

Knowledge, attitude, and practice of healthcare professionals about adverse drug reaction in major tertiary care teaching hospital in Punjab

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Received: 14 August 2015

Accepted: 10 September 2015

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ABSTRACT

Background: Adverse drug reaction (ADR) has a severe morbidity and mortality associated with it. The safe use of medicines is a critical issue for all healthcare professionals, including physicians, pharmacists, and nurses as well as the public. The main objective of this study was to evaluate the knowledge, attitude, and practice (KAP) of healthcare professionals about ADRs in a tertiary care teaching hospital.

Methods: A cross-sectional survey was carried out among the health care professionals in India using a pre-tested questionnaire with 30 questions (18 questions on knowledge, 6 on attitude, 5 on practice, and 1 on training about reporting of ADR). The study was conducted, over a period of 6 months.

Results: The questionnaire was distributed to the respondents (n=200). The response rate of 85% was recorded. Among these, only 82 questionnaires were filled in pre-test and 88 questionnaires were filled in post-test after improving awareness through pamphlets. Of the total completed questionnaire (88), 34.88% were filled by physicians, 8.53% by pharmacists, 27.9% by nurses, and 31.3% by medical and paramedical interns.

Conclusions: The health care professionals have little KAP toward ADR reporting. Healthcare professionals with higher experience such as (>10 years experience) have better KAP. With additional training on pharmacovigilance, the Indian healthcare professionals working in different sectors can become part of ADR reporting system.

Keywords: Adverse drug reaction, Pharmacovigilance, Knowledge, Attitude, Practice

INTRODUCTION

Pharmacovigilance (PV) defined as the science and activities relating to the detection, evaluation, understanding, and prevention of adverse reactions to medicines and any other medicine related problems. Adverse drug reactions (ADRs) are one of the major problems associated with medicines. ADRs are responsible for a significant number of hospital admissions ranging from 0.3% to 11%.¹ ADRs are defined as a noxious, unintended and undesirable effect that occurs as a result of drug treatment at doses normally used in humans for diagnosis, prophylaxis, and treatment.² ADRs are rather a complex issue which requires special attention. ADR is associated with significantly prolonged length of hospital stay, increased the economic burden and almost two-fold increased

death.³ It has been suggested that annual rates of ADR related deaths ranged from 0.08/100,000 to 0.12/100,000 and rate increase significantly over time at a rate of 0.0058 per year.⁴ It is imperative to monitor ADRs to minimize or prevent harm to patients arising from their drugs, to detect ADRs before they are clinically manifested, and to obtain much more knowledge to ensure safe usage of drugs.¹ A chain of clusters of cases resulted due to use of some drugs (thalidomide disaster, sulfonamide disaster, etc.) created an awareness of ADR in the 18th century and more and more attention is going to pay until date which resulted in emergence of a new science so called PV.⁵ World Health Organization (WHO) defines PV as “the science and activities relating to the detection, evaluation, understanding, and prevention of adverse reactions to medicines or any other medicine-related problems.”⁶ The Uppsala Monitoring

Centre (UMC, WHO), Sweden is maintaining the international database of ADR reports (currently about 4.7 million case reports) received from several national centers (96 member countries). Although, India is participating in the program, its contribution to UMC database is very little.^{3,7} The PV Program of India was launched with a broad objective in patient safety for more than one billion people of India. In July 2010, the Central Drug Standard Control organization, New Delhi has initiated a nationwide PV program under aegis of Ministry of Health and Family Welfare, Government of India with All India Institute of Medical Sciences (AIIMS), New Delhi as a National Coordinating Center to monitor ADR.⁸ To inculcate the culture of PV activities, the Medical Council of India has made it mandatory to have functional PV unit in each medical college.⁹ Despite the better ADR reporting culture of the developed nations, under-reporting is a major issue with spontaneous reporting.¹⁰ The preventable nature of adverse reactions is the motivation for current ADR reporting programs.¹¹ Hence, the present study was undertaken to ascertain the beliefs of a sample of healthcare professionals and their knowledge base, attitude, and practice (KAP) of the healthcare professionals.¹² Despite the better ADR reporting culture of the developed nations, under-reporting is a major issue with spontaneous reporting.¹³ The goal of this study was evaluation of clinical pharmacists' interventions in improvement of knowledge, attitude, and perception about ADRs in a tertiary care teaching hospital.¹⁴

METHODS

Study design

This was a cross-sectional, questionnaire-based survey conducted in a tertiary care teaching hospital. Enrolled participants were explained the nature and purpose of the study. A questionnaire was a self-developed, pre-validated, semi-structured questionnaire consisting of both open and closed ended questions. The following information was obtained: demographic characteristics; KAP of ADR reporting; and suggestions on possible ways to improve ADR reporting.

Study site

The study was conducted at Guru Gobind Singh Medical College and Hospital (GGSMCH), a tertiary care teaching hospital in Faridkot, Punjab.

Study duration

The study was conducted in the time period of 6-month from November 2014 to April 2015.

Sample size

In the pre and post study, 200 questionnaires were distributed among the respondents who are healthcare professionals doctors, pharmacists, nurses, and interns.

Procedure

All study participants were contacted directly in their respective department, explained the purpose of the study and distributed the questionnaires, given appropriate time to them for filled and hand it back. Any clarification needed in understanding the questionnaires and to filled form was provided. The KAP survey questionnaire was analyzed, question wise and their percentage value was calculated.

RESULTS

During the study, a total of 100 questionnaires were circulated to the health care professionals, of which only 82 were received filled. After the pre-test, the questionnaires were redistributed and finally in post-test, 88 filled questionnaires were received.

In the study from the total population in the pre-test and the post-test, the percentage response given by various health care professionals were recorded (Table 1).

In Tables 2 and 3, the year of experience of the doctors, pharmacists, nurses, and interns were recorded in pre- and post-test, respectively. The doctors, pharmacists, nurses, and interns were categorized into four groups based on their year of experience.

The Tables 4 and 5 show awareness of doctors, pharmacists, nurses, and interns year of experience wise in pre- and post-test.

According to the above data, the percentage of awareness is increased after intervention in post-test as compared to the pre-test (Table 6).

Before the intervention, in the pre-test the ADR reporting in the hospital is little which is increased in the post-test after intervention (Table 7).

There are several factors which encourage the healthcare professionals for reporting ADR. Among the factors, reaction due to a new product and serious reaction were the two main factors (Table 8).

There are several factors which discourage the healthcare professionals from reporting ADR. Among the factors concern that the report may be wrong, lack of time, lack of confidence, fear of the negative impact, mild ADR are the main factors (Table 9).

Table 1: Distribution of health care professionals.

Profession	Number of responders		Percentage response	
	Pre-test	Post-test	Pre-test	Post-test
Doctors	28	30	34.14	34.88
Pharmacists	07	07	08.53	08.53
Nurses	22	24	26.82	27.90
Interns	25	27	30.48	31.39

Table 2: Distribution by experience wise (pre-test).

Experience (in years)	N (%)			
	Doctors	Pharmacists	Nurses	Interns
<5	14 (50)	03 (42.86)	05 (22.73)	25 (100)
5-10	08 (28.57)	02 (28.57)	11 (50)	-
>10	06 (21.43)	02 (28.57)	06 (27.27)	-
Total	28 (100)	07 (100)	22 (100)	25 (100)

N: Number of respondents, %: Percentage of appropriate healthcare professionals

Table 3: Distribution by experience wise (post-test).

Experience (in years)	N (%)			
	Doctors	Pharmacists	Nurses	Interns
<5	11 (36.66)	03 (42.86)	10 (41.66)	27 (100)
5-10	13 (43.34)	02 (28.57)	08 (33.33)	-
>10	06 (20)	02 (28.57)	06 (25.01)	-
Total	30 (100)	07 (100)	24 (100)	27 (100)

Table 4: Awareness of ADR experience wise (pre-test).

Experience (in years)	Awareness rate (%)			
	Doctors	Pharmacists	Nurses	Interns
<5	04 (28.57)	02 (66.67)	02 (40)	06 (24.1)
5-10	03 (37.5)	01 (50)	05 (45.55)	-
>10	04 (66.67)	01 (50)	03 (50)	-

ADR: Adverse drug reaction

Table 5: Awareness of ADR experience wise (post-test).

Experience (in years)	Awareness rate (%)			
	Doctors	Pharmacists	Nurses	Interns
<5	07 (63.63)	02 (66.67)	02 (60)	24 (88.89)
5-10	10 (76.92)	01 (66.67)	05 (75)	-
>10	05 (83.33)	01 (100)	03 (83.33)	-

ADR: Adverse drug reaction

Table 6: Awareness of ADR reporting system in hospital.

Test	N (%)			
	Doctors	Pharmacists	Nurses	Interns
Pre-test	15 (53.57)	03 (42.85)	05 (20)	18 (28)
Post-test	28 (93.33)	06 (85.71)	18 (75)	22 (81.48)

ADR: Adverse drug reaction

Table 7: ADR reporting in the hospital.

Test	N (%)			
	Doctors	Pharmacists	Nurses	Interns
Pre-test	08 (40)	02 (28.57)	04 (18.18)	05 (20)
Post-test	16 (53.33)	03 (42.85)	09 (37.5)	12 (44.44)

ADR: Adverse drug reaction

Respondent’s opinion about ADR reporting before and after intervention for newly marketed agents is based on some common factors like ADRs should be reported for newly marketed agents (Table 10).

There are several methods to improve the ADR reporting were identified. Among them, the most suggested method was found to be continuous medical education, training program, refresher course, reminders and increased awareness from the ADR monitoring committee, encouragement from the ADR Monitoring Committee and head of each medical department in the hospital, leaving ADR reporting forms on the ward for easy accessibility, increased collaboration with other healthcare professionals, making reporting a professional responsibility (Table 11).

Table 8: Factors encouraging ADR reporting.

Factors	Doctors (%)		Pharmacists (%)		Nurses (%)		Interns (%)	
	Pre-test n=28	Post-test n=30	Pre-test n=07	Post-test n=07	Pre-test n=22	Post-test n=24	Pre-test n=25	Post-test n=27
Reaction was serious	78.57	66.67	57.14	85.71	36.36	62.5	64	70.37
Reaction was unusual	50	20	57.14	28.57	50	58.33	40	40.74
Reaction was due to a new product	53.57	43.33	57.14	28.57	27.27	37.5	40	40.74
Reaction was certainly an ADR	28.57	30	8.16	71.42	68.18	62.5	36	25.92
Reaction was recognized for a particular drug	42.85	26.67	71.42	42.85	13.63	50	48	37.03

ADR: Adverse drug reaction

Table 9: Factors discouraging ADR reporting.

Factors	Doctors (%)		Pharmacists (%)		Nurses (%)		Interns (%)	
	Pre-test	Post-test	Pre-test	Post-test	Pre-test	Post-test	Pre-test	Post-test
Concern that the ADR detection may be wrong	75	43	42.85	57.14	63.63	63	36	51.85
Unaware of the ADR reporting systems	53.57	40	28.57	43	22.72	52	60	12
Concern that reporting may generate extra work	25	3	14.28	14.28	4.54	30	20	17
Lack of time	64.28	43.33	85.71	28.57	64	85	64	78
Level of clinical knowledge makes it difficult to decide whether or not an ADR has occurred	11	20	43	28.57	22.72	7	4	15
Lack of confidence regarding ADR reporting	46.42	13	14.28	14.28	10	11.11	12	7
Fear of the negative impact	46.42	40	43	57.14	59	67	36	36
Tedious process	14.28	3.33	28.57	42.85	27.27	48	36	15
Mild ADR	46.43	10	14.28	14.28	10	30	80	22
Too well known to report	7.14	10	14.28	14.28	4.54	4	4	5
Do not know how to report	39.28	27	57.14	57.14	36	56	36	29

ADR: Adverse drug reaction

Table 10: Opinions of ADR reporting.

Opinions of reporting	Doctors (%)		Pharmacists (%)		Nurses (%)		Interns (%)	
	Pre-test	Post-test	Pre-test	Post-test	Pre-test	Post-test	Pre-test	Post-test
All ADRs be reported for newly marketed agents	85.71	96.67	57.14	71.42	72.72	75	60	59.25
Serious reactions should be reported for established products	25	56.66	71.42	85.71	50	54.16	40	48.14
Reporting of only one ADR makes no significant contribution to the reporting system	46.42	50	57.14	71.42	54.54	66.5	32	37.03
ADR reporting should be compulsory	71.42	73.33	42.85	57.14	54.54	66.67	68	44.44
ADR reporting should be voluntary	73.57	43.66	42.85	28.57	36.36	41.67	32	22.22

ADR: Adverse drug reaction

DISCUSSION

The present study was a questionnaire-based study, which included all prescribers of a tertiary care teaching hospital.

Our results showed that 85% of healthcare workers of our hospital that participated in the study. This preliminary study showed that while the right attitude for ADR reporting existed among most prescribers, the actual practice of ADR

Table 11: Suggested methods of improving ADR reporting.

ADR improving methods	Doctors	Pharmacists	Nurses	Interns
Continuous medical education, training program, and refresher module	68	12	59	52
Spending more time on the wards with patient	12	04	14	17
Alerting all outpatients to watch out for possible ADR when new drugs are prescribed	10	05	25	11
Instituting and encouraging feedback between patients, prescribers, and dispensers of drugs	21	07	19	22
Reminders and increased awareness from the ADR monitoring committee	42	11	39	17
Encouragement from the ADR monitoring committee and head of each medical departments	16	09	29	37
Remuneration for every reported case of ADR	10	08	14	09
Leaving ADR reporting forms on the ward for easy accessibility	43	11	37	23
Incentives to every outpatient that takes time to report ADR	14	05	09	07
More publicity about the scheme in local journals and media about the ADR reporting scheme	30	06	21	27
Encouraging on-line or telephone-based reporting	39	04	32	25
Increased collaboration with other healthcare professionals	29	08	19	21
Making reporting a professional responsibility	11	05	17	08
Having an ADR specialist in every department	22	03	10	06
Increased awareness among other professional that they could report ADRs	42	05	20	14

ADR: Adverse drug reaction

reporting was lacking. The fact that majority of respondents agreed that ADRs are an important problem in medical practice is an encouraging finding from our study. This common observation about the lack of knowledge about the yellow forms could also indicate that under-reporting of ADRs is a major issue in Nigeria with its attendant consequences. Some studies in the USA and France had shown that ADRs contribute significantly to morbidity and mortality in clinical practice with its associated economic consequences. It seems that the situation in Nigeria may not be very different, and the problem is unrecognized due to gross underreporting.^{15,16} Before the clinical pharmacists' interventions, a little of the responders sent ADR reports to the IPC (Indian Pharmacopoeial Commission), Ghaziabad at the Ministry of Health and after that all the reports have set to this center. It shows that interventions improve participant information regarding the center that is responsible for analyzing and managing of their reports. In previous research in Shiraz, Iran, 11% of the reports were sent to the IPC.¹³ In the first phase of the study, the main reasons of under-reporting of ADR were in order of had not enough information from the patient, too well known to report, did not know how to report, uncertain association and being unaware of the existence of a national ADR reporting system. Although there are many studies that assess some causes of under-reporting ADR, a little of them have evaluated these barriers in hospitals. In the present study, serious and unusual reactions, unreported ADR before and reactions to a new product were selected as more important ADR for reporting by the participants. The reasons for under-reporting of ADRs have been summarized by Inman as the "seven deadly sins." This includes:

1. Financial incentives (rewards for reporting)
2. Legal aspects (fear of litigation)
3. Complacency (belief that the serious ADRs are already documented when a drug is introduced in the market)
4. Diffidence (belief that reporting should be done when there is certainty that the reaction is caused by the use of a particular drug)
5. Indifference (belief that a single report would make no difference)
6. Ignorance (that only serious ADRs are to be reported)
7. Lethargy (excuses about lack of time or disinterestedness). In our study, a major reason observed was ignorance about the reporting system.

Limitations of the study

The main limitation of our study was the relatively small number of respondents especially pharmacists. Another limitation of our survey was incompletely filled questionnaires that consequently we could not enroll all 100 questionnaires for the analysis. Educational program including workshops, oral presentations, group discussion, designing ADR newsletters in hospitals, providing information about PV for healthcare workers by mail, email, verbal reminders, advertisement and continuous education program for nurses, physicians and pharmacists about ADRs, regular attending of pharmacists in the medical wards and involving actively in patient's pharmaceutical care are essential for improving healthcare workers knowledge, attitudes, and perceptions about ADRs.

CONCLUSIONS

In the present study, we observed that doctors have more awareness and knowledge about PV and ADR reporting compared to other health care professionals. PV continues to play a crucial role in meeting the challenges posed by the ever increasing range and potency of medicines, all of which carry an inevitable and sometimes unpredictable potential for harm. In conclusion, interventions can improve knowledge, attitude, and perception of healthcare workers about ADR that is a great issue of importance regarding PV and public health. Under-reporting of ADRs can be due to various reasons. Educational interventions, acknowledgment, feedback to reporters about the ADRs reported by them, and professional support offered to the prescribers. Widening the reporter base by extending it to nurses, pharmacists, and other healthcare professionals would also help strengthen ADR reporting.

ACKNOWLEDGMENTS

Authors would like to wish appreciation and sincere thanks to the healthcare professionals of GGSMCH (Baba Farid University of Health Sciences) Faridkot for their valuable time, support and cooperation. Authors also want to express gratitude to Shri Parveen Garg Ji, Chairman I.S.F. College of Pharmacy, Moga, Punjab for providing excellent research facilities and the environment.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Kaur M, Kosey S, Kumar R. Knowledge, attitude, and practice of healthcare professionals about adverse drug reaction in major tertiary care teaching hospital in Punjab. *Int J Basic Clin Pharmacol* 2015;4:993-8.