Original Article

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An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting in a tertiary care teaching hospital of Sikkim

Abstract

Aim: Spontaneous voluntary adverse drug reaction (ADR) reporting is paramount to the success of the Pharmacovigilance Programme of India. There has however been minimal and sporadic voluntary reporting of ADR's at the ADR Monitoring Centre (AMC) Gangtok, Sikkim. Knowledge, perception, attitude, and awareness of health professionals are determinants of reporting practices. This questionnaire study aims at evaluating these indicators in the teaching hospital attached to the Medical Institute and find out methods to improve existing reporting practices. **Materials and Methods:** This is a cross-sectional questionnaire-based observational study carried out in the Medical, Surgical and Pathology Departments of the Teaching Hospital, Gangtok, Sikkim over a period of 2 months. The questionnaires were filled by the respondents and returned back to us within the next 24 h. Data obtained from filled questionnaires were thereby analyzed. **Results:** The overall correct response rate to the knowledge-based questions was 56.3%. While 97% of respondents were of the view that ADR reporting was necessary, 35% of the respondents felt that the difficulty in deciding the causality of an ADR discouraged them from reporting. 79% of the respondents were not aware of the presence of an AMC affiliated to the hospital, and 87% of the respondents admitted that they were not sending filled ADR forms to the AMC. **Conclusions:** The study indicates that the respondents have an average knowledge and positive attitude toward ADR reporting and pharmacovigilance. There is however a lack of awareness and poor ADR reporting practices. Efforts are required to enhance awareness and attitude toward pharmacovigilance and ADR reporting.

Key words: Adverse drug reaction monitoring, knowledge, attitude and practice study, pharmacovigilance, Pharmacovigilance Programme of India

INTRODUCTION

Rational drug therapy is based on the two essential parameters of safety and efficacy. Practically, no drug can be absolutely devoid of adverse effects, but their use has to be associated with an acceptable risk-benefit ratio. In order to be able to make a rational and judicious selection of a therapeutic agent, it is important for the prescriber to be aware of the quantum and frequency of possible untoward risks. It is not statistically possible to encounter all the deleterious effects of a drug during the first three phases of clinical trials, largely because the population, in which they are evaluated, is a fraction of the intended target population. Apart from the limited study population, selective recruitment of patients with resulting limited heterogeneity and consideration of few predefined adverse

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drug reactions (ADR's) limit the generalizability of clinical trials to clinical practice. It is possible to create a more realistic safety profile of a drug after it has been scrutinized for untoward adverse events in a larger heterogenous population of patients over an extended period. Building a database of knowledge pertaining to the adverse effects of drugs is what forms the core principle of pharmacovigilance.

The Uppsala Monitoring Centre (UMC) in Sweden maintains the international database of the ADR reports. India contributes to this database in the form of the Pharmacovigilance Programme of India (PvPI) which has been operational from July 2010. Since September 2010, only 2823 ADR's have been reported,[1] which is obviously very small, to provide any conclusive and meaningful evidence. India has vast ethnic populations and a wide spectrum of prevalent diseases. Comprehensive knowledge on the adverse effect of drugs specific to the Indian population is lacking, and we rely mostly on data available from Western countries. It is thus imperative to have an efficient, effective, and broad-based ADR reporting culture to enhance the rather limited information and knowledge that we currently have. This is only possible when health professionals, practicing clinicians in particular, take the time and effort to voluntarily report any ADR that they encounter.

The ADR Monitoring Centre (AMC) in Sikkim Manipal Institute of Medical Sciences (SMIMS), Gangtok, Sikkim is facing the challenge of minimal spontaneous reporting of ADRs. This study has been carried out to evaluate the knowledge, attitude, awareness, and practice of doctors working in the teaching hospital, toward ADR monitoring and pharmacovigilance with a questionnaire based research instrument. The results derived from the study would be able to give direction to the corrective measures required to be taken to enhance voluntary ADR reporting. Sikkim is a North-Eastern State characterized by an ethnically diverse population, which makes it all the more important to recognize any difference in the pattern and nature of ADR's from the vast majority of the populace. Observing such differences would not be possible, unless a relatively significant number of ADR's are reported, added, and compared to the existing database. This study is a preliminary effort in this direction.

MATERIALS AND METHODS

Study site

The study was conducted at the Central Referral Hospital attached to SMIMS, Gangtok, East Sikkim.

Study design and study participants

This was a cross-sectional questionnaire-based observational study carried out in the Medical, Surgical, and Pathology Departments, over a period of 2 months (June to July, 2014). The Department of Pathology was included due to their involvement in the activities of the blood bank, which has an important role to play in hemovigilance. Approval for conducting the study was obtained from the Institutional Ethical Committee. Informed consent from the participants was obtained verbally, and confidentiality was assured. Feedback was received from a total of 13 departments in addition to interns. Interns were considered as a separate group and were not included in any specific department due to their rotational posting. The respondents were divided into five groups on the basis of their respective designations.

Study questionnaire

The study instrument was a standard structured questionnaire of the PvPI. The questionnaire has a format that provides information regarding three distinct domains–knowledge, attitude, and practice (KAP). Aspects that are explored include the knowledge of the respondents regarding ADR's, their attitudes and awareness to reporting, factors that may influence reporting, their training, and actual ADR reporting practices being followed by the respondents. The original questionnaire comprises 25 questions, of which 17 were incorporated in the final version to make it concise and suit the objectives of the current study.

Sampling procedure and sample size

The questionnaire was administered to all the clinicians and pathologists of the hospital with instructions to fill and return it back within next 24 h. A total of 120 questionnaires were distributed, of which a total of 75 were returned.

Data analysis

Collected data were analyzed for frequency, percentage, mean, and standard deviation (SD). Statistical software used was SPSS version 20 (IBM SPSS statistics version 20 manufactured by IBM Corp.). Chi-square test was used where applicable and $P < 0.05$ was considered significant.

OBSERVATIONS AND RESULTS

A total of 120 questionnaires were distributed, of which 75 were duly filled and returned (response rate of 62.5%). Table 1 gives the frequency distribution of Departments of the Respondents and Table 2 gives their designations. Postgraduate residents and junior residents comprised the largest group (34.7% and 37.3%, respectively). The study questionnaire was divided into three different sections–knowledge (seven questions), attitude and awareness (six questions) and practice (four questions).

Knowledge

Table 3 gives details of the responses to the knowledge-based questions. The average number of correct responses was

Table 1: Departments of the study respondents

Department	Number of respondents	Percentage
OBG	8	10.7
Dental	2	2.7
Psychiatry	7	9.3
Medicine	6	8.0
Surgery	8	10.7
Pathology	9	12.0
ENT	9	12.0
Orthopedics	5	6.7
Ophthalmology	4	5.3
Pediatrics	6	8.0
Dermatology	1	1.3
Respiratory medicine	1	1.3
Interns	8	10.7
Anesthesia	1	1.3
Total	75	100.0

OBG=Obstetrics and Gynecology, ENT= Ear, Nose and Throat

Table 2: Designation of study respondents

Designation	Number of respondents	Percentage
PG/R	26	34.7
Assistant professors	28	37.3
Associate professors	6	8.0
Professors	7	9.3
Interns	8	10.7
Total	75	100.0

PG/R=Postgraduate students/resident medical officers

3.8 ± 1.3 (mean ± SD) out of a total of seven. The associate professors had the maximum correct response rate (66.6%) while interns had the least (51.7%). The overall correct response rate was 56.3%. Pearson's Chi-square test was applied to find out any association between designation and knowledge. However, no significant association was found ($\chi^2 = 40.6$; $P = 0.058$).

Twenty-eight subjects out of the total of 75 (37%) responded to the definition of pharmacovigilance correctly. Professors were the most accurate (71.4%) while postgraduates/residents, the least (19.2%). 83% of the respondents knew that doctors, pharmacists, and nurses could all report ADR's. 63% of the respondents could correctly identify spontaneous reporting system as the most commonly employed method to monitor ADR's. 73% of respondents were aware that CDSCO was the regulatory body responsible for monitoring ADR's. However, only 23% of the respondents were aware that the National Coordinating Centre for ADR monitoring was located in IPC, Ghaziabad. 43% respondents correctly responded to the World Health Organization (WHO) scale as that used most commonly to establish causality of an ADR. 60% respondents knew that rare ADR's could be identified in phase-4 clinical trials. Thirty respondents (40%) could correctly respond to four out of the total of seven, followed by five correct responses provided by 19 (25.3%) of the respondents.

Attitude and awareness

Table 4 gives a detailed overview of the responses for the attitude- and awareness-based questions. A total of 73 out of the total 75 respondents (97%) felt that ADR reporting was necessary, but only 63% felt that it was a professional obligation. 35% of the respondents felt that it was difficult to decide the causality of an ADR, which in turn discouraged them from reporting. 33% cited lack of time as the most important factor that acted as a deterrent to reporting. 63% opined that every hospital should have an AMC while only 8% felt that it was not necessary for every hospital. 79% of the respondents were not aware of the presence of an AMC affiliated to the hospital. All the respondents were of the view that they required some sort of training modules or workshops for a better understanding of pharmacovigilance activities.

Practice

The response to the practice-based questions is depicted in Table 5. Majority of the respondents (75%) had come across an ADR while discharging their professional duties while only 24% had actually documented an ADR. 24% of the respondents did not know about the suspected ADR form and 16% did not know how and where to report ADR's. 87% of the respondents admitted that they were not sending filled ADR forms to the AMC. Few (9%) respondents were filling the ADR forms but did not know how and where to send them.

DISCUSSION AND CONCLUSION

World Health Organization defines an ADR as "a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function."[2] The incidence of serious ADR's is 6.7% in India.[3] A study in South India showed that 0.7% of hospital admissions were due to ADR's, and a total of 3.7% of the hospitalized patients experienced an ADR, of which 1.3% were fatal.[4] Another study showed that ADR's were responsible for 3.4% of the hospital admissions, and 3.7% developed ADR's during their hospital stay.[5] A study by Lazarou described ADR's to be the 4th–6th largest cause of death in the USA.[6] ADR's thus contribute significantly to the burden of disease by causing drug-related hospital admissions, prolongation of hospital stay and increasing emergency department visits.[7]

Reporting of ADRs is essential for the success of any pharmacovigilance program. The progress of the PvPI has

Table 3: Response to knowledge based questions

Question	Options	Interns *n*=08	PG/R *n*=26	Assistant professors *n*=28	Associate professors *n*=06	Professors *n*=07
1. Define pharmacovigilance	Process of improving safety of drugs	0	8	1	0	0
	Detection, assessment, understanding and prevention of ADR'S	3 (37.5)	5 (19.2)	11 (39.2)	4 (66.6)	5 (71.4)
	Science detecting type and incidence of ADR	1	12	9	2	1
	Science of monitoring ADR occurring in a hospital	4	1	7	0	1
2. Healthcare professionals responsible for reporting	Doctor	1	4	2	0	1
	Pharmacist	0	0	3	0	1
	Nurses	0	1	0	0	0
	All of the above	7 (87.5)	21 (80.7)	23 (82)	6 (100)	5 (71.4)
3. Method commonly employed to monitor ADR's	Meta-analysis	2	6	6	1	0
	Spontaneous reporting system	2 (25)	16 (61.5)	18 (64.2)	5 (83.3)	6 (85.7)
	Population studies	2	2	3	0	1
	Regression analysis	2	2	1	0	0
4. Regulatory body responsible for monitoring ADR's	Central Drugs Standard Control Organization	4 (50)	25 (96)	16 (57)	6 (100)	4 (57)
	Indian Council Of Medical Research	3	1	9	0	1
	Indian Clinical Research Institute	1	0	3	0	2
5. Location of NCC	AIIMS-New Delhi	1	15	15	4	7
	KEM-Bombay	0	2	4	1	0
	IPC-Ghaziabad	3 (37.5)	6 (23)	7 (25)	1 (16.6)	0
	IISC-Bangalore	4	3	2	0	0
6. Scale most commonly used to establish ADR causality	Hartwig scale	1	3	5	1	2
	Naranjo algorithm	1	5	6	0	2
	Schumock and Thornton scale	1	9	6	1	0
	WHO scale	5 (62.5)	9 (34.6)	11 (39.2)	4 (66.6)	3 (42.8)
7. Rare ADR's can be identified in which phase of a clinical trial	Phase-1	0	0	2	0	1
	Phase-2	2	3	3	2	2
	Phase-3	1	4	6	2	2
	Phase-4	5 (62.5)	19 (73)	17 (60)	2 (33.3)	2 (28.5)

Figures in parenthesis indicate percentage. PG/R=Postgraduate students/resident medical officers, ADR=Adverse drug reaction

Table 4: Response to attitude- and awareness-based questions

Question	Options	Interns *n*=08	PG/R *n*=26	Assistant professors *n*=28	Associate professors *n*=06	Professors *n*=07
1. Is reporting necessary	Yes	7	26	28	6	6
	No	1	0	0	0	1
2. Factors that discourage you from reporting	No remuneration for reporting	2	5	6	0	0
	Lack of time to report ADR	1	5	10	6	3
	A single unreported case may not affect ADR database	1	7	3	0	0
	Difficult to decide whether ADR has occurred or not	4	9	9	0	4
3. Is reporting a professional obligation	Yes	8	15	15	3	6
	No	0	5	10	0	1
	Don't know	0	6	2	1	0
	Perhaps	0	0	1	2	0
4. Opinion about establishing ADR monitoring center in every hospital	Should be in every hospital	4	17	17	3	6
	Not necessary in every hospital	2	1	3	0	0
	One in a city is sufficient	1	6	4	2	0
	Depends on number of bed size in the hospital	1	2	4	1	1
5. Is there any ADR monitoring centre under PVPI in your college affiliated hospital	Yes	2	3	0	0	1
	No	0	4	5	1	0
	Don't know	6	19	23	5	6
6. Do you require training program/workshop for pharmacovigilance activities under PVPI	Yes	8	26	28	6	7

PG/R=Postgraduate students/resident medical officers, ADR=Adverse drug reaction, PVPI=Pharmacovigilance Programme of India

Table 5: Response to practice-based questions

Question	Options	Interns *n*=08	PG/R *n*=26	Assistant professors *n*=28	Associate professors *n*=06	Professors *n*=07
1. Have come across an ADR	Yes	5	18	22	5	6
	No	3	8	6	1	1
2. Given training or attended workshops on ADR reporting	Yes	1	5	2	1	3
	No	7	21	26	5	4
3. Documented ADR's	Yes	2	5	7	1	3
	No	6	11	5	2	3
	Don't know about suspected ADR form	0	5	9	3	1
	Don't know how and where to report	0	5	7	0	0
4. Sending filled ADR forms to AMC	Yes	1	1	0	0	1
	No	6	22	26	5	6
	Filled but don't know how to send and where	1	3	2	1	0

PG/R=Postgraduate students/resident medical officers, ADR=Adverse drug reaction, AMC=ADR Monitoring Centre

to a large extent been impeded by the lack of coordinated spontaneous reporting which is a matter of concern, not only in India, but also around the world. Western investigators have attempted to investigate into the reasons behind under-reporting. Studies specific to Indian, as well as North-Eastern context, are necessary to identify the possible drawbacks specific to our system and take proper and adequate corrective measures. There are a number of studies to suggest that the attitude of health professionals towards ADR monitoring is a critical determinant of reporting rate.[8,9]

The responses to the knowledge-based questions in this study indicate an average degree of knowledge regarding diverse aspects of pharmacovigilance. There was no significant correlation between designation or duration of experience and the number of correct responses. The reasonable knowledge of the respondents observed in this study is at par with the findings of a study done by Kharkar and Bowalekar.[10] The awareness and practice parameters however do not match the relatively better standards of knowledge. Another study in Eastern India also noted good knowledge about ADR reporting, but attitude and perception/practice was an area of concern.[11] Majority (84%) of the respondents in this study had not received any training or attended any educational seminar/workshop/continuing medical education (CME) on pharmacovigilance, though all the respondents did feel a need for the same. Educational interventions have been found to update knowledge and consequently bring a greater degree of awareness to pharmacovigilance.[12-14] Concerted efforts aimed at an active and progressive enhancement of knowledge, through educational workshops, CME's, seminars, and clinical meets could possibly translate into better awareness and ADR reporting practices. This is an avenue where there is an ample scope of improvement, and needs to be certainly addressed.

A vast majority (97%) of the respondents shared the view that the reporting of ADR's was necessary, but only 63% considered it to be a professional obligation. It is an indication of a positive attitude toward the need to report, but a relative lack of commitment to do so. This finding is similar to another study in which 66.2% of respondents considered reporting to be a professional obligation.[15] In a study done by Pimpalkhute *et al*.[16] in Nagpur, only 35.7% of respondents, felt that ADR reporting was a professional commitment, which was much lower than that seen in our study. The uncertainty of whether an ADR had occurred (35%) and lack of time (33%) were the most important factors discouraging reporting. This finding is similar to studies done by Khan *et al*. and Reddy *et al*.,[15,17] which also cited a lack of time and determining causality of an ADR as the main reasons for under-reporting. Determining a possible causal relationship between an adverse reaction and a drug can be done very easily with popular and simple causality assessment tools such as the WHO-UMC scale and the Naranjo algorithm. Training pertaining to the use of these scales could remove a major deterrent of ADR reporting. 17% respondents cited the lack of remuneration for reporting as a discouraging factor, similar to findings in another study in Nagpur.[16] Financial incentives for reporting have been suggested in a study to enhance ADR reporting.[18] This however does not appear to be a viable solution, as this increases the possibility of dubious over reporting.[19]

A majority of the respondents (63%) opined that every hospital should establish an AMC, compared to the number of respondents who felt that it was not necessary in every hospital (8%), and that one center in a city was sufficient (17%). This indicates a positive attitude of the respondents toward the importance of ADR monitoring and the need to increase its presence as well as functional ambit. The need for establishing ADR monitoring centers in all the hospitals in India coincides with the view of

experts who have made similar recommendations.[20] 75% of the respondents agreed that they had come across an ADR, which clearly indicates that lack of ADR's is not a contributing factor to under-reporting. A vast majority (79%) of the participants were not aware of the presence of an AMC in the institute, did not know about the suspected ADR form (24%), and did not know how and where to report (16%), indicating an overwhelming lack of awareness about pharmacovigilance in general and the AMC at SMIMS, Gangtok in particular. Lack of awareness was also highlighted in a study by Hardeep *et al.*[21] in which 60.6% of the participants did not know how and where ADR's had to be reported. The dismal reporting practice is evident from the fact that only 24% had documented ADR's, and a miniscule 4% were sending filled ADR forms to the AMC. These findings indicate that concrete steps are required to make any meaningful increase in the existing reporting practices.

Some suggestions are offered on the basis of findings of this study.

1. The PvPI should be widely publicized in the visual and print media to make health professionals, as well as the general population at large aware of its presence and scope
2. CME's, workshops, symposia should be conducted at all AMC's, with assistance of funding agencies if necessary
3. Follow-up educational sensitization programs should be conducted at all the centers regularly to reinforce and emphasize the importance of pharmacovigilance and ADR monitoring
4. Pharmacovigilance should be integrated in undergraduate and postgraduate medical courses
5. The practice of reporting should gradually be incorporated as an essential part of the regular professional duties of health professionals
6. Paramedical staff like nurses and pharmacists should increasingly be involved in the reporting process
7. The process of reporting should be made as seamless, hassle free, convenient, and less time-consuming as possible
8. Coordination between the National Coordinating Centre, regional and peripheral AMC and the hospitals where the actual adverse drug event is encountered is required.

The attitude and perception of the study participants toward pharmacovigilance can thus be concluded to be positive. There is however an alarming deficiency of awareness regarding the process of ADR reporting as well as the presence and activities of the PvPI. The lack of reporting practices in this teaching hospital can thus to an extent, be attributed to these very reasons. It would be interesting to carry out a similar study after there has been an active educational and awareness campaign on the importance and technical aspects of the pharmacovigilance program and ADR reporting. A similar study could be carried out at peripheral health care centers of Sikkim to have an understanding of the outreach of the pharmacovigilance program. A KAP study in paramedical staff such as nurses and pharmacists could evaluate their knowledge and attitudes toward ADR monitoring.

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