



Empowering Staff Nurses in a Tertiary Care Hospital in India: A Comprehensive Training Program on Pharmacovigilance and Patient Safety

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Abstract

Background

Nurses comprise the largest group among healthcare professionals and by virtue of being in constant touch with patients hold a pivotal position to positively influence medication safety related aspects. However, the lack of pharmacological knowledge, awareness and ignorance about the Pharmacovigilance program among nurses fabricate underreporting of ADRs. The present training program was conducted to sensitize, educate and spread awareness about Pharmacovigilance program among staff nurses.

Methods: The training program was conducted on staff nurses posted in various inpatient and intensive care units in our hospital. Training comprised of 3 phases: pre intervention phase, intervention phase (nurses were trained with the help of theme lectures, hand on training exercises, small group case-based learning including role plays and case scenarios) and a post intervention phase including feedback about the program. The participants' knowledge, attitude and practice about pharmacovigilance were assessed before and after the training program.

Results and conclusions: A total of 90 nurses participated in the program. Post program there was a consistent increase in the number of correct responses to all knowledge-based questions with a significant improvement in knowledge scores from baseline. There was also a positive change in the attitude about medication errors among nursing students. The participants rated the overall quality of program as excellent and agreed on its applicability in their practice. The training program was quite successful in educating nurses on pharmacovigilance. There is unmet

need to constantly train and sensitize nurses which can potentially prove instrumental in managing, reporting of ADRs and well functioning of PvPI for better patient safety.

Keywords: Pharmacovigilance; ADRs; patient safety; hands on training; case based learning

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Introduction: Pharmacovigilance, as delineated by the World Health Organization, encompasses a comprehensive range of scientific endeavors and activities aimed at the identification, evaluation, comprehension, and mitigation of adverse effects and other drug-related concerns [1]. The Pharmacovigilance Programme of India (PvPI), launched by the Central Drugs Standard Control Organization in July 2010, stands as a nationwide initiative. The Indian Pharmacopoeia Commission (IPC) Ghaziabad assumes the pivotal role of the national coordinating center, dedicated to monitoring adverse drug reactions (ADRs) and upholding public health standards.

The significance of Adverse Drug Reactions (ADRs) has considerably escalated, becoming a prominent clinical challenge and a persistent focal point of concern within public healthcare systems. These reactions contribute substantially to hospital admissions and in-hospital morbidity, emerging as a noteworthy factor. In the United States, ADRs are established as the fourth to sixth leading causes of mortality [3]. Similarly, in the context of India, empirical evidence reveals that ADRs are attributed to 1.8% of overall mortality among 0.7% of total admissions [4].

Central to Pharmacovigilance is the expeditious reporting and dissemination of information pertaining to ADRs, which remains the bedrock for sustaining patient safety [5]. Regrettably, there exists a prevailing culture of underreporting among healthcare practitioners, potentially

stemming from inadequate training, lack of awareness, and unfamiliarity with reporting protocols, as elucidated by prior literature [6,7].

The nursing cohort constitutes the largest contingent among healthcare professionals, occupying a pivotal role due to their consistent interaction with patients. Nurses often serve as the initial informants, alerting physicians to potential ADRs associated with administered drugs. Existing studies underscore significant gaps in knowledge among nurses regarding ADRs and Pharmacovigilance, exposing a void in their routine curriculum and training [8]. This highlights the compelling necessity to furnish nurses with comprehensive education on Pharmacovigilance. Thus, this study seeks to enhance awareness, education, and adeptness in Pharmacovigilance among nurses, inspiring them to proactively identify and report ADRs.

Methodology

Study Setting: This study was conducted at Pandit B. D. Sharma, Postgraduate Institute of Medical Sciences (PGIMS) Rohtak, a prominent 2080-bed public tertiary care teaching hospital located in North India. The hospital features an Adverse Drug Monitoring (AMC) center within the Pharmacology department, which ranks among the top 5 AMC centers nationally based on Individual Case Study Reports (ICSR), overseen by the Indian Pharmacopeia Commission (IPC).

Sample Recruitment: The participants in this study were staff nurses assigned to various inpatient and intensive care units within our hospital. Using a convenient sampling approach, around 100 nurses were informed about and invited to join the training program. Ultimately, 90 nurses expressed their willingness and were included in the study after providing written informed consent.

Study Conduct: The study was carried out in three distinct phases: pre-intervention, intervention, and post-intervention.

Pre-intervention Phase: During the pre-intervention phase, participating nurses completed a paper-based questionnaire to gauge their baseline knowledge, attitudes, and beliefs related to pharmacovigilance and adverse drug reactions. The initial version of the questionnaire, comprising 25 questions, underwent review by five expert researchers to ensure clarity and content validity. After piloting the questionnaire with 10 nurses to assess its duration, clarity, and sequence, adjustments were made, resulting in a final questionnaire containing 20 questions.

Intervention Phase: The educational-cum-sensitization program was conducted in a lecture theater and spanned 4-6 hours per session. Each session encompassed theme lectures, focus group discussions, small group case-based learning exercises, and the distribution of informative pamphlets and booklets. The training program focused on various educational modules, covering topics such as the introduction to PvPI, the significance of drug interactions in adverse drug reactions, ADR collection and reporting procedures, and practical case-based scenarios.

Post-intervention Phase: Following the educational sessions, participants were provided with a post-test questionnaire to assess improvements in their knowledge and attitudes regarding pharmacovigilance. Additionally, a feedback form was administered to gather participants' opinions and suggestions concerning the educational program.

Statistical Analysis: Data collected were compiled and entered into Microsoft Excel. The proportion of correct responses was presented as percentages using tabulated data. Pre- and post-program knowledge scores for each learning module were expressed as percentages and compared using the chi-square test. A p-value of less than 0.05 was considered statistically significant.

Results

Participant Demographics: Ninety dedicated nurses enthusiastically participated in this study, engaging in both pre- and post-test assessments, as well as completing ADR reporting forms. The diverse distribution of nurses across various departments is illustrated in Figure 1.

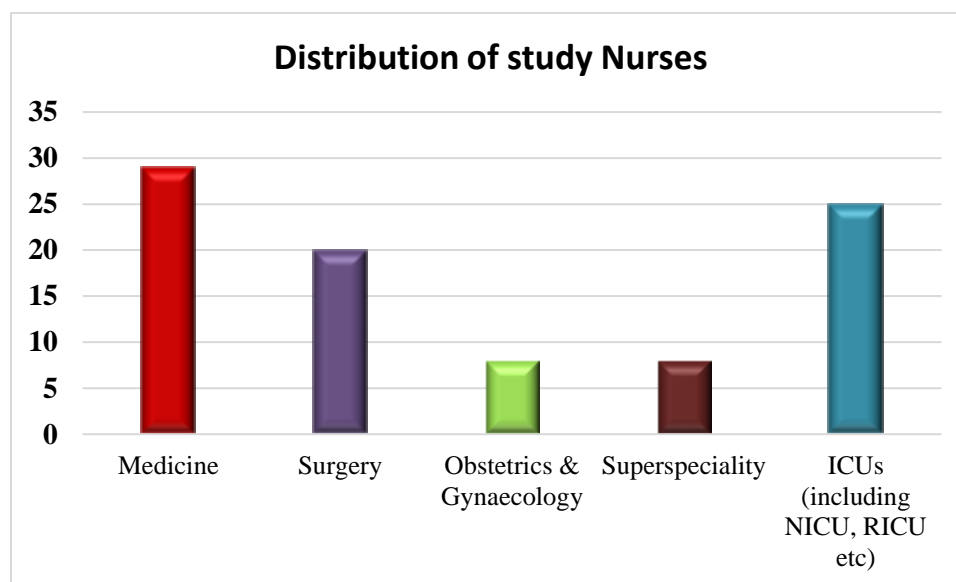


Figure 1: Distribution of study nurses by their work stations

Knowledge Enhancement through Training: Before the training program, the overall knowledge concerning pharmacovigilance stood at 55% during the pretest. However, after the program, this figure surged significantly to an impressive 87% in the post-test questionnaire. Initially, only 30 participants (33.3%) correctly defined pharmacovigilance according to the World Health Organization (WHO). Remarkably, after the training, 88 participants (97.7%) accurately understood the definition. Prior to the training, a mere 36 participants (40%) recognized the importance of pharmacovigilance in drug safety assessment, while only 25 participants (27.7%) associated it solely with calculating ADR incidences. Post-training,

participants expanded their understanding; 86 participants (95.5%) recognized that pharmacovigilance could also unveil predisposing factors and previously unrecognized ADRs. Awareness of the PvPI program, dedicated to ADR collection and reporting, was initially confined to 25 participants (27.7%), but this number escalated to 86 (95.5%) post-training. Additionally, familiarity with the regulatory body, CDSCO, responsible for monitoring ADRs, increased substantially from a mere 19 participants (21%) to 93.3% after the program.

Transforming Attitudes: Initially, the majority of nurses believed that ADR reporting was primarily the domain of doctors. However, this perception underwent a shift after the training, with 82 participants (91.1%) recognizing the potential role of nurses and pharmacists in reporting ADRs. While nearly 59% of participants believed that pharmacovigilance should be part of their curriculum, an overwhelming 91.1% acknowledged the need for in-depth education on ADR monitoring for healthcare professionals. Please see Table 1 for a comprehensive overview of attitude changes pre and post-training.

Table No. 1 Changes in Nurses' Attitudes towards Pharmacovigilance before and after Training

Q. No.	Question Asked	Positive Response (n=90, %)		P-Value
		Pre test	Post Test	
1.	Do you think ADR reporting is responsibility of yours?	57(63.3%)	82 (91.1%)	<0.05
2.	Do you think reporting of ADRs is necessary?	62 (68.8%)	85(94.4%)	<0.05

3.	Do you think Pharmacovigilance should be taught in detail?	53 (58.8%)	82(91.1%)	<0.05
4.	Have you anytime read any article on prevention of ADRs?	31(34.4%)	37 (41.1%)	<0.05
5.	Opinion about establishing ADR monitoring centre in the hospital	44 (48.8%)	69 (76.6%)	<0.05

Enhancing Practical Application: About half of the participants (53.3%) had encountered ADRs in patients during their practice, often hindered by an inability to recognize them. Reporting of ADRs to the AMC center was limited to 13.3% of nurses, partially due to their lack of familiarity with reporting forms. Only 12 nurses had received prior training in ADR reporting.

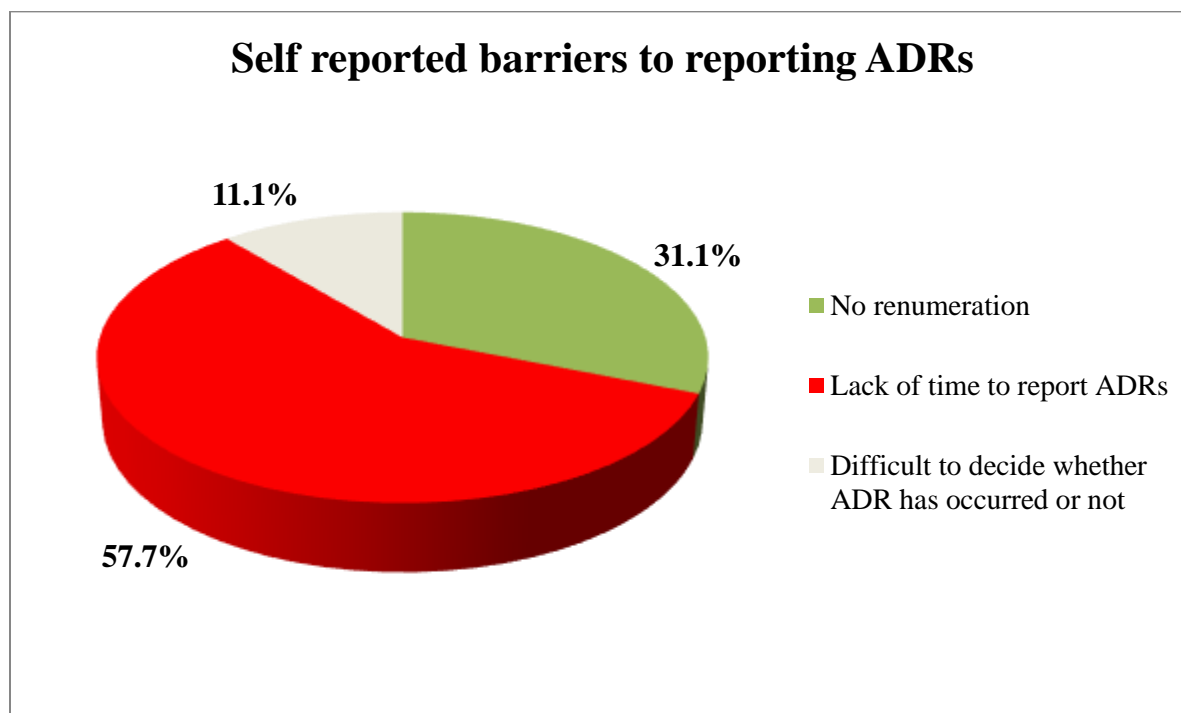


Figure 2: Distribution of the study participants by self reported barriers to reporting ADRs.

The reluctance to report ADRs was commonly attributed to time constraints stemming from patient workload. The training program received high praise, with 85% rating it as very good and 12% as good. An overwhelming 90% expressed keen interest in future training sessions, underscoring the impact of interactive techniques such as pictorial presentations and hands-on ADR form filling. A striking 84% believed that this training program would positively influence their clinical practice, while feedback emphasized the need for further training on topics like medication errors and antimicrobial resistance to enhance their skills and overall healthcare delivery to patients

Discussion: Nurses play a crucial role in patient care, yet their contribution to Pharmacovigilance (PV) and Drug Safety is often overlooked, with this unique role falling outside the mainstream of traditional healthcare nursing [9]. This oversight stems from nurses' belief that their knowledge of pharmacology is insufficient to identify the signs and symptoms of Adverse Drug Reactions (ADRs), leading them to delegate this responsibility to doctors or pharmacists and resulting in severe underreporting of ADRs by nurses [9]. This study aims to bridge this knowledge gap by improving nurses' knowledge, attitude, and practice in pharmacovigilance, ultimately enhancing patient safety.

Insufficient Knowledge of Pharmacovigilance: Nurses' understanding of pharmacovigilance is limited, a finding consistent with previous studies in Turkey and Iran [5] [10]. This lack of awareness can be attributed to the omission of pharmacovigilance education from their curriculum. Earlier research indicated that only approximately 23.3% of nurses in Turkey and 32.1% in Iran accurately defined pharmacovigilance [10] [5]. Our study similarly revealed that only 30% of nurses could correctly define the term. However, following educational

intervention, there was a notable improvement in knowledge, including understanding the location of key centers, the purpose of ADR monitoring, and the process of ADR reporting.

Positive Attitude Shift: In line with a study by Zaveri et al. [11], our findings indicate that a considerable percentage of participants initially viewed ADR reporting as a professional obligation (63.3% in our study) [11]. At the outset, only 68.8% of participants exhibited a positive attitude toward the necessity of ADR reporting. However, after the educational intervention, this attitude experienced a significant shift to 94.4%, aligning with results from similar interventions [11].

Reporting Practices: Similar to research by Vural et al. [13] and Zaveri et al. [11], where only a small proportion (8% and 12%, respectively) of participants reported ADRs, our study observed a reporting rate of 13.3% [13] [11]. Nonetheless, the study's results revealed a significant increase in knowledge and attitude post-intervention, underscoring the importance of ongoing training for healthcare professionals.

Limitations and Future Directions: The study was confined to nurses in a tertiary hospital during a specific training session. However, broader studies indicate a lack of pharmacovigilance awareness among other healthcare professionals, including doctors and pharmacists [14]. To address this, regular training programs should be extended to all healthcare providers, thereby fortifying ADR reporting and management and enhancing the overall national pharmacovigilance program [15].

Conclusion: The study emphasizes the urgent need to train nurses, as well as other healthcare providers, in medication safety and pharmacovigilance. The evident knowledge gap signals the

necessity of targeted training sessions to heighten awareness and understanding. By doing so, the aim is to collectively improve patient safety and the effectiveness of the pharmacovigilance program

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