

Original Research Article

A questionnaire based cross sectional study of the knowledge, attitude and practice of pharmacovigilance among the health care professionals in a tertiary care teaching hospital in upper Assam, India

Swapnanil Gohain, Sahid Aziz*, Meghali Chaliha

Department of Pharmacology, Jorhat Medical College & Hospital, Jorhat, Assam, India

Received: 02 August 2019

Accepted: 09 September 2019

*Correspondence:

Dr. Sahid Aziz,

E-mail: drshahidaziz86@gmail.com

Copyright: © the author(s), publisher and licensee Medip Academy. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

ABSTRACT

Background: Adverse drug reactions (ADR) are one of the major reason of morbidity, mortality and increase in health-care costs. The pharmacovigilance programme of India (PvPI) encourages the active participation of all health care professionals (HCP) in reporting suspected ADR to ensure enhanced patient safety. But present statistics shows under reporting of suspected ADR. So, this study was undertaken with the objectives of assessing knowledge, attitude and practice (KAP) of pharmacovigilance among the HCP and to evaluate various reasons of under reporting of suspected ADR.

Methods: This is a cross-sectional observational study of knowledge, attitude and practice (KAP) of HCP including faculties, resident doctors and postgraduate trainee (PGT), internship doctors and nurses on pharmacovigilance; conducted at department of Pharmacology, Jorhat Medical College and Hospital(JMCH). The pretested and peer reviewed questionnaire was distributed among 150 HCP and the responses were collected after one day. Data were analyzed using MS-excel software and was expressed in percentage.

Results: Out of 150 questionnaires, 118 responses were received (32 faculties, 27 PGT, 38 internship doctors and 21 nurses). Good knowledge (78.4%) and fair attitude was found among the HCP but there was lack of practice of pharmacovigilance due to reasons mainly non availability of suspected ADR reporting form (27.1%), didn't think reporting was necessary (34%), fear of consequences (16.1%) and lack of awareness (16.1%) among others.

Conclusions: Good attitude was observed among HCP. With proper measures like sensitization and educational intervention ADR, reporting may be improved in the future.

Keywords: Adverse drug reactions, Attitude, Health-care Professionals Practice, Knowledge, Pharmacovigilance

INTRODUCTION

Adverse drug reactions (ADR) are any noxious and unintended response to a medicinal product.¹ It is one of the major reasons for morbidity, mortality and also increase in health care costs.^{2,3} As per the WHO guidelines and government regulations, it is mandatory for all Pharmaceutical companies to survey and report ADR related to newly marketed drugs as a part of Post Marketing Surveillance (PMS). But it is impossible to

detect long term effects and possible ADR during the development phase itself. Therefore it is necessary to continue vigilance for any possible ADR for both newly marketed as well as the older drugs in the market. Spontaneous reporting system (SRS) is the major method of monitoring safety of drugs.⁴

The Pharmacovigilance Programme of India (PvPI) is a constant endeavour which encourages the active participation of all health care professionals (HCP)

including doctors, nurses, pharmacists and medical students in reporting any suspected ADR to the CDSCO by filling an suspected ADR reporting form.⁵ As the PvPI is still in a very nascent stage, there is under reporting of ADR in the entire country mainly due to lack of awareness and unfavourable attitude among the HCP.⁶

Therefore, this study was undertaken with the aims and objectives to assess the knowledge, attitude and practice of pharmacovigilance and ADR reporting among the HCP at Jorhat Medical College & Hospital (JMCH), a tertiary care teaching hospital in Upper Assam, and to evaluate the various reasons of under reporting of suspected ADR to ADR monitoring centre (AMC). JMCH has been recognized as an AMC under PvPI since 2014. Although there is regular reporting of ADR from the AMC of JMCH, there are still scopes of increasing the reporting culture.

METHODS

This was a cross-sectional, observational, questionnaire based study, conducted at the Department of Pharmacology, JMCH after obtaining prior ethical approval from the Institutional Ethics Committee (IEC) Human, JMCH (Approval letter no. SMEJ/JMCH/MEU/841/Pt-1/2011/5339).

The study was conducted within a period of three months from June 2018 to August 2018. Health-care professionals including faculties, PGT, internship doctors and nurses of tertiary care teaching hospitals in Upper Assam, India.

Inclusion criteria

Health care professionals working in the hospital during the study period and who were willing to participate in the study after providing informed consent.

Exclusion criteria

Those who refused to give informed consent.

KAP questionnaire was designed by referring to previous studies 7,8,9. The questionnaire was pretested in a small group of doctors and nurses by doing a pilot study. Modified questionnaire (Annexure I) was distributed among HCP including faculties, resident doctors and post graduate trainees (PGT), internship doctors and nurses. Informed consent was obtained from each participant prior to obtaining their responses. The questionnaire was designed to assess the knowledge and attitude towards pharmacovigilance and their practice of reporting ADR to the concerned authority and the AMC.

There were 20 questions in all. One question was related to professional details of the respondents, 6 questions were asked to assess the knowledge, 7 questions were asked to assess attitude towards pharmacovigilance, 5 questions were asked to evaluate practice of pharmacovigilance and ADR reporting and one question was to assess various reasons of under reporting. The questionnaire was distributed among 150 health care professionals. One day time was given to each respondents to respond to the questionnaire.

Statistical Analysis

Data analysis was carried out using MS Excel spread sheet and GraphPad Prism V5 software. The results were expressed in percentage (%).

RESULTS

The questionnaires were distributed among 150 health care professionals including 40 faculties, 35 PGT, 40 internship doctors and 35 nurses, 118 (78.66%) (Table 1) responses obtained in total and 32 remained non respondent. The results were analyzed taking n=118.

Table 1: Professional details.

| Characteristics | Total | Faculty | PGT/Residents | Internship doctors | Nurses |
|-----------------|----------|----------|---------------|--------------------|----------|
| Sample size | 150 | 40 | 35 | 40 | 35 |
| Responders | 118 (=N) | 32 (80%) | 27(77.14) | 38(95%) | 21(60%) |
| Non responders | 32 | 8(20%) | 8 (22.86%) | 2 (5%) | 14 (40%) |

In this study, the HCP had good knowledge about ADR. While the faculties and PGT had good knowledge on pharmacovigilance and PvPI, but only half of the internship doctors (57.9%) and nurses (47.6%) could respond correctly. 81.3% and 70.4% of faculties and PGT respectively were correct about who can report ADR against 52.6% and 66.7% of internship doctors and nurses respectively (Table 2).

Majority of health care professionals think that herbal medicine can cause ADR and should be reported. Majority of health care professionals showed supportive attitude towards ADR reporting being made mandatory, need of sensitization on pharmacovigilance and also think that ADR reporting may benefit health care delivery system and improve patient safety. While 87.5% faculties and 70.4% PGT were aware of existence of AMC in their

institute, but only 42.1% internship doctors and 42.8% nurses were aware of the same. A huge proportion of internship doctors (73.7%) had not seen ADR reporting

form and a majority of the health care professionals were not aware of existence of mobile software and application for ADR reporting (Table 3).

Table 2: Results showing Knowledge on Pharmacovigilance among health care professionals.

| Questions | Faculties n (%) | | | PGT/Residents n (%) | | | Internship doctors; n (%) | | | Nurses n (%) | | |
|---|-----------------|---------------|-------------|---------------------|---------------|-------------|---------------------------|---------------|-------------|--------------|---------------|-------------|
| | Correct/ Yes | Incorrect/ No | No response | Correct/ Yes | Incorrect/ No | No response | Correct/ Yes | Incorrect/ No | No response | Correct/ Yes | Incorrect/ No | No response |
| What is an ADR? | 32 (100) | 0 (0) | 0 (0) | 27 (100) | 0 (0) | 0 (0) | 37(97.4) | 0 (0) | 1(2.6) | 20 (95.2) | 0 (0) | 1 (4.8) |
| What is Pharmacovigilance? | 24 (75) | 3 (9.4) | 5 (15.6) | 25 (92.6) | 2 (7.4) | 0 (0) | 22 (57.9) | 11 (28.9) | 5 (13.2) | 10 (47.6) | 7 (33.3) | 4 (19.1) |
| What is PvPI stands for? | 24 (75) | 1 (3.1) | 7 (21.9) | 18 (66.7) | 2 (7.4) | 7 (25.9) | 22 (57.9) | 0 (0) | 16 (42.1) | 10 (47.6) | 5 (23.8) | 6 (28.6) |
| Who can report an ADR? | 26 (81.3) | 5 (15.6) | 1 (3.1) | 19 (70.4) | 8 (29.6) | 0 (0) | 20 (52.6) | 18 (47.4) | 0 (0) | 14 (66.7) | 5 (23.8) | 2 (9.5) |
| Do you think herbal medicine can cause ADR? | 31 (96.9) | 1 (3.1) | 0 (0) | 27 (100) | 0 (0) | 0 (0) | 34 (89.5) | 4 (10.5) | 0 (0) | 16 (76.2) | 5 (23.8) | 0 (0) |
| Have you ever seen any suspected ADR? | 29 (90.6) | 3 (9.4) | 0 (0) | 23 (85.2) | 4 (14.8) | 0 (0) | 26 (68.4) | 12 (31.6) | 0 (0) | 19 (90.5) | 0 (0) | 2 (9.5) |
| Correct responses | 86.45% | | | 85.80% | | | 70.61% | | | 70.63% | | |
| Over all average knowledge | 78.4% | | | | | | | | | | | |

Table 3: Results showing Attitude on Pharmacovigilance and ADR reporting among health care professionals.

| Questions | Faculties n (%) | | | PGT/Residents n (%) | | | Internship doctors; n (%) | | | Nurses n (%) | | |
|---|-----------------|-----------|-------------|---------------------|-----------|-------------|---------------------------|-----------|-------------|--------------|-----------|-------------|
| | Yes | No | No response | Yes | No | No response | Yes | No | No response | Yes | No | No response |
| Are you aware of existence of AMC in your institution? | 28 (87.5) | 4 (12.5) | 0 (0) | 19 (70.4) | 8 (29.6) | 0 (0) | 16 (42.1) | 20 (52.6) | 2 (5.3) | 9 (42.9) | 7 (33.3) | 5 (23.8) |
| Do you think reactions due to herbal medicinal product should be reported? | 32 (100) | 0 (0) | 0 (0) | 27 (100) | 0 (0) | 0 (0) | 37 (97.4) | 0 (0) | 1 (2.6) | 17 (81) | 4 (19) | 0 (0) |
| Have you seen the ADR reporting form? | 22 (68.8) | 10 (31.2) | 0 (0) | 17 (63) | 10 (37) | 0 (0) | 10 (26.3) | 28 (73.7) | 0 (0) | 15 (71.4) | 2 (9.5) | 4 (19.1) |
| Are you aware of mobile software and application for suspected ADR reporting? | 16 (50) | 16 (50) | 0 (0) | 8 (29.6) | 19 (70.4) | 0 (0) | 4 (10.5) | 34 (89.5) | 0 (0) | 0 (0) | 19 (90.5) | 2 (9.5) |
| Do you think ADR reporting should be made mandatory? | 30 (93.7) | 2 (6.3) | 0 (0) | 27 (100) | 0 (0) | 0 (0) | 38 (100) | 0 (0) | 0 (0) | 17 (81) | 1 (4.7) | 3 (14.3) |
| Do you think sensitization to Pharmacovigilance is necessary? | 32 (100) | 0 (0) | 0 (0) | 27 (100) | 0 (0) | 0 (0) | 37 (97.4) | 0 (0) | 1 (2.6) | 19 (90.5) | 0 (0) | 2 (9.5) |
| Do you think ADR reporting will benefit the health care delivery system? | 31 (96.9) | 0 (0) | 1 (3.1) | 27 (100) | 0 (0) | 0 (0) | 36 (94.8) | 1 (2.6) | 1 (2.6) | 14 (66.7) | 1 (4.7) | 6 (28.6) |

While majority of respondents had said that ADR reporting forms were available at their workplace, but only a little fraction of PGT (18.5%) and none of the internship doctors had ever reported an ADR. A large

number of respondents had never attended any sensitization programme and only a smaller fraction had

visited AMC of their institute (Table 4). Among various reasons of under reporting of ADR, 33.9% respondents think that it is not necessary to report ADR; 27.1% responded that ADR reporting form were not available at their workplace and 16.1% had responded lack of awareness and fear of consequences as the major reasons of under reporting (Table 5).

Table 4: Results showing Practice of Pharmacovigilance and ADR reporting among health care professionals.

| Questions | Faculties n (%) | | | PGT/Residents n (%) | | | Internship doctors; n (%) | | | Nurses n (%) | | |
|--|-----------------|---------------|-------------|---------------------|---------------|-------------|---------------------------|---------------|-------------|--------------|---------------|-------------|
| | Correct/ Yes | Incorrect/ No | No response | Correct/ Yes | Incorrect/ No | No response | Correct/ Yes | Incorrect/ No | No response | Correct/ Yes | Incorrect/ No | No response |
| Is ADR reporting form available at your workplace? | 22 (68.8) | 9 (28.1) | 1 (3.1) | 17 (63) | 10 (37) | 0 (0) | 15 (39.5) | 20 (52.6) | 3 (7.9) | 11 (52.4) | 5 (23.8) | 5 (23.8) |
| Have you ever reported any suspected ADR? | 16 (50) | 16 (50) | 0 (0) | 5 (18.5) | 22 (81.5) | 0 (0) | 0 (0) | 38 (100) | 0 (0) | 11 (52.4) | 8 (38.1) | 2 (9.5) |
| Did you encounter any difficulty while reporting? | 2 (6.4) | 22 (68.8) | 8 (25.0) | 4 (14.8) | 11 (40.7) | 12 (44.5) | 9 (23.7) | 16 (42.1) | 13 (34.2) | 5 (23.8) | 5 (23.8) | 11 (52.4) |
| Have you attended any sensitization programme? | 18 (56.3) | 14 (43.7) | 0 (0) | 2 (7.4) | 25 (92.6) | 0 (0) | 1 (2.6) | 37 (97.4) | 0 (0) | 10 (47.6) | 9 (42.9) | 2 (9.5) |
| Have you ever visited the AMC in your institution? | 16 (50) | 16 (50) | 0 (0) | 12 (44.5) | 14 (51.8) | 1 (3.7) | 4 (10.5) | 33 (86.9) | 1 (2.6) | 9 (42.9) | 10 (47.6) | 2 (9.5) |

Table 5: Reasons of under reporting of ADRs.

| Reasons | Frequency N(%) |
|--|----------------|
| Don't think necessary | 40 (33.9) |
| ADR reporting forms not available at workplace | 32 (27.1) |
| Fear of consequences | 19 (16.1) |
| Lack of awareness | 19 (16.1) |
| Lack of emphasis and effort | 1(0.8) |
| Lack of sensitization about ADR reporting | 2 (1.7) |
| High patient load | 1(0.8) |
| Lack of time | 1(0.8) |
| Lengthy procedure | 2 (1.7) |
| Difficult to report | 1(0.8) |
| Others | 13 (11.0) |
| No response | 3 (2.5) |

DISCUSSION

The proper implementation and success of PvPI greatly depends on the spontaneous reporting of ADR, but the same is also related to under reporting of ADR.² Among several factors, the spontaneous reporting of ADR primarily depends on the proper knowledge, attitude and

practice of pharmacovigilance and ADR reporting among the various health care professionals.

Therefore the present study was conducted to assess the knowledge, attitude and practice of pharmacovigilance among the health care professionals in a tertiary care teaching hospital in Upper Assam and to evaluate various reasons of its under reporting. Although a few similar studies were conducted in Assam, but data pertaining to Upper Assam was lacking. This study was first of its kind in Upper Assam.

In this study, the knowledge on pharmacovigilance and PvPI was low among internship doctors and nurses (57.9% and 47.6% respectively), 47.4% internship doctors followed by 29.6% PGT had incorrect knowledge on who can report an ADR. But the average percentage of correct responses by all the respondents was 78.4% suggesting that the HCP had good knowledge on ADR and pharmacovigilance. In a study by Het. B. Upadhyaya et.al found lack of knowledge on pharmacovigilance among PGT (64.08%).¹⁰ In another study by MB Vora et.al. it was found that average knowledge on pharmacovigilance among PGT and faculties were

27.82% and 40.76% respectively, which was lower compared to our study.¹¹

In this study, authors found a mixed attitude towards pharmacovigilance practice by the health care professionals. Majority of the respondents were aware of existence of AMC in their institute. More than 90% of respondents think ADR reporting should be made mandatory, 97% respondents think sensitization about pharmacovigilance is necessary and 89.6% respondents think it will benefit the health care delivery system and patient safety. In a similar study conducted by Monika Agarwal et al, also found similar attitude among health care professionals.⁵ In their study, more than 90% respondents thought ADR reporting should be made mandatory and the practice of ADR reporting would contribute to patient safety in the long run. Although several studies and the present study suggested that ADR reporting should be made mandatory, it remains a matter of debate as compulsion may lead to false reporting and may compromise the quality of reporting and data generated.^{2,5,10} In our study 42.4% respondents had never seen ADR reporting form and 75% were not aware of existence of any ADR reporting mobile application and software.

This study also demonstrated poor practice of pharmacovigilance among HCP, 50% of faculties and 52.4% nurses had reported suspected ADR to their AMC, while only 18.5% PGT and none of the interns had reported any ADR. Only 26.3% of respondents had attended sensitization programme on pharmacovigilance in their institution. Srinivasan et.al in their study had found favourable attitude towards pharmacovigilance as 83.9% of the respondents thought reporting ADR was necessary and 91.3% thought it was necessary to teach health care professionals about pharmacovigilance in details.¹² But despite a favourable attitude in their study, they found poor practice of ADR reporting among different HCP (36.5%). Similar results were also found in a study by Supratim Dutta et al, and Subramanyam Ganesan et al, in their studies.^{13,14}

Under reporting of ADRs has been the major cause of concern for the success of PvPI.¹² Several studies had suggested multiple factors that contribute to under reporting of ADR. The major reasons of under reporting of ADR cited by various previous studies were cumbersome procedure, feeling of extra work, lack of time, fear of litigation from various stakeholders, insufficient knowledge on whom to and how to report, does not think necessary, insufficient clinical knowledge, busy schedule, lack of incentives, patient confidentiality issues etc.^{6,15-18.}

The major reasons of ADR under reporting found in our study were non-availability of ADR reporting forms, didn't think reporting was necessary, fear of consequences, lack of awareness and sensitization to pharmacovigilance etc. Other noteworthy reasons were high patient load, lack of time, lack of knowledge about

ADR reporting, lack of guidelines, lengthy and difficult procedures of reporting etc.

In this study and other studies from various parts of the country had demonstrated that Indian health care professionals have a favorable attitude towards pharmacovigilance, but due to the reasons as discussed above had led to under reporting of ADR.¹²⁻¹⁴ If proper measures like training of HCP on pharmacovigilance, conducting sensitization programmes to increase awareness, educational intervention at the level of undergraduate curriculum and favorable work environment are provided to the HCP, the rate of reporting may be improved.

CONCLUSION

The present study clearly indicates the good knowledge of the health care professionals and a fair attitude on pharmacovigilance. But the translation of the knowledge and attitude to practice is however not satisfactory. This suggests that a lot needs to be done to improve the practice of pharmacovigilance, especially among the internship doctors, PGT. Educational intervention as discussed above, will immensely help bridge this transitional gap in future.

ACKNOWLEDGEMENTS

Authors acknowledge the help of all the health care professionals who took part in this study. authors also acknowledge the help provided by the faculties of the Department of Pharmacology, Jorhat Medical College and Hospital, Assam, India.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: Ethical approval for the study was obtained from the Institutional Ethics Committee (Human) bearing approval number SMEJ/JMCH/MEU/841/Pt-1/2011/ 5339 on 5th May 2018.

REFERENCES

- Schurig AM, Böhme M, Just KS, Scholl C, Dormann H, Plank-Kiegele B, et al. Adverse Drug Reactions (ADR) and Emergencies: The Prevalence of Suspected ADR in Four Emergency Departments in Germany. *Deutsches Ärzteblatt Int.* 2018 Apr;115(15):251-8
- Ahmed A, Patel I, Balkrishnan R, Mohanta GP, Manna PK. An evaluation of knowledge, attitude and practice of Indian pharmacists towards adverse drug reaction reporting: A pilot study. *Perspect Clin Res.* 2013 Oct-Dec;4(4):204-10.
- Dhikav V, Singh S, Anand KS. Adverse drug reaction monitoring in India. *J Ind Aca Clin Med.* 2004;5(1):27-33.
- Guidance Document for Spontaneous Adverse Drug Reaction Reporting version 1.0. Indian

- Pharmacopoeia Commission. National Coordination Centre- Pharmacovigilance Programme of India. Ministry of Health and Family Welfare, Government of India; 2014.
5. Agarwal M, Ahmed J, Roy V. Knowledge, Attitude and Practice About Pharmacovigilance Among Healthcare Providers of a Tertiary Care Teaching Hospital in New Delhi (India). *MAMC J Med Sci.* 2017;3(3):146-51.
 6. Tandon VR, Mahajan V, Khajuria V, Gillani Z. Under-reporting of adverse drug reactions: A challenge for pharmacovigilance in India. *Ind J Pharmacol.* 2015;47(1):65-71.
 7. Borah A, Bezbaruah BK, Gohain S, Singha B. Knowledge, Attitude and Practices of Pharmacovigilance among junior doctors of a tertiary health care institute in North East India. *Sch J App Med Sci.* 2016;4(9A):3248-53.
 8. Palaian S, Ibrahim MI, Mishra P. Health professionals' knowledge, attitude and practices towards pharmacovigilance in Nepal. *Pharm Pract.* 2011;9(4):228-35.
 9. Meher BR, Joshua N, Asha B, Mukherji D. A questionnaire based study to assess knowledge, attitude and practice of pharmacovigilance among undergraduate medical students in a Tertiary Care Teaching Hospital of South India. *Perspect Clin Res.* 2015 Oct-Dec;6(4):217-21.
 10. Upadhyaya HB, Vora MB, Nagar JG, Patel PB. Knowledge, attitude and practices towards pharmacovigilance and adverse drug reactions in postgraduate students of Tertiary Care Teaching Hospital in Gujrat. *J Adv Pharm Technol Res.* 2015 Jan-Mar; 6(1):29-34.
 11. Vora MB, Barvaliya M. Knowledge, attitude and practices towards pharmacovigilance and adverse drug reactions in health care professional of tertiary care hospital, Bhavnagar. *Int J Pharm Sci Res.* 2014 Nov;5(11):820-6.
 12. Srinivasan V, Sheela D, Mridula D. Knowledge, attitude and practice of pharmacovigilance among the healthcare professionals in a tertiary care hospital-A questionnaire study. *Biomed and Pharmacol J.* 2017;10(3):1441-7.
 13. Dutta S, Sengupta S. An evaluation of knowledge, attitude and practice of adverse drug reaction reporting in a tertiary care teaching hospital of Sikkim. *Persp Clin Res.* 2015 Oct-Dec;6(4):200-6.
 14. Ganesan S, Vikneswaran G, Reddy KC, Subrahmanyam DK, Adithan C. A survey on knowledge, attitude and practice of pharmacovigilance towards adverse drug reactions reporting among doctors and nurses in a tertiary care hospital in South India. *J Young Pharm.* 2016;8(4):471-6.
 15. Gupta P, Udupa A. Adverse drug reaction reporting and pharmacovigilance: Knowledge, attitudes and perceptions amongst resident doctors. *J Pharm Sci and Res.* 2011;3(2):1064-9.
 16. Hardeep JK, Rakesh K. A survey on the knowledge, attitude and the practice of pharmacovigilance among the health care professionals in a teaching hospital in northern India. *J Cli Dia Res: JCDR.* 2013 Jan;7(1):97.
 17. Gupta R, Malhotra A, Malhotra P. A study on determinants of underreporting of adverse drug reactions among resident doctors. *Int J Res Med Sci.* 2018 Feb;6(2):623-7.
 18. Rishi RK, Patel RK, Bhandari A. Under reporting of ADRs by medical practitioners in India-Results of pilot study. *Adv Pharmacoepeidem Drug Safety.* 2012;1(3):112.

Cite this article as: Gohain S, Aziz S, Chaliha M. A questionnaire based cross sectional study of the knowledge, attitude and practice of pharmacovigilance among the health care professionals in a tertiary care teaching hospital in upper Assam, India. *Int J Res Med Sci* 2019;7:3833-8.