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Research Article

Pharmacovigilance-Related Knowledge, Attitudes and Practices among Institutional Doctors: A Prospective Questionnaire-based Internet Study

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Abstract

Objective: To determine level of knowledge, attitudes and practices (KAPs) in relation to pharmacovigilance amongst institutional doctors working in clinical departments.

Materials and Methods: A prospective cross-sectional study in which a questionnaire on KAPs about pharmacovigilance was served to the 450 prospective respondents comprising only doctors working in clinical departments of four medical colleges in the capital city of Lucknow, India, by e-mails. The data was analysed by employing standard statistical methods.

Results: Out of the 450 doctors who were served the questionnaire, a total of only 201 (44.7%) responded with appropriately filled proformas attached to original e-mails followed by two further reminders, each at fortnightly interval. Amongst the 201 respondents, only 62% showed reasonable knowledge, closely followed by 59.5% with adequate attitudes. Adequate practices, on an average, were observed in just 19%.

Conclusion: KAPs in relation to pharmacovigilance, even in institutional doctors working in clinical departments of tertiary care centres, need to be boosted through various endeavours.

Keywords: *Adverse Drug Reactions; Attitudes; Knowledge; Perceptions; Pharmacovigilance; Practices; Rational Drug Therapy; Spontaneous Reporting; Under-Reporting*

Introduction

Pharmacovigilance (PV) deals with the activities aimed at detection, assessment, understanding, management and prevention of adverse effects or any other drug-related problem [1,2]. It is the lifeline of rational and safe drug therapy [3,4]. Its application involves not just the doctors in health facilities and office practice, but also nurses, pharmacists and other healthcare providers and caretakers, and patients (consumers) and their attendants.

A review of the literature shows that the ADR reporting rate is globally low though this underreporting is more remarkable in the low-income countries [5,6]. In the Indian subcontinent, it is as low as < 1 to 3% compared to the global rate of 5%. The factors contributing to such low reporting include poor knowledge attitudes and practices as also poor sensitisation towards pharmacovigilance among the healthcare professionals.

Management of ADRs is an expensive affair. The average cost involved in managing these ADRs comes to around INR 900 (around US$ 12)/patient. Besides, avoidable ADRs are liable to be a bottleneck in carrying out the basic treatment of the primary disease. As a consequence, the prognosis and outcome may get significantly impacted.

Identification of level of KAPs is considered to be the most logical way of determining the factors responsible for underreporting [7-9]. Understandably, reasonably good KAPs associated with pharmacovigilance in India, may lead to increasing reporting of ADRs, and thereby, reducing additional suffering and health care cost of patient.

Aim of the Study

This prospective questionnaire-based cross-sectional study aims at determining the level of KAPs among clinical doctors in 5 teaching institutions in Lucknow, India.

Materials and Methods

Setting

A cross sectional study was conducted. Target responders consisted of doctors, including junior and senior residents, working in clinical departments of the following four different teaching medical institutions in Lucknow, India:

1. King George Medical University
2. Prasad Institute of Medical Sciences
3. Career Institute of Medical Sciences
4. Eras Lucknow Medical College.

Design

The questionnaire employed was adapted from studies regarding concerns of health care professionals about adverse drug reaction reporting and reasons of underreporting these reactions, information and knowledge about reporting of ADR.

According, to the questionnaire performa was e-mailed to clinical doctors (whose e-mail IDs were available) of the designated four teaching medical institutions. Only properly filled proformas were included for analysis of the data.

Statistical analysis

Information obtained from the questionnaire was analysed using standard statistical methods. The statistical significance value was calculated at a $P = 0.05$ and a confidence interval of 95%.

Results

Table 1 presents the response of the potential participants to the initial and subsequent two e-mail requests. The overall response rate was 44.4% in spite of two reminders at a fortnightly interval.

E-mail	Total No (%) with positive response
After first mail	145 (32)
After second mail	184 (41)
After third mail	201 (44.4)

Table 1: *Response of 450 potential participants to e-mail requests.*

Questionnaire item	Yes No. (%)
Aware about pharmacovigilance/ADRs	140 (70)
Aware regarding the existence of a National Pharmacovigilance Programme of India	105 (52.5)
Aware of the Pharmacovigilance Committee/centre in the institution	106 (53)
Familiarity with ADR reporting procedure	56 (23)
ASR reporting is necessary	190 (95)
ADR reporting is a professional obligation for doctors	150 (75)

Table 2: *Response to questionnaire items on "knowledge".*

Questionnaire item	Yes No (%)
Belief that ADR reporting is primarily the responsibility of the attending doctor, nurse and pharmacist	114 (57)
Not only serious but also minor ADRs need reporting	104(52)
OTC medicines can also cause side effects	179 (89.5)
Herbal medicines can cause side effects	86 (43)
Inclination in education/training programmes for ADR reporting	111(55.5)

Table 3: *Response to questionnaire items on "attitudes", including beliefs and perceptions.*

Questionnaire item	Yes No (%)
Reported ADR at least once	43 (21.5)
Promoting ADR reporting in some way	25 (12.5)
Asking medical representatives about likely ADRs of new molecules	34 (17)
Familiarity with filling of ADR reporting form	50 (25)

Table 4: *Response to questionnaire items on "practices".*

Discussion

That ADRs are under-reported globally, more so in the Indian subcontinent, stands well documented [1-6] from time to time. The contributing factors for their under-reporting include patient and attendant-related factors like failure to recognize ADR or inability to link

the ADR with a drug [4] and healthcare personnel-related factors. The usual doctor-related factors are the feeling of guilt, fear of litigation, ignorance, lethargy, inadequate risk perception about newly marketed drugs, diffidence, insufficient training to identify ADRs, and lack of awareness about pharmacovigilance.

Identification of deficiencies in KAPs is expected to contribute to determining the reason(s) for under-reporting. A review of medical literature shows a number of studies on KAPs in relation to pharmacovigilance from India and abroad highlighting deficiencies in KAPs. Only a few studies are exclusively on clinical doctors in teaching hospitals from India [8-19].

A recent meta-analysis [12] has highlighted the significant gap in KAPs in relation to ADR reporting. Over 50% healthcare professionals were not aware of the Pharmacovigilance Programme of India. Some 32% considered all marketed drugs to be safe. Nearly 75% had never reported an ADR. Almost 30% were not interested in reporting them.

Most of the available studies exclusively on doctors dealt with small samples which are less likely to be representative of doctors across the board [8,11,13-17].

The present prospective study was, therefore, conducted to determine the status of KAPs among clinicians drawn from four medical institutions in Lucknow. This is a prospective, cross-sectional internet study and employs a questionnaire in which respondents were supposed to answer as "yes" or "no".

According to our observations, a majority of the doctors working in clinical; departments of four tertiary institutes in Lucknow have a reasonable knowledge about ADRs and pharmacovigilance. This more or less applies to the attitudes, including beliefs and perceptions, as well. However, when it comes to practices, the observations depict a sordid picture.

An examination of table 5, presenting the mean of the correct answers ("es") in case of knowledge, attitudes and practices among the participants, highlights a very vital point. Though the mean of the items about "knowledge" was higher than that of the "attitude", the difference was not statistically significant. ($p>0.5$). However, the mean of the items about "practices" was far lower than that of "knowledge as well as "attitude". Statistically, the difference was highly significant with P value < 0.001.

Component	Mean No (%)
Knowledge	124 (62)
Attitudes	119 (59.5)
Practices	38 (19)

Table 5: *Mean numbers (%) of correct ("yes') answers regarding three individual components of KAPs.*

More precisely, a close look at our observations shows:

1. Most doctors evince a perceptible gap between knowledge and attitudes, including beliefs and perceptions on one hand and their application in actual practice on the other hand.
2. Even though a majority of the doctors have reasonable knowledge as well as attitudes, the fact remains that a significant proportion is deficient in these.
3. When it comes to practices, the observations are a sordid reflection on the performance of the participants as far as ADR reporting is concerned. Only 43 (21.5%) admitted having reported ADRs at least once. What is worst, just 50 (25% were familiar with proper filling of the ADR reporting form).

That roots of inadequacies in KAPs in doctors are laid in undergraduate career has been pointed out time and again. A recent study by Hema., *et al*. [20] from Mysore, South India suggests that it is mandatory to include pharmacovigilance in the undergraduate training programme. Furthermore, interns and the postgraduates should be sensitised to the ADR reporting during their training period.

Rehan., *et al*. [21] in a survey of 107 MBBS students of 5th semester found that their KAPs needed improvement. They emphasized the need for suitable changes in the undergraduate teaching curriculum.

Kumbar., *et al*. [22] from has also argued for to sensitize undergraduate medical students about ADRs. This is likely to prepare them for boost ADR reporting rate as and when they enter actual clinical practice.

In our considered opinion, in order to boost the ADR reporting rate, there is a dire need to augment endeavours targeted at enhancing the KAPs of even doctors involved in clinical departments of teaching hospitals. A significant emphasis on teaching of pharmacovigilance during undergraduate career may go a long way in achieving this mission.

Summary and Conclusion

Overall, the knowledge and attitudes about pharmacovigilance and ADRs in a majority of the teaching institutional doctors working in clinical departments are reasonably good. However, a very high proportion of them, including senior faculty, are lacking in actual practices, especially with regard to reporting of ADRs.

Though an overwhelming majority of the participants admit reporting and monitoring to be important, only 21% have in actuality reported ADRs.

To conclude, there is a need for continuing education and sensitization regarding pharmacovigilance and ADR reporting system even for doctors working in clinical departments in order to improve the ADR reporting and other ongoing pharmacovigilance activities. The teaching of the pharmacovigilance at the undergraduate level may contribute significantly to achieving this goal.

Recommendations

1. Establishment of one separate unit of pharmacovigilance under pharmacology department. This Unit should remain in continuous to uch with clinical doctors, who actually observe drug reaction.
2. Organising sensitisation workshop on pharmacovigilance and ADR reporting from time to time.
3. Strengthening of the Pharmacovigilance teaching in undergraduate career.

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Conflict of Interest

Nil.

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