Research Article

An evaluation of knowledge, attitude and perception about adverse drug reactions and pharmacovigilance among intern doctors at a teaching hospital of Rajasthan

Manoj Kumar Saurabh[1], Rakesh Kumar Karnani[2]

[1]Department of Pharmacology, GMERS Medical College, Gotri, Vadodara, Gujarat, India.
[2]Department of Pharmacology, Jhalawar Medical College, Jhalawar, Rajasthan, India.

Correspondence to: Manoj Kumar Saurabh, E-mail: manojkumarsaurabh@gmail.com

Received October 31, 2015. Accepted November 23, 2015

Abstract

Background: Underreporting of adverse drug reactions (ADRs) by clinician is a common problem. As interns will be budding doctors to serve the community, this study was undertaken to evaluate knowledge, attitude and perception about ADR and pharmacovigilance in them. **Aims and Objective:** To assess knowledge, attitude and perceptions of interns about ADR and pharmacovigilance program and find out possible ways of improving spontaneous reporting. **Materials and Methods:** A cross-section questionnaire-based study was conducted after approval by ethics committee. Pretested and validated questions consisting of 20 questions (knowledge 12, attitude 4, and perception 4) were administered to 68 interns. The filled questionnaires were collected and analyzed on Microsoft Excel sheet. **Result:** All interns were well aware of term "pharmacovigilance." They have an idea to where they should report ADR and about the nearest AMC center but only 3.33% were able to differentiate adverse effect and adverse event. Only 27.94% of the interns were revealing clear knowledge about who could report and types of the ADR to be reported at adverse drug monitoring center. Nobody was able to explain "rechallenge" or "dechallenge" in reference to ADRs 100% correctly. Majority of interns (85.29%) had not reported even single case of ADR till date. Poor reporting among interns were because of various reasons, which were busy in preparing postgraduate entrance examination (51.47%), problems in communicating patients (22.06%), inadequate training (22.06%), unavailability ADR form (4.41%), and overload of work (1.47%). Majority of interns (73.52%) were comfortable in ADR reporting by means of telephone. Of 68 interns, 48 (70.59%) supported that ADR reporting exercises should be taught in pharmacology practical classes. **Conclusion:** The deficit in ADR reporting can be resolved if we adequately train our undergraduates regarding ADR reporting system, how to report, importance of reporting, and their obligation to report.

KEY WORDS: Adverse Drug Reactions (ADRs); Interns; Pharmacovigilance; Spontaneous Reporting

Introduction

The pharmaceutical industry in India is growing at the rate of 12%–14% per annum, and its present value is about Rs. 90,000 crores.[1] Most important things are more and more new drugs are being introduced, which include new chemical entities (NCE), vaccines and new dosage forms, new routes of drug administrations, and new therapeutic claims of existing drugs. Drugs are foreign substance to our body, and it is administered to more than 1.2 billion of Indians with vast ethnic variation. So, they are suspected to cause adverse drug reactions (ADRs), which are defined by World Health Organization (WHO) as "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the modification of physiological function."[2]

Many studies have estimated that ADRs are the fourth to sixth leading causes of death, and they have 5% to 10% of the

Access this article online

Website: http://www.njppp.com

Quick Response Code:

DOI: 10.5455/njppp.2016.6.3110201593

hospital costs.[3] It is a major health problem affecting both mobility and mortality of people.[4,5] This increases the need of strong and effective adverse drug monitoring and pharmacovigilance program. WHO has defined pharmacovigilance as "The science and activities which are related to the detection, assessment, understanding and the prevention of adverse effects or any other drug related problems."[6] Most of the reporting of ADR is done by developed country. The ADR reporting rate in India is below 1% compared with the worldwide rate of 5%.[7,8]

After unsuccessful attempt in 1986 and 1987, the National Pharmacovigilance Program for India was started with sponsorship from the WHO and funding from the World Bank. The program was inaugurated on November 23, 2004, and became operational on January 1, 2005, under Central Drugs Standard Control Organization (CDSCO), New Delhi. But, it was not very effective to monitor ADR. The CDSCO, New Delhi, has launched Pharmacovigilance Program of India (PvPI) in July 2010 under Ministry of Health and Family Welfare, Government of India, and All India Institute of Medical Sciences (AIIMS), New Delhi, was the National Coordinating Center (NCC) to monitor ADR.[9] To implement program in a more effective way, NCC shifted to the Indian Pharmacopoeia Commission, Ghaziabad (Uttar Pradesh) in April 2011 under Uppsala Monitoring Center–World Health Organization (UMC–WHO). Presently, approximately, 150 ADR monitoring centers (AMC) are working in our country under NCC.

Our objectives of the study were to determine the knowledge, attitude, and practice about ADRs among first-batch intern doctors of Jhalawar in a teaching hospital of Rajasthan, India:

a. to assess knowledge about ADR and pharmacovigilance program;
b. to assess attitude and perceptions;
c. to focus possible ways of improving spontaneous reporting, so that when the budding doctors come into the community, their habit to report will develop, which will lead to the success of pharmacovigilance program for the safety of community.

Materials and Methods

This was a cross-sectional, questionnaire-based descriptive study that was conducted on first batch of intern doctors at Jhalawar Medical College-associated hospital. A set of 20 questions was prepared by the authors with the help of teachers of their department and previous published studies under knowledge, attitudes, and practice regarding pharmacovigilance and ADR.[7,8,10–13] The questions were suitably modified according to the need of the study. All questions were separately validated by a pilot study on 10 interns. Among 20 questions, sixteen were closed-ended question to assess knowledge and attitude, respectively, while four open-ended questions were to assess perceptions.

After obtaining the requisite permission from the institutional ethics committee of Jhalawar Medical College, the interns were instructed to tick the best possible option of each questionnaire to assess their knowledge and attitude and write answer to assess perceptions. Participants were given freedom to offer their suggestions regarding improvements of ADR reporting.

Result

A set of questionnaires were distributed among 68 students and asked to return the next day after completely ticking or filling it. Of the total 68 interns, 43 were male and 25 female subjects. Data analysis was done on Excel sheet. All interns were well aware of the term "pharmacovigilance," have an idea to where should report the ADR, and nearest AMC, but only 3.33% were able to differentiate adverse effect and adverse event. Only 27.94% of the interns showed clear knowledge about who could report and types of the ADR to be reported at AMC. Half of the interns knew the year of inauguration of National Pharmacovigilance Program (NPvP) whereas 60% of interns knew the sequence of ADR report form after submission. More than 40% of interns were unaware of mandatory pharmacovigilance unit or committee of own college whereas 85.29% of interns were well aware about the types of ADRs that would be reported. Of 68 interns, 57 revealed confusion about who could or whether nonmedical person can report ADR. No one could explain "rechallenge" or "dechallenge" in reference to ADRs 100% correctly [Table 1].

Reflection about attitude among interns toward ADR reporting and pharmacovigilance is shown in Table 2. Of 68 interns, 64.71% (44) interns believed that adverse drug reporting should be made compulsory for all doctors. All interns supported that pharmacovigilance would improve patient care and their safety. About 64.71% of interns supported that undergraduates and interns should have to take active part in ADR reporting. It was very unfortunate finding of our study that only 14.71% (10) had reported ADR to the concerned authority; majority of interns (85.29) had not reported even single case of ADR till date.

Reasons for poor reporting of ADR by clinician and interns are shown in Table 3; 50% of interns perceived that patients overload was the important reason for underreporting of ADR, whereas 20.59% and 14.70% of them gave reasons as nonmandatory of reporting ADR and undeveloped reporting culture, respectively. Some of the interns (11.76%) believed that no incentive for the reporter and few others that difficulty of reporting and apprehension about future problem were the reasons of less reporting. Poor reporting among interns were owing to various reasons, which were busy in preparing for postgraduate (PG) entrance examination (51.47%), problems in communicating patients (22.06%), inadequate training (22.06%), unavailability ADR form (4.41%), and overload of work (1.47%).

Majority of interns (73.52%) were comfortable in ADR reporting by means of telephone and by direct contact of faculty

Table 1: Knowledge among interns about adverse drug reaction and pharmacovigilance

Questionnaire No.	These questions were asked in form of multiple choice for assessing knowledge (*N* = 68)	Correct response, *n* (%)	Incorrect responses, *n* (%)
1.	Are you aware of the term of pharmacovigilance?	68 (100)	0 (0)
2.	Is it mandatory to have pharmacovigilance unit in the medical college?	48 (70.59)	28 (41.12)
3.	National pharmacovigilance program (PvPI) was officially inaugurated at New Delhi in the year	34 (50.00)	34 (50.00)
4.	Is any difference between ADR and ADE	2 (3.33)	66 (97.06)
5.	Is audit of pharmacovigilance mandatory?	58 (85.29)	10 (14.71)
6.	Who can report ADR?	19 (27.94)	49 (72.06)
7.	Where should you report ADR?	68 (100)	0 (0)
8.	Which types of ADR should be reported?	58 (85.29)	10 (14.71)
9.	The nearest AMC located at which medical college?	68 (100)	0 (0)
10	Can nonmedical people report ADR to a nearby medical person?	54 (79.41)	14 (20.59)
11.	ADR report submission follows which order	60 (88.24)	8 (11.76)
12.	Can you explain “rechallenge” or “dechallenge” in reference to adverse drug reactions 100% correctly?	0 (0)	68 (100)

members (14.71%). They were less like to report by filling ADR form, e-mail, or post. Of 68 interns, 48 (70.59%) supported that ADR reporting exercises should be included in pharmacology practical classes but 17.65% were against of it and others confused about it.

Discussion

Our study tried to evaluate knowledge, attitude, and perception about pharmacovigilance among intern doctors, as they were going to serve community. Patient safety should be prime importance for them. This study showed mixed response: they revealed fair knowledge on some points whereas lacking in some areas of pharmacovigilance. Interns showed right attitude for ADR reporting but the practice of its reporting was very poor. It was probably because of better sensitization to pharmacovigilance but they showed priority to prepare for postgraduation. All of the participants were aware of the nearest AMC and where should be ADR reported. It was higher than the studies conducted in Mumbai[10] and Mysore,[14] where nearly only 50% and 89% of participants, respectively, knew reporting center. The average knowledge score of interns was around 66%, but it varied from question to question as high as 100% to as low as 3.33%. This showed that education intervention is needed to train our undergraduates and interns. Our interns showed better knowledge in comparison with prescribers in study conducted by Desi et al.,[11] although they had been subjected to different questions. Only 14.71% of interns had reported ADR; poor reporting practice was seen not only in our study but also in the previous studies conducted in India, Nepal, and Nigeria,[8,10,11–13,15] which have shown poor knowledge, attitudes, and deficient practice of ADR among prescriber and health-care professionals. Our interns showed strong attitude of reporting of ADR as more than 64% of them supported to make reporting mandatory, whereas 72.06% revealed confusion regarding who should report the ADR. Right attitude of doctors (71%) was also observed in previous studies conducted by Gupta and Udupa among residents (90%),[10] Singh et al.[12] ad Belton et al.[16]

As per our interns observations, poor reporting of ADR among doctors were owing to patients overload (50%), reporting was not compulsory (20.59%), and lack of reporting culture (14.70%). The result of this study showed that the major factors that discourage the interns to report ADR were busy in preparing PG entrance examinaation (51.47%), problem

Table 2: Attitude among interns toward adverse drug reaction reporting and pharmacovigilance

Serial No.	These questions were asked for assessing attitude	*n* (%), *N* = 68	
1.	ADR reporting should be made compulsory for all doctors	44 (64.71)	24 (35.29)
2.	Pharmacovigilance would improve patient care and their safety	68 (100)	0 (0)
3.	Undergraduates and interns have to take active part in ADR reporting	44 (64.71)	24 (35.29)
4.	Have you reported any adverse drug reaction to department of pharmacology/pharmacovigilance committee to own institute or any AMC?	10 (14.71)	58 (85.29)

Table 3: Perceptions of interns toward adverse drug reaction and pharmacovigilance

Serial No.	Open-ended question were asked for assessing perception toward adverse drug reaction and pharmacovigilance	*n* (%)
1.	Reasons for underreporting of ADR by clinician (*N* = 68)	
	Patients overload	34 (50.00)
	Reporting is not mandatory	14 (20.59)
	Lack of well-developed ADR reporting culture	10 (14.70)
	Not any incentive for reporter	8 (11.76)
	Other factor(difficulty in reporting, apprehension about future problem)	2 (2.94)
2.	What are reasons that discourage you take part in pharmacovigilance program of India (*N* = 68)	
	Busy in preparing PG entrance examination	35 (51.47)
	Problems in communicating patients	15 (22.06)
	Inadequate training	14 (20.59)
	Unavailability of ADR form	3 (4.41)
	Overload of work	1 (1.47)
3.	By which mode of communication would you like to prefer while reporting ADR (*N* = 68)	
	Telephone	50 (73.52)
	Direct contact to pharmacology faculty	10 (14.71)
	By filling ADR form	6 (8.82)
	E-mail	1 (1.47)
	Post	1 (1.47)
4.	Do you think that ADR reporting exercises should be included in pharmacology practical classes (*N* = 68)	
	Yes	48 (70.59)
	No	12 (17.65)
	Cannot say	8 (11.76)

in communicating patients (22.06%), inadequate training (20.59%), and other (unavailability of ADR form, 4.41%, and work overload, 1.47%). As per abovementioned two findings, we can suggest educational intervention including training in communication skills for undergraduates and interns are needed to improve reporting. A study conducted by Tabeli et al.[17] noted that an educational intervention could increase the physicians' awareness and knowledge on ADR, which would increase reporting and ultimately improve patient's care.[17] This was also true and applicable for our interns. More than two-third of interns were wanted ADR reporting practical exercise to be included in undergraduate practical training. Many of medical colleges in our country have incorporated it.[18,19] We should also include it in practical learning, which can increase knowledge and awareness about ADR and would be helpful in developing ADR reporting culture. Our interns (73%) were more comfortable in reporting ADR by means of telephone, but study conducted among PG students (30.69%) by Upadhyaya et al.[20] showed that reporting with direct contact to faculty was preferred. Indian Pharmacopeia Commission has given toll-free number and mobile reporting software for the same. In addition, a technical associate to each of AMC, which would be helpful to overcome underreporting owing to patient overload. For the widening the reporter base, not only undergraduates, interns, doctor, and paramedical staffs but also consumers should be motivated, educated, and sensitized properly. This can be easily done by our undergraduates, interns, and residents. Spontaneous reporting of ADR from the patients is also common in developed country,[21] but we have to go miles in this regard.

Limitation of This Study

(i) Participation of study was voluntarily; (ii) answer (response) of closed-ended questions given by interns was totally depends on honesty of subjects included in the study; and (iii) our study was restricted to one center only.

Conclusion

The deficit in ADR reporting can be resolved when we adequately trained our undergraduates about ADR reporting system, how to report, importance of reporting, and their obligation to report. Continuous education intervention such as CME and workshop should be conducted in frequent intervals to refresh knowledge of interns and prescribers.

References

1. Pharmacovigilance Programme of India (PvPI) for Assuring Drug Safety. Available at: http://www.cdsco.nic.in/pharmacovigilance.htm Pharmacovigilance Programme of India (PvPI) for Assuring Drug Safety. Available athttp://www.cdsco.nic.in/pharmacovigilance.htm.

2. World Health Organization. International drug monitoring: the role of national centres. Report of a WHO meeting. World Health Organ Tech Rep Ser. 1972;498:1–25.
3. Srinivasan R, Ramya G. Adverse drug reaction causality assessment. Int J Res Pharm Chem. 2011;1(3):606–11.
4. Pirmohamed M, James S, Meakin S, Green C, Scott AK, Walley TJ, et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18820 patients. Br Med J. 2004;329:15–9.
5. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. JAMA. 1998;279:1200–55.
6. World Health Organization. Safety of Medicines: A Guide to Detecting and Reporting Adverse Drug Reactions. Geneva, Switzerland: WHO/EDM/QSM, 2002.
7. Sangeetha. Pharmacovigilance: the extent of awareness among the final year students, interns and postgraduates in a government teaching hospital. J Clin Diagn Res. 2012;6(7):1248–53.
8. Elizabeth ST, Kia RA, Yagnik RM, Nagaraju K. Knowledge, attitude and skills of nurses of Delhi towards adverse drug reaction reporting. Indian J Pharm Pract. 2012;5:45–51.
9. Pharmacovigilance Programme in India (PvPI)—Indian Scenario. Available at: http://www.ipc.gov.in/PvPI/Pv_home.html [accessed November 6, 2015] Pharmacovigilance Programme in India (PvPI)—Indian Scenario. Available at: http://www.ipc.gov.in/PvPI/Pv_home.html [accessed November 6, 2015].
10. Gupta P, Udupa A. Adverse drug reaction reporting and pharmacovigilance: knowledge, attitudes and perceptions amongst resident doctors. J Pharm Sci Res. 2011;3:1064–9.
11. Desi CK, Iyer G, Panchal J, Sah S, Dixit RK. An evolution of knowledge, attitude and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. Perspect Clin Res. 2011;2:129–36.
12. Singh H, Bajaj JK, Kumar R. A survey on the knowledge, attitude, and the practice of pharmacovigilance among the health care professional in a teaching hospital in northern India. J Clin Diagn Res. 2013;7:97–9.
13. Subish P, Izham MM, Mishra P. Evolution of knowledge, attitude and practices on adverse drug reactions and pharmacovigilance in a Nepalese hospital: a preliminary study. Internet J Pharmacol. 2008;6:1.
14. Ramesh M, Parthasarathi G. Adverse drug reaction reporting, attitudes and perceptions of medical practitioners. Asian J Pharm Clin Res. 2009;2:10–4.
15. 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.
16. Belton KJ, Lewis SC, Payne S, Rawlins MD, Wood S. Attitudinal survey of adverse drug reaction reporting by medical practitioners in the United Kingdom. Br J Clin Pharmacol. 1995;39:223–6.
17. Tabeli M, Jeschke E, Bockelbrink A, Willich SN, Ostermann T, Matthes H. An educational intervention to improve the physician reporting of adverse drug reaction (ADRs) in a primary care setting in complementary and alternative medicines programs. BMC Public Health. 2009;9:274.
18. Saurabh MK, Agrawal J. The opinion of undergraduate medical students on current curriculum and teaching methodology of pharmacology in four medical colleges of India: a questionnaire based study Int J Basic Clin Pharmacol. 2015;4(5):970–5.
19. Naeem SS, Rizvi W, Kumar A. Revisiting undergraduate practical pharmacology. J Pharmacol Pharmacother. 2012;3(1):76–9.
20. 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;6:29–34.
21. de Langen J, van Hunsel F, Passier A, de Jong-van den Beg LT, van Grootheest K. Adverse drug reporting by patients in the Netherlands: three years of experience. Drug Saf. 2008;31:514–24.

How to cite this article: Saurabh MK, Karnani RK. An evaluation of knowledge, attitude and perception about adverse drug reactions and pharmacovigilance among intern doctors at a teaching hospital of Rajasthan. Natl J Physiol Pharm Pharmacol 2016;6:111-115

Source of Support: Nil, **Conflict of Interest:** None declared.