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Original Research Article

Knowledge, attitude and practice of pharmacovigilance among medical professionals at a tertiary care hospital in Mumbai, Maharashtra, India

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ABSTRACT

Background: Many adverse drug reactions (ADRs), interactions and specific toxicities are known once drug is exposed to a larger population. Spontaneous reporting adverse events (AEs) are fundamental to a robust pharmacovigilance (PhV). Increasing physician awareness about the pharmacovigilance and ADR reporting can significantly contribute the safety of medicines. Objective of the study was to assess the knowledge, attitude and practices related to PhV among medical professionals at a tertiary care teaching hospital.
Methods: Postgraduate students (PGs) and medical teachers at a Medical College and tertiary care hospital were evaluated for their knowledge, attitude and practice of pharmacovigilance with the help of a structured questionnaire. Suggestions for improving the effectiveness of the pharmacovigilance practices were also sought.
Results: One-hundred and fifty doctors [91 (60.7%) PGs and 59 (39.3%) medical teachers] participated. Overall, 48.7% were males. 96% believed that PhV is important in medical practice but only 79.3% knew the definition of pharmacovigilance. Only 24.7% were aware of the existing nationwide pharmacovigilance program whereas the international collaborating center was known to 26% of the participants. 96% believed that it is the duty of a treating physician to report an ADR while 36.7% felt that ADR reporting should be the responsibility of a separate team. Surprisingly, 54% felt that financial aid should be provided for ADR reporting. 42.7% have not reported any ADR whilst only 16% have reported more than 10 ADRs in their career. To create an ADR database (79.3%) was the common expectation from the PhV center. 98.7% suggested continued medical education (CME) and trainings to improve the effectiveness of PhV in Indian setting.
Conclusions: Regardless of a fair attitude towards PhV, the practice of ADR reporting is poor probably because of lack of sufficient knowledge about PhV. Motivating the physicians through CMEs and trainings so as to improve and strengthen the pharmacovigilance practices is the current need in India.

Keywords: ADR, Attitude, Doctors, Knowledge, Practice, Spontaneous reporting

INTRODUCTION

World health organization (WHO) defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.[1] Once a medicine leaves the protected and scientific environment of clinical development, a larger population is exposed. It is therefore essential that medicines are monitored for their safety and effectiveness

in real-life situation.[1,2] Many adverse effects of the drug, drug interactions, interactions with food and other risk factors like specific toxicities are known years after release of a medicine. Some rare adverse effect (1:100000) manifest only after the exposure of drug to a large population.[1,3] Such rare adverse effects of a drug can only be known through effective pharmacovigilance.

Various methods of detecting an adverse event include spontaneous reporting, prescription event monitoring (PEM) and others.[4] Reporting of adverse events (AEs) from doctors to adverse drug reactions (ADRs) database by use of these methods can significantly impact the signal detection of unexpected and rare ADRs. Further it can also ascertain the risk: benefit ratio of current drugs. Nearly 20% patients experience some adverse event during hospitalization and 2.37% to 4.01% admissions to hospital are caused by ADRs but it is estimated that only 6-10% of all ADRs are reported.[3,5,6] Thus under reporting can delay the signal detection and have impact on public health.

There is lack of knowledge and practice of ADR reporting by the doctors.[6,7] Various reasons for underreporting of AEs by doctors can be lack of time, feeling that a single case report may not be important, concern that reporting will generate extra work, and fear of legal implications.[4,8,9] Pharmacovigilance aims to enhance the patient care and safety in relation to the use of medicines.[1,10] There is a need to create awareness among healthcare professionals about the importance of AE/ADR reporting. This questionnaire based survey assessed the current knowledge, attitude towards pharmacovigilance and its practice by doctors at a tertiary care teaching hospital in Mumbai, Maharashtra, India.

METHODS

The study was conducted at a tertiary care teaching hospital in Mumbai, Maharashtra, India. The population of doctors consisted of postgraduate medical students (PGs) and medical teachers. This was a cross-sectional questionnaire based survey; doctors at a tertiary care hospital were assessed for their knowledge, attitude and practice of pharmacovigilance. Doctors who answered survey questionnaire at a single point of contact were included in the analysis.

Questionnaire was structured to obtain the demographics of the doctors like age, gender, designation, their knowledge of pharmacovigilance and ADR reporting, attitudes towards reporting and their practice of pharmacovigilance, and factors that may influence ADR reporting. We also sought the feedback they would expect from the pharmacovigilance center/committee. Suggestions were also pursued on possible ways to improve ADR reporting and pharmacovigilance. The questionnaire was validated and pretested to confirm appropriateness and identify whether questionnaire can be self-administered by the doctors.

Ethical statement

Institutional Ethics Committee approved the study. A verbal consent of the participants was taken before they were administered with the questionnaire.

Data collection

Survey questionnaire was focused to assess the knowledge, attitude and practice of pharmacovigilance. Doctors were approached and explained in brief about the study. Questionnaire was administered after a verbal consent. They were requested to reply to the questionnaire within sufficient time at single contact. Access to any information source was restricted while questionnaire being answered.

Statistical analysis

Data collected was analyzed using the Statistical Package for Social Sciences (SPSS) software version 15 using descriptive frequency method. Results are represented as frequency and percentages.

RESULTS

Demographics

Of the total 150 participants, 91 (60.7%) were PGs and 59 (39.3%) were medical teachers. 73 (48.7%) of the participants were males and 77 (51.3%) were females. All the approached doctors answered the survey providing a response rate of 100%.

Knowledge of pharmacovigilance and ADR reporting

119 (79.3%) correctly understood the components of pharmacovigilance. 39 (26%) were aware of the WHO international collaborating Uppsala monitoring center while only 37 (24.7%) knew the name of the nationwide pharmacovigilance program. Responses to other questions related to knowledge are summarized in Table 1.

Table 1: Knowledge related to ADR reporting (know or did not know).

Question	Observation [n (%)]
Prescription event monitoring as a method of ADR data collection	59 (39.3)
ADR reporting is voluntary in India	59 (39.3)
Did not know differences between the terms AE and ADR	126 (84.0)
Naranjo's scale is used for causality assessment of an AE	30 (20.0)
All serious ADRs of the drug are NOT well documented before marketing	92 (61.3)

Attitudes to reporting ADRs

144 (96%) believed that pharmacovigilance is very important in medical practice. 144 (96%) believed that it is the duty of a treating doctor to report an adverse event, 55 (36.7%) felt that ADR reporting should be the responsibility of a separate team whereas 90 (60.0%) felt that a separate team is not required. Responses to other attitude related questions are summarized in Table 2.

Practice of pharmacovigilance

Reponses to the questions related to practice are tabulated in Table 3.

Table 2: Attitude of doctors to ADR reporting.

Question	Observation [n (%)]
ADR should be reported even if causality is not established	113 (87.3)
Financial aid should be provided to doctors for ADR reporting	81 (54.0)
ADR reporting can be detrimental to one's career - Disagreed	121 (80.7)
Even a single reported ADR can contribute to medical knowledge	129 (86.0)
ADR case reports should be published in popular medical journals	132 (88.0)

Table 3: Practice of pharmacovigilance by doctors.

Question	Response	Observation [n (%)]
Ever reported any ADR to the PV center	Yes	86 (57.3)
	No	64 (42.7)
Preferred way of reporting ADRs	self / junior doctor	107 (71.3)
	Report to the senior doctor only	49 (32.7)
Explain about possible ADRs of medications to the patients		73 (48.7)
Ask leading questions to the patients to find out any ADRs during follow up visits	Always	54 (36.0)
	Sometimes	93 (62.0)
	Never	3 (2.0)
Enquire about ADRs to medical representatives when they visit for product promotion	Always	54 (36.0)
	Sometimes	66 (44.0)
	Only for new drugs	24 (16.0)
	Never	6 (4.0)
Attended any continued medical education (CME) or symposium or workshop related to pharmacovigilance	Never	103 (68.7)
	Yes	47 (31.3)
Visited any websites related to pharmacovigilance	Never	134 (89.3)
Aware of whom to report or where to report ADR at our hospital		138 (92.0)

Table 4: Measures suggested that can improve the Pharmacovigilance and ADR reporting.

Measures	Observation [n (%)]
CME, training and refresher studies or courses	148 (98.7)
Increase awareness among other healthcare professionals like nurses, pharmacists	146 (97.3)
Instituting and encouraging the feedback between patients, prescribers and dispensers of the drugs	145 (96.7)
Frequent reminders and increased awareness from ADR monitoring committee	144 (96.0)
Increased collaboration by physicians and regulators with other healthcare professionals	143 (95.3)
Encouragement from monitoring committee and heads of respective departments	141 (94.0)
Encouraging online and/or telephone reporting	137 (91.3)
Alerting all outpatients to watch for the ADRs while prescribing new drugs	137 (91.3)
More publicity of the reporting scheme	136 (90.7)
Ask patients to report ADRs	117 (78.0)
Making reporting a mandatory professional obligation	98 (65.3)
Establishing a separate pharmacovigilance OPD	97 (64.7)
Having an ADR specialist in every department	89 (59.3)
Incentive to every outpatient who reports an ADR	72 (48.0)

Measures suggested for improving the pharmacovigilance and ADR reporting practices

The following measures were suggested to participants. These are given in Table 2 in decreasing frequency of their acceptance by the doctors.

Feedback expected from pharmacovigilance centre/committee

Figure 1 represents the feedback expected by the doctors from the pharmacovigilance center/ committee at our hospital.

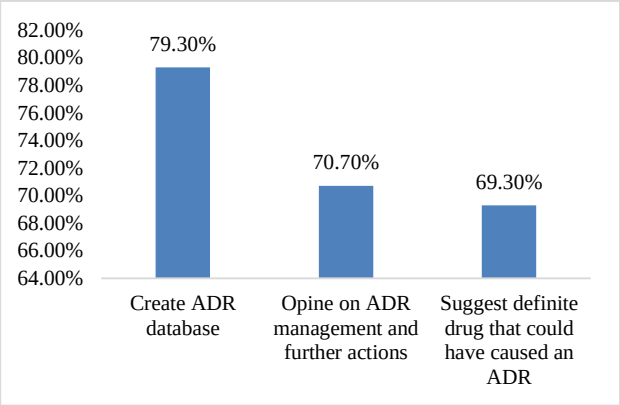

Figure 1: Feedback expected from the pharmacovigilance center by the doctors.

Other open suggestions

The participants were asked for suggestions to improve pharmacovigilance practices as well as on expected feedback. Most of the suggestions were similar to that given in Tables 4 and Figure 1, notably 4 (2.66%) were keen to know how to prevent ADRs and what measures can be taken to that effect.

DISCUSSION

In the present study, we evaluated the knowledge, attitudes and practices of the doctors related to PhV at a tertiary care center. Essentially, any medicines, new and old, have to be monitored for ADRs throughout its life cycle. This objective can be achieved by a robust Pharmacovigilance system. However, there is significant lack of awareness about PhV among health care professionals.[6-8] Implementing PhV in their practice by the doctors can contribute in a large way to the safety of medicines.

PhV involves activities related to the detection, assessment, understanding and prevention of adverse events.[10] Majority of the doctors (79.3%) were aware of it suggesting their understanding of the PhV and its essential components. Two terms, AE and ADR are frequently used in interchangeably but 84% doctors were aware of the difference between these two terms. This further strengthens the finding of basic knowledge of the pharmacovigilance. Causality assessment is an important aspect ADR evaluation. Of the various known scales for causality assessment, Naranjo's scale is one of the frequently used scales.[10]

Only, 20% of the doctors were aware of this specific scale. However, this finding should not be a deterrent since causality is implied in spontaneously reported cases. Beside Naranjo's scale, WHO causality scale is also commonly used.[11] Though spontaneous reporting of ADR is one of the common methods followed in routine practice, nearly 40% of the participants were aware of prescription event monitoring method also. The importance of pharmacovigilance lead to the development of international and nationwide pharmacovigilance program but only 26% knew about the existing WHO International Monitoring Centre. Few of them (24.7%) knew about nationwide program. In contrast to this, Gupta et al identified 43% of the participants being were aware of National Pharmacovigilance centers in India.[8] In another similar survey, Oshikoya KA, et al from Nigeria reported that 51.5% of the doctors were aware of existing national pharmacovigilance center.[6] In another survey conducted by Ramesh M, et al identified 90% of participants knowing of NPC.[12]

The importance of pharmacovigilance in medical practice is perceived by a majority (96%) similar to the results of Gupta et al who identified 89.5% participants suggesting necessity of ADR reporting. Also, study from Rehan HS, et al finds 82% of prescribing doctors felt the need of ADR reporting.[13] As the need of ADR reporting by doctors seen in many studies, we observed that 92% of the participants were aware of where to report an ADR at our hospital. Gupta P, et al also found 89 and of participants knowing ADR reporting center at their hospital.[8]

Despite knowing the existing ADR center, 42.7% haven't reported any ADR to hospital pharmacovigilance center. Quing Li, et al reported that 62% of the participants from their study encountered ADRs but did not report it. Ramesh M, et al found 64% of participants reporting ADRs.[12,13] Findings from all the studies including our study imply that there is a significant dearth of ADR reporting practice in spite of a fair attitude towards ADR reporting. Since the doctors are the first tier to come across the patient, they should be motivated to report ADRs.

We further observed that most of the doctors ask patients about possible ADRs (62.0%) and some explain to them about the ADRs (48.7%) reflecting their positive attitude towards patient care and safety. Nearly one-third of the doctors feel ADR reporting should be a professional obligation similar to the results of Oshikoya KA et al (63.6%), Gupta P, et al (80.9%). Bateman DN et al

identified majority of general practitioners, consultants as well as junior doctors agreeing that ADR reporting should be professional obligation.[6,8,14]

One of best solutions to this is that they should be reminded of their duty as a physician to report ADRs which was agreed upon by 96% implying fair attitude to ADR reporting. As reporting of ADR is voluntary in India which was known to 42% of the participants. Oshikoya KA et al observed 36.4% of the doctors who agrred on volunatry reporting of ADRs as agianst 52.5% who believed to make it compulsory to all doctors.

Reporting ADR is important if the causality can't be established was practiced by 87.3%.[6] This can substantially be improved by reporting even a single case report (86%) and can contribute to the medical knowledge by generating signal for future AEs. Moreover, the post-marketing surveillance is important for identifying the rare ADRs since all ADRs are not documented in clinical development. This was known to 61.3% of present study participants. PMS is an ongoing process of medicine safety to which physicians can contribute substantially by reporting ADRs. Creation of an ADR database as suggested by the majority (79.3%) of the doctors can help to identify the rare ADRs as well as help in quantifying the relative frequencies of occurrence of known ADRs.

One of the reasons for underreporting may be the fear of negative effect to one's medical career if they report the ADRs frequently. However, surprisingly study found 80.7% doctors believe that frequent reporting of ADRs may not be a hurdle in their career. While 60.0% reported ADR themselves, 32.7% reported ADRs to their seniors and 11.3% reported telephonically to pharmacovigilance center at our hospital. The study findings clearly identify the gap between knowledge, attitude and practice pharmacovigilance by the doctors. Additional information from pharmaceutical representatives on ADRs can be beneficial and 36.0% of them do seek for it.

Amongst the various measures to improve the pharmacovigilance, continued medical education (CME) and training was the most common measure suggested. It was found that 68.7% never attended any CME, workshop, symposium or training session related to pharmacovigilance thus implying the need for the same. The other suggested measures included increasing awareness among other healthcare professionals like nurses, pharmacists that they can also report (98.7%). Ramesh M, et al also observed 95% of the participants agreeing on pharmacist assistance in pharmacovigilance.[12]

ADR Reminders and increased awareness creation from ADR monitoring committee (96.7%) more publicity of the reporting scheme (90.7%), establishing a separate pharmacovigilance OPD (64.7%), and having an ADR specialist in every department (59.3%). It has been reported that educational interventions can improve ADR reporting practices.[6,9] Interestingly, 81 (54%) felt that financial aid should be provided for reporting an ADR in contrast to results of Oshikoya KA et al (28.6%) and Gupta P, et al (73.6%).[6,8]

Educating the doctors about pharmacovigilance and creating awareness about ADR reporting scheme and repeated reminders to maintain the good attitude are must for its success. The study on educational intervention by Tabali M et al clearly identifies the importance of educating the physician and also reminding them on a periodic basis.[15] Figueiras A, et al have concluded that a targeted outreach program may improve the quality of reporting of ADRs by physicians.[16] Incorporating pharmacovigilance in undergraduate and postgraduate curriculum as well as repeated reinforcement of its importance would be the best measures to inculcate reporting culture.

Further we suggest such studies to be conducted using the qualitative research methods like in-depth interviews on national basis and comparative amongst the various hospitals in a given locality. Comparative studies involving different medical and paramedical staff can help us identify the weak links in the chain of pharmacovigilance activities and suggest necessary measures. Moride Y et al discussed the underreporting of ADRs in general practice.[17]

Underreporting is unavoidable and identified that awareness of physician and extents of information needed are the important factors in GPs. There is constant need to identify barriers to the ADR reporting so that one can define interventions addressing such barriers. 18 Involvement of private physician and general practitioners in such studies and further educating them about the pharmacovigilance and ADR reporting can contribute in a big way to the successful implementation of pharmacovigilance.

Finding from a recent meta-analysis by Bhagavathula et al suggested greater proportion of participants with unawareness of PvPI [55.6% (95% confidence interval (CI) 44.4–66.9; $p<0.001$] and poor reporting of ADR as 74.5% (95%CI 67.9–81.9; $p<0.001$) of participants having never reported an ADR to PhV center.[19] These finding further strengthen our results and suggest a strong need for improving knowledge of PhV and ADR reporting practices.

Limitations of the study

Use of qualitative research methodology involving face to face and in-depth interviews would have been more appropriate. The study didn't discuss about the factors that are responsible for underreporting or not reporting of ADRs. Inclusion of other healthcare professionals in such studies can give us a better insight into the current state of affairs and suggest appropriate measures.

CONCLUSION

Present study identifies that in spite of having fair attitude; there is poor practice of ADR reporting probably because of lack of knowledge about the pharmacovigilance. There is an unmet need of creating awareness among the doctors about pharmacovigilance and ADR reporting. CME, workshops, training programs are required for the same purpose. Making ADR reporting an integral part of clinical activities is the only way by which pharmacovigilance can be implemented successfully.

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REFERENCES

1. WHO Policy Perspectives on Medicines, Pharmacovigilance: ensuring the safe use of medicines, October 2004 World Health Organization, Geneva. Available from http://apps.who.int/ medicinedocs/ pdf/ s6164e/ s6164e.pdf Accessed on 26/09/2016.
2. Mehta U, Dheda M, Steel G, Blockman M, Ntilivamunda A, Maartens G, et al. Strengthening pharmacovigilance in South Africa. SAMJ. 2014;104(2):104-6.
3. Oberg KC. Adverse Drug Reactions. Ame J Pharma Edu. 1999;63:199-204.
4. British Medical Association. Reporting adverse drug reactions: a guide for healthcare professionals. 2006 May. Available from http://www.isoponline.org/wp-content/uploads/2015/01/BMAreport.pdf Accessed on 26/09/2016
5. Pouyanne P, Haramburu F, Imbs JL, Bégaud B. Admissions to hospital caused by adverse drug reactions: cross sectional incidence study. British Med J. 2000;320:1036.
6. Oshikoya KA, Awobusuyi JO. Perceptions of doctors to adverse drug reaction reporting in a teaching hospital in Lagos, Nigeria. BMC Clinical Pharmacology. 2009;9:14.
7. Bello SO, Umar MT. Knowledge and attitudes of physicians relating to reporting of adverse drug reactions in Sokoto, North-Western Nigeria. Annals of African Medicine. 2011;10(1):13-8.
8. Gupta P, Udupa A. Adverse Drug Reaction Reporting and Pharmacovigilance: Knowledge, Attitudes and Perceptions amongst Resident Doctors. J Pharm Sci & Res. 2011;3(2):1064-9.
9. Li Q, Zhang SM, Chen HT, Fang SP, Yu X, Liu D, et al. Awareness and attitudes of healthcare professional in Wuhan, China to the reporting of adverse drug reactions. Chinese Medical Journal. 2004;117(6):856-61.
10. WHO Essential medicines and health products: Pharmacovigilance, Available from: http://www.who.int/medicines/ areas/quality_safety/ safety_efficacy/ pharmvigi/en/ Accessed on 26/09/2016
11. Srinivasan R, Ramya G. Adverse drug reaction-causality assessment. Int J Res Pharm Chem. 2011;1(3):606-12.
12. Ramesh M, Parthasarathi G. Adverse Drug Reactions Reporting: Attitudes and Perceptions of Medical Practitioners. Asian J Pharma Clin Res. 2009;2(2):10-4.
13. Rehan HS, Vasudev K, Tripathi CD. Adverse drug reaction monitoring: Knowledge, attitude and practices of medical students and prescribers. Nat Med J Ind. 2002;15(1):24-6.
14. Bateman DN, Sanders GLS, Rawlins MD. Attitudes to adverse drug reaction reporting in the Northern Region. Br J Clin Pharmac. 1992; 34:421-6.
15. Tabali M, Jeschke E, Bockelbrink A, Witt CM, Willich SN, Ostermann T, et al; Educational intervention to improve physician reporting of adverse drug reactions (ADRs) in a primary care setting in complementary and alternative medicine. BMC Public Health. 2009;9:274.
16. Figueiras A, Herdeiro MT, Polonia J, Gestal-Otero JJ. An Educational Intervention to Improve Physician Reporting of Adverse Drug Reactions A Cluster-Randomized Controlled Trial. JAMA. 2006;296(9):1086-93.
17. Moride Y, Haramburu F, Requejo AA, Be´gaud B. Under-reporting of adverse drug reactions in general practice. Br J Clin Pharmacol. 1997;43:177-81.
18. Mirbaha F, Shalviri G, Yazdizadeh B, Gholami K, Majdzadeh R. Perceived barriers to reporting adverse drug events in hospitals: a qualitative study using theoretical domains framework approach. Implementation Science. 2015;10(1):1.
19. Bhagavathula AS, Elnour AA, Jamshed SQ, Shehab A. Health Professionals' Knowledge, Attitudes and Practices about Pharmacovigilance in India: A Systematic Review and Meta-Analysis. PloS one. 2016;11(3):e0152221.

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