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Letter to the Editor

Adverse drug reaction (ADR) reporting in India: a long way to go

Sir,

New drugs are regularly introduced for treatment, diagnosis or prevention of diseases. Adverse drug reactions (ADR) can be seen in clinical practice with both new as well as marketed medicines. Spontaneous reporting of ADR is commonly practiced method for monitoring of ADR. Healthcare practitioners have an important role in pharmacovigilance and ADR reporting.[1] Many studies[2-8] have been conducted to understand the knowledge, attitude and practice of ADR reporting among healthcare practitioners in India. The population surveyed in these studied ranged between 90-1200. One large study[4] included population of 1200 physicians across India out of which 1000 were contacted for study participation. Table 1 shows the profile of participants included in these studies.

All of the studies were conducted in teaching hospital/tertiary care hospital except the study conducted by Kharkar and Bowalekar[4] which included medical practitioners across India.

Table 1: Profile of study participants.

Author	Profile of study participants
Desai CK et al[2]	Doctors in a civil hospital
Chopra D et al[3]	Doctors in a teaching hospital
Kharkar and Bowalekar[4]	Medical practitioners across India
Rehan SH et al[5]	Nurses and resident doctors
Pimpalkhute SA et al[6]	Resident doctors in a teaching institute
Hardeep et al[7]	Doctors from the clinical, paraclinical and the preclinical fields in a teaching hospital
Khan SA et al[8]	Doctors in a teaching hospital

Table 2: Reasons of less ADR reporting.

Authors	Reasons of underreporting/study findings
Chopra D et al[3]	• Low rate of knowing correct definition of pharmacovigilance and adverse event • Lack of awareness of National Pharmacovigilance Program • Lack of awareness of ADR reporting (what and whom to report)
Kharkar and Bowalekar[4]	• Less awareness about the ADR centres • Less familiarity with ADR reporting procedure
Desai CK et al[2]	• Lack of awareness about where and how to report adverse events • Lack of access to reporting form • Managing patient was more important than reporting ADR • Legal liability issues • Concerns about professional liability • Did not think it to be important • Patient confidentiality issues
Khan SA et al[8]	• Inadequate risk perception • Fear • Diffidence • Lack of clarity on ADR form • Lethargy • Insufficient training to identify ADRs • Lack of awareness about pharmacovigilance program and ADR monitoring centre
Pimpalkhute SA et al[6]	• Lack of knowledge about the reporting process • Lack of time to report

Hardeep et al[7]	• Lack of awareness on how and where to report the adverse events • Lack of time • Patient confidentiality issues • Managing patient is more important
Rehan SH et al[5]	• Knowledge about elements of pharmacovigilance • Information of what to report and whom to report

Table 3: Suggestions for improving ADR reporting.

Authors	Suggestions for improving ADR reporting
Kharkar and Bowalekar[4]	• Need for more ADR centres • Electronic reporting of ADR • Education and creating awareness • Simplifying the process of submission • Toll free number for reporting ADR • Financial compensation for reporting ADR
Chopra D et al[3]	• Continuous medical education (CMEs) • Training • Integration of adverse event reporting into the clinical activities of the doctors
Desai CK et al[2]	• Email/online reporting through websites • Personal communication for reporting • Creating awareness about ADR monitoring through educational programs • Making easy access to ADR reporting forms • Simplification of reporting process • Providing feedback about the causality • Posting of pharmacologist in wards
Pimpalkhute SA et al[6]	• Making booklets and posters on ADR reporting guidelines • Increasing awareness through training, workshops, CMEs • Making reporting compulsory • Incentives for reporting • Simplifying reporting process
Rehan SH et al[5]	• Reporting via telephone, drop box kept • Need of frequent workshops, CMEs and other educational activities
Hardeep et al[7]	• Seminars or workshops on pharmacovigilance awareness • Compulsory reporting
Khan SA et al[8]	• Not to reveal identity of the prescriber and reporter

The response rate for the survey questionnaire ranged between 61%-100%, whereas the ADR reporting rate ranged between 15%-30% in most of the studies. Kharkar and Bowalekar study[4] reported that 18.5% participants reported ADR to ADR centres while large number of practitioners (89.7%) reported ADR to medical representatives of pharmaceutical company or Drugs Controller General of India (DCGI), NGOs or others. In the study conducted by Rehan HS et al, 87% of resident doctors and 89% of nurses mentioned that they monitored and reported ADRs. However, the study results reported that 75% nurses compared to only 33% of the resident doctors had knowledge about "whom to report" an ADR. Based on these observed difference between the reporting rate and knowledge about whom to report ADR, the possibility of incorrect reporting cannot be excluded. The important reasons for less ADR reporting rate are mentioned in table 2.

Similarly, the suggestions to improve ADR reporting rate are given in table 3.

Although many studies have been conducted in this field, most of them are conducted in teaching institute/tertiary care hospital.

A recently published study from Nepal had 20.1% reporting rate among healthcare professionals working at Regional Pharmacovigilance Centres (RPCs)[9] while another study in Venezuela among physicians and pharmacists had 24.7% reporting rate of a suspected ADR.[10] The ADR reporting rate from these countries is almost similar to many studies conducted in India.

The important reasons of underreporting included mainly lack of awareness about reporting of adverse events like when, what, where and how to report ADR. This implies

the need of training and educational activities for improvement of the awareness about reporting of ADRs. Not surprisingly, the suggestions to improve the reporting rate are mainly related to training and education on adverse event reporting. There is a need for conducting regular training programs and educational activities like CMEs focusing on adverse event reporting for healthcare practitioners across India. Emphasis on adverse event reporting should be given while teaching undergraduate and post graduate students.

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