A STUDY ON KNOWLEDGE AND AWARENESS OF COMMUNITY PHARMACIST TOWARDS ADR REPORTING

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ABSTRACT

Background: Adverse Drug Reactions (ADRs) are a major cause of drug related morbidity and mortality. Pharmacovigilance is the science that plays an essential role in the reduction of ADRs, thus the evolution and growth of this science are critical for effective and safe clinical practice. Objectives: This study is considered the first study in the region to evaluate pharmacist’s knowledge, practice and attitudes toward ADRs reporting after establishing the national ADRs reporting center in Telangana state. Method: A cross sectional study was used to evaluate pharmacist knowledge and attitude toward ADRs reporting. A structured validated questionnaire was developed for this purpose and a total of 300 pharmacists were recruited to participate in this study. Results: The majority of pharmacists have insufficient awareness and lack of knowledge about pharmacovigilance and ADRs reporting. Also the rate of reporting of ADRs was extremely poor. Several factors were found to discourage pharmacists from reporting ADRs, which include inadequate information available from the patient, unavailability of pharmacist ADRs form when needed, unawareness of the existence of the national ADRs reporting system. Also pharmacists think that ADRs are unimportant or they did not know how to report them. Conclusion: The results of this study suggest that pharmacists have insufficient knowledge about the concept of pharmacovigilance and spontaneous ADRs reporting. On the other hand, pharmacists had positive attitudes toward pharmacovigilance, despite their little experience with ADRs reporting. Educational programs are needed to increase pharmacist’s role in the reporting process, and thus to have a positive impact on the overall patient caring process.
INTRODUCTION

Adverse Drug Reactions (ADRs) are a major cause of patient-related morbidity and mortality (Lee and Thomas, 2007) and they are associated with a high prevalence of hospital admission reaching about 6.5% as well as a considerable economic burden; in which around £466 million was reported as an annual total cost for drug-related admissions in the United Kingdom (Pirmohamed et al., 2004). Thus, reporting of ADRs is considered to be an important step in maintaining and achieving a safe drug therapy use.

Most countries developed their national pharmacovigilance systems after the thalidomide disaster in 1960s (Rawlins, 1995). World Health Organization (WHO) has established the definition of pharmacovigilance as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems” (WHO, 2002).

Pharmacovigilance plays an essential role in the reduction of ADRs, thus the evolution and growth of this science are critical for effective and safe clinical practice. ADRs spontaneous reporting systems are the basic components for the comprehensive post-marketing surveillance of drug-induced risks (Stricker and Psaty, 2004).

These systems are inexpensive and simple to operate and they enable the generation of signals indicating potential problems, allowing the identification of new and rare ADRs, but also enable continuous monitoring of all drugs used in real-life situations from the time they are first marketed. However, their strength is tightly connected to the actual reporting rate by health care professionals (Wiholm et al., 2002).

All sectors of the healthcare system would need to be involved in the reporting process, such as public and private hospitals, general practitioners, nurses, retail dispensaries and pharmacists. Wherever medicines are being used, there should be a readiness to observe and report unwanted adverse events (both expected and unexpected) (WHO, 2002, 2004).

Pharmacists were found to have an important role in ADRs reporting and constitute a potentially valuable source for spontaneous ADRs reports (Kaboli et al., 2006; van Grootheest et al., 2004). However, under-reporting of ADRs is a main intrinsic problem, in which reporting of serious ADRs rarely exceeds 10% (Granas et al., 2007; Su et al., 2010; Toklu and Uysal, 2008; Vessal et al., 2009).
It was found that the main reasons for poor reporting rate were either due to legislative restrictions or because of lack of tradition (van Grootheest and de Jong-van den Berg, 2005; van Grootheest et al., 2004).

The Jordanian Pharmacovigilance Center (JPC) was established in January 2001 in cooperation with Sweden International Development Agency (SIDA) and the Higher Council for Science and Technology (Yadav, 2008). Since that time, no studies have assessed pharmacists’ knowledge and attitudes toward ADRs reporting in the hospital and community settings in Jordan.

Our study was in the unique position to study pharmacist’s attitudes toward ADRs reporting after the initiation of the national ADRs reporting center and their understanding and knowledge of the yellow card spontaneous ADRs reporting scheme.

An Adverse Drug Reaction (ADR) is an injury caused by taking a medication. ADRs may occur following a single dose or prolonged administration of a drug or result from the combination of two or more drugs.

The meaning of this expression differs from the meaning of "side effect", as this last expression might also imply that the effects can be beneficial. The study of ADRs is the concern of the field known as pharmacovigilance.

An Adverse Drug Event (ADE) refers to any injury occurring at the time a drug is used, whether or not it is identified as a cause of the injury.

Pharmacovigilance (PV or PhV), also known as drug safety, is the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products.[1] The etymological roots for the word "pharmacovigilance" are: pharmakon (Greek for drug) and vigilare (Latin for to keep watch).

As such, pharmacovigilance heavily focuses on adverse drug reactions, or ADRs, which are defined as any response to a drug which is noxious and unintended, including lack of efficacy (the condition that this definition only applies with the doses normally used for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological disorder function was excluded with the latest amendment of the applicable legislation[2]).
Medication errors such as overdose, and misuse and abuse of a drug as well as drug exposure during pregnancy and breastfeeding, are also of interest, even without an adverse event, because they may result in an adverse drug reaction.\[3\]

Information received from patients and healthcare providers via pharmacovigilance agreements (PVAs), as well as other sources such as the medical literature, plays a critical role in providing the data necessary for pharmacovigilance to take place.

In fact, in order to market or to test a pharmaceutical product in most countries, adverse event data received by the license holder (usually a pharmaceutical company) must be submitted to the local drug regulatory authority. (See Adverse Event Reporting below).

Ultimately, pharmacovigilance is concerned with identifying the hazards associated with pharmaceutical products and with minimizing the risk of any harm that may come to patients. Companies must conduct a comprehensive drug safety and pharmacovigilance audit to assess their compliance with worldwide laws, regulations, and guidance.

**Adverse Drug Reaction**

Any noxious, undesired, or unintended response to a therapeutic agent, which may be expected or unexpected and may occur at dosages used for the prophylaxis, diagnosis, or therapy of disease, or for modifying physiologic function. ADRs do not include therapeutic failures, poisoning, accidental or intentional overdoses. ADRs occur in up to 15% of all drug administrations, but are rarely fatal. They can be divided into type A-dose-dependent or predictable or type B-idiosyncratic or allergic reactions.

Clinical findings Pruritus, nausea, vomiting, rash, confusion, lethargy, etc. Culprits ADR are most commonly caused by analgesics and narcotics, antibiotics, cardiovascular agents, anticoagulants and psychotherapeutics. Regulatory process In the preapproval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established, all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions; a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility—i.e., the relationship cannot be ruled out.
The World Health Organization defines an adverse drug reaction (ADR) as any noxious, unintentional and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or therapy. Numerous organizations have their own definition. Any drug may cause an adverse drug reaction. Undoubtedly, all drugs produce an ADR in someone who has used them. Three to five percent (3-5%) of hospital admissions are caused by ADRs. The incidence of serious and fatal adverse reactions in hospital patients has been reported between 0.32% and 6.7%. Adverse drug reactions may be separated into two groups, Type A and Type B.

**Type A reactions** are expected exaggerations of the drugs known effect. These are usually dose dependent and predictable and account for the majority of ADRs. Characteristics Type A reactions include: higher than normal dose administered, impaired metabolism or excretion, or very sensitive individuals. These reactions are often found in the FDA approved product labeling.

**Type B reactions** are idiosyncratic and usually unrelated to the drug's known pharmacology. Normally they are not related to the dose, are unpredictable, uncommon and usually more serious than Type A. Examples are carcinogens and teratogens. These reactions are more commonly reported after a drug has been on the market for a number of years.

Type A reactions include medication errors. Therefore, there may be some difficulty in deciding the correct reporting procedure. If the reaction is caused by a prescribing, administering or monitoring error, a medication error has occurred and medication error report should be completed. If the patient develops an ADR when the prescribing, administering and monitoring are appropriately carried out, an adverse drug reaction report form should be completed.

The FDA compiles information on *adverse drug events*. If a medicine causes a serious adverse event due to a either medication error or ADR the FDA should be notified. If a medication is commonly associated with medication errors the FDA should be notified. This feedback is essential so that the package labeling can be updated and the risk benefit ratio of the drug may be better understood.

In order for drugs to obtain FDA approval they must be proven safe and effective. The 1962 amendment to the Federal Food, Drug, and Cosmetic Act requires manufacturers to report
adverse drug events detected in post marketing settings to the FDA. The Food and Drug Modernization act of 1997 states that substantial evidence of drug effectiveness may consist of data from one adequate and well-controlled clinical investigation plus confirmatory evidence.

Most drugs are studied in less than 4,000 patients before FDA approval. Drug reactions that occur in less than 1 in 1000 patients are difficult to detect. Premarketing trials generally excluded special populations such as children, elderly, and women of child bearing age. Most drug withdrawn from the market for serious side effects, are withdrawn within 1-2 years of FDA approval, as experience is gained in a larger population outside of the narrow confines of clinical trials.

METHODOLOGY

Study design, settings and study subjects
This is a cross-sectional study that was conducted in two of the largest cities in Hyderabad and Secunderabad. The study commenced in Nov-2015 and continued for 6 months. Three hundred were included in the study with a response rate of 96.7%. Each pharmacist was asked to fill a validated structured questionnaire delivered by hand. The participated pharmacists were from independent and chain pharmacies. The community pharmacies coverage represented about 5.2% of the total number of pharmacies in Hyderabad.

Questionnaire
Content validity was assessed by distributing the questionnaire to 300 pharmacists recruited to complete the validation process. The initial draft of questionnaire was hand delivered to those pharmacists to help review the structured questionnaire and perform any amendments needed.

The final form of the questionnaire consisted of pharmacist demographic data, and a total of 20 questions that covered two main areas of interest. These areas included: (1) assessment of pharmacist knowledge regarding ADRs reporting, (2) Barriers of pharmacists towards ADR reporting.

Statistical analysis
Data were analyzed using statistical package for social science version 17 (SPSS, Inc., Chicago, IL, USA). The descriptive analysis was done using mean and SD for continuous
variables and percentage for qualitative variables. Pearson Chi-Square was used to calculate p-values for categorical variables.

**Ethical clearance**

Ethical clearance was obtained from the institutional ethics committee. All the pharmacists participate in the survey at Telangana state with CADR those who fit in the category of probable or possible drug reaction as per WHO causality assessment. From November 2015 to April 2016 were included in this cross-sectional study after obtaining return in form questionnaire. The drug reaction pattern observed in the study population was determined and the common offending drugs were identified.

**RESULTS**

Table 1: Percentage of students selecting options yes/no by course-wise and m/f wise

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Fig. No. 1: Percentage of students selected options for each question and each course m/f wise
Assessment of pharmacists knowledge using pre-questionnaire and post-questionnaire

1. Have you heard about ADR?

2. Do you know that ADR’s can be reported?
3. Do you know where to obtain ADR forms?

![Graph](image)

Fig. No. 4: Percentage of students for question no. 3

4. Have you ever reported ADR?

![Graph](image)

Fig. No. 5: Percentage of students for question no. 4

5. Have you observed any ADR that caused?

![Graph](image)

Fig. No. 6: Percentage of students for question no. 5
6. Is reporting of ADR apart of pharmaceutical care?

![Fig. No. 7: Percentage of students for question no. 6](image1)

7. Before reporting any ADR, consulting a doctor is important?

![Fig. No. 8: Percentage of students for question no. 7](image2)

8. Do you think ADR reporting is compulsory?

![Fig. No. 9: Percentage of students for question no. 8](image3)
9. Whether ADR reporting should be voluntary?

![Graph showing percentage of students for question no. 9]

**Fig. No. 10: Percentage of students for question no. 9**

**CONCLUSION**

Our basic study was that we have undergone during the survey out of 300 pharmacists only few pharmacists have the knowledge and awareness of ADR in the twin cities of Telangana state. The basic things like not knowing the nearest ADR reporting centers and unawareness of national Pharmacovigilance program of India, creates the great space for the drug safety authorities and regulatory agencies to step forward in direction of pharmacist to make them educated about ADR.

As they are more amounts of diploma holders in India or particularly more in Telangana state it is our duty to make awareness to each and every pharmacist has the complete knowledge of ADR. Several approaches like continuing medical education (CME), training programmes, seminars and conferences should be adopted by the regulatory authorities to stimulate the community pharmacists to be an integral part in reporting of ADRs.

**REFERENCES**


59. India Ministry of health and family welfare. CDSCO. Pharmacovigilance Programme of India. Suspected adverse drug reaction reporting form: FDA Bhawan.