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Original Article

Knowledge, Attitude and Practice of Clinician Regarding Reporting of Adverse Drug Reaction (ADR) in Dr. Panjabrao Deshmukh Memorial Medical College, Amravati

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ABSTRACT

Introduction: Pharmacovigilance (PV) is essential to detect and prevent adverse drug reactions (ADR) after a drug is marketed. However, ADRs are significantly underreported worldwide. **Objective:** To assess knowledge, attitude and practice of clinician towards Pharmacovigilance, to get an in-sight into the causes of under-reporting of ADR and to suggest possible ways of improving current methods of ADR reporting. **Material &Method:** A cross sectional questionnaire-based study conducted on 117 medical practitioners in tertiary medical care hospital. **Results:** 57.75% of participants were aware of the concept of Pharmacovigilance. 80% of doctors have 5-25% patients with ADRs. Objectives of ADR monitoring are identify safe drugs (27%); calculate ADR incidence (27%); patients benefit (21%). Major encouraging factor for ADR reporting are patient safety (35%), improving drugs qualities (24%), Lack of time (26%) and lack of knowledge (23%) are major factors to discourage reporting of ADRs. Almost everyone is in favor of teaching pharmacovigilance to healthcare students during curriculum. Nearly 2/3rd of healthcare practitioners (60%) have reported ADR. **Conclusion:** There was huge gap between the ADR experienced and ADR reported by prescribing doctors. Participants agreed that reporting of ADR is necessary and pharmacovigilance should be taught in detail to healthcare professionals.

Keywords: Adverse drug reactions, attitude, knowledge, pharmacovigilance, practice, spontaneous reporting, under-reporting.

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INTRODUCTION

Adverse drug reactions (ADRs) are one of the major problems associated with medicines and are recognized hazards of drug therapy. World Health Organization (WHO) defined ADR as "Any noxious, unintended and undesired effect of a drug which occurs at doses used in humans for prophylaxis, diagnosis or therapy of disease, or for the modification of physiologic function."[1] The etymological roots for the word "pharmacovigilance" are: Pharmakon (Greek word for 'drug') and vigilare (Latin word for 'to keep watch').[2] According to the World Health Organization, Pharmacovigilance is defined as "The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problem, particularly long term and short term adverse effects of medicines"[3,4] Pharmacovigilance studies is becoming more important as new drugs are entering the market in jet speed and increase in number of drugs withdrawn because of ADRs.[5] Adverse drug reactions are an important cause of morbidity and mortality [6] and are responsible for a significant number of hospital admissions ranging from 0.3% to 11%.[7,8] Adverse reaction monitoring and reporting are very important in identifying the adverse reaction trends and to minimize or prevent harm to patients arising from prescribed drugs.[9] The Indian doctors have gained wide knowledge of drugs but the area of adverse drug reactions still remains neglected. Indian Government launched National Pharmacovigilance Programme in 2004 to inculcate the culture of Adverse Drug Reaction reporting among Indian health professionals. Still the picture is disheartening. Under-reporting and failure to calculate the incidence of ADRs are some of the disadvantages of this method.[10,11] Motivated to improve Adverse Drug Event reporting in Hospital, the present survey was conducted to find Knowledge, Attitude, Practices (KAP) of physicians, surgeons regarding Adverse Drug Reaction reporting.

Objective: To assess knowledge, attitude and practice of clinician towards Pharmacovigilance. To get an in-sight into the causes of under-reporting of ADR. To suggest possible ways of improving current methods of ADR reporting.

MATERIAL & METHOD

A cross sectional questionnaire-based study conducted on 117 participants. [12] Doctors with minimum qualification of MBBS working in clinical departments of Dr. Panjabrao Deshmukh Memorial Medical College, Amravati took part in this study. This includes clinicians and post graduate students in clinical department. Study started after taking clearance from Institutional Ethics Committee. Study completed over a period of six months. Pretested and precalculated questionnaire is used as data collection tool. Written consent taken from all participants before starting study. Knowledge domain is assessed by scoring each response as 1 for correct answer and 0 for wrong answer. Score calculated out of 13. Participants categorized into Good and Poor knowledge participants depending upon there score. (Good knowledge= ≥ 6; Poor knowledge= < 6) Data entered into Microsoft Excel and analyzed by using SPSS software version 16 and appropriate test of significance applied. All participants who won't give consent or returned questionnaire are excluded from study. Structured pretested questionnaire contained 13 items to check knowledge, 10 for attitude, and 5 to study practices. In addition, space was provided to give suggestions and furnish any additional information.

RESULTS

One hundred and seventeen questionnaires were distributed among the healthcare professionals and out of them 76 responded (response rate 64.95%).

Knowledge: Majority of participants (74%) are categorized into Good participants as their knowledge score = ≥ 6. Participants then were asked about definition of Pharmacovigilance, out of them 57.75% of participants were aware of the concept of Pharmacovigilance and know the definition. Majority of healthcare professionals know the location of international center for ADR monitoring (68%) and National coordination Center (NCC) i.e. 50% but only 28% aware of the fact that Indian Pharmacopoeia Commission (IPC) is the NCC.

55% of participating doctors know about ADR Monitoring Center of this institute. Majority of participants 80% have 5-25% patients with ADRs. 93% of healthcare professionals are aware of ADR reporting system in India, out of which 85% know how to report ADR. 30% of them know correctly about IPC form used to report ADR while 40% think CDSCO form is used. 75% of participants believe that doctors, nurse or pharmacist can report the ADR. According to participants objectives of ADR monitoring is identify safe drugs (27%); to calculate ADR incidence (27%); for patients benefit (21%).(Diagram -1) 43% believes Naranjo's algorithm is most commonly used scale to assess causality of ADR and VigiFlow is WHO online database for ADR reporting.

Attitude: Participants are more interested (48%) in reporting ADRs by filling form from the department. They less prefers mobile app (12%), email (9%). 66% of medical practitioner are in opinion of ADRs reporting should be voluntary. Majority of healthcare practitioner (62%) are in the favor of reporting all type of ADRs, but some of them (18%) are in opinion of reporting only serious and life threatening ADRs. Patient safety (35%) is most important encouraging factor in reporting ADRs, followed by improving quality of drugs (24%). (Diagram- 2) Certainty about ADR hospital motivation policy, ethical binding are other deciding factors. Lack of time (26%) and lack of knowledge (23%) are two major factors to discourage reporting of ADRs. Other factors to discourage are reporting does not influence treatment scheme, afraid of legal action, forget to report.(Diagram- 3) 70% healthcare practitioner always feel role in ADR reporting. Almost everyone is in favor of teaching pharmacovigilance to healthcare students during curriculum. Healthcare practitioners expect feedback from ADR monitoring center. Almost 2/3rd of healthcare practitioner (68%) doesn't support direct ADR reporting by patient instead of physician. Majority doctor (92%) thinks ADRs monitoring can helps to promote rational use of medicine.

Practice: Nearly 2/3rd of healthcare practitioners (60%) have reported ADR. 37% of doctors have attended CME and workshop related to ADR reporting. Common problem in filling ADR form are difficulty to pinpoint suspected drugs (22%), difficult form (21%), forms not available (15%), don't know how to fill form (13%) etc. Half of doctors regularly explain possible ADR of drugs used to patients.

DISCUSSION

In India Pharmacovigilance is rapidly growing with new development of drugs and clinical trials. Hence it is important to develop the system to handle trials and patient care as per ICH-GCP. [13] Reporting ADR is an essential component of Pv program. Numerous studies suggest that physicians' attitude toward ADR reporting is a significant determinant of the reporting rate.[14, 15] Underreporting of ADR is a universal phenomenon and major limiting factor in PV program worldwide. This preliminary study showed that while the right attitude for ADR reporting existed among most prescribers the actual practice of ADR reporting was lacking. The aim of this study was to assess the participant's knowledge, attitude and practices with regard to ADRs reporting, to determine the major barriers and to identify the factors that prohibit the implementation of a PV reporting, and to suggest possible ways of improving current methods of ADR reporting.

In our study 64.95% response was found from prescribing doctors. The percentage of completed response was nearabout similar to other studies carried out in Germany [16], Italy [17], United Kingdom [18], and different Indian studies from Trivandrum [19], Nagpur [20], Banglore [21], Ahmadabad [22] and Indore [23] However this response rate was lower than studies carried in Nigeria [24], Netherlands [25] and northern region of England [26].

Our findings, like previously published results of earlier surveys, suggest that there is a reasonable amount of knowledge or awareness in medical practitioner.[27-30] There was no significant correlation between designation or duration of experience and the number of correct responses. The reasonable knowledge of the respondents observed in this study is as par with the findings of a study done by Kharkar and Bowalekar.[29] In our study majority of practitioner were aware of concept of pharmacovigilance and ADR in terms of their definition and purposes. However our results are contradictory with study conducted by Ramesh and Parthasarthi. [31 -32] It is well known fact that information regarding ADR changes on daily basis hence the need for constant updating of the knowledge of health care professionals in this area. Most respondents in this study obtained their information on ADRs from patients, drug information sheets and texts on drugs. Lack of or inadequate access to the internet can be a major limiting factor (where internet facilities are poor) for obtaining current reports on ADRs as most information from drug inserts and text books on drugs may be outdated and may not reflect the current state of information on ADRs. In order to address some of the determinants of under-reporting found in this study, ADR reporting guidelines should be made available in the form of booklets and posters at conspicuous locations in health care facilities to serve as a constant reminder.

Almost everyone is in favor of teaching Pv to healthcare students during curriculum. Educational interventions have been found to update knowledge and consequently bring a greater degree of awareness. Similar results are seen by Rehan HS [33] in a survey of MBBS undergraduate students and 117 prescribers found that the knowledge, attitude, and practices of both undergraduates and prescribers comparable yet need further improvement. According to him there is a need for suitable changes in the undergraduate teaching curriculum and also that prescribers need a periodic

reinforcement regarding ADR monitoring. Suparna Chatterjee [30] in a survey of 138 clinicians from East India has similar findings.

37% of respondents in this study had attended CME or workshops related to ADR reporting. Educational interventions have been found to update knowledge and consequently bring a greater degree of awareness to pharmacovigilance. [17, 34, 35] Concerted efforts aimed at an active and progressive enhancement of knowledge, through educational workshops, CME's, seminars, and clinical meets could possibly translate into better awareness and ADR reporting practices. This is an avenue where there is an ample scope of improvement, and needs to be certainly addressed.

The reasons for reporting ADRs, as reported by Biriell and Edwards. [36] are, a desire to contribute to medical knowledge, identifying a previously unknown ADR, reactions to new drugs, and severity of the ADR. In our study also identify safe drug (27%), calculate ADR incidence (27%), patient benefit (21%) are common objectives for reporting ADR. Almost 75% of prescribers are in favor of reporting can be done by doctors, nurses or pharmacist. This is a welcome sign of ADR reporting. Reporting can be done by all the responsible personnel at any time, so that maximum ADRs can be covered in minimum time. These results are in accordance with other studies like Subramaniyan et.al. [37] Torwane et.al. [38] Voluntary reporting of ADR is 66 % hence it clearly notes that most of participants are in favor of voluntary reporting. The use of financial incentives as a tool to stimulate reporting of ADRs is rejected (0%). Apart from the fact that the use of incentives have not been widely accepted and practiced, it raises the possibility of over-reporting by some health care workers in a bid to obtain financial rewards. This should not be supported because ADR reporting should be a fundamental responsibility of health care workers and, therefore, it should be understood as such.

Majority of healthcare practitioner (62%) are in favor of reporting all type of ADRs. It is indicating positive attitude toward need to report. This finding is similar to another study by Khan et al [23] While a study done by Pimplekhute et al. [20] in Nagpur, only 35.7% of respondents, felt that ADR reporting was a professional commitment, which was much lower than that seen in our study.

Doctors felt that the most common encouraging factors for reporting an ADR is patient safety (35 %), improve quality of drugs (24%). Similar results were seen in study conducted by Desai et. al [22] Shalini et. al [28] The reasons for reporting ADRs, as reported by Biriell and Edwards [42] are, a desire to contribute to medical knowledge, identifying a previously unknown ADR, reactions to new drugs, and severity of the ADR.

Interestingly majority of participants have noticed ADR sometimes but only half of them have reported ADR. In our study results had shown the good knowledge as well as attitude for ADR reporting among participants but real scenario, rare practices of ADRs reporting. A study at Mysore, [31] Mumbai [39] and Muzzafarnagar [40] showed that high knowledge but poor practices for ADRs reporting in doctors. Here Lack of time (26%), lack of knowledge (23%) and difficulty in ADR form filling were the most important factors discouraging reporting. The observations were similar to a study by Vallano A et. al in Spain, where the potential obstacles to spontaneous reporting of ADRs were identified to be difficulty in diagnosis of ADRs, clinical workload on the doctors, a concern for patient confidentiality, and possible legal implications of reporting. [41] There are other studies also which agrees with our results. [22, 30, 42-44] Common problems in filling ADR form are difficulty to pinpoint suspected drugs (22%) and difficult form (21%) These results are accordance with study of Desai CK et. al [22] and Het B et. al [32] A study from Italy reported that doctors had little information concerning ADRs and ADR reporting systems [18]. A recent study from India also identified that the awareness about Pharmacovigilance program and the knowledge of ADR reporting were very low among the doctors [24]. In our study, similar results were found out. These findings suggest the need for interventions to improve the KAP of the healthcare professionals. The strategies suggested by the doctors to enhance ADR reporting in this study were giving feedback on the reported ADEs to the prescribers and organizing CMEs, teaching Pv to undergraduates, constant motivation etc. [Table 1]. Drug information and feedback to the doctors have shown improvement in ADR reporting. [33, 45]

LIMITATION

The major limitation of study was the relatively small number of respondents. The limitations of the study include, as it was the questionnaire based study, there could be a chance of subjective and recall bias. Other health care professionals like Nurses and Pharmacist who are continuously in touch with patients are not included in study. Similarly pharmacovigilance knowledge and attitude of undergraduate students can be evaluated. The opinion of non-responders in general and participants who did not respond to certain aspects

of the questionnaire could also have affected the interpretation.

CONCLUSION

In conclusion, this study showed that majority of the healthcare professionals had good knowledge and attitude about pharmacovigilance and understand the need for reporting. In spite of that the reporting rate of ADRs by them is very low. Hence, there was huge gap between the ADR experienced and ADR reported by prescribing doctors. Here Lack of time, lack of knowledge and difficulty in ADR form filling were the most important factors that discourage ADR reporting. This can be prevented by teaching Pv to undergraduates, constant motivation, organizing CMEs, giving feedback on the reported ADEs to the prescribers etc. Participants agreed that reporting of ADR is necessary and pharmacovigilance should be taught in detail to healthcare professionals. Hence there need continuous education and sensitization regarding Pharmacovigilance and ADR reporting system to residents doctors and faculties that improving the ongoing Pharmacovigilance activities in our hospital. With an ADR reporting system in place at the institution, one needs to go a step forward and implement these suggestions for strengthening the existing spontaneous ADR reporting system. ADR reporting should be made an integral part of the clinical activities in order to improve the patient care.

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Table 1: Suggested Methods for Improving ADRs Reporting

Sr. No.	Suggested methods
1.	Continuous medical education, training, CME etc
2.	Instituting and encouraging feedback between patients, prescribers and dispensers of drugs
3.	Reminders and increased awareness from the ADR Monitoring Committee
4.	Increasing awareness among other professionals that they could report ADRs
5.	Increased collaboration with other healthcare professionals
6.	Encouragement from the ADR Monitoring Committee and various head of departments
7.	Making reporting a professional obligation.
8.	Maintaining record of ADR reported by every individual.

Diagram 1: Objective of ADR monitoring

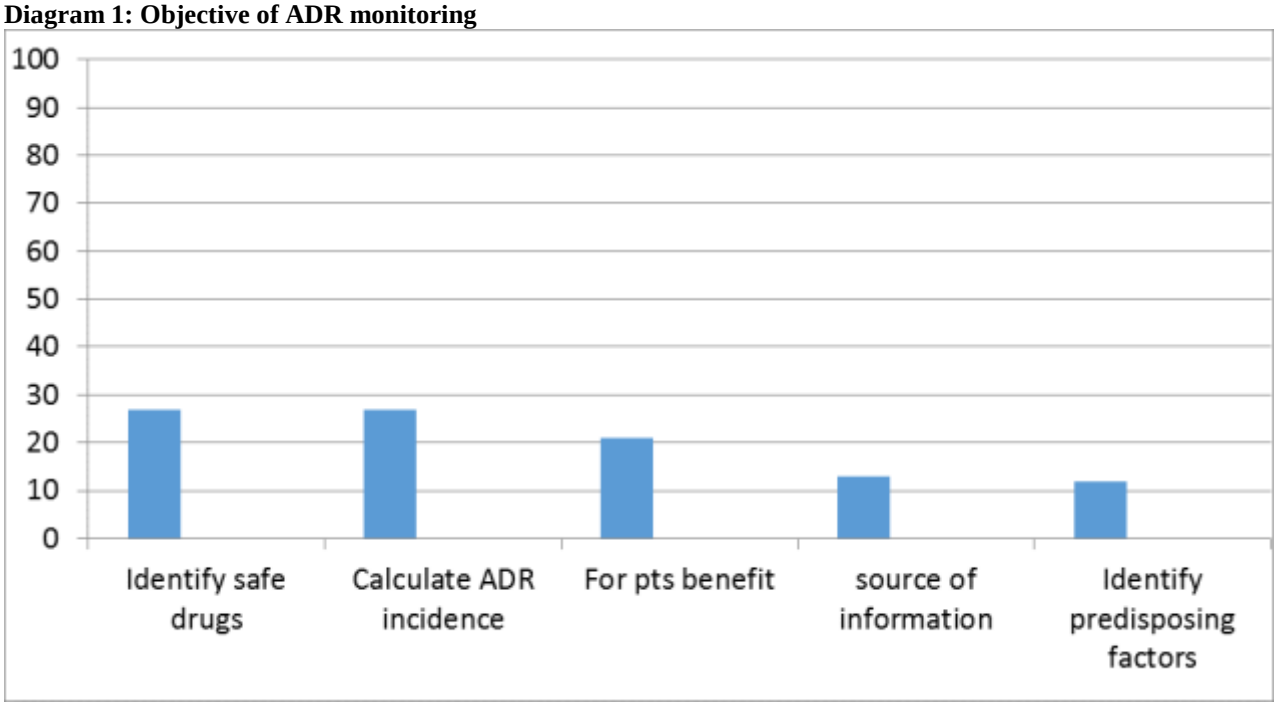


Diagram 2- Encouraging factors to report ADR

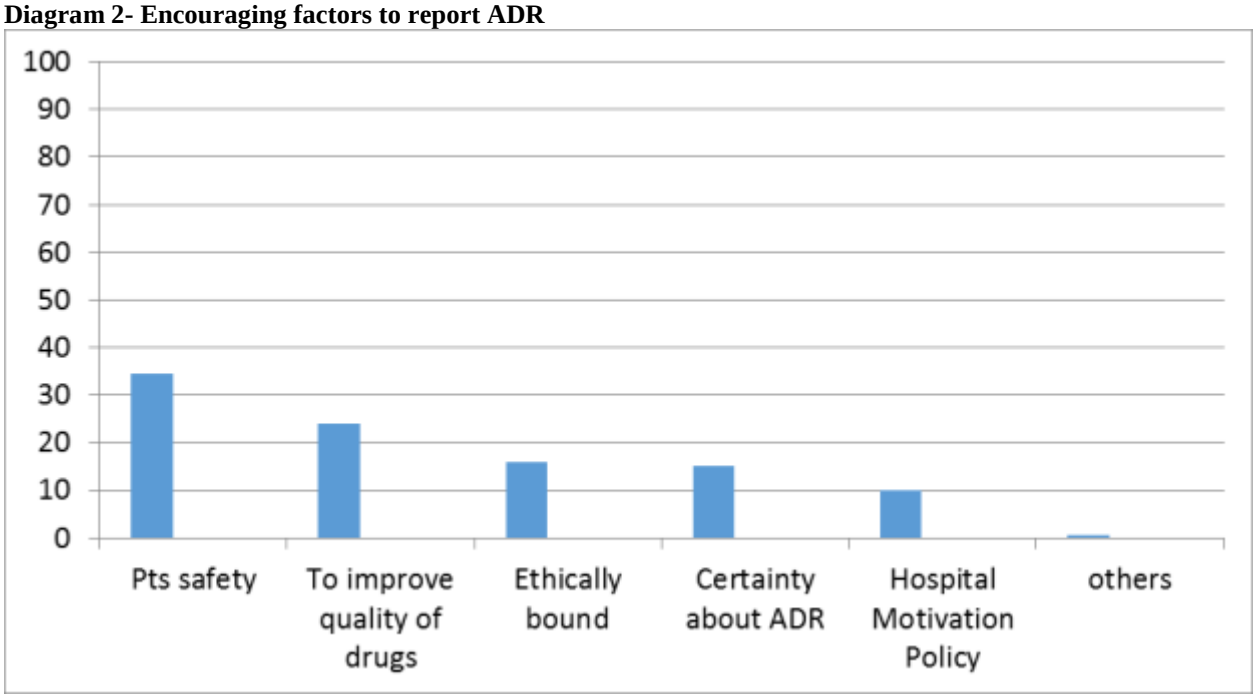
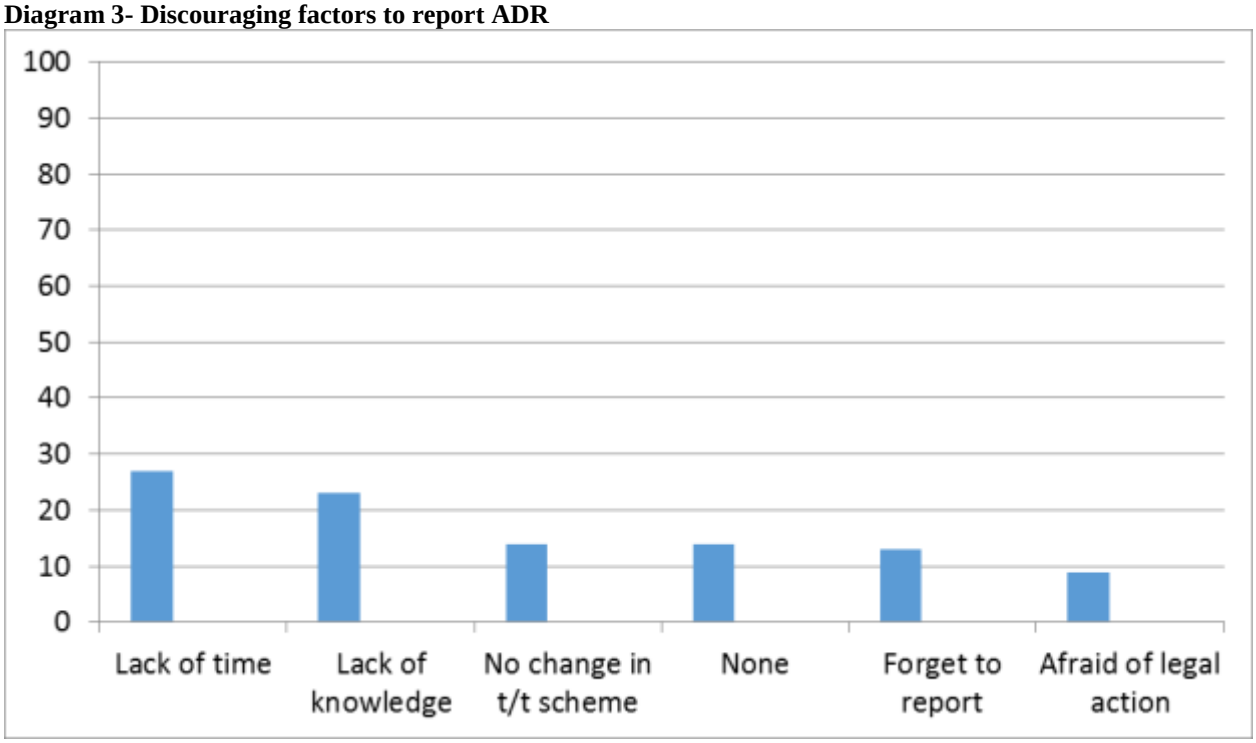


Diagram 3- Discouraging factors to report ADR



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