

RESEARCH ARTICLE

Knowledge, attitude, and practice of adverse drug reaction reporting among nurses in a South Indian tertiary health-care center

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ABSTRACT

Background: Nurses who are bedside caregivers have a unique position monitoring patient's drug therapy, and they are the ones who observe adverse drug reactions (ADRs) first hand. Knowledge of ADRs and practice of pharmacovigilance by nurses will definitely help to elevate the quality of pharmacotherapy in hospitals and effectively decrease the occurrence of ADRs. **Aims and Objective:** To assess the knowledge, attitude, and practice of hospital's nurses in a tertiary health-care center, toward ADR reporting. **Materials and Methods:** This study was a cross-sectional questionnaire-based study. The questionnaire was distributed to 100 nurses serving in different departments in the hospital. Nurses who did not fill the questionnaire were excluded from the study. **Results:** The response rate was 63%. The overall level of knowledge was found to be 56.4%. The level of attitude was 68.92%. 89.9% of the nurses agree that spontaneous reporting should be made compulsory. Awareness about the regional center for reporting ADR was nil among the nurses. Only 11.1% of nurses in the hospital had reported an ADR before. **Conclusion:** Although nurses had a high level of attitude, they had only moderate level of knowledge, and practice was very poor. Necessary measures to be taken to create awareness among nurses about Pharmacovigilance Programme in India. They should be trained to spontaneously report ADRs.

KEY WORDS: Adverse Drug Reactions; Pharmacovigilance; Knowledge; Attitude and Practice; Nurses; South India

INTRODUCTION

Adverse drug reactions (ADRs) are one of the important causes of morbidity and mortality.^[1] The WHO defines ADR as any noxious, unintended, and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.^[2]

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.^[3] Pharmacovigilance is always considered a critical activity by all health-care professionals and also by the pharmaceutical companies. Ever so often, episodes such as thalidomide tragedy in 1962; COX-2 inhibitors contributing to cardiovascular problems in 2005, have emphasized the importance of this evolving medico-regulatory discipline. Pharmacovigilance is now more focused on post-marketing surveillance and has become an integral part of the new drug development process. Thalidomide tragedy, in 1961, paved the way for the formation of national ADR centers to register and analyze the side effects of drugs in different countries and also became responsible for initiation of ADR voluntary reporting system.

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Pharmacovigilance has been more visible these days even though for undesirable reasons. On the positive side, the Union Health Ministry of India has relaunched National Pharmacovigilance Programme in July 2010, reflecting a greater focus on the monitoring of safety of medicines in India.^[4,5]

Nurses who are bedside caregivers have a unique position monitoring patient's drug therapy, and they are the ones who observe ADRs first hand. Knowledge of ADRs and practice of pharmacovigilance by nurses will definitely help to elevate the quality of pharmacotherapy in hospitals and effectively decrease the occurrence of ADRs. The goal of our study was to assess the knowledge, attitude, and practice of ADR reporting among nurses in a tertiary health-care center.

MATERIALS AND METHODS

Study Design

This study was a cross-sectional, questionnaire-based study which involved nurses who are working in various departments in a tertiary health-care center in South India. A questionnaire was prepared which consisted of questions to assess knowledge about ADR reporting, attitude toward pharmacovigilance, and practice of ADR reporting separately. The study was conducted after receiving the approval from the Institutional Ethics Committee of Father Muller Medical College, Mangalore.

Study Questionnaire

A questionnaire comprising of 40 questions was used in this study. The questionnaire was newly designed, based on the similar studies that have been conducted previously and was modified to make it relevant in our set up and was tested for its validity and reliability conducting a pilot study. The correct responses were scored 1 point and wrong responses were given zero point for knowledge-related questions and practice-related questions, whereas attitude-related questions were scored using the Likert scale based on the participant's degree of agreement as: "0"-strongly disagree, "1"-disagree, "2"-uncertain, "3"-agree, and "4"-strongly agree.

Study Participants

The study included nurses from the Father Muller Medical College, Mangalore, Karnataka, India. Subjects were selected randomly, and informed consent was taken the questionnaire was distributed to 100 nurses working in different wards of the hospital. The duly filled forms were collected on the same day. Nurses who did not return the questionnaire and who gave back incompletely filled questionnaire were excluded from the study. 63 nurses participated in the study.

Statistical Analysis

The data collected was entered into the Excel software and then analyzed using frequency, percentage, mean and standard deviation by SPSS version 19.0.

RESULTS

Of the 100 questionnaires distributed in the tertiary care center, we got back 63 of them duly filled. Therefore, the response rate was 63%.

Assessment of Knowledge

About 82.5% of respondents were aware of suspected ADR reporting system in India, but only 7.9% of nurses were aware of regional center for ADR monitoring. 66.7% of the nurses were aware of the drugs withdrawn from the market because of safety reasons. According to our study, factors commonly associated with ADRs were old age (66.7%), multiple comorbidities (68.3%), polypharmacy (71.4%), patients in ICU (33.3%), and children aged 1-4 years (31.7%).

Reasons for not Sending the ADR Report

About 76.4% of the nurses felt apprehension about sending inappropriate report and was the main reason which discouraged them from sending an ADR report. The other reasons for not reporting an ADR were busy schedule to fill the form (46.83%); non-remuneration for sending the report (51.98%); concern that extra work is required to fill and send the report (54.76%); not sending one report may not contribute a lot to patient care (57.14%); busy practice to look actively for ADR (66.27%); difficult to diagnose ADR (61.11%); non-availability of reporting form at workplace (57.54%); feeling that reporting of previously known ADR is not required (53.57%); poor feedback from regulatory agency (53.57%). Factors encouraging reporting of adverse drug reactions is shown in Figure 1. Overall level of knowledge and attitude among the participants is shown in Table 1.

Assessment of Practice

Only 7 of 63 nurses, i.e., 11.1% had actually reported an ADR before. Therefore, practice of ADR reporting was really poor among these respondents.

DISCUSSION

Our study was done to evaluate the attitudes and knowledge of nurses to spontaneous ADR reporting in India. The response rate was 63% against the 36% response rate of a study conducted in Iran and 65% in a study conducted in Delhi.^[3,6]

Table 1: Overall level of knowledge and attitude among the participants. (*n*=63)

Parameters	<i>n</i>	Minimum	Maximum	Maximum possible score	Mean±SD	Mean (%)
Over all knowledge	63	2	16	17	9.59±3.057	56.40
Over all attitude	63	46	84	84	57.89±5.845	68.92

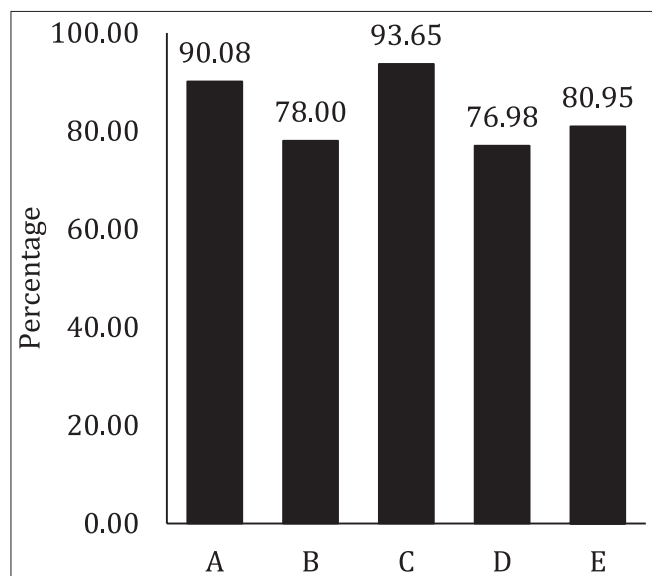


Figure 1: Factors encouraging reporting of adverse drug reactions. (A) Seriousness of event, (B) unusual reaction, (C) reaction to a new drug, (D) certainty that reaction is an adverse drug reaction, (E) well-recognised events that are known to occur with the drug

Although 82.5% of nurses were aware of ADR reporting system in India, only 7.9% nurses in the hospital knew about the regional center for ADR reporting, and 92.1% of nurses were not aware of it in our study. According to a similar study conducted in Delhi, 7.69% knew the correct reporting centers of Delhi, an Iranian study, which states that 48% nurses were aware of ADR center.^[3,6] However, a study of Li Q in China observed that just 2.2% nurses knew the correct reporting center.^[7] This could be one of the reasons for under-reporting of ADRs by nurses. The existence of ADR center in the hospital can increase the awareness of physicians, nurses, and pharmacists toward ADRs and the number of ADR reports. Among the participants, 66.7% of the nurses were aware of drugs withdrawn from the market because of safety reasons. Every health-care professional should be aware that for ADR reporting confirmation of the relationship between a drug and the side effect is not needed.

In general, the attitude of our nurses toward ADRs and its reporting was found to be acceptable. 93.25% of nurses agreed that reporting of ADR is a duty of health-care professional similar to an Iranian study where 91% of the respondents propounded that ADR reporting is one of the duties of health-care professionals.^[3] Thus, the attitude level toward the responsibility of health-care professional about ADR reporting was at the highest level compared to other attitude questions. Most of the nurses in our study agreed

that apprehension about sending an inappropriate report was the main reason for not reporting ADRs. In a study on physicians, 28% of them did not report ADR because of a lack of confidence on the reason for that particular ADR.^[8]

Under-reporting of ADRs is a worldwide problem, and this has been established from previous studies.^[8-10] Despite the fundamental importance of reporting of suspected ADRs, <10% of serious ADRs are reported.^[9] The majority of nurses in our study (88.9%) had never reported an ADR, which differs from a study done in China where 22% of nurses had reported an ADR.^[7]

Many studies including that of Inman has reported various obstacles for ADR reporting, such as lack of time to report an ADR due to the workload of clinical activities^[11-16] and lack of information about the spontaneous reporting system,^[14-17] were also seen in our study. It has been shown in the studies of Sweis et al. in the UK and Ribeiro Vaz in Portugal that education and/or training improves ADR reporting.^[18,19]

The factors, which have resulted in under-reporting of ADR according to our study, include lack of knowledge about ADR forms for reporting ADR, ignorance about pharmacovigilance system, and also not being sure of the type of reactions to be reported. According to a study conducted by Vallano et al., four types of obstacles to spontaneous reporting were considered particularly important: Problems with the ADRs diagnosis; problems with the usual workload and lack of time; problems related to the organization and activities of the pharmacovigilance system; problems related to potential conflicts.^[20]

There are many vigorous activities going on regarding pharmacovigilance conducted by Pharmacovigilance Programme in India, and still, there is a lack of awareness to be filled by educating nurses, doctors, and other health-care professionals regarding this issue.

CONCLUSION

The results of our study showed that nurses who participated in this study had moderate knowledge about ADR reporting system, they knew little about the purpose of pharmacovigilance and its usefulness. Although the level of attitude of our nurses was favorable, practice of ADR reporting was very poor. Therefore, it is necessary to conduct continuous ADR-related educational programs until we reach the point that voluntary reporting of ADRs becomes

conventional and habitual, and routine among the nursing staff.

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