



Effective Reporting by Pharmacist in Pharmacovigilance Programme of India

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Abstract

Background: Pharmacist is the very important link between the healthcare provider and patient.

Objective: The objective of this study is to analyze the reporting by pharmacist in Pharmacovigilance Programme of India (PvPI).

Method: Individual Case Safety Reports (ICSRs) submitted by pharmacists spontaneously to the NCC-PvPI were extracted from the data base of July 2011 to December 2014. We analyzed these reports for patients Sex, Age and Seriousness of the reactions, etc.

Results: Out of 1,10,000 ICSR in the database 16646 ICSR were reported by Pharmacists. 3782 reports were serious and 9601 reports were non serious and 1979 reports were of unknown criteria.

Conclusion: The pharmacist can help in buildup of an effective Pharmacovigilance system not only in India but throughout the world.

Keywords: Analysis of pharmacist's ADR reporting under pharmacovigilance programme of India; Involvement of pharmacist's in pharmacovigilance activities in India; Trends of reporting of ADR through pharmacists in India

Introduction

Pharmacist plays an important role in field of medicinal drugs including safety of drugs, i.e., Pharmacovigilance [1]. The occurrence of Adverse Drug Reactions (ADRs) through any drug is very frequent now days. In such situation pharmacist seems to act as back bone who educate patients regarding benefit risk ratio of prescribed medicines, make people more aware towards various ADRs associated with drugs and reporting of that ADRs to competent authority [2].

Pharmacists are the health professionals most accessible to the public. They supply medicines in accordance with a prescription or, when legally permitted, sell them without a prescription. In addition to this they ensure an accurate supply of appropriate products, their professional activities also cover counseling of patients at the time of dispensing of prescription and non-prescription drugs, to patients and the general public, and participate in health-promotion programme [3,4]. They maintain links with other health professionals in primary health care. In many countries, the community pharmacist is in a unique position to be fully aware of the patient's past and current drug history and, consequently, can provide essential advice to the prescriber [3]. Moreover pharmacist is a person who belongs from our own society and has sound knowledge of medical terminology, medicines and other drug related issues.

It is easier for a pharmacist to understand the problem of public in regards of health and convey any ADR or any other drug alerts to the relevant authority. The role of pharmacist in the reporting ADRs is not appreciated globally on contrary India is among those countries that widely accepts and promotes ADRs reporting through pharmacist. [5] As stated in literature many countries are accepting ADR reporting from pharmacist yet very few offend the same [1,6,7]. Contribution is bit high in countries like Canada, USA, Australia, Netherland, Spain and Japan [8]. After looking into this pharmacist in the country will gain more encouragement to report ADRs and can lead to better patient care

Pharmacovigilance is a key tool to ensure patient safety for both newly released drugs and those that are well established in the market. Attention towards patient safety has marked its significance both at national and international level. Urging the needs for patient safety, India also setup its own surveillance system "Pharmacovigilance Programme of India" (PvPI). PvPI was launched in the year 2010 by the Ministry of Health and Family Welfare, Government of India to monitor the drug safety and thereby reducing the risk associated with use of medicines in Indian population. Indian Pharmacopoeia Commission (IPC) is functioning as National Coordination Centre (NCC) for PvPI since 15th April 2011. It collects and evaluates spontaneous reports of adverse reactions to medicines, vaccines, medical devices and herbal products from all Health Care Professionals (HCPs) and consumers/patient. To monitor ADRs and report to NCC ADR Monitoring Centers (AMCs) have been setup all over India [9,10]. These AMCs are Medical Council of India (MCI) approved medical colleges and hospitals, medical/central/autonomous institutes, public health programmes and corporate hospitals. All these centers are provided with qualified pharmacy degree holders, dentists, etc. as Technical Associates (TAs). They are responsible for collecting the adverse event information from the patients, performing follow ups with them to check the completeness of the ADR reports as per Standard Operating Procedures (SOPs), entering information in the prescribed software (VigiFlow™) and sending them to the NCC. VigiFlow™ is web-based software for International Drug Monitoring in the WHO Programme. VigiFlow™ is used by the IPC for transmission of reports to the WHO database. Database holds more than one lakh reports, providing

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support to Central Drug Standard Control Organization (CDSCO) for regulatory action [11,12].

This article focuses the contribution of pharmacist in reporting ADRs and further recommendations to promote more awareness and reporting ADRs. Decade's back Health professionals play a vital role in safeguarding the health of the population by ensuring the benefits of use of medicine and outweigh the risks associated with its use. In today's era, the pattern has changed even different categories of health professional are working out on ADR reporting [13]. Similarly the role of pharmacist has also changed from merely the dispensing of drugs to health care and patient safety, looking into Indian Scenario, reports from pharmacist are acceptable. Individual Case Safety Reports (ICSRs) are entered manually by TAs placed at AMCs into VigiFlow™ along with mandatory field.

1. Pharmacist as a reporter of ADR: The foremost step in detection of ADR is collection of data. Pharmacists can provide early detection of ADRs and other drug related problems by ward visits and interacting with patients. Pharmacist is responsible to report any suspicion of drug unexpectedly causing a risk situation for a patient. TAs as pharmacist with HCPs plays an important role to ensure safety of drugs by identifying and investigating certain patient subgroups with exceptional sensitivities and monitoring the patients prescribed with drugs highly susceptible to cause ADRs [14,15]. The collected ADRs report with all relevant data are entered into VigiFlow™ for completeness and sent to NCC for further quality review.

2. Pharmacist in ADR assessment: Pharmacist's investigate every suspected ADRs for its nature, probability, severity, identification of the co-morbidities, past and present illness [14]. Also review the reported ADRs to differentiate between suspected ADRs and medication error, alongside develop risk reduction strategies and helps to reduce the risk of ADRs through detecting, reporting and assessing suspected ADRs [3]. They play key role in determining the probability that the event is drug related, categorize severity, track ADRs and incidence. [16,17]. They monitor and document the suspected ADRs and does critical evaluation of drug information for further reporting of the suspected ADRs to the NCC-PvPI.

3. Pharmacist in ADR prevention: Pharmacist keeps the track record and monitors the patients who are at greater risk of developing ADRs. They keep the Follow up of patients to assess the outcome of the reaction, its management and counsel patients while they are discharged. Pharmacists play an integral role in educating patients on various aspects of medication use, including safety as many patients are not aware of risk benefit information about their medications [18-20]. Timely conferences and training sessions are organized for the awareness and betterment of public health.

Methodology

All the 1,10,000 ICSRs received by the NCC-PvPI during the period of July 2011 to December 2014 were analysed. The reports were examined for the information like reporter's professional category; patient age and sex, seriousness criteria, etc. Year wise progresses in contribution of Pharmacist were also studied. The incomplete reports were reverted back to AMC to get more detailed information. ADR reported through pharmacist were upgraded for the coding of reactions and drugs as per WHO-ART and WHO-DD respectively. The duplicate reports were nullified.

Results

The ICSRs reported by Pharmacists were selected and analyzed for serious, non serious and unknown; The ICSRs were segregated as per their age and sex group. The total numbers of ICSRs reported by pharmacist 16646 out of which 8406 (50.5%) were male and 8010 (48.12%) were females and 132 (0.79%) were found to be in unknown category. Age criteria were assessed as pharmacist collected 15199 (91.31%) ICSRs were of adults, 899 (5.4%) ICSRs were of children, 546 (3.28%) ICSRs were of elderly Patients. 3782 (22.2%) ICSRs were found be serious and 9601 reports were non-serious (57.68%) and 1979 (11.88%) ICSR's criteria of seriousness were unknown (Table 1). Year per year contribution of pharmacist was found to increased, In year 2011, 2351 ICSRs were reported where as in 2012, 2013 and 2014 they were 3510, 4364, 6421 ICSRs respectively (Figure 1). In the further analysis we observed that the seriousness unknown and Gender unknown reports were decreasing with time as the awareness of programme is being disseminated by the PvPI Personnel, as shown in graphs (Figure 2).

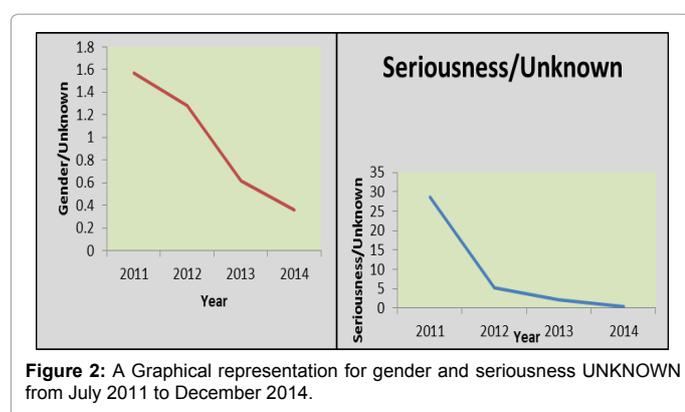
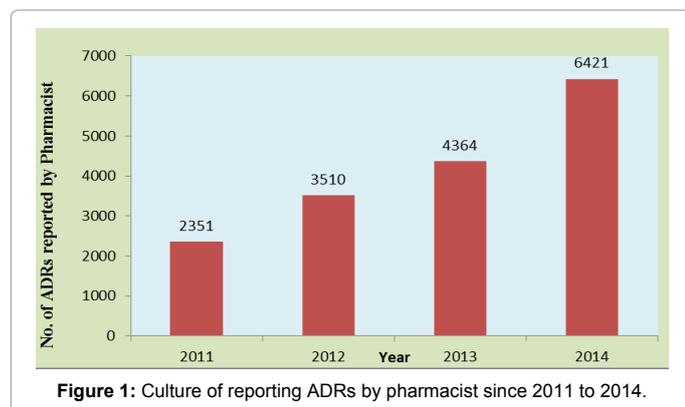
Discussion

This is the first study to describe the ADR reporting by pharmacist in PvPI. The result suggests ADR reporting by the pharmacist in PvPI is encouraging and is increasing rapidly since 2011. The ICSRs submitted by pharmacists were critically reviewed by the PvPI team of experts, in the initially stage we found that the ICSRs submitted by Pharmacist were not of good quality but after conducting several trainings and Continuing Medical Education in the hospitals the quality and quantity of ICSRs submitted by Pharmacists has been increased. Initially the pharmacists were unable to do the causality assessment that was upgraded or downgraded by the expert reviewers at NCC-PvPI. After that the ICSRs were committed to the WHO-UMC. Lack of knowledge of where, what and how to report ADRs affects the reporting system which is being overcome slowly and steadily by devastating strategies of creating awareness among all HCPs.

Many countries have authorized pharmacist to report and to write certain prescription [1,16]. Already the country like ours has authorizes pharmacist to report still their contribution to system is under the mark. They need to be more actively involved in reporting ADRs by implementing new approaches [5]. It's the Fundamental's role of pharmacist is to ensure that medicines are used safely. The PvPI ADR reporting system shows that pharmacist contribution is yet to be enhanced as compared to PV system in other countries.

Gender	Number of ICSRs	Percentage (%)
Male	8406	50.5
Female	8010	48.12
Unknown	132	0.79
Age group		
Adult	15199	91.31
Child	899	5.4
Elderly	546	3.28
Seriousness		
Serious	3782	22.72
Non Serious	9601	57.68
Unknown	1979	11.88

Table 1: ADRs by pharmacist on basis of gender, age group and seriousness from July 2011 to Dec 2014.



Conclusion

Pharmacists are considered as back bone of health care system and have an important responsibility in monitoring, detecting and preventing ADRs. The reporting by pharmacist is appreciable with the expansion of programme; still a lot have to be done as compared to the status of other countries. More awareness programmes CMEs have to be organized to expand and to make understand the importance of Reporting ADRs. Till now reporting is done only by Hospital Pharmacist is yet to frame this to community pharmacist as at the time of dispensing of prescription and non-prescription drugs, counseling of patients can be done.

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