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Students initiated ADR reporting activity in pharmacy colleges - a survey

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ABSTRACT

ADR monitoring is an important function of many pharmacists working in the clinical field. The aim of this study is to assess the student knowledge about Pharmacovigilance and activities done in ADR centers and to find out the impact of pharmacy student service in ADR monitoring. An 11 item web based questionnaire was developed and employed to collect data from Pharm D students at different colleges in South India. A thorough review was conducted of relevant literature pertaining to knowledge, views, and practices of pharmacy students towards the ADR monitoring and reporting in pharmacy colleges. About 61 students were responded through Google forms. The majority students from Vth year and VIth year Pharm D students of about 67.25% were responded well. About 42.62% responders have the correct knowledge of about Pharmacovigilance. About 77.04% of responders having ADR reporting centres in their colleges or their hospital. Responders of about 75.40% were communicates the reported ADRs to consulting physicians by communicating, during ward rounds or by informing to corresponding department faculties. 86.88% of responders were documented the reported ADR. This study demonstrated that knowledge, attitude and practices towards pharmacovigilance is gradually improving among pharmacy students that may improve the patients' quality of life by correcting adverse reactions, but unfortunately the actual practice of ADR reporting is still deficient among them.

Keywords: ADR, pharmacovigilance, ADR monitoring, questionnaire, documentation

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INTRODUCTION

Interaction of drugs i.e. either drug-drug interaction

or drug-food interaction into the human body generates numerous problems to the individual. Adverse Drug Reactions (ADRs) represents one of several identified classes of 'drug associated complications' [1]. According to the definition providing by World Health Organization (WHO), Adverse Drug Reaction (ADR) is "any noxious, unintended and undesired effect of a drug which occurs at doses used in humans for prophylaxis, diagnosis or therapy" [2]. ADRs are considered a major cause of patients' morbidity, mortality, hospital admissions, as well as increasing length of hospitalization and cost of treatment. Literature demonstrates the importance of involving pharmacists in ADR reporting and considered pharmacists the most valuable sources of spontaneous reporting of ADRs. The World Health Organization (WHO) defines pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems" [3]. Pharmacovigilance is essential for the safe, rational, as well as cost-effective utilization of medicines worldwide; it plays an important role in improving the clin-

ical outcomes and also decreasing mortality and morbidity rates. The main aim of establishment of a Pharmacovigilance are (a) Detection of severe and unexpected adverse drug reactions to the established drugs and even the minor ones to newer drugs, (b) Identification of the risk factors associated with the development of adverse drug reactions and mechanisms of their causation like Type A, Type B, Type C, etc., (c) Quantitative estimation of the risk factors, incidence, and prevalence of adverse drug reactions, (d) Systematic analysis of the obtained data and dissemination to the health agencies, regulatory authorities, pharmaceutical companies, physicians, and other members of the health care system (e.g., nurses, dentists, and paramedics, etc.), so that the safety of drugs and modification of the prescribing patterns can be ensured [4]. The success of pharmacovigilance centers depends on the rate of effective and spontaneous reporting of suspected adverse drug reactions (ADRs) by filling an ADR form of the Central Drugs Standard Control Organization (CDSCO), as is considered the core component of pharmacovigilance activities.

Assessment of awareness of Pharmacovigilance among the healthcare professionals is very important due to under reporting of adverse drug reactions. Although previous studies indicated that pharmacists are pivotal players in ADR monitoring and reporting, most pharmacists are unaware or not knowledgeable about the guidelines used by their respective countries, drug regulatory bodies responsible for assessing ADRs. As drug experts, pharmacists should be equipped with the skills to prevent, identify, and resolve drug related problems and counsel patients on drug therapy. The involvement of pharmacists in pharmacovigilance programs is considered to be vital. Modern Pharmacists consider Pharmaceutical care as their prime focus and play an important role in patient care. Ensuring the safe use of drugs is a combined responsibility of the healthcare team that includes Doctors, Nurses, Pharmacists and other supporting staff [5].

The ADR monitoring and reporting should practice from the training time onwards. So, this study is designed to know how the pharmacy students are monitoring and reporting ADRs and knowledge about pharmacovigilance.

METHODOLOGY

Study design and site: A Cross-Sectional observational questionnaire-based study was carried out using the information gathered from some of the pharmacy students in different pharmacy colleges in South India. Knowledge of ADR monitoring, collection and documentation of ADR were analyzed. The duration of the study was 1 month, in October 2018.

Study sample: A total students of about 61 from 27 pharmacy colleges in South India were responded.

The inclusion criteria are students from Pharm.D (Doctor of Pharmacy) both regular (IV, V, and VI) and post baccalaureate (PB) and exclusion criteria are the students from Ist and IInd Pharm D and other pharmacy batches.

Design of Questionnaire: Initially, the questionnaire comprised of 15 inventories, modified to 11 in final by 02 step validation process. In step 01, Questionnaire Validation are done by three pharmacy lecturers with experience in drug use research and ADR reporting studies were asked to evaluate the clarity, relevance and conciseness of items included in the questionnaire. The observations and comments of the lecturers were taken in to the account. In step 02, Questionnaire Validation to test the validity and reliability of the questionnaire, the survey form was pilot tested by administering it to sample of 10 pharmacy students who did not participate in the study. The overall Cronbach's alpha value calculated was 0.71, which required no further modifications in questionnaire. The final questionnaire consisted of 11 questions out of which: section A: Includes 3 questions related to basic details of the responder, section B: Includes 1 question related to knowledge about pharmacovigilance and section C: Includes 7 questions related to perception regarding identification of ADR and reporting nature.

Data collection: An 11 item web based questionnaire were thus developed and employed to collect data from Pharm D students at different colleges in South India. It was prepared in Google form and distributed through sending link to Pharm D students through social media. A thorough review was conducted of relevant literature pertaining to knowledge, views, and practices of pharmacy students towards the ADR monitoring and reporting in pharmacy colleges.

Data Analysis and Evaluation: The responses to the questionnaire were analyzed performing descriptive statistics. Data were analyzed using SPSS version 11.0. The level of statistical significance was set at $p < 0.05$.

RESULT

About 61 students were responded through Google forms. The majority students from Vth year and VIth year Pharm D students of about 67.25% were responded well. About 42.62% responders have the correct knowledge of about Pharmacovigilance. Responders of about 77.04% were actively participating in ADR monitoring and from that about 88.52% responders are doing ADR related activities such as monitoring by checking medication error, drug interaction, prescription auditing, survey of prevalence of ADRs in suspected drugs, patient counselling about suspected ADRs and their management, etc. About 2 (3.70%) of the responders are calculated the severity

of suspected ADRs through Naranjo scale and categorizes them and trying to change the offending drug. Responders of about 72.13% were reporting the suspected ADRs in their clinical pharmacy department of their college. From that about 20.45% responders re

Figure 1: Among 61 responders 2% explains safe, effective, appropriate and economic use of medicines, 42% explains Detection, assessment, understanding and prevention of adverse effects.

Figure 2: Among 61 responders, 77.04% (n=47) participated in ADR monitoring and 22.9% (n=14) were not participated

Figure 3: Among 61 responders, 14% were documented and 86% were not documented

ported through ADR reporting form and 13.63% responders were reported in Drug Information Centre (DIC). One responder had reported through preparing yellow card and note down the ADRs found in the hospital, another one responder had reporting by maintaining ADR reporting book. Responders of about 44.26% were reported less than 5 ADRs in a day, 14.75% responders reported about 5-10 ADRs in a day, 11.47% responders were not reported any

ADRs in a day. About 77.04% of responders having ADR reporting centers in their colleges or their hospital. Responders of about 75.40% were communicates the reported ADRs to consulting physicians by communicating, during ward rounds or by informing to corresponding department faculties. About 86.88% of responders were documented the reported ADR.

Figure 4: Among 15 responders of reporting ADR, 6 responders were reported in DIC and 9 responders were reported in reporting form

DISCUSSION

Pharmacists could play an important role in ADRs reporting, because they are close to patient both in communities and hospitals and have good knowledge about side effects of drugs, so it is logical to involve them more in ADRs reporting [6].

The present study was a questionnaire-based study, which attended about 27 pharmacy colleges in South India. As most of the students don't know about right knowledge about Pharmacovigilance, about 88.52% responders are doing ADR related activities such as monitoring by checking medication error, drug interaction, prescription auditing, survey of prevalence of ADRs in suspected drugs, patient counselling about suspected ADRs and their management, etc.

Results of a similar KAP (knowledge attitude and practice) study in India shows that undergraduate pharmacy students had good knowledge but poor attitude and practice compare to prescribers ($p < 0.001$) regard to ADRs monitoring and reporting. Authors emphasized about the need for changes in undergraduate curriculum [7].

In our study, responders of about 44.26% were reported less than 5 ADRs in a day, 14.75% responders reported about 5-10 ADRs in a day, which is a positive reflection on the clinical skills and awareness about ADRs among the pharmacy students. Responders of about 75.40% were communicates the reported ADRs to consulting physicians by communicating, during ward rounds or by informing to corresponding department faculties, which shows that a good attitude among pharmacy students in patient care.

Limitations of the Study: The major limitation of this study was the essentially small number of participants from 27 pharmacy colleges in South India. In addition, some other factors such as communication problem to the participants, lack of interest to answer the questionnaire by the participants due to their own reasons, could also have affected the results of this study in some ways.

CONCLUSION

This survey on pharmacovigilance and ADR reporting among pharmacy students in south India suggests that the pharmacy students in this country may lack in-depth understanding of the facts about ADR reporting and may need more information on the National Pharmacovigilance System and ADR reporting process. Pharmacy student's education should include topics related to the methods of detecting, preventing, and reporting of ADRs to enable and play vital role in prevention of ADRs through their interactions with both prescribers and patients.

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CONFLICTS OF INTEREST

The author declares no conflict of interests.

CONFLICTS OF INTEREST: None

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