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Original Research Article

A survey on knowledge, attitude and practice of pharmacovigilance and adverse drug reaction reporting among healthcare professionals in a tertiary care hospital of Bihar, India

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ABSTRACT

Background: This study was conducted to assess the knowledge, attitude and practice of pharmacovigilance (PV) and adverse drug reaction (ADR) reporting among healthcare professionals in a tertiary care hospital of Bihar.
Methods: It was a questionnaire based cross- sectional study carried out for a period of 3 months by a preformed structured questionnaire consisting of 19 questions (11 questions on knowledge, 5 on attitude and 3 on practices) in various departments of I.G.I.M.S., Patna. 120 filled questionnaires by healthcare professionals were collected from department and analysed for mentioned parameters. Among healthcare professionals there were 46 Interns, 20 junior and senior residents, 2 professors, 2 associate professors, 2 assistant professors, 48 nurses of the hospital. A descriptive analysis of data was done.
Results: Out of total 120 distributed questionnaires, 112 were completely filled up and considered for analysis. The response rate was 93.3%. Regarding knowledge, attitude and practice based questions 58.9% and 75% were knew the correct definition and important purpose of PV respectively. Among participants 62.5% have knowledge of post marketing surveillance studies done by Pharmaceutical companies and 79.4 % knew that within how many days serious adverse event (SAE) reported in India. Lack of time (36.6 %) followed by non- remuneration (33.3%) were major discouraging factor in ADR reporting. 36.6 % think reporting is a professional obligation for healthcare professionals and 19.6 % opined that ADR monitoring centre should be in every hospital. 89 % agree with necessity of ADR reporting where as 91% think PV should be taught in detail to healthcare professionals. 60.7 % had read an article on prevention of adverse drug reaction, 51.7 % had come across with an ADR and less than half (41.9 %) had been trained on how to report.
Conclusions: Findings strongly suggest that there is a great need to create awareness and to promote the reporting of ADR amongst prescribers since knowledge and awareness are the most important parameters that can minimize the under reporting of ADRs.

Keywords: Adverse drug reaction, Attitude and practice, Knowledge, Pharmacovigilance

INTRODUCTION

Every drug has therapeutic effect as well as harmful effects. These effects are only identified after the drug is widely used by a large community of the people. Clinical trial conducted prior to drug approval cannot uncover every aspect of health hazards of the approved drug. For example, teratogenic effects of thalidomide and more recently of isotretinoin were identified through observational method but not through experimental methods. So post marketing surveillance i.e. pharmacovigilance is the need of the hour.

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects of drugs, or any other drug-related problems.[1] Pharmacovigilance is particularly concerned with the adverse drug reactions (ADRs) which are defined as an unintended and noxious response to a drug that occurs at doses normally used for the

prophylaxis, diagnosis or therapy of diseases, or for the modification of physiological function.[2] None of the drug is free from adverse effects. Adverse drug reactions (ADRs) are responsible for about 5% to 20% of hospital admissions.[3,4] They affect both children and adults with varying magnitudes; causing morbidity and mortality.[5,6]

Pharmacovigilance Programme of India (PvPI) has been established by the Ministry of Health and Family Welfare, Government of India in July 2010 to provide the safe and effective healthcare system in India promote rational use of medicines. The programme is being coordinated by the Indian Pharmacopoeia commission (IPC), Ghaziabad as a National Coordination Centre (NCC). The goal of the programme is to ensure that the benefit of use of medicine outweigh the risk and thus safeguard the health of the Indian population. Any one such as Doctors, Nurses, Pharmacists, patient itself or their relatives can report adverse drug reaction to the ADR monitoring centre (AMC). Reports collected at AMC and causality assessment is done, data is entered in web based vigiflow and channelized to NCC. The generated data will then be forwarded to global pharmacovigilance database at the WHO-Upsala Monitoring Centre in Sweden.[7] In India the ADR reporting rate is less than 1% whereas the world wide rate is 5%.[8] Various study suggest that several reasons for under reporting of ADR in India are lack of interest and time, fear of litigation, ignorance, inadequate risk perception about newly marketed drugs, diffidence, insufficient training to identify ADRs, poor knowledge on reporting process and lack of awareness about PV program.[9] In order to improve participation of healthcare professionals in spontaneous reporting, it might be necessary to design strategies that modify Knowledge, Attitude, and Practice about Pharmacovigilance and ADR reporting.[10]

Thus, one of the aims of the study is to create awareness among healthcare professionals of this institution and with this we can move forward to inculcate the culture of ADR reporting. Therefore, this study was planned to assess and analyse the Knowledge, Attitude and Practice of pharmacovigilance and ADR reporting.

METHODS

It was a questionnaire based cross- sectional study carried out for a period of 3 months (April 2016-June 2016) by a preformed structured questionnaire consisting of 19 questions (11 questions on knowledge, 5 on attitude and 3 on practices) in various departments of I.G.I.M.S., Patna, Bihar, India.

Inclusion criteria

- Interns
- Residents
- Consultants
- Nurses

Exclusion criteria

- Pharmacist
- Undergraduate students and staffs
- Unanswered questions by a participant

Operational modality

A preformed structured questionnaire consisting of 19 questions (11 questions on knowledge, 5 on attitude and 3 on practice) were distributed directly to the participants in their respective department and the purpose of the study was explained. Any query regarding questionnaire were discussed and asked to fill questionnaire which was collected after one hour of distribution. The study protocol was approved from Institutional Ethics Committee of IGIMS, Patna.

Statistical analysis

The filled questionnaire was analysed question wise and their percentage value was calculated with the help of using Microsoft Excel spread sheet in MS Office2010.

RESULTS

Table 1: Demographic details and characteristic features of participants.

Category	Sub-Category	Total (n=112) %
Age (years)	**20-25**	23 (20.5)
	26-30	46 (41.0)
	31-35	28 (25)
	36-40	9 (8.0)
	41-45	4 (3.5)
	46-50	2 (1.7)
Sex	**Male**	59 (52.6)
	Female	63 (47.3)
Professional qualification	**Doctors**	71 (63.3)
	Nurses	41 (36.6)
Speciality	**MBBS**	46 (41.0)
	MD/MS	25 (22.3)
	BSc Nursing	31 (27.6)
	GNM	10 (8.9)
Work experience (Years)	**<1**	46 (41.0)
	1-5	20 (17.8)
	6-10	16 (14.2)
	11-15	20 (17.8)
	16-20	10 (8.9)

A total of 120 questionnaires about PV and ADR reporting were distributed among participants which include Interns (46), Residents (20), Consultants (5) and Nurses (41) in various department. 112 questionnaires were completely filled with response rate 93.3%. Among participants majority 41% were in the age group of 26-30

years. There were 59 males and 63 females which includes 71 doctors and 41 nurses. Among doctors 46 have MBBS degree and 25 have MD/ MS degree. In nurses 31 have BSc nursing and 10 have GNM degree.

Table 2: Assessment of knowledge of health care professionals regarding pharmacovigilance and ADRs.

Questions	Interns (46)		Residents (20)		Consultants (5)		Nurses (41)		Total (n=112)	
	Right	Wrong	Right	Wrong	Right	Wrong	Right	Wrong	Right	Wrong
Definition of pharmacovigilance	37 (80.4)	9 (19.5)	12 (60)	8 (40)	3 (60)	2 (40)	14 (34.1)	27 (65.8)	66 (58.9)	46 (41.0)
Important purpose of pharmaco-vigilance	42 (91.3)	4 (8.6)	16 (80)	4 (20)	4 (80)	1 (20)	22 (53.6)	19 (46.3)	84 (75)	28 (25)
Method use by pharmaceutical companies to monitor ADRs after drug launch	38 (82.6)	8 (17.3)	18 (90)	2 (10)	5 (100)	0 (0)	9 (21.95)	32 (78.0)	70 (62.5)	42 (37.5)
Serious Adverse Event (SAE) reported in India within how many days	35 (76.0)	11 (23.9)	14 (70)	6 (30)	3 (60)	2 (40)	37 (90.2)	4 (9.7)	89 (79.4)	23 (20.5)
The international centre for ADR monitoring is at	28 (60.8)	18 (39.1)	12 (60)	8 (40)	3 (60)	2 (40)	8 (19.5)	33 (80.4)	51 (45.5)	61 (54.4)
Drug banned due to ADR	26 (56.5)	20 (43.4)	14 (70)	6 (30)	2 (40)	3 (60)	4 (9.7)	37 (90.2)	46 (41.0)	66 (58.9)
Major risk factor for occurrence of maximum ADRs	34 (73.7)	12 (26.0)	15 (75)	5 (25)	4 (80)	1 (20)	16 (39.0)	25 (60.9)	69 (61.6)	43 (38.3)
Regulatory body responsible for monitoring ADR	31 (67.3)	15 (32)	10 (50)	10 (50)	3 (60)	2 (40)	14 (34.1)	27 (65.8)	58 (51.7)	54 (48.2)
Scales most commonly used to establish causality of an ADR	36 (78.2)	10 (21.7)	17 (85)	3 (15)	3 (60)	2 (40)	2 (4.8)	39 (95.1)	58 (51.7)	54 (48.2)
City where zonal/ subzonal centre placed	40 (86.9)	6 (13.0)	15 (75)	5 (25)	2 (40)	3 (60)	4 (9.7)	37 (90.2)	61 (54.4)	51 (45.5)
Healthcare professional responsible for reporting ADR	34 (73.9)	12 (26.0)	11 (55)	9 (45)	3 (60)	2 (40)	24 (58.5)	17 (41.4)	72 (64.2)	40 (35.7)

Regarding knowledge based questions 58.9% and 75% were knew the correct definition and important purpose of pharmacovigilance respectively. Among participants 62.5% have knowledge of post marketing surveillance studies done by Pharmaceutical companies and 79.4% knew that within how many days SAE reported in India. 45.5% had knowledge of International centre for ADR monitoring, 41% knew about drug banned due to ADR and 69% knew about major risk factors for occurrence of maximum ADRs. 51.7% knew about regulatory body responsible for monitoring ADR and scales most commonly used to establish causality of an ADR while 54.4% knew the city where zonal/subzonal centre placed. 64.2% participant believed that healthcare professional responsible for reporting of ADR (Table 2).

Regarding attitude based questions, lack of time (36.6 %) followed by non-remuneration (33.3%) were major discouraging factor in ADR reporting. 36.6 % think reporting is a professional obligation for healthcare professionals and 19.6 % opined that ADR monitoring centre should be in every hospital. 89 % agree with necessity of ADR reporting where as 91% think PV should be taught in detail to health care professionals (Table 3).

Regarding practice based questions, 60.7 % had read an article on prevention of adverse drug reaction, 51.7% had come across with an ADR and less than half (41.9 %) had been trained on how to report (Table 4).

DISCUSSION

The present study was conducted among healthcare professionals to evaluate the knowledge, attitude and practice of PV and ADR reporting in a tertiary care hospital. Response rate was 93.3% which is acceptable and comparable to previous studies. Higher percentage of female participants may be due to number female nursing staff working in the hospital. While looking at the age and working experience of the participants, mostly young healthcare professionals were participated in this study.

Regarding knowledge the result showed that doctors especially interns gave the more correct definition of pharmacovigilance compared to nurses, overall was 66% which is low, however a higher percentage (81%) of healthcare professionals knew the purpose of PV.

Table 3: Assessment of attitude of healthcare professionals regarding pharmacovigilance and ADRs.

Questions	Interns (46)	Residents (20)	Consultants (5)	Nurses (41)	Total (n=112)
	Response (%)	Response (%)	Response (%)	Response (%)	Response (%)
Which factor discourages you from reporting ADRs?	20 (43.4)	2 (10)	0 (0)	12 (29.9)	34 (30.3)
a) Non-remuneration	6 (13.0)	14 (70)	4 (80)	17 (41.4)	41 (36.6)
b) Lack of time	8 (17.3)	2 (10)	1 (20)	5 (12.1)	16 (14.2)
c) Single case not affect ADR database	12 (26.0)	2 (10)	0 (0)	7 (17.0)	21 (18.7)
d) Difficulty in decision whether ADR has occurred or not					
Do you think reporting is a professional obligation for you?	18 (39.1)	8 (40)	1 (20)	14 (34.1)	41 (36.6)
a) Yes	14 (30.4)	7 (35)	2 (40)	25 (60.9)	48 (42.8)
b) No	8 (17.3)	4 (20)	1 (20)	1 (2.4)	14 (12.5)
c) Don't know	6 (13.0)	1 (5)	1 (20)	1 (2.4)	9 (8.0)
d) Perhaps					
What is your opinion about establishing ADR monitoring centre in every hospital?	7 (15.2)	6 (30)	1 (20)	8 (19.5)	22 (19.6)
a) Should be in every hospital	12 (26.0)	7 (35)	2 (40)	24 (58.5)	45 (40.1)
b) Not necessary in every hospital	14 (30.4)	5 (25)	1 (20)	8 (19.5)	28 (25)
c) One in city is sufficient	13 (28.2)	2 (10)	1 (20)	1 (2.4)	17 (15.1)
d) Depends on number of bed size in the hospital					

Do you think reporting of ADR is necessary?	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
	40 (86.9)	6 (13)	18 (90)	2 (10)	3 (60)	2 (40)	38 (92.6)	3 (7.3)	98 (89)	14 (11)
Do you think PV should be taught in detail to health care professionals?	44 (95.6)	2 (4.3)	19 (95)	1 (5)	3 (60)	2 (40)	36 (88)	5 (12)	102 (91)	10 (8.9)

Table 4: Assessment of practice of healthcare professionals regarding pharmacovigilance and ADRs.

Questions	Interns (46)		Residents (20)		Consultants (5)		Nurses (41)		Total (n=112)	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Have you any time read an article on prevention of adverse drug reaction?	38 (82.6)	8 (16.6)	14 (70)	6 (30)	4 (80)	1 (20)	12 (29.2)	29 (70.7)	68 (60.7)	44 (39.2)
Have you ever come across with an ADR?	17 (36.9)	29 (63.0)	12 (60)	8 (40)	5 (100)	0 (0)	24 (58.5)	17 (41.4)	58 (51.7)	54 (48.2)
Have you ever been trained on how to report?	40 (86.9)	6 (13.0)	5 (25)	15 (75)	2 (40)	3 (60)	18 (43.9)	23 (56.0)	47 (41.9)	65 (58)

Doctors knew better about methods like post marketing surveillance by pharmaceutical companies to monitor ADR whereas nurses knew better about within how many days serious adverse effect reported in India. Participants' knowledge on the location of the international centre for ADR monitoring was only 45. 5% and only few participants were aware about the 'WHO online database' for reporting ADR and the most commonly used scales to establish the causality of an ADR. Knowledge of ADR reporting among nurses was very low as compared to that of Doctors. This is may be because of less awareness and education among nurses.

From the results, it was noticed that the main factor which discourage ADR reporting were lack of time among consultants & nurses where as non-remuneration in interns which concurs with study conducted by Chatterjee et al.[11]

A majority of the doctor opined that ADR reporting is necessary and it should be taught in detail to healthcare professionals. Various studies reported that all the ADRs encountered by healthcare professionals during their work are never reported.[12]

This study also showed the similar results. Regarding practice 68% participants had read an article on prevention of ADR and more than half of the participants had come across with ADR. Only 58% had been trained on how to report ADR. Considering the need to create awareness and to promote the reporting of ADR amongst healthcare professionals, our department which have ADR monitoring system are taking steps to improve the ADR reporting by organizing CME, workshops for clinicians and paramedical staffs, one to one contact with the clinicians, our technical associate is also working tirelessly round the clock to collect ADR reports. We have facilitated an easy contact and quick access to the hospital ADR monitoring centre with the help of toll free number displayed over OPD prescriptions. We are also organizing one workshop on ADR reporting exclusively for budding healthcare professionals the interns in our institute as they are the future clinicians as well as the backbone of our healthcare systems and by training them we are creating "agent of transformations" in the field of ADR reporting and pharmacovigilance.

The present study has some limitations such as the small population size and the study findings could not be applied to the wider medical community as the study was restricted to nurses and doctors working at Indira Gandhi Institute of Medical Sciences; Sheikhpura, Patna. Therefore we recommend that such type of similar studies should be conducted among healthcare professionals so as to develop strategies to improve the knowledge, attitudes, practice of PV & ADR reporting in India.

CONCLUSION

By this study we came to conclusion that ADR reporting can be improved by creating awareness and knowledge by continuous education and sensitization regarding PV and ADR reporting among healthcare professionals and the patients to achieve the final goal of Pharmacovigilance Programme of India. The nurses should also be encouraged to the ADR reporting, since they are in closure contact with the patients round the clock and they can play important role in making the pharmacovigilance programme more efficacious.

Awareness programmes among healthcare professionals, collaboration among healthcare professionals, training and making ADR reporting compulsory are the highly suggested ways to improve ADR reporting.

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REFERENCES

1. World Health Organization. Safety of Medicines: A guide to detecting and reporting adverse drug reactions, Geneva, 2002.
2. International drug monitoring: the role of national centres. Report of a WHO meeting. World Health Organ Tech Rep Ser. 1972;498:1-25.
3. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. Journal of the American Medical Association, 1998; 279(15): 1200-1205.
4. Pirmohamed M, James S, Meakin S, et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18,820 patients. British Medical Journal. 2004;329(7456):15.
5. Oshikoya KA, Adverse drug reaction in children: types, incidence and risk factors. Nige Jou Pediat. 2006;33:29-35.
6. Martinez-Mir I, Garcia-Lopez M, Palop V, Ferrer JM, Rubio E, Morales- Olivas FJ, A prospective study of adverse drug reactions in hospitalized children. British Journal of Clinical Pharmacology. 1999;47:681-8.
7. Singh A, Bhatt P. comparative evaluation of adverse drug reaction reporting forms for introduction of a spontaneous generic ADR form. Journal of Pharmacology and Pharmacotherapeutics. 2012;3(3):228-32.
8. Upadhyaya HB, Vora MB, Nagar JG, Patel PB. Knowledge, attitude and practices toward pharmacovigilance and adverse drug reactions in postgraduate students of tertiary care hospital in Gujarat. J Adv Pharm Technol Res. 2015;6(1):29-34.
9. Tandon VR, Mahajan V, Khajuria V, Gillani Z. Underreporting of adverse drug reactions: A challenge for pharmacovigilance in India. Indian J Pharmacol. 2015;47:65-71.
10. Desai CK, Iyer G, Panchal J, Shah S, Dikshit RK. An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. Perspect Clin Res. 2011;2(4):129-36.

11. Chatterjee S, Lyle N, Ghosh S. A survey of the knowledge, attitude and practice of adverse drug reaction reporting by clinicians in eastern India. Drug Saf. 2006;29:641-2.

12. Oshikoya KA, Awobusuyi JO: Perceptions of doctors to adverse drug reaction reporting in a teaching hospital in Lagos, Nigeria. BMC Clin Pharmacol. 2009;9:14.

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