Print ISSN 2319-2003 | Online ISSN 2279-0780

IJBCP International Journal of Basic & Clinical Pharmacology

doi: 10.5455/2319-2003.ijbcp20150424

Research Article

Knowledge, attitude, and practice among healthcare professionals of adverse drug reactions reporting in a tertiary care center

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Received: 27 January 2015
Accepted: 19 February 2015

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ABSTRACT

Background: There has been a rapid increase in the number of drugs entering the market from last few decades. Preclinical and clinical data are insufficient to conclude the complete safety of drugs. Hence, it is necessary to have a robust pharmacovigilance system in place to generate safety signals. Under reporting of adverse drug reactions (ADRs) exists as an inherent weakness of current voluntary reporting scheme. This study was therefore taken up, to evaluate the knowledge, attitude, and practice about ADR reporting among doctors in a tertiary care center.
Methods: The present study was a cross-sectional questionnaire-based study, which included prescribers of a tertiary care teaching hospital. We tried to find out the possible ways to improve reporting of ADR and factors responsible for deficient reporting of ADRs.
Results: After analyzing the data, we observed that 59% of the responders were aware of the ADRs reporting system. And the most encouraging finding was 94% of the respondents think that this reporting system is necessary. However, the practice was very poor just 14% among the respondents. 74% and 61% of participants felt creating awareness among healthcare professionals, and training to healthcare professionals would lead to improvement in reporting of ADRs respectively. Main factors which discouraged ADR reporting by healthcare professionals were reporting would lead to extra work 70.5%, non-availability of forms 64.5%.
Conclusion: The deficiencies in ADR reporting require attention so as to improve spontaneous reporting and enhance safety of patients.

Keywords: Pharmacovigilance, Safety signals, Under-reporting

INTRODUCTION

Adverse drug reactions (ADRs) are important public health problem imposing a considerable economic burden on the society and health care systems. ADRs lead to number of medical and economic consequences like prolong hospital stay; increase in the cost of treatment and risk of death also increases. It is one of the important causes of hospitalization varying between 5% and 13%[1] ADRs accounts for 0.2-24% of hospital admissions, 3.7% of the patient experiences fatal ADRs.[2] There has been steady increase in drugs entering Indian market since last two decades and no amount of preclinical and clinical data can conclude the complete safety of drugs specially rare adverse drug effect.

Pharmacovigilance is a science and activities related to detection, assessment, understanding and prevention of adverse effects or any other drug-related problems.[3] The probability of causative agent is assessed by the ADR probability and classified as definitive, probable, possible, and suspected with a scale developed by Naranjo et al.[4] Gross under-reporting of ADR is a cause for a concern; it delays early detection of ADR and can increase associated morbidity, mortality in the patient.[5]

Monitoring of adverse drugs reactions is carried out by various methods, of which voluntary or spontaneous reporting is commonly practiced. In order to improve participation of health professionals in spontaneous reporting, it might be necessary to design strategies that modify intrinsic (Knowledge, Attitude, and Practice [KAP]) and the extrinsic factors (Relationship between healthcare professionals and patients, health system and regulators).[6]

Reporting ADRs is a paramount importance for the success of a pharmacovigilance program of a country.

Healthcare professionals are the primary reporters of the ADR cases.[5]

Despite many efforts and presence of large number of tertiary care facilities pharmacovigilance is still in its infancy. Findings from various studies have revealed that ADR reporting is linked to the KAP of the healthcare professionals.[7-9]

Before carrying out any intervention, it is necessary to evaluate the baseline KAP of the healthcare professionals regarding ADR monitoring and pharmacovigilance so that the intervention can be targeted, based on the specific findings. Identifying the factor influencing reporting is essential to suggest measures to enhance reporting. Considering the deep concern over the under-reporting prevailing among the prescribing doctors, the present study was done to know the KAP of pharmacovigilance among prescribers.

Aims and objectives

To assess KAP among healthcare professionals. Identify the factors for deficient reporting of ADRs and factors which would encourage reporting.

METHODS

Type of study: Cross-sectional study. Study population: A total 200 doctors participated in this cross-sectional survey during the period of September to October 2014. Ethical consideration: The approval from Institutional Ethical Committee was sought before the initiation of the study. After reaching to the study subjects, they were explained about the purpose of undertaking this study before taking a due written consent of the study subjects. Study design: Amongst prescribers' KAP of ADR reporting was assessed by open ended and closed ended self-administered questionnaire; which included the following domains: Questions about knowledge regarding ADR reporting, questions about attitude towards ADR reporting and questions about frequency of ADR reporting. Data recording: Data recording was done by interviewing the study subjects as per designed and pretested proforma at each visit by the principle investigator. Statistical Analysis: Collected data were entered and analyzed by Epi-info software.

RESULTS

Of the 200 KAP questionnaires circulated, a total of 200 doctors responded and were included in the study. 59% respondents were aware of existing ADR reporting system of suspected ADR (Figure 1). Table 1 depicts the knowledge of doctors for ADR reporting. 36.5% of respondents were able to tell correctly adverse reaction monitoring center in Nagpur. Response rate for questions asked regarding awareness about recently banned drug due to ADR was 60% and 34.7% could give the correct name of the drug with cause. For the question asked about type of ADR should be reported 70.5% responded as all ADRs should be reported whereas 2.5% responded as to new drug, 1.5% as unknown ADR to old drugs, 22% as all serious ADRs should be reported. 53% of the respondents reported that ADRs should be reported to ADR reporting center, to head of the department by 9%, to nearby hospital by 0.5% and to drug manufacturer by 15% while 22.5% of the

Table 1: Knowledge among doctors for ADR reporting.

Knowledge about ADR reporting	Yes (%)	No (%)
Are you aware of suspected ADR reporting system in India?	118 (59)	82 (41)
Are you aware of any drug that has been banned recently due to ADR?	120 (60)	80 (40)
Which one among these is a pharmacovigilance reporting center for Nagpur? (%)		
No response	13 (6.5)	
GMC Nagpur	67 (33.5)	
IGGMC Nagpur	26 (13)	
MGIMS Sewagram	7 (3.5)	
All of the above	87 (43.5)	
Which type of ADR should be reported? (%)		
None	3 (1.5)	
All	141 (70.5)	
All serious	44 (22)	
To new drugs	5 (2.5)	
Unknown to old drug	3 (1.5)	
To whom ADR should be reported? (%)		
ADR reporting center	106 (53)	
HOD of institute	18 (9)	
Nearby hospital	1 (0.5)	
Drug manufacture	30 (15)	
All of the above	45 (22.5)	
Which of the following scales is used to establish the causality of an ADR pharmacovigilance center in India? (%)		
No response	76 (38)	
Hardwig and Siegel	36 (18)	
WHO-UMC scale	36 (18)	
Naranjo scale	32 (16)	
Schumock and Thomton Scale	20 (10)	
Difference between ADR and adverse event?	13%	
Difference between toxic effect and side effects?	21%	

ADRs: Adverse drug reactions

respondents were of the opinion that from any of the above ADRs can be reported.

Another question sought information about the scales used to establish the causality of ADRs and according to the data only 18% of the doctors gave a correct response. 13% and 21% of the respondents were able to answer the questions asked about the difference between ADRs and Adverse event and the difference between toxic effect and side effect, respectively.

In this study, it was observed that reporting of ADR is necessary according to the majority (94%) of the responses of the investigated doctors. Most (86.5%) of the investigated doctors agreed that ADR reporting system would benefit patient's care.

About 63.5% respondents think that reporting is a professional obligation for them. 87.5% responders think that the educational program is effective in improving ADR reporting.

Figure 2 shows the importance of ADR reporting, 68.5% of doctors gave more importance to the improvement of the patients' safety and least importance was given to sharing information about ADRs with colleagues by the 28.5% respondents.

Figure 3 shows sources of information used to gather information about ADRs. Sources used to gather information about ADR to new drug, from textbook (35%), journals (39.5%), advertisements and product catalogue (27.5%), medical representatives (0.75%), seminar and conferences (36.5%), direct mail brochures (0.4%), and internet (53.5%).

About 61% were having knowledge that all doctors, pharmacist, nurses are responsible for reporting ADR in hospital.

Table 2 shows factors discouraging ADRs reporting where 70.5% of respondents felt it would lead to extra work, reporting forms are not available when needed 64.5%, fear of legal liability 64.5%, concern that report may be wrong 58%, lack of time 64%, not confident to decide whether or not an ADR has occurred 63.5%, other colleague are not reporting 55.5%, belief that only safe drugs are marketed 54.5% and ambition to publish report personally 44% were other factors which discouraged them from reporting ADRs.

Table 3 shows data collected for factors important to improve reporting. Most of the respondents 74% gave first preference to the educational intervention. Another important

Table 2: Factors discouraging ADRs reporting.

Factors discouraging to report ADRs	Responses N (%)
Concern that report may be wrong	116 (58)
Lack of time to fill and single report may not affect ADR database	136 (64)
Not confident to decide whether ADR or not	127 (63.5)
Fear of legal liability	129 (64.5)
Concern that report will generate extra work	141 (70.5)
Belief that only safe drugs are marketed	109 (54.5)
Ambition to publish case report personally	98 (44)
Reporting forms are not available when needed	129 (64.5)
Other colleagues are not reporting	111 (55.5)

ADRs: Adverse drug reactions

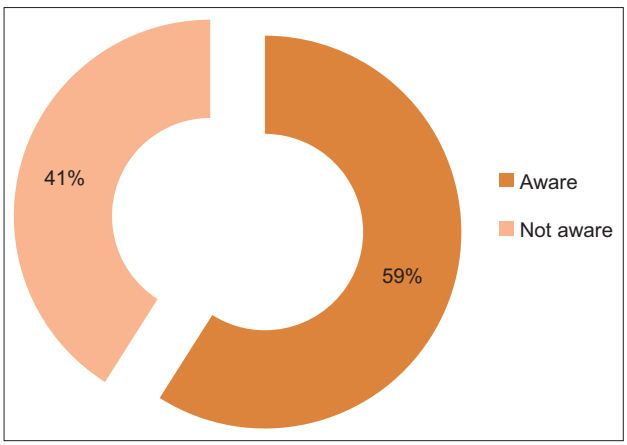

Figure 1: Awareness of doctors about adverse drug reaction reporting system.

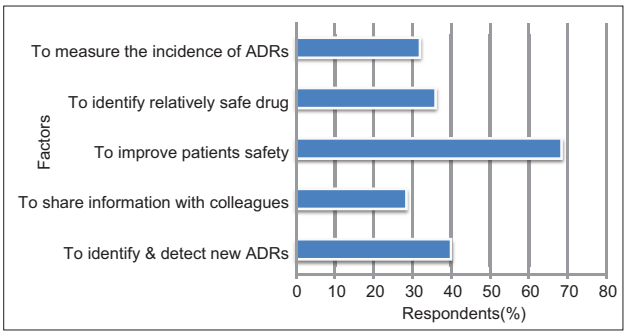

Figure 2: Importance of adverse drug reaction reporting

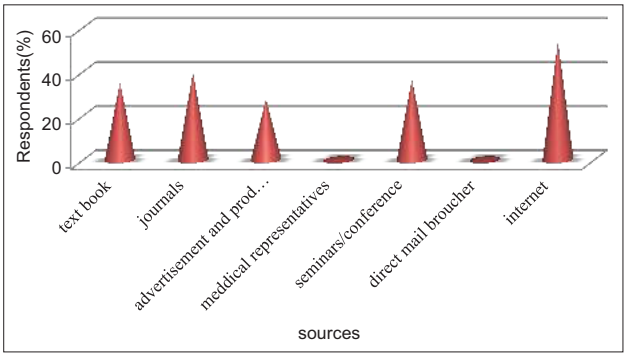

Figure 3: Sources used to gather information of adverse drug reaction.

way which can improve reporting is training by 61% of the respondents.

Other encouraging factors like involvement of pharmacist, providing electronic option for submission, making reporting mandatory and remuneration for ADR submission by 52%, 54%, 52.5%, and 38% responders, respectively, are the possible ways to improve reporting was observed in our study.

Figure 4 shows factors considered important while reporting ADRs According to 49% of the respondents' seriousness of the reaction, unusual reactions (7.5%), reactions to new product (10.5%); new reactions to old products (0.7%), confidence in the diagnosis of ADR (0.4%) are the important factors while reporting ADRs.

Figure 5 shows ADR reporting practice in our hospital where just 14% of the responders had ever reported any suspected ADR.

Table 3: Ways to improve reporting.

Possible ways to improve ADR reporting	Responses N (%)
Awareness among healthcare professionals	148 (74)
Collaboration among other healthcare professional	97(48.5)
Training to the healthcare professional	122(61)
Involve pharmacist for ADRs reporting	104(52)
Remuneration for ADR submission	76(38)
Make reporting mandatory	105(52.5)
Providing electronic option for submission	108(54)
Providing toll-free number for reporting	105(52.5)
Having an ADR specialist in every department	89(44.5)

ADRs: Adverse drug reactions

Table 4 shows practice of ADRs reporting among doctors, 98% of the doctors take proper history while just 22% keep records of ADR, Only 21.3% had attended any Continuing Medical Education (CME) on ADR reporting only 11.5% had ever been trained on how to report an ADR. And (46%) responders reported they ever came across with an ADR. Most of the responders who had come across with the ADR had shared information of ADR to the college pharmacovigilance cell.

DISCUSSION

Reporting of ADRs is necessary for the success of pharmacovigilance program. Spontaneous reporting of ADRs may find out:

- New unlabeled adverse events,
- An observed increase in labeled event in its severity and specificity

Table 4: Practice of ADRs reporting among doctors.

Practices of ADR reporting	N (%)	
	Yes	No
Q19. Have you ever reported any suspected ADR?	28 (14)	172 (86)
Q20. Have you attended any CME on ADR reporting?	43 (21.0)	157 (78.5)
Q21. Have you ever shared information about ADR with anyone?	98 (49)	102 (51)
Q22. Have you ever come across with an ADR?	92 (46)	108 (54)
Q23. Have you ever been trained on how to report ADRs?	23 (11.5)	177 (88.5)
Q24. Do you take proper medical history?	196 (98)	4 (2)
Q25. Do you keep records of ADR?	44 (22)	156 (78)

ADRs: Adverse drug reactions

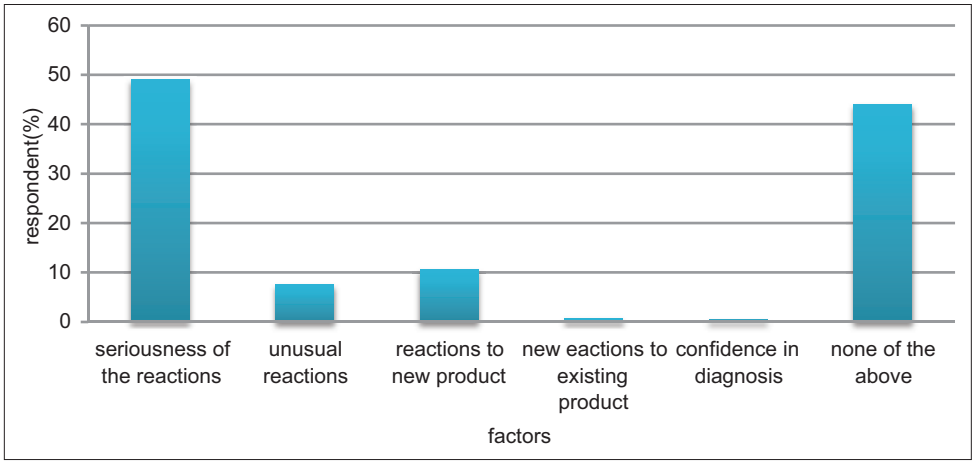

Figure 4: Factors important while reporting adverse drug reactions.

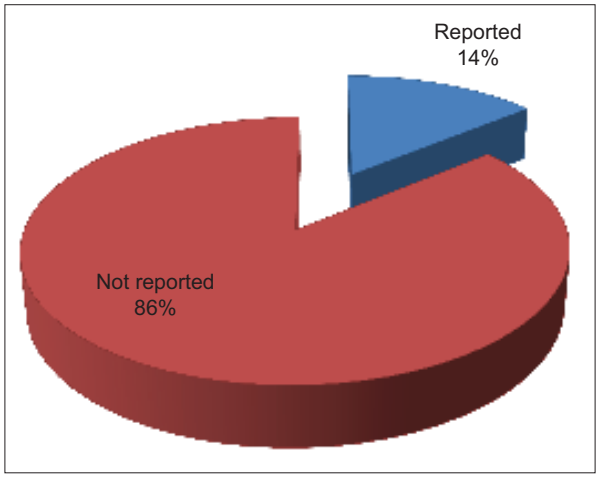

Figure 5: Adverse drug reaction reporting practice among doctors.

- New drug or food interactions
- Newly identified risk population.

This would help regulatory authorities to do the benefit/risk evaluation, which may lead to editing of product information or authorization of withdrawal of drug from the market leading to enhanced safety of patient and society at large.

Underreporting of ADRs is a major threat to the success of pharmacovigilance program. Various factors have been found to be responsible for underreporting of ADRs by doctors. These factors are mainly related with the knowledge and attitudes.

Our study observed that despite the adequate knowledge (59%) and attitude (94%) among doctors only 14% have ever reported any ADRs indicating the existence of poor ADR reporting. A similar study conducted reported that besides awareness and attitude there was poor practice of ADR reporting in a tertiary care hospital in South India.[10] A similar study conducted observed that, even though, medical practitioners were aware of ADR reporting and had the right perceptions towards it, their practice of ADR reporting was very poor. Their results were comparable to our study.[11] A survey conducted by Chatterjee which included 138 clinicians observed good knowledge, but poor attitude and practice with regard to ADR reporting.[12]

Our study observed that few respondents 46.5% could identify correct ADR reporting center in Nagpur, which was similar (11.7%) to one of the previous the study.[10] Regarding the kind of reactions to be reported 70.5% gave a correct answer which was similar to two other studies.[13,14] In our study, 60% of the respondents were aware of the drug that has been banned recently whereas 95% were aware in the previous study. Only 18% of the respondents correctly answered about scales used to establish the causality of an ADR on the contrary 87% of the respondents were aware in a study conducted by Rajesh and Vidyasagar.[15] It was interesting to note that 94% of the respondents think that reporting is necessary which was similar to the study by Rajesh and Vidyasagar.[15] This was an encouraging finding from our study. Even as ADR reporting was considered to be important by a large majority of the respondents, the actual reporting was very low as reported by Desai et al. which was similar to our study.[6] 98.3% felt that reporting of ADR would benefit patients care in the study conducted by Thomas, whereas in our study 86.5% were of the same opinion. From this study we found that 35%, 39.5%, 27%, 0.75%, 36.5%, 0.4%, 53.5% doctors were gathering information about ADR to new drug from the sources like textbook, journals, advertisement and product catalogue, medical representative, seminars and conferences, direct mail brochure, internet, respectively, which were similar study by Fadare and Okezie who observed that drug information sheet, texts, medical representative, scientific journals, and drug information bulletin were the sources utilized by 56.5%, 23.9%, 8%, 2.2%, and 2.2% of the respondents, respectively.[14] It has been observed that 63.5% think that it is an obligation of doctors whereas the study of Thomas and Udaykumar reported 98% of all the doctors' thinks it is duty of health care professionals to report an ADR.[10] In a survey conducted by Thomas and Udaykumar, it was observed that factors that discourage ADR reporting included uncertainty about causality, not sure of the type of ADRs to be reported, lack of knowledge of the forms for reporting, ignorance of the rules on ADRs reporting didn't knew that ADRs should be reported, complex to fill the form and many such reasons. Similarly, another study conducted in Nepal reported similar discouraging factors for reporting ADRs, which were similar to our study.[16]

From the present study, we found that the reasons which were the important factors for reporting ADRs were same as reported by Thomas and Udaykumar.[10] Those were unusual reactions, seriousness of the reactions, reactions to new product, new reactions to an existing product, and confidence in diagnosis of ADR by 49%, 7.5%, 10.5%, 0.7%, and 0.4% of the respondents, respectively.

Just 14% of the respondents stated that they had ever reported any suspected ADR, indicating that there is under-reporting in our tertiary care hospital. This finding was similar to the two previous studies by Kharkar and Bowalekar; Desai et al., which showed 19% and 15% practice respectively.[11,6] In our present study, 78.5% of doctors had never attended any CME on ADR reporting. Similarly, a study in South India also cited similar findings that 96.7% of the respondents have never attended any CME.[10] In the present study, we observed that 11.5% of the doctors received training on how to report ADR to pharmacovigilance committee. These findings were comparable to the study conducted by Mishra and Kumar which showed only 9% result for training.[17]

The results of the study show that there is gross underreporting of ADR in our hospital; however, it has been observed that according to most of the respondents, an educational intervention can improve physicians' awareness of ADRs and enable them to incorporate the knowledge into their daily

clinical practices. Thus, if the knowledge on ADR reporting is improved then the attitude also improves which would be reflected on the ADR reporting schemes in a positive manner. Apart from this, out of the major suggestions include proper training to health care professionals, providing electronic option for submission, involvement of pharmacist, and making reporting mandatory to every health care professional ADR monitoring can be improved. This improvement has been demonstrated in the similar study conducted by Rajesh as pre-KAP and post KAP survey.[15] These measures could improve the quantum and quality of the reports. Thus, the overall result of the study indicates the need to conduct CMEs at regular intervals and give training about ADR reporting to doctors to extend the level of sensitization for health care professions to improve their ADR reporting and enhance safety of patients.

Limitations

The main limitation of our study was that the sample does not represent the whole population of healthcare professional of Nagpur, as it was conducted only in one hospital. We could have also included nurses and pharmacist as they also play an important role in pharmacovigilance. In addition, some other factors that are associated with self-reporting studies such as, accuracy of recall, personal bias and could also have affected, in some ways the results of this study.

ACKNOWLEDGMENTS

Authors would like to acknowledge all the doctors who responded promptly to the questionnaires. We want to acknowledge ICMR for funding the project as STS 2014.

Funding: Indian Council of Medical Research
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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doi: 10.5455/2319-2003.ijbcp20150424
Cite this article as: Dharmadhikari PP, Date AP, Patil KS. Knowledge, attitude and practice among healthcare professionals of adverse drug reactions reporting in a tertiary care centre. Int J Basic Clin Pharmacol 2015;4:300-5.