

ATTITUDINAL SURVEY TO ASSESS MEDICAL AND DENTAL STUDENTS' BELIEF OF ADR REPORTING IN PAKISTAN

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Received: 15 Mar 2014 Revised and Accepted: 15 Apr 2014

ABSTRACT

Background: Adverse drug reactions are an imperative public health crisis striking a substantial fiscal burden on the society and health-care systems. Healthcare professionals are the pertinent candidates to examine these effects because of their close immediacy with their patients. Therefore, the present study was designed to evaluate the knowledge, attitude and perception of adverse drug reaction reporting among the medical and dental students.

Methods: This transversal study was conducted from March till Aug 2013 by adopting a pre validated questionnaire distributed to senior medical and dental students in different medical universities of Karachi. Descriptive statistics were used to demonstrate students' demographic information and their response to the questionnaire items. Pearson's chi-squared test was executed to evaluate the association of gender, institution and professional year of students with their response.

Results: Out of 650 survey questionnaires, only 531 were returned back in useable form. The study showed that 88.13% of the students have the knowledge of ADRs and 82.67% considered that reporting of ADRs to pharmaceutical company and Ministry of Health is necessary. Majority of the students (70.80%) agreed that the ADR reporting system in Pakistan needs further improvement. Few respondents (27.49%) have information about the availability of DRAP form for reporting of ADR. More than 55% of the students did not know the term pharmacovigilance. Only 9.79% and 8.85% of the students know where to report and how to report ADRs respectively.

Conclusion: The survey based study greatly emphasized on creating awareness through regular training, re-enforcing of guide lines and promoting the reporting of ADRs amongst health professionals ensuing in improving the quality of pharmacovigilance in their future practices.

Keywords: Adverse Drug reactions, Medical and Dental students, Pharmacovigilance, Pakistan.

INTRODUCTION

Drug exhibits medicinal, stimulating, intoxicating, or other effects when taken or put into a human body. The approach of using the drug concludes clinically good or adverse outcome such as restoration to a healthy state or adverse drug reactions. Barker suggested three possible actions of drug: the one you want, the one you don't want, and the one you don't know about [1]. Adverse Drug Reactions (ADRs) are an imperative public health crisis striking a substantial fiscal burden on the society and health-care systems. It is one of the significant basis of hospitalization varying between 5-20% [1-8]. Detection, recording and reporting of adverse drug reactions is of vital importance and health experts should be encouraged to execute this appropriately. Inman (1976) who anticipated seven reasons for underreporting (seven deadly sins) pointed out that underreporting is the primary constraint of ADR reporting systems in all countries [9].

It is accepted globally that efficient pharmacovigilance system have updated knowledge and skills related to detection, assessment, prevention, management and transparent reporting of ADRs [2, 10-12]. The aim of ADR reporting systems is to aid in post marketing surveillance of FDA approved medications and to discover ways to lessen adverse drug reaction risks [13]. Several studies have shown that spontaneous reporting has contributed significantly to improved levels of pharmacovigilance in many countries [14, 15]. Development of ADR databases worldwide and the role of healthcare workers in the area of spontaneous reporting of ADRs is well recognized in preceding studies [16]. The discipline of pharmacovigilance based upon vigilance in respect of risk; care; watchfulness; circumspection related to drug use is well established in advance countries, budding in some developing countries and virtually non-existent in many countries including Pakistan [17]. Adverse drug reaction reporting system is environs of drug information that has been given diminutive contemplation yet. [18].

The government bodies and health professionals are not effectively aware of the necessitate for detecting, monitoring, reporting and communication of feedback. Physicians, pharmacist, and nurses are the pertinent candidates of examining the unpredicted effects which may be either adverse or potentially useful because of their close immediacy with their patients.

It is also believed that generating awareness on the relevance and importance of adverse drug reaction monitoring is an assurance for beginning and sustaining sound adverse drug reactions reporting program [19]. In Pakistan, few studies were carried out regarding the knowledge and attitude to report ADR. Thus, the present study was designed to evaluate the knowledge, attitude and perception (KAP) of adverse drug reaction reporting among the medical and dental students.

MATERIAL AND METHOD

Study design and setting

This transversal study was conducted from March till Aug 2013 by adopting a pre validated questionnaire distributed to senior medical and dental students (third, fourth and final year) in different private and public sector medical universities of Karachi. Overall, five hundred and thirty one undergraduate students participated in the study. Students were encouraged to fill up the given questionnaire on spot. After completion the questionnaires were subsequently collected for further analysis.

Ethical Approval

Prior verbal ethical approval was taken from each institution's head of department to instigate the study in their institute. Each institution's head of department and the students' participating in the study were briefed about the rationale of the study. Participants were assured about the confidentiality of their personal information and responses.

Data Collection

A pre validated questionnaire comprising of 31 questions (knowledge 15 and attitude 16) used in other studies was adapted and modified [20, 21]. The questionnaire was prepared to acquire the demographics of the students, information about their attitude and knowledge towards ADR reporting.

Statistical analysis

The filled questionnaires were analyzed by using SPSS 20.0. Descriptive statistics were used to demonstrate students' demographic information and their response to the questionnaire items. Pearson's chi-squared test was executed to evaluate the association of gender, institution and professional year of students with their response. A p value < 0.05 was considered as significant.

RESULT

Demographic characteristics

Out of 650 survey questionnaires, only 531 were returned back in useable form. Hence the response rate was 81.69%. Table 1 showed the demographic of the study population. The study population comprised of 74% females and 26% males. Near about 60% of the participants belonged to the public sector and 40.5% belonged to private sector universities. Around 64% and 35.59% of the participants were medical and dental students respectively. More than 45% of the participants were final year students whereas 39.9% and 14.7% were fourth and third year students respectively.

Knowledge of medical and dental students about ADR reporting

Responses of the students regarding their knowledge are illustrated in Table 2. The result showed that 88.13% of the students have the knowledge of ADRs, 82.67% of the students considered that reporting of ADRs to pharmaceutical company and Ministry of

Health is necessary. Majority of the students (70.80%) agreed that the ADR reporting system in Pakistan needs further improvement. Most of the students (52.16%) considered doctors while 22.03% considered pharmacist to be the most qualified health professionals to report ADRs. On the other hand only 12.61% of the students have the knowledge about the existence of ADR reporting system in any hospital of Karachi, 27.49% of the respondents have information about the availability of DRAP form for reporting of ADR. More than 55% of the students did not know the term Pharmacovigilance and only 26.55% have ever experienced an ADR.

Attitude of medical and dental students about ADR reporting

Attitude of medical and dental students to report ADR is illustrated in Table 3. Approximately, 59.88% of the students considered that ADR reporting should be included in course contents, 53.29% considered ADR reporting is a professional obligation and 52.73% have the confidence to discuss ADR with their colleagues.

Whereas only 9.79% and 8.85% of the students know where to report and how to report ADRs respectively. Only 9.98% have ever been trained on how to report ADR and 15.25% have an excess to ADR reporting system. Around 36% considered that reporting of a single ADR makes no significant contribution to the ADR reporting system and have time to actively look for ADR while at work. Only 34.46% considered that managing patient is more important than reporting ADR

Purpose of reporting ADR

Purpose of reporting ADR from students' point of view is illustrated in Fig 2. The study showed that 64.4% of the students considered the purpose of reporting ADR is to calculate incidence of ADR, identify predisposing factors to ADR and identify previously unrecognized ADR whereas 20.15% and 9.98% considered that purpose of reporting ADR is to identify safe drugs and to improve patient safety respectively.

Table 1: Characteristics of study population

Characteristics	Number (Percentages)
Gender	
Male	139(26.2%)
Female	392(73.8%)
Academic year	
Third year	78 (14.7%)
Fourth year	212 (39.9%)
Final year	241 (45.4%)
Bachelor program	
Medical	342(64.40%)
Dental	189(35.59%)
Institute	
Private	215 (40.5%)
Public sector	316 (59.5%)

Table 2: Knowledge of medical and dental students to report ADRs

Opinion	Yes	No	Don't know
Know the term Pharmacovigilance	172(32.39)	300(56.49)	59(11.11)
Aware of Adverse drug reactions	468(88.13)	56(10.54)	7(1.31)
Know different types of ADR	312(58.75)	166(31.26)	53(9.98)
Have ever experience an ADR	141(26.55)	294(55.36)	96(18.07)
Know any drug that has been banned due to ADR	255(48.02)	135(25.42)	141(26.55)
ADRs should be reported for only newly marketed drugs	356(67.04)	41(7.72)	134(25.23)
Unknown reactions should be reported for established products	427(80.41)	30(5.64)	74(13.93)
Reporting of ADR to Ministry of Health or pharmaceutical company is necessary	439(82.67)	34(6.40)	58(10.92)
Knowledge about the existence of ADR reporting system in any hospital of Karachi	67(12.61)	255(48.02)	209(39.35)
Knowledge about the existence of DRAP form	146(27.49)	211(39.73)	174(32.76)
Is there any need for improvement of ADR reporting system	376(70.80)	48(9.03)	107(20.15)

Students' response for reporting ADR is illustrated in Fig.1. It showed that 60.26% considered that ADR reporting should be made compulsory and 11.67% considered ADR reporting voluntary.

Table 3: Attitude of medical and dental students to report ADRs

Opinion	Yes	No	Don't know
Know where to report ADR	52(9.79)	292(54.99)	187(35.21)
Know how to report ADR	47(8.85)	355(66.85)	129(29.29)
Have an access to ADR reporting system	81(15.25)	329(61.95)	121(22.78)
Have sufficient time to fill in ADR forms	179(33.70)	204(38.41)	148(27.87)
Managing patient is more important than reporting ADR	183(34.46)	168(31.63)	180(33.89)
ADR reporting generates extra work	256(48.21)	203(38.22)	72(13.55)
Have time to actively look for ADR while at work	194(36.53)	180(33.89)	157(29.56)
Is there a need to report already recognized ADR	360(67.79)	104(19.58)	67(12.61)
ADR reporting is a professional obligation	283(53.29)	105(19.77)	143(26.93)
ADR reporting should be included in your course	318(59.88)	129(24.29)	84(15.81)
Can confidently discuss the ADR with other colleagues	280(52.73)	115(21.65)	136(25.61)
Have ever been trained on how to report ADR	53(9.98)	380(71.56)	98(18.45)
Reporting of only one ADR makes no significant contribution to the ADR Reporting system	193(36.34)	246(46.32)	92(17.32)

Table 4: Influence of gender, institution and professional year of students on their response.

Behavior	Gender		Institute		Professional year	
	χ^2	Sig.	χ^2	Sig.	χ^2	Sig.
Know the term Pharmacovigilance	52.537	0.000*	66.377	0.000*	74.410	0.000*
Aware of Adverse drug reactions	9.379	0.009*	5.585	0.061	43.864	0.000*
Know different types of ADR	28.028	0.000*	3.755	0.153	15.043	0.005*
Have ever experience an ADR	33.998	0.000*	2.755	0.252	10.634	0.031
Know any drug that has been banned due to ADR	2.784	0.249	16.735	0.000*	21.883	0.000*
ADRs should be reported for only newly marketed drugs	3.497	0.174	5.016	0.081	37.010	0.000*
Unknown reactions should be reported for established products	0.883	0.643	9.580	0.008*	7.185	0.126
Reporting of ADR to Ministry of health or pharmaceutical company is necessary	0.478	0.788	3.422	0.181	2.749	0.601
Knowledge about the existence of ADR reporting system in any hospital of Karachi	30.683	0.000*	9.504	0.009*	27.464	0.000*
Knowledge about the existence of DRAP form	17.848	0.000*	17.907	0.000*	6.074	0.194
Is there any need for improvement of ADR reporting system	4.722	0.094	4.931	0.085	14.288	0.006*
Know where to report ADR	15.613	0.000*	23.071	0.000*	14.199	0.007*
Know how to report ADR	17.435	0.000*	41.988	0.000*	18.595	0.001*
Have an access to ADR reporting system	0.786	0.675	17.890	0.005*	15.981	0.003*
Have sufficient time to fill in ADR forms	27.853	0.000*	23.032	0.000*	14.662	0.005*
Managing patient is more important than reporting ADR	3.406	0.182	7.846	0.020*	29.615	0.000*
ADR reporting generates extra work	0.394	0.821	6.047	0.049*	9.733	0.045*
Have time to actively look for ADR while at work	24.207	0.000*	4.961	0.084	47.373	0.000*
Is there a need to report already recognized ADR	4.604	0.100	8.657	0.013*	9.492	0.050*
ADR reporting is a professional obligation	34.280	0.000*	10.698	0.005*	38.416	0.000*
ADR reporting should be included in your course	11.658	0.003*	17.490	0.000*	16.164	0.003*
Can confidently discuss the ADR with other colleagues	10.494	0.005*	21.640	0.000*	32.285	0.000*
Have ever been trained on how to report ADR	3.791	0.150	9.694	0.008*	1.764	0.779
Reporting of only one ADR makes no significant contribution to the ADR Reporting system	7.565	0.023*	4.865	0.088	13.345	0.010*

Note: In the table-4 value of sig. < 0.05 considered as significant.

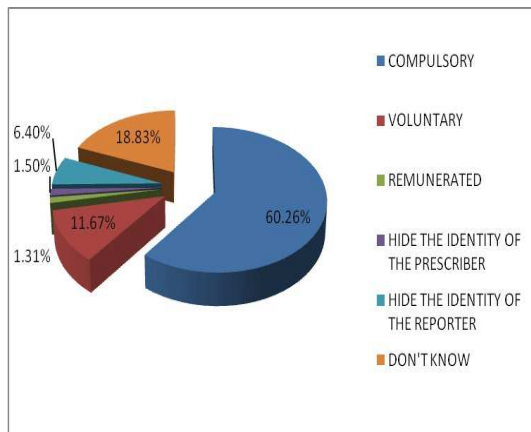


Fig. 1: ADR reporting from students' point of view

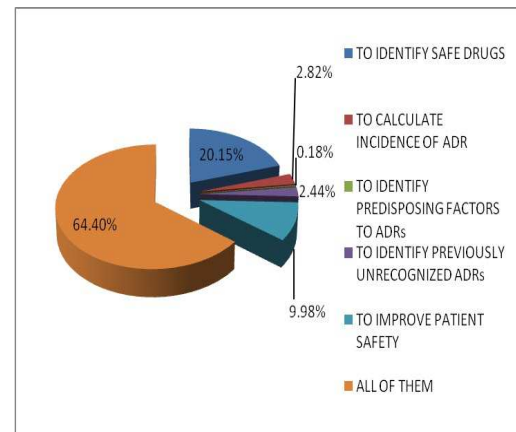


Fig. 2: Purpose of reporting ADR from students' point of view

Factors encouraging ADR reporting

Factors that may encourage the students to report ADR is illustrated in Fig 3. It revealed that 44.06% student considered that they will report if the reaction is unusual, serious and well recognized to a particular drug.

Table 4 summarizes the influence of gender, institution and academic year of students on their response.

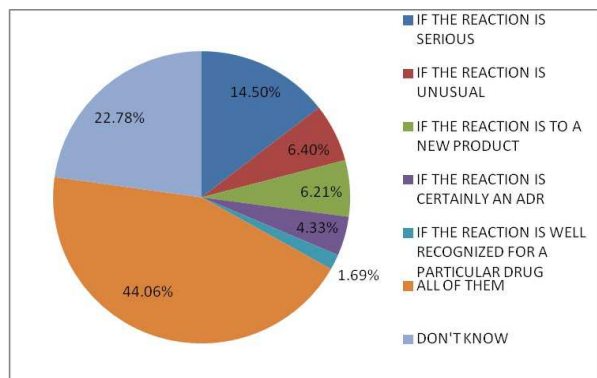


Fig. 3: Factors that may encourage students to report ADR

DISCUSSION

Adverse drug reactions results in unnecessary health care expenditures through augmented patient morbidity and mortality [3,8]. Several studies recognized ADRs as significant factors leading to hospital admissions [22]. Therefore, monitoring of ADRs should be an essential constituent of patient care. It is now a well established fact that health care professionals plays a vital role in adverse drug reaction reporting [16]. Various studies had been carried out in different countries to assess the knowledge of pharmacovigilance among the medical and dental students and practitioners [1, 23-26]. These studies have established under-reporting of ADRs is universal phenomenon common to all health care professionals [26-28]. The other factor contributing to under reporting includes lack of time, ignorance about pharmacovigilance, complex ADR reporting form, complacency and uncertainty about adverse drug reaction – causality, belief that all medicines are safe, lack of trained staff, lack of awareness about detection, communication and spontaneous monitoring of ADRs [21, 29-31]. Awareness about ADRs can minimize the factor contributing to adverse drug reaction reporting. Therefore, the present study was designed to evaluate the knowledge, attitude and perception (KAP) of adverse drug reaction reporting among future medical practitioners.

The present study revealed that more than 55% of the students did not know the term Pharmacovigilance. Graille reported lacked knowledge of pharmacovigilance in a survey among medical residents in France [32]. Only 12.61% of the students have the knowledge about the existence of ADR reporting system in any hospital of Karachi, 27.49% of the respondents have information about the availability DRAP form for reporting of ADR. The result were similar to the studies which also revealed that little information on ADRs reporting systems and hence underreporting were the most contributing factor among the doctors [33-35]. Majority of the students 70.80% agreed that the ADR reporting system in Pakistan needs further improvement. The survey result signifies the need of adequate promotion of reporting form and reporting system and to strengthen the link between regulatory bodies with health facilities in general and health professionals in particular. Near about 60.26% of students considered that ADR reporting should be made compulsory. This clearly indicates the inclination of the medical and dental students towards the implementation of ADR reporting as an essential component of the undergraduate, internship and post graduate training program,

ensuring the active involvement of nurses and paramedical staff in reporting the ADRs.

The medical student showed positive attitude regarding ADR reporting. Around 59.88% of the medical and dental students emphasized on including ADR reporting in course contents. Number of fundamental components of a pharmacovigilance course for pharmacologists and other healthcare personnel has been recommended by Uppsala Monitoring Centre (UMC), the international collaborating centre for ADR monitoring. Pharmacovigilance modules taught to the undergraduate students must be associated to modules on the rational use of medicines (RUM)[36]. Phillips has reported that over 50% of iatrogenic events can be avoided using quality assurance tools such as educational strategies and prospective ADR monitoring[37]. About 53.29% students' considered ADR reporting is professional obligation. These results are similar to study conducted among health professionals in Southwest Ethiopia [38]. More than 50% of the students have the confidence to discuss ADR with their colleagues. The interns and the post graduates play a major role by interacting with the patients and their peers in the clinical departments. They prove to be invaluable sources for collecting, analyzing and reporting ADRs. Only 9.79% and 8.85% of the students know where to report and how to report ADRs respectively. Few respondents 9.98% have ever been trained on how to report ADR and 15.25% have an access to ADR reporting system. It is evident from the study that the lack of knowledge of where and how to report ADRs would directly affect ADR reporting, therefore, the need of the hour is to improve ADR reporting among medical practitioners by creating awareness through various programmes and through publicity. The medical and dental students needs to be adapted with the ADR reporting and the methods for evaluating the causality and the severity of ADRs. Around 36% considered that reporting of a single ADR makes no significant contribution to the ADR reporting system and have time to actively look for ADR while at work. The result obtained from the survey showed a lower percentage than the study conducted among health professionals in Southwest Ethiopia [38]. Every single ADR case report is important and can make a major difference [17]. Different studies highlighted the significance of patient self-reporting is another way to increase the reporting of ADRs [39, 40].

CONCLUSION

The survey based study greatly emphasized on creating awareness through regular training, re-enforcing of guide lines and promoting the reporting of ADRs amongst health professionals. The regulatory bodies in Pakistan should aspire to attain the real essence of pharmacovigilance as mean to provide safer medicines. This in turn would facilitate the healthcare professionals to be diligently involved in improving the quality of pharmacovigilance in their future practices.

CONFLICTS OF INTEREST

All authors have none to declare.

ACKNOWLEDGEMENT

None

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