

Knowledge, Attitude and Practices towards Pharmacovigilance and Adverse Drug Reactions in health care professional of Tertiary Care Hospital, Bhavnagar

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Abstract

Purpose: Adverse drug reactions (ADRs) are adverse consequences of drug therapy. ADRs are representing a major concern of health systems in terms of early recognition, proper management and prevention. Under reporting of Adverse Drug Reactions (ADRs) is a common problem in Pharmacovigilance programs. Poor perceptions of doctors about ADRs and risk management have contributed to high rate of ADR under-reporting in India. Underreporting has also been attributed to lack of time to doctor, misconceptions about spontaneous reporting and lack of information on how to report, where to report and a lack of availability of report forms, and also physicians' attitudes to ADRs. The objective of our study was to evaluate the knowledge, attitude and practices (KAP) of health care professional towards Pharmacovigilance and adverse drug reactions in a tertiary care hospital, Bhavnagar, Gujarat, India.

Methods: A cross-sectional questionnaires based study was carried out in Post graduate students and faculties of tertiary care hospital attached with Govt. Medical College, Bhavnagar, Gujarat. Post graduate students and faculties of different clinical subjects working in the tertiary care teaching hospital, Bhavnagar, Gujarat (India) were enrolled and present throughout in study. 22 questionnaires about knowledge, attitude and practices towards ADRs and Pharmacovigilance were developed and peer viewed of all questionnaires by expert faculties from Pharmacology department. We were contacted directly to post graduate students and faculties of respective clinical department, questionnaires were distributed, 30 minutes time given to filled form. Any clarification and extra time was needed, provided to them. The filled KAP questionnaires were analyzed in question wise and their percentage value was calculated by using Microsoft excel spread sheet and online statistical software.

Results: In study, postgraduate residents (n=81) and faculties (n=63) from different clinical departments were present throughout study. Of all post graduate students, an average 27.82% and 40.76% faculties were true knowledge about ADRs and Pharmacovigilance. From attitude of students and faculties towards reporting ADRs, an average 91.77% and 91.53% were agreed to reporting ADRs is necessary, mandatory and increased patient's safety. In practice based questionnaires, 74.07% students and 71.43% faculties found difficulty like non-availability of ADR form, do not have time, patient co-operation etc. to report ADR. 47.62% in faculties and 43.21% in students said managing patient are more important than reporting ADR. Only 11.11% and 12.35% of faculties and students were found the factors like how to report, where to report etc. discouraging factors for reporting ADRs.

Conclusion: From our study, we concluded that post graduate students and faculties of tertiary care hospital have better attitude towards reporting ADRs, but have lack of knowledge and practices of ADRs. The majority of postgraduate students and faculties were felt ADR reporting and monitoring is very important but few had ever reported ADRs because lack of motivation and knowledge about ADR.

Key-words: Adverse drug reaction, health care professional, Knowledge, attitude, practices (KAP), Post graduate student, Pharmacovigilance

Key message: Being the key healthcare professionals, mainly Post graduate students and doctors have immense responsibility in reporting ADRs and strengthening the Pharmacovigilance mechanisms that exists in their vicinity. Providing information on suspected ADRs is as much a moral duty for the doctor as other aspects of patient care.

Introduction:

Adverse Drug Reactions (ADRs) are global problems of major concern. Adverse drug reaction means a noxious, unintended and undesirable effect that occur as a result of drug treatment at doses normally used in man for diagnosis, prophylaxis and treatment.¹ Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems.² ADR are rather a complex issue which requires special attention; they involve patients, Medical professionals, the Pharmaceuticals industries, drug regulatory agencies and academic scientist.³

An adverse drug reaction is associated with significantly prolonged length of stay, increased economic burden and almost 2-fold increased death.² An ADR contributes to overall health care cost by increasing morbidity and even mortality in severe cases.⁴

They affect both children and adults with varying magnitudes; causing both morbidity and mortality.⁵⁻⁶

In addition to the human cost, ADRs having major impact on public health by imposing considerable economic burden on the society and already stretch health care system.⁷

The success of a Pharmacovigilance program depends upon active involvement of the healthcare professionals like Doctors, Pharmacist, nurses. Reporting ADRs have immense responsibility towards patient care and strengthen the Pharmacovigilance programs.^{8,9} Being the key healthcare professionals, providing information on suspected ADRs is as much a moral duty for the DOCTOR as other aspects of patient care.¹⁰

An ongoing ADR monitoring and reporting program can provide benefits to the organization, doctors, nurses, pharmacists and also patients. The benefit includes increasing level of awareness regarding ADRs and to reduces morbidity and mortality of patient due to ADRs.⁵ ADR reporting does not currently appear to be considered a part of routine professional practice by health care professional.¹¹

The Uppsala Monitoring centre (UMC, WHO), Sweden is maintaining the international database of adverse drug reaction reports received ADRs report data from several national centers of different countries. However, still, it is estimated that only 6-10% of all ADRs are reported in all over world¹². Although, India is one of participating in the program, its contribution to UMC database is very little. This is essentially due to the absence of a vibrant ADR monitoring system and also lack of a reporting culture among health care professional in India.

In order to improve the reporting rate and successful running Pharmacovigilance programme and also prevent underreporting of ADRs, it is important to improve the knowledge, attitude and practices (KAP) of the healthcare professionals regarding ADR reporting and Pharmacovigilance. The best time to do it is probably during the under graduate and also post graduate education training of the doctors. But this is our duty as doctor to continue this activity during actual practicing.

Therefore this study was planned and primary objective was to evaluate the knowledge, attitude and practices towards Pharmacovigilance and adverse drug reactions reporting in post graduate students and faculties of tertiary care hospital, Bhavnagar, Gujarat because Post graduate students are the resident doctor to observe the patient 24 hrs and faculties are also visited and help to PG students during emergency while the patient is admitted in the hospital.

Material and Method:

Ethical approval was taken before start the study. The study was cross sectional, anonymous questionnaires based. In this study, post graduate students and faculty of different clinical subjects were enrolled and conducted in tertiary care teaching hospital attached with Govt. Medical College, Bhavnagar, Gujarat, India.

The survey questionnaires were administered to post graduate doctors pursuing their post graduation in clinical subjects and faculties working in this hospital. Before study, The KAP questionnaires towards Pharmacovigilance and ADRs were developed and peer viewed of all questions by expert faculties from pharmacology and different clinical department of our institute. Few changes were made and the finalized KAP Questionnaires consisted of 22 questions: Q. 1-10, 15, 20, 22, Q.11-14, Q.16-19, 21 was knowledge, attitude and practice aspects of Pharmacovigilance and ADRs reporting, respectively. The correct answer was given a score of '1' and the wrong answer given '0', maximum possible score of '22'.

Process: All post graduate students and faculties of different clinical department were consented and briefed about purpose of the study. All study participants were contacted directly in their respective department and distributed the questionnaires, given 30 minutes to fill them. Any clarification needed in understanding the questionnaires and additional time to filled form was provided. The KAP survey questionnaire was analyzed, question wise and their percentage value was calculated with the help of Microsoft excel spread sheet.

Results: In our study, Post graduate resident doctors (n=81) and faculties (n=63) were enrolled from different clinical department. All participants were filled form and sent back it.

Table 1: Correct Knowledge of adverse drug reaction and Pharmacovigilance in PGs and Faculties (Question wise)

Sr. No	Questions	Post Graduate Students (n=81)	Faculties (n=63)
1	Have you heard the name of Pharmacovigilance?	100.00	100.00
2	Pharmacovigilance means	0	25.4
3	Adverse drug reactions mean,	7.41	12.4
4	Which of the following system reported and commonly affected by adverse drug reaction is	72.84	90.48
5	The national centre for Adverse drug reaction monitoring is located at	13.58	33.33
6	Who has given a guideline for setting up and running a Pharmacovigilance Centre?	27.16	33.33
7	As per new Pharmacovigilance Programme, the Zonal Pharmacovigilance Center in West Zone India located at	48.15	46.03
8	Which important factor necessary to report an adverse drug reaction is	13.58	44.44
9	Which of following are responsible factors for the occurrence of adverse drug reactions?	20.99	39.68
10	Adverse drug reaction is serious, when?	30.86	34.92
15	Which of the following "WHO online data base" available for reporting adverse drug reaction?	17.28	14.29
20	In your opinion, Which of these are qualified to report ADRs?	8.64	22.22
22	Do you know "Yellow Card" ADR reporting form under	1.23	33.33
	Pharmacovigilance activity adopted in one of the countries?		
	If Yes, which Country?		
	% of average knowledge of PG students and Faculties	27.82	40.76

- Figure shown in percentage

In above table 1 shown, average knowledge of faculties slightly more than PG students but not up to mark. Both of them still need to be training on ADR and Pharmacovigilance is required.

Table 2: Average knowledge means score of PGs and faculties

	Post Graduate students (n=81)	Faculties (n=63)	t-value
Mean Score \pm SD	3.32 to 3.91 \pm 1.34	4.86 to 5.74 \pm 1.77	6.514
	Unpaired t-test $p < 0.0001$		

Above table shown by applied unpaired t-test, knowledge of ADR and Pharmacovigilance mean score of faculties are more that PGs. This mean difference was found to be statistically significant.

Table 3 Attitude towards Pharmacovigilance and ADRs reporting (PGs & faculty)

Q. No	Questions	PG students Agree (n=81)	Faculties Agree (n=63)
11	Do you think reporting adverse drug reaction is necessary?	97.53	95.24
12	Do you think reporting adverse drug reaction should be Mandatory?	85.19	85.71
13	Do you think reporting adverse drug reaction will increase patient safety?	92.59	93.65
14	Which of the following are challenges for implementing Pharmacovigilance programme in India?		
	Political	53.09	79.37
	Lack of trained personal	14.81	85.71
	The Reporting culture	9.88	98.41
	Adequate Communication	8.64	84.13

*Figure shown in percentage PG= Post graduate student

In table 3 shown, 97.53%, 85.19%, 92.59% of post-graduate students and 95.24%, 85.71%, 93.65% from faculties were agreed that reporting ADRs is necessary, mandatory, increased safety of patient, respectively. Of them 53.09 % of post graduate students agreed that political and 98.41% of faculties were agreed that reporting culture are major challenging factors for implementing Pharmacovigilance programme in India.

Table 4: Practices towards Pharmacovigilance & ADRs (PGs & Faculties)

Questions	Options	PG students (n=81)	Faculties (n=63)
Do you find any difficulty in reporting adverse drug reactions?	Yes	74.07	71.43
	No	25.93	28.57
If Yes, what difficulties?	Non availability of ADR form	16.67	
	Patient Co-operation	16.67	33.33
	Do not have time	58.33	66.67
	Doctor/patient communication	8.33	22.22
	Any other (Please specify)*		
	Dose reduced	12.35	12.70
Upon occurrence of serious an adverse drug reaction. What needs to be done with the suspected drug?	Stopped immediately	44.44	63.49
	Dose tapered and stopped	12.35	6.35
	Depending upon the drug & ADR	30.86	17.46
Have you reported an Adverse drug reaction?	Yes	20 (24.79)	17 (26.98)
	No	61 (75.31)	46 (73.02)
If Yes, Where?	At your Institute	12	16
	An ADR reporting center	1	8
	Concerned Pharma Company	00	00
	Other (Please specify) **		

Which method would you prefer send ADR information to an ADR Reporting Center?	Direct contact	34.92	32.10	
	By Post	11.11	6.17	
	Telephone	17.46	34.57	
	To mail/ on web site	36.51	27.16	
Which are the factors that discourage you to reporting ADRs? (You may tick multiple reasons)	Did not know how to report?	11.11	12.35	
	Not knowing where to report?	9.52	12.35	
	Managing the patient was more important than reporting ADR			
			47.62	43.21
	Legal liability issues	31.75	30.86	
	Other (Please specify)***			

Figure shown in percentage

* forget, not communicate to other staff member

** Inter-departmental meeting

*** Patient load, difficulty distinguish ADR due to disease or drug

In table 4 shown, 74.07% and 71.43% of PG students and faculties were find difficulties during reporting ADRs, respectively. Of them 33.33% and 66.67% in faculties were found difficulties like patient co-operation and do not have time to report ADR, respectively. And 16.67% and 58.33% in students were difficulties found like non-availability of ADR reporting form and do not have time to report ADRs, respectively. 44.44% and 63.59% of students and faculties were practices of stop drug immediately when serious ADR occurred, respectively. 26.98% and 23.49% of students and faculties were only report ADR, respectively. 36.51% and 34.57% of students and faculties were preferred to report ADR on mail/on website and on telephone, respectively. 46.64% and 43.51% of students and faculties believed that managing patient is more important that reporting ADR, respectively.

Discussion:

Reporting ADRs is an essential component of Pharmacovigilance programme. Spontaneous reporting system is important method for reporting ADR and also new ADR of new drug.

In our study, an average 53.25 % response was found complete response from faculties and post graduate resident doctors. Of them only 54% PGs and 52.5% faculties were interest to filled Questionnaires form and others did not have interest to fill it. Of them, 27.83% PGs and 40.78% (Table 1) faculties were found true knowledge about ADR and Pharmacovigilance. The reason behind not to filled form were not to give intensive/remuneration for reporting ADR, not to train themselves, do not have time, do not want to take over all responsibilities etc.

In some studies carried out in Germany¹³, northern Italy¹⁴, and United Kingdom¹⁵, the percentage of completed response (61%) was found. This was lower than the studies carried out in Nigeria¹⁶, Netherlands¹⁷, and northern region of England¹⁸. This study shows that the postgraduate students (70.7%) responded significantly more than the faculty members (34.5%). This may be because these students are easily accessible and on call 24 hours, as against the faculty members who are present in the hospital only during the office hours.

Lack of knowledge is also one of cause of underreporting. A study conducted by medhan ramesh et al. that stated doctors were less aware or lack of knowledge of national and international Pharmacovigilance program.¹⁹ In some other study or the literature noted, a lack of time and knowledge about ADRs is often considered to be a cause of underreporting.²⁰⁻²²

In our study, on average 91.77% and 91.53% of PGs and faculties agreed that reporting ADRs is necessary, mandatory, increased safety of patient, respectively. In another study²³ found that adverse drug reaction reporting was considered to be important by 97.3% of the respondents.

The need to improve patient safety (28.8%) and the detection of new ADRs (24.6%) were the common reasons cited for reporting.²³ Also 53.09% of PGs, 98.41% faculties agreed, political and reporting culture is most challenges factor for implementing Pharmacovigilance programme in India, respectively. In our study results had shown the good attitude for ADR reporting among post graduate students but real scenario, no practices of ADRs reporting. A study at Mumbai,²⁴ showed that high knowledge but poor practices for ADRs

reporting in doctors. But in our study, not only poor practices but little knowledge of ADR reporting was found. (Table 1, 4) The average correct knowledge score of the post graduate students and faculties 27.82% and 40.76%, respectively. Remained was incorrect knowledge (82.17% PGs, 59.22% faculties). This was indicating that continuing education and sensitization are required regarding ADR reporting and Pharmacovigilance both faculties and PGs students.

This preliminary study showed that while the right attitude for ADR reporting existed amongst PGs and faculties, the actual practice of ADR reporting was lacking. Another two studies conducted in Mysore¹⁹ and Muzzafarnagar²⁵ have shown high knowledge, but poor practice for ADR, among prescribers. In contrast our study has found not only poor practice, but also inadequate knowledge regarding ADR reporting.

The result of the present study showed that the major factors that discourages the doctors of reporting ADRs, majority doctors believed that managing patient are more important than reporting ADRs (47.62% PGs, 43.21% faculties) and also legal issue liabilities (31.75% PGs, 30.86% faculties). In our study, most of doctors know how to report and where to report ADR. But one of study in residents, found that Lack of knowledge on how (68%) and where (70%) to report the ADRs were the major factors that discouraged reporting. In this study, greater percentage of residents responded that they did not know how to report it.²³

The observations were similar to a study done in a teaching hospital in Spain, where major reason to not to report ADRs were identified to be difficulty in diagnosis of ADRs, lack of knowledge regarding the ADR reporting system, clinical workload on the doctors, and possible legal issues of reporting.¹³

In our study, 74.07% and 71.43% of PG students and faculties were find difficulties during reporting ADRs, respectively. 47.50% of post graduate doctors found difficulties to report ADRs, of them non availability of form (16.67% only in PGs), but major are do not have time (58.33% in PGs and 66.67% in faculties). In another study, lack of easy access to ADR reporting form (49.2%) was major factor for discouraged reporting.¹⁵ Other difficulties stated our PGs and faculties are forget to reporting, not communicate to other staff members. The study conducted by chatterjee et al which stated that clinical negligibility or underreporting of ADRs from clinicians due to lack of time and no or little knowledge about types of reactions to be reported.²⁶

Even as ADR reporting was considered to be important by a large majority of the respondents but the actual practices of ADR reporting was very low. In our study, 20 of PGs and 17 faculties of the respondents stated that they had reported an ADR previously. Of them, 12 PGs and 16 faculties reported at institute, 08 PGs and 01 faculty reported at ADR monitoring center. Some of faculties and students were also report in during interdepartmental meeting. In study conducted in Mumbai²⁴, of the 39 respondents who had reported an ADR previously, 16 had reported to an ADR reporting center, 13 to the concerned pharmaceutical company, while 06 had reported them at conferences or in journals. ADRs reported to pharmaceutical companies were part of a clinical trial protocol or as a personal interaction with the respective medical representatives.

An interesting observation of our study that most of PGs and faculties know about how to report and where to report ADRs but 47.62% PGs and 43.21% faculties said managing patient more important than reporting ADRs. 31.75% and 30.86% of students and faculties think about legal liability issues when ADR report. Some of PGs and faculties were also found the patient load, difficult to distinguished ADR due to disease or drug, factor that discouraging to report ADR.

A study from Northern India reported that the KAP regarding ADR monitoring was low and the knowledge scores needed an improvement and update knowledge, attitude and practices about ADR and Pharmacovigilance¹⁴. A survey among medical residents in France showed that the majority of them had a lower knowledge regarding Pharmacovigilance¹⁵. A study from Italy reported that doctors had little information concerning ADRs and ADR reporting systems¹⁵. A recent study from India also identified that the awareness about Pharmacovigilance program and the knowledge of ADR reporting were very low among the doctors¹⁶. In our study, similar results were find out. These findings suggest the need for interventions to improve the KAP of the healthcare professionals.

Conclusion

In conclusion of this study, the post graduate resident doctors and faculties had a relatively better attitude but lack of knowledge and least practices towards ADRs and Pharmacovigilance. The majority of the healthcare professionals felt ADR reporting and monitoring to be important, but only a few had ever reported an ADR. The major difficulties are do not have time and patient co-operation and discourages factors like managing patient more important than reporting ADR and legal issues from reporting by both PGs and faculties. The findings of the study suggest that there is need for continuous education and sensitization regarding Pharmacovigilance and ADR reporting system to resident's doctors and faculties that improving the ongoing Pharmacovigilance activities in our hospital.

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