

Evaluation of knowledge, attitude and practice of adverse drug reaction reporting among registrars and consultants in a tertiary care hospital

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Abstract

Background: Spontaneous reporting is considered the main mechanism in the pharmacovigilance system by which the adverse drug reactions are identified after the drug is released onto the market. However, pharmacovigilance is still in its infancy. The major reason behind this is poor understanding of the resident doctors toward the existing pharmacovigilance program. **Objective:** To evaluate the knowledge, attitude and practices (KAP) of registrars and consultants regarding ADR reporting and to find out reasons behind under-reporting of ADRs. **Materials and Methods:** This observational prospective questionnaire-based study was conducted in the Postgraduate Department of Pharmacology, Government Medical College, Jammu for a period of six months. A pretested KAP questionnaire containing 30 questions was distributed among 100 registrars and consultants each, randomly selected from all specialties of the institute. Those who were not willing to participate or did not return the questionnaire within the stipulated time were excluded. A total of 77 registrars and 67 consultants participated in this study. Data collected were characterized by their frequencies and percentages. Statistical analysis was done using Microsoft Excel sheet and chi-square test. **Results:** The response rate of respondents was 72% (144/200) in the present study. Out of these, 82 (56.94%) were male and 62 (43.06%) female respondents. The mean age of the respondents was 31.25 years with a range of 29 to 47 years. Mean affirmative response for knowledge of ADR reporting was 59.03%, while those of attitude and practice were 82.64% and 63.19% respectively. Affirmative response of consultants for knowledge and attitude towards ADR reporting was more for all queries as compared to registrars.

Key Words: Pharmacovigilance, Adverse drug reaction, KAP.

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Received Date: 12/01/2018 Revised Date: 08/02/2018 Accepted Date: 20/03/2018

DOI: <https://doi.org/10.26611/1010633>

Access this article online

Quick Response Code:



Website:
www.medpulse.in

Accessed Date:
25 June 2018

INTRODUCTION

The safe use of medicine is an important aspect that affects each and every member of society. However, its

usage is usually associated with undesirable adverse reactions and sometimes fatal reactions¹. Adverse drug reactions (ADRs) are the cause of hospital admission in 3 to 6% of patients of all ages, while in elderly patients it is 3 to 24%². ADR incidence has been reported to range from 5.9 to 22.3% of all emergency department admissions³. Spontaneous reporting of adverse drug events (ADEs) comprise the primary method for detecting signs in pharmacovigilance, because they are effective for identifying serious unexpected ADR, medication errors, therapeutic ineffectiveness and inconsistencies in drug quality, besides its low cost⁴. Healthcare professionals and even patients are encouraged to report suspected ADRs to Pharmacovigilance Programme India (PvPI). The Indian Spontaneous Reporting System (SRS) like

other SRSs around the world suffers from ADR underreporting from healthcare providers⁵. In India, the gross under-reporting of ADRs is a cause of concern, the reasons for which may be due to lack of trained staff and lack of awareness regarding detection, communication, and spontaneous monitoring of ADRs among the healthcare professionals⁶. This study was carried out to evaluate the knowledge, attitude and practices (KAP) of registrars and consultants of a tertiary care hospital in Jammu region of Jammu and Kashmir State and to find out reasons for under-reporting of ADRs in the institution.

MATERIALS AND METHODS

The present observational questionnaire-based study was conducted in the Postgraduate Department of Pharmacology, Government Medical College, Jammu for a period of six months after approval from the Institutional Ethical Committee. A total of 100 registrars and 100 consultants, randomly selected from all specialties working in the hospital were approached for the enrolment in the study. Those who were not willing to participate or did not return the questionnaire within the stipulated time were excluded. 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. The questionnaire was finalized after ambiguous and unsuitable questions were modified based on the result of pretest. Registrars and consultants were contacted directly in their department and the questionnaires were distributed. Every prescriber was given 30 minutes to fill up the questionnaire. Any clarification needed in understanding the questionnaire was provided. Additional time was given for the professionals who requested for extra time in filling up the questionnaire. Anonymity and confidentiality were ensured. Consent for participation was implied by the completion and return of the questionnaire. All the obtained data were entered into a personal computer on Microsoft Excel Sheet and analyzed using Statistical Package for Social Science (SPSS) version 21. The variables were characterized by their frequencies and differences between groups were assessed using chi-square tests. The statistically significant level was set at $p < 0.05$.

RESULTS

Table 1: Evaluation of knowledge of ADR reporting by prescribers

S. No.	Knowledge Variable	Registrars (n=77)		Consultants (n=67)	
		Yes	%	Yes	%
K1	Do you know what an ADR is?	72	93.50	64	95.52
K2	Do you know where to report an ADR?	52	67.53	51	76.11
K3	Do you know who can report an ADR?	55	71.42	53	79.10
K4	Does ADR reporting centre exist in your institution?	52	67.53	60	89.55
K5	Have you seen an ADR reporting form?	36	46.75	43	64.17
K6	Do you know how to fill an ADR reporting form?	30	38.96	41	61.19
K7a	Do you know what happens to the reported ADR?	40	51.94	39	58.20
K7b	If yes, where it is sent?				
	PV centre	11	14.28	14	20.89
	ADR centre	9	11.69	10	14.93
	AIIMS	4	5.19	6	8.96
	PGI	3	3.90	1	1.49
	Pharma deptt.	8	10.39	4	5.97
	WHO Uppsala	1	1.30	2	2.98
	Drug control centre	4	5.19	2	2.98
K8	Do you know how to use Naranjo algorithm scale to establish the causality of an ADR?	22	28.57	18	26.86
K9	Do you know where the National Pharmacovigilance Centre of India is located?	51	66.23	45	67.16
K10	Do you know where the International Centre for ADR monitoring is located?	33	42.85	33	49.25
K11	Do you know the WHO online database for reporting an ADR by the member countries?	21	27.27	26	38.80

Table 2: Evaluation of attitude towards ADR reporting by prescribers

S. No.	Attitude Variable	Registrars (n=77)		Consultants (n=67)	
		Yes	%	Yes	%
A1	Does your work place encourage you to report an ADR?	40	51.94	42	62.68
A2	Do you think ADR reporting is necessary in every institute?	72	93.50	64	95.52
A3	Do you fear facing legal problems following ADR reporting?	47	61.03	41	61.19
A4	Do you think ADR reporting is a professional obligation?	62	80.51	65	97.01
A5	Do you think it is mandatory to report an ADR?	66	85.71	66	98.50
A6	Do you think ADR reporting should be made mandatory?	65	84.41	65	97.01
A7	Do you recommend an integrated approach towards training and education about ADR reporting in medical institute and for general public?	75	97.40	66	98.50

Table 3: Evaluation of practice of ADR reporting by prescribers

S. No.	Practice Variable	Registrars (n=77)		Consultants (n=67)	
		Yes	%	Yes	%
P1	Do you have free access to ADR reporting forms?	18	23.37	19	28.35
P2	Have you ever reported an ADR?	29	37.66	28	41.79
P3	Have you ever been trained about how to report an ADR?	19	24.67	24	35.82
P4	Do you treat the ADRs in your institution?	75	97.40	64	95.52
P5	Do you report ADRs to old drugs?	24	31.16	25	37.31
P6	Do you report ADRs to vaccines?	26	33.76	22	32.83
P7	Do you encounter ADRs in your practice?	75	97.40	59	88.05
P8	Do you find any difficulty in reporting ADRs?	56	72.72	31	46.26
P9	Does your workload cause hindrance in reporting an ADR?	62	80.51	29	43.28
P10	Do you recommend that ADR reporting should be included in undergraduate curriculum?	73	94.80	66	98.50
P11	Do you recommend increasing awareness in ADR reporting through trainings or workshops or CME?	74	96.10	65	97.01
P12	Do you expect any circumstantial benefit in patient care by ADR reporting?	70	90.90	64	95.52

A total of 144 questionnaires were returned out of 200, giving a response rate of 72%. The participants included 77 (53.47%) registrars, 67 (46.53%) consultants. There were 82 (56.94%) male respondents and 62 (43.06%) female respondents. The mean age of the respondents was 31.25 years with a range of 29 to 47 years. Mean positive response for 'knowledge' of ADR reporting was 59.03% in this study. Positive response to 'what is an ADR' was given by 94.44% prescribers, followed by 'ADR reporting centre exists in the institution' by 77.78%, 'who can report ADR' 75%, 'where to report ADR' 71.53% and 'where NPvC of India is located' by 66.67%. Least positive response was given for query 'how to use Naranjo algorithm scale' by 27.78% respondents (Table 1). Most mean positive response for queries under the head 'knowledge' of ADR reporting was given by consultants (64.18%), followed by registrars (54.54%), the association between the two being statistically non-significant ($p=0.30$). Mean positive response for 'attitude' was 82.64% in this study. Positive response to 'integrated approach towards training and education about ADR reporting' was given by 97.92% prescribers, followed by 'ADR reporting is necessary in every institute' 94.44%, 'ADR reporting should be made mandatory' 91.67%, 'it

is mandatory to report ADR' 91.67%, 'ADR reporting is a professional obligation' 88.19% and 'fear of legal problems following ADR reporting' by 61.11%. Least affirmative response was given for 'work place encourages to report an ADR' by 56.94% respondents (Table 2). Most mean positive response for queries under the head 'attitude' towards ADR reporting was also given by consultants (86.57%), followed by registrars (79.22%), the association between the two being statistically non-significant ($p=0.27$). Mean positive response for 'practice' was 63.19% in this study. Positive response to three questions – 'treat the ADRs in your institution', 'recommend that ADR reporting should be included in undergraduate curriculum' and 'recommend increasing awareness in ADR reporting through trainings or workshops/CME' was given by 96.53% prescribers each, followed by 'encounter ADRs in your practice' and 'expect any circumstantial benefit in patient care by ADR reporting' by 93.05% respondents each. For 'workload causes hindrance in reporting an ADR' 63.19% prescribers gave positive response, while for 'difficulty in reporting ADRs' 60.42% gave positive response. For other queries like 'reported an ADR' 39.58%, 'report ADRs to old drugs' 34.03%, 'report ADRs to vaccines'

33.33%, 'trained about how to report an ADR' 29.86% and 'free access to ADR reporting forms' by 25.69% respondents, there were considerably less number of positive response (Table 3). Most mean positive response for queries under the head 'practice' of ADR reporting was given by registrars (64.93%), followed by consultants (61.19%), the association between the two being statistically non-significant ($p=0.72$).

DISCUSSION

In the present observational questionnaire-based study, response rate was 77% from the registrars and 67% from the consultants. Out of 200 questionnaires, a total of 144 (72%) questionnaires were returned. Response rate from registrars 77 (53.47%) was more as compared to consultants 67 (46.53%). In a study conducted by Kamtane and Jayawardhani⁷, 94 out of 120 respondents filled and returned the questionnaire giving a response rate of 78.33%, which is similar to our study. Desai *et al.*⁸ reported percentage of completed response as 61% in their study, while Karelia and Piparava⁹ reported response rate of 55.33% which is much less as compared to the present study. In the present study, positive attitude towards ADR reporting was observed in 82.64% respondents, actual practice of ADR reporting was present in 63.19%, while knowledge regarding ADR reporting existed in 59.03% respondents. However, only 39.58% had ever reported any ADRs indicating lackness of pharmacovigilance among the respondents. Thomas *et al.*¹⁰ in their study on practice of ADR among doctors reported that only 25% out of 60 doctors ever reported any ADRs. Similarly, Kharkar and Bowalekar¹¹ observed that though medical practitioners had right perception of ADR reporting, practice of ADR reporting was very poor. Factors that discouraged ADR reporting in the present study included difficulty in accessing ADR reporting forms, lack of training on how to report an ADR, hindrance due to work load in reporting an ADR. In a study conducted by Belton (12) also observed that unavailability of report forms, contact number or address of the reporting agency, lack of knowledge on how to report and lack of enough time to report ADRs were some of the factors that discouraged ADR reporting. Chatterjee *et al.*¹³ stated that a main reason for under reporting of ADRs was the clinical negligibility of the adverse reaction due to lack of time and little knowledge about the types of reactions to be preferentially reported. In the present study, location of NPvC of India was known to 66.67% respondents, what happens to the reported ADR was known to 54.86%, where the International Centre for ADR monitoring is located was known to 45.83% respondents, while how to use Naranjo algorithm scale to establish the causality of an ADR was known to 27.78%

and WHO online database for reporting an ADR by the member countries was known to 32.64% respondents. Amrita *et al.*¹⁴ reported low knowledge of the reporting centres among medical practitioners (5.85%) in a study conducted in Delhi. In their study, 98.14% respondents did not know the ADR reporting procedures to the ADRs monitoring system, while Li *et al.*¹⁵ found same to be 71.4% in their study conducted in China. In the present study, ADR reporting was considered to be important by a large majority of the respondents (94.44%), however the actual reporting was low (39.58%). In a study conducted by Desai *et al.*⁸, only 15% of the respondents stated that they had reported an ADR previously. Similarly, Gupta and Udupa¹⁶ also cited similar findings of under-reporting of ADR to the national ADR monitoring centers (2.9%) in spite of 90% of the respondents considering it important. Oshikoya and Awobusuyi¹⁷ suggested that imparting continuous medical education, training, encouraging feedbacks from patients, prescribers and dispensers, appointing an ADR specialist in every hospital can play an important role for improving ADR reporting. These measures could improve the quantum and quality of the reports.

CONCLUSION

The resident doctors and consultants in the present study showed favourable attitude but approach towards knowledge and practice of ADR reporting was found to be inadequate and poor. There is a need to include pharmacovigilance awareness programmes on regular basis so that there is increase in awareness regarding the regular reporting of ADR and training should be imparted to medical professionals on how to report an ADR.

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Source of Support: None Declared
Conflict of Interest: None Declared

