that 89.9% of respondent considered physicians responsible for reporting ADR (Oshikoya and Awobusuyi, 2009). On the other hand, a study carried out in Karachi, Pakistan shows 64% respondents believed physicians and 31.2% considered pharmacists are the most appropriate persons to report ADR (Iffat et al., 2014). But in the present study, a different trend was observed as 63.2% stated that both physicians and pharmacists are qualified to report ADR while 21.8% believed physicians and only 15% believed that pharmacists are qualified to report ADR. A large number of respondents do not have access to ADR reporting form and this is the main reason for poor reporting of ADR which in contrast to the developed countries like USA where Med Watch is used for ADR reporting and it is freely available to all healthcare professionals (Toklu et al., 2016).

The National Pharmacovigilance Centre is present in Islamabad, Pakistan as well as there is a website with ADR reporting form and it is available for all healthcare professionals for voluntary reporting of ADR but the present study reveals lack of awareness of a national ADR reporting centre among respondents. The results are consistent with a study conducted in Kuwait where web based ADR reporting system is present but healthcare professionals are not aware of it (Alsaleh et al., 2016). Educational training related to ADR reporting should be conducted where training to healthcare professionals should be given regarding; where and how to report ADR.

## 5. Conclusions

Collective results disclose that physicians and pharmacists have poor knowledge and poor ADR reporting practice in public and private hospitals. However both physicians and pharmacists have a positive attitude towards ADR reporting. The major factor which discourage them from reporting ADR is a lack of knowledge regarding where and how to report ADR. Moreover, the seriousness of ADR reaction is a factor which encourages most the physicians and pharmacists to report ADR. Based on the findings of the present study following recommendations are concluded. ADR reporting forms should be freely available in all hospitals as it can improve the reporting rates of ADR in the country. ADR reporting should be mandatory for all healthcare professionals. Each hospital should have a database on ADR which should be assessed by healthcare professionals. ADR reporting workshops should be conducted all over the country to provide guidance to physicians and pharmacists regarding ADR reporting. National Pharmacovigilance Centre should be established which collect ADR reports from all over the country and further should be sent to Uppsala Monitoring Centre in Sweden. Official website related to ADR reporting should be developed where ADR can be reported voluntarily. Good pharmacovigilance practice should be developed comparable to the

international standards. Incentives could be offered to the healthcare professionals for regular reporting of ADR, this will increase ADR reporting rate. Educational training related to ADR reporting should be conducted where training to healthcare professionals should be given regarding where and how to report ADR. Further studies are recommended at a national level to determine ADR reporting practice and factors which hinder in reporting ADR.

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