

An Evaluation of Knowledge, Attitude and Practice of Adverse Drug Reaction Reporting Among Health Care Professionals in Government Medical College, Jammu: An Prospective Study

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Abstract

The present study was done to assess the knowledge, attitude and practices (KAPs) of the healthcare professionals regarding ADRs reporting, to get an insight into the reasons for non-reporting and to suggest possible ways of improving spontaneous reporting based on our findings. This observational prospective questionnaire-based study was conducted at Postgraduate Department of Pharmacology and Therapeutics, Government Medical College, Jammu for a period of six months. A pretested KAP questionnaire containing 30 questions was distributed among 500 healthcare professionals randomly selected from all specialties of the institute. The KAP questionnaire was distributed among peer group and corrected according to the inputs received from them. Those who were not willing to participate or did not return the questionnaire within the stipulated time were excluded. A total of 371 healthcare professionals participated in this study, including 67 consultants, 77 registrars, 81 postgraduates/interns, 92 undergraduates and 54 pharmacists/nurses. Anonymity and confidentiality were ensured. Consent for participation was implied by the completion and return of the questionnaire. All the data obtained was entered in Microsoft Excel Sheet in a personal computer and the variables were characterized by their frequencies and percentages. The response rate of respondents was 74.20% (371/500) in the present study. Out of these, 215 (57.95%) were male and 156 (42.05%) female respondents. The mean age of the respondents was 33.5 years with a range of 20 to 54 years. Mean affirmative response for knowledge of ADR reporting was 48.25%, while those of attitude and practice were 78.98% and 53.37% respectively. Affirmative response of consultants for knowledge and attitude towards ADR reporting was more for all queries as compared to other healthcare professionals. Least affirmative response was given by pharmacists/nurses for all knowledge and attitude related queries.

Key Words

Adverse Drug Reaction, KAP, Healthcare Professional

Introduction

Adverse drug reactions (ADRs) have a major impact on the public health system and impose unnecessary and unreasonable economic burdens on the society although most of these ADRs are preventable. The tragedy of the thalidomide disaster led many countries to set their observational systems for early detection of potential adverse drug reactions associated with pharmacotherapy. These systems became known as the pharmacovigilance systems (1). To improve the pharmacovigilance activities in India, the Ministry of Health and Family Welfare had initiated the National Pharmacovigilance Program (NPP) on 1st January, 2005 which was further revived in July

2010 (Pharmacovigilance Programme India, PvPI). This program is overseen by Central Drugs Standard Control Organization (CDSCO), New Delhi (2). Similarly, the Drug Controller General of India and Indian Council of Medical Research have established ADR monitoring centers in many hospitals in major cities of India (3). Despite these efforts and the presence of a large number of tertiary care facilities, pharmacovigilance is still in its infancy. The major reason behind this is poor understanding of the health-care professionals toward the existing pharmacovigilance program (4). Spontaneous reporting is considered the main method in the

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pharmacovigilance system by which the ADRs are identified and it is the foundation of the WHO data base (5). Unfortunately, the spontaneous ADR reporting system is affected by a number of weaknesses, the most noticeable of these being the phenomena of ADRs underreporting from healthcare professionals. The Indian Spontaneous Reporting System (SRS) like other SRSs around the world suffers from ADR underreporting from healthcare providers (1).

Inman (7) was the first to present a list of seven attitudes related to the causes of underreporting, calling them the seven deadly sins, which included - complacency (believing that serious ADRs are well documented when the drug is released in the market), fear of getting involved in a lawsuit (legal process), guilt for having been responsible for the damage observed in the patient, ambition of group and publish case series or financial benefit, ignorance on how to describe the notification (believing that only serious and unexpected ADRs must be reported), insecurity about reporting suspicions of ADR (belief that there should be notification only if there is certainty that the damage was caused by the use of specific medication) and indifference, that is, lack of interest, time or other excuses related to postponing the notification of damage due to drug use. Much later, Varallo et al. (8) carried out a systematic review to identify the main causes for underreporting of ADR by health professionals and added another cause i.e., lack of training in pharmacovigilance as the eighth sin in underreporting.

Previously reported studies have found that underreporting of ADR is related with shortcomings in the knowledge and attitude among health-care professionals (9,10). The active participation of health-care professionals in the pharmacovigilance program can improve the ADR reporting (11).

The present study was undertaken to assess the knowledge, attitude and practices (KAPs) of the health-care professionals regarding ADRs reporting.

Material and Methods

The present observational prospective questionnaire-based study was conducted for a period of six months after approval from the Institutional Ethical Committee.

A total of 500 healthcare professionals, comprising 100 each of Consultants, Registrars, Postgraduate Students/ Interns, Undergraduate Students (prefinal and final) and Pharmacists/Nurses respectively, randomly selected from all specialties working in the hospital were approached for the enrolment in the study.

A KAP questionnaire containing 30 questions (knowledge 11, attitude 7 and practice 12) was designed using the precedence set by similar studies, to obtain information regarding the demographics of the respondents, knowledge regarding the ADR reporting system, attitude and practice of ADR reporting and the factors that encouraged and discouraged reporting. Pretesting of questionnaire was done by distributing it

among peer group. The questionnaire was finalised after ambiguous and unsuitable questions were modified based on the inputs received from peer group. All the healthcare professionals were contacted directly in their departments and the questionnaires were distributed. Every healthcare professional was given 20 minutes to fill up the questionnaire.

Results

A total response rate was of 74.20%. The participants included 92 (24.80%) undergraduates, 81 (21.83%) postgraduates/interns, 77 (20.75%) registrars, 67 (18.06%) consultants and 54 (14.56%) pharmacists/nurses. There were 215 (57.95%) male respondents and 156 (42.05%) female respondents. The mean age of the respondents was 33.5 years with a range of 20 to 54 years. Table 1 shows 'knowledge' of ADR reporting among different healthcare professionals. Mean affirmative response for 'knowledge' of ADR reporting was 48.25% in this study.

Table 2 shows 'attitude' towards ADR reporting among healthcare professionals. Mean affirmative response for 'attitude' was 78.98% in this study.

Table 3 shows 'practice' of ADR reporting among healthcare professionals. Mean affirmative response for 'practice' was 53.37% in this study.

Discussion

In the present observational prospective questionnaire-based study, response rate was overwhelming from undergraduates (92/100), followed by postgraduates/interns (81/100) and registrars (77/100), while consultants (67/100) and pharmacists/nurses (54/100) showed somewhat less enthusiasm in this study. A total of 371 questionnaires were returned, giving an overall response rate of 72.40%. Response rate from non-practicing undergraduates was more 92 (24.80%), followed by practicing postgraduates/ interns 81 (21.83%), registrars 77 (20.75%), consultants 67 (18.06%) and pharmacists/nurses 54 (14.56%).

Li et al. (12) observed a response rate of 85% in ADR reporting by healthcare professionals. They included physicians, pharmacists and administrators. Desai et al. (13) reported percentage of completed response as 61% in their study. This study also showed that the postgraduate students (70.7%) responded more than the faculty members (34.5%). Amrita et al. (14) included physicians, pharmacists and nurses as healthcare professionals while studying status of ADR reporting in Delhi. The overall response rate of their survey was 63.73%.

The present study showed that while the right attitude towards ADR reporting existed among most (78.98%) prescribers, the actual practice of ADR reporting was lacking (53.37%) and the knowledge regarding ADR reporting was inadequate (48.25%). Similar observations were also made by Desai et al. (13). However, other Indian studies reported by Ramesh and Parthasarathi (15), Ghosh et al. (16) and Gupta and Udup (17) have shown

Table 1. Evaluation of Knowledge of ADR Reporting Among Healthcare Professionals

Knowledge		Consultants (n=67)		Registrars (n=77)		PG/ Interns (n=81)		Under- graduates (n=92)		Pharmacist/ Nurses (n=54)	
S. No.	Variable	Yes	%	Yes	%	Yes	%	Yes	%	Yes	%
K1	Do you know what an ADR is?	64	95.52	72	93.50	74	91.35	77	83.69	32	59.25
K2	Do you know where to report an ADR?	51	76.11	52	67.53	49	60.49	42	45.65	19	35.18
K3	Do you know who can report an ADR?	53	79.10	55	71.42	56	69.13	47	51.08	22	40.74
K4	Does ADR reporting centre exist in your institution?	60	89.55	52	67.53	48	59.25	61	66.30	13	24.07
K5	Have you seen an ADR reporting form?	43	64.17	36	46.75	33	40.74	39	42.39	9	16.66
K6	Do you know how to fill an ADR reporting form?	41	61.19	30	38.96	29	35.80	24	26.08	8	14.81
K7a	Do you know what happens to the reported ADR?	39	58.20	40	51.94	36	44.44	52	56.52	16	29.62
K7b	If yes, where it is sent?										
	PV centre	14	20.89	11	14.28	4	4.94	11	11.96	0	0
	ADR centre	10	14.93	9	11.69	17	20.99	31	33.69	7	12.96
	AIIMS	6	8.96	4	5.19	8	9.87	2	2.17	1	1.85
	PGI	1	1.49	3	3.90	0	0	0	0	0	0
	Pharma deptt.	4	5.97	8	10.39	3	3.70	7	7.61	6	11.11
	WHO Uppsala	2	2.98	1	1.30	4	4.94	0	0	0	0
	Drug control centre	2	2.98	4	5.19	0	0	1	1.09	2	3.70
K8	Do you know how to use Naranjo algorithm scale to establish the causality of an ADR?	18	26.86	22	28.57	19	23.45	19	20.65	6	11.11
K9	Do you know where the National Pharmacovigilance Centre of India is located?	45	67.16	51	66.23	42	51.85	48	52.17	13	24.07
K10	Do you know where the International Centre for ADR	33	49.25	33	42.85	30	37.03	26	28.26	9	16.166

high knowledge, but poor practice for ADR, among prescribers.

In the present study, 85.98% participants knew the meaning of an ADR, while in a study by Li *et al.* (12) only 2.7% of healthcare professional knew the meaning of ADR and Amrita *et al.* (14) reported that in their study 58.24% of the healthcare professionals knew the correct meaning of ADR. As per National Pharmacovigilance Program (NPP) of India, adverse drug reactions should be reported to national or regional centres in the prescribed

ADR reporting form (18). In the present study, 63.07% healthcare professionals knew that ADR reporting centre exist in their institution, 62.80% knew who can report it, 57.41% knew where to report an ADR, 43.12% answered that they have seen an ADR reporting form and 35.57% knew how to fill in ADR reporting form. In a study by Li *et al.* (12), 60.4% healthcare professionals were devoid of ADR reporting form, while in a study by Amrita *et al.* (14), significant percentage (88.83%) of healthcare professionals were devoid of ADR reporting

Table 2: Evaluation of Attitude towards ADR Reporting by Healthcare Professionals

Attitude		Consultants (n=67)		Registrars (n=77)		PG/ Interns (n=81)		Under- graduates (n=92)		Pharmacist/ Nurses (n=54)	
S. No.	Variable	Yes	%	Yes	%	Yes	%	Yes	%	Yes	%
A1	Does your work place encourage you to report an ADR?	42	62.68	40	51.94	48	59.25	Not applicable		19	35.18
A2	Do you think ADR reporting is necessary in every institute?	64	95.52	72	93.50	74	91.35	82	89.13	44	81.48
A3	Do you fear facing legal problems following ADR reporting?	41	61.19	47	61.03	43	53.08	79	85.86	29	53.70
A4	Do you think ADR reporting is a professional obligation?	65	97.01	62	80.51	73	90.12	89	96.73	31	57.40
A5	Do you think it is mandatory to report an ADR?	66	98.50	66	85.71	66	81.48	86	93.47	41	75.92
A6	Do you think ADR reporting should be made mandatory?	65	97.01	65	84.41	71	87.65	88	95.65	40	74.07
A7	Do you recommend an integrated approach towards training and education about ADR reporting in medical institute and for general public?	66	98.50	75	97.40	76	93.82	89	96.73	46	85.18

form. In the present study, while evaluating the knowledge of healthcare professionals it was found that 53.63% knew where the NPVC of India is located, 49.05% professionals knew what happens to the reported ADR, 35.31% knew where the International Centre for ADR monitoring is located, while 22.64% knew how to use Naranjo algorithm scale to establish the causality of an ADR and 22.64% knew WHO online database for reporting an ADR by the member countries.

Amrita *et al.* (14) found the knowledge of the reporting centres of Delhi quiet low among healthcare professionals (5.85%). Furthermore, 98.14% of healthcare professionals did not know the ADR reporting procedures to the ADRs monitoring system, which was much higher than that was found in China (71.4%) as reported by Li *et al.* (12).

It is recognized that the attitude of the healthcare professionals towards the reporting of ADRs is of great importance in determining whether they actually generate reports. In the present study, 94.88% recommended an integrated approach towards training and education about ADR reporting in medical institute and for general public, 90.5% agreed that ADR reporting is necessary in every

institute, 88.68% answered that ADR reporting should be made mandatory, while 87.60% replied that it is mandatory to report an ADR. There were 86.25% healthcare professionals who answered that ADR reporting is a professional obligation, whereas 64.42% feared facing legal problems following ADR reporting and only 40.16% professionals answered that their work place encourage them to report an ADR.

Desai *et al.* (13) found that the adverse drug reaction reporting was considered to be important by 97.3% of the respondents. Thirty-nine (15%) respondents said that they had reported an ADR previously. The reasons cited by prescribers for not reporting ADRs were lack of knowledge on how (68%) and where (70%) to report the ADRs and lack of easy access to ADR reporting forms (49.2%). A greater percentage of residents responded that they did not report ADRs because they did not know how to do it.

Amrita *et al.* (14) found in their study that only 45.48% healthcare professionals reported an ADR, while 79.52% agreed that they did not report ADR because they did not know where to report. ADR reporting should be mandatory on doctors was the opinion of 87.90%

Table 3: Evaluation of Practice of ADR Reporting by Healthcare Professionals

S. No.	Attitude Variable	Consultants (n=67)		Registrars (n=77)		PG/ Interns (n=81)		Under-graduates (n=92)		Pharmacist/ Nurses (n=54)	
		Yes	%	Yes	%	Yes	%	Yes	%	Yes	%
P1	Do you have free access to ADR reporting forms?	19	28.35	18	23.37	39	48.41	Not applicable		6	11.11
P2	Have you ever reported an ADR?	28	41.79	29	37.66	36	44.44	Not applicable		7	12.96
P3	Have you ever been trained about how to report an ADR?	24	35.82	19	24.67	26	32.09	Not applicable		4	7.40
P4	Do you treat the ADRs in your institution?	64	95.52	75	97.40	72	88.88	Not applicable		39	72.22
P5	Do you report ADRs to old drugs?	25	37.31	24	31.16	24	29.62	Not applicable		12	22.22
P6	Do you report ADRs to vaccines?	22	32.83	26	33.76	49	60.49	Not applicable		16	29.62
P7	Do you encounter ADRs in your practice?	59	88.05	75	97.40	74	91.35	Not applicable		46	85.18
P8	Do you find any difficulty in reporting ADRs?	31	46.26	56	72.72	52	64.19	Not applicable		43	79.62
P9	Does your workload cause hindrance in reporting an ADR?	29	43.28	62	80.51	63	77.77	Not applicable		47	87.03
P10	Do you recommend that ADR reporting should be included in undergraduate curriculum?	66	98.50	73	94.80	77	95.06	84	91.30	42	77.77
P11	Do you recommend increasing awareness in ADR reporting through trainings or workshops or CME?	65	97.01	74	96.10	71	87.65	88	95.65	50	92.59
P12	Do you expect any circumstantial benefit in patient care by ADR reporting?	64	95.52	70	90.90	78	96.29	87	94.56	48	88.88

physicians. Healthcare professionals strongly felt the need to undergo training to increase their participation in the ADR reporting.

While evaluating practice of ADR reporting in the present study, it was observed that 93.80% healthcare professionals recommended increasing awareness in ADR reporting through trainings or workshops or CME and 93.53% expected circumstantial benefit in patient care by ADR reporting. There were 92.18% professionals who recommended that ADR reporting should be included in undergraduate curriculum. Moreover, 91.03% healthcare professionals encountered ADRs in their practice. These included 97.40% registrars, 91.35%

postgraduates/interns, 88.05% consultants and 85.18% pharmacists/nurses. Undergraduate students were not evaluated as they do not fall under practicing professionals. Also, 40.50% professionals reported ADRs to vaccines and 30.46% reported ADRs to old drugs. A total of 89.60% gave affirmative answer for treating ADRs in their work place.

Even as ADR reporting was considered to be important by a large majority of the respondents (90.5%) in the present study, the actual reporting was low (35.84%). In a study by Desai *et al.* (13), only 15% of the respondents stated that they had reported an ADR previously. Similarly, Gupta and Udupa (17) also cited similar findings of under-reporting of ADR to any of the

national ADR monitoring centers (2.9%) in spite of 90% of the respondents considering it important.

The reasons for reporting ADRs, as reported by Biriell and Edwards (19) are, a desire to contribute to medical knowledge, identifying a previously unknown ADR, reactions to new drugs and severity of the ADR.

The reasons for under-reporting of ADRs have been summarized by Inman (7) as the "seven deadly sins". This includes financial incentives, legal aspects, complacency, diffidence, indifference, ignorance and lethargy. Some of these sins were also documented by Ramesh and Parthasarathi (15), Ghosh *et al.* (16) and Gupta and Udupa (17) (complacency, lethargy and ignorance respectively).

In the present study, a major reason observed was never seen an ADR reporting form (56.84%), how to fill an ADR reporting form (64.43%), fear of facing legal problems (64.42%), ADR reporting forms not easily available (70.61%), lack of training (73.84%) and workload causes hindrance in reporting ADR (72.04%). The observations were similar to a study done in a teaching hospital in Spain, where the potential obstacles to spontaneous reporting of ADRs were identified to be difficulty in diagnosis of ADRs, lack of knowledge regarding the ADR reporting system, clinical workload on the doctors, a concern for patient confidentiality, and possible legal implications of reporting (20).

When intra-professional comparison was undertaken in the present study, it was found that the pharmacists/nurses were limping behind the postgraduates/ interns, registrars and consultants in their knowledge, attitude and practice of ADR reporting. The suggestions given by the respondents in the present study to improve ADR reporting corresponds with those observed in other studies. In a study carried out Oshikoya and Awobusuyi (21), imparting continuous medical education, training, encouraging feedbacks from patients, prescribers and dispensers, appointing an ADR specialist in every hospital, were some of the suggestions put forward by the prescribers for improving reporting. These measures could improve the quantum and quality of the reports.

Conclusion

The healthcare professionals in the present study had inadequate knowledge and poor practice of ADR reporting but showed favourable attitude towards ADR reporting. Therefore, there is a need to increase the awareness regarding the pharmacovigilance programmes.

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