

The Role of Implementing Pharmacovigilance Program for Staff Nurses and its Effect on Patients' Safety at Chest Diseases General Dekernes Center Hospital

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Abstract

Background: Pharmacovigilance (PV) and patient safety are two essential aspects of healthcare. In order to ensure proper use of medications which enhances patient safety, PV systems are therefore more important than ever. **Aim:** To evaluate the role of implementing pharmacovigilance program for staff nurses and its effect on patients' safety. **Methods:** The design was Quasi-experimental. Three tools used for data gathering namely; Pre/Post-test Knowledge Assessment Questionnaire, Staff Nurse Pharmacovigilance Attitude Questionnaire and Patient Safety Scale. **Results:** Nurses improved knowledge from zero good level preprogram to more than three-quarters good level immediate program. Also, improved from negative attitude level toward pharmacovigilance preprogram to positive attitude immediate after program. As well as, patients' safety improved to moderate level immediate and post program than preprogram. In addition, highly statistically significant relationship among knowledge of nurses, attitude besides patients' safety pre, immediate and post program. **Conclusion:** Patients' safety improves after applying pharmacovigilance program for staff nurses. **Recommendations:** Improving awareness among other healthcare providers, particularly those in nursing and pharmacy fields who work closely with patients and nurse managers should regularly assess and monitor patients' safety facets among nurses to achieve safe and healthy environment for patients.

Keywords: Adverse Drug Reactions, Patients' Safety, Pharmacovigilance & Staff Nurses.

Introduction:

Over the world, adverse drug reactions (ADRs) are leading cause of morbidity and mortality. Therefore, proper monitoring of PV program is the keystone of ADRs. All healthcare personnel have an obligation to report any major ADRs as well as any suspicious drug responses they may observe. Healthcare personnel should be aware of where and how to report adverse drug reactions. Patient safety and ADR reporting are enhanced by healthcare providers' active involvement in PV program (Veena, et al., 2021).

The World Health Organization (WHO) defines pharmacovigilance as " pharmacological science and activities related to identification, evaluation, comprehension, and prevention of adverse effects or any other drug-related issue, especially acute and chronic side impacts of medications" (Ajri-Khameslou, et al., 2021). Rapid detection of adverse drug events, identification of potential causal links between an adverse event and medicine after introduction of a new drug or drug combination, and evaluation of these signals to assess clinical relevance, causality, frequency, and distribution of ADR, with focus on specific population groups are aims of PV. These goals assist in evaluating efficacy and risk of medicine by comparing safety of various medications and by explicitly identifying risk factors.

Also, it offers prompt advice and communication to public, physicians, and regulatory agencies (Bepari, et al., 2019).

Maintaining and monitoring drugs' efficacy and safety is serious point in clinical practice. Therefore, pharmacovigilance is an important clinical discipline to guarantee the suitable usage of medicines and patient safety (Tekel, et al., 2021). Patient safety well-defined as " absence of preventable destruction to patient during process of health care and reduction of danger of unnecessary harm associated with health care to satisfactory minimum" (International Patient Safety Goals, 2021). Patient safety is "framework of systematized activities that produces cultures, processes, procedures, behaviors, technologies and environments in health care that constantly and sustainably lesser risks, diminish the incidence of avoidable harm, make error less likely and lessen its impact when it does occur" (WHO, 2023).

The efficacy of improving patient safety has been demonstrated in very disparate ways. In terms of insurance premiums and malpractice costs, hospitals typically concentrate on the incidence of adverse events and the degree of patient adversity. Moreover, risk management sectors in hospitals also include these variables while evaluating the performance of various units (Donaldson, et al., 2021).

However, different strategy is needed to promote patient safety in clinical practice. This strategy standardizes and evaluates clinical action effectiveness and patient harm avoidance based on scientific evidence. The National Patient Safety Goals (NPSG) are updated on a regular basis taking into account their efficacy, cost, and impact. Furthermore, these encompass, irrespective of the domain of care, the precision of patient identification, communication between caregivers and patients, pharmaceutical safety, clinical alarm systems, infection prevention, and verification (Hopkins, 2022).

The delivery of health services while maintaining patient safety is essential to a functional healthcare system. A powerful organizational culture that prioritizes patient safety and quality can enhance service providers' readiness for emergency situations, foster healthier communities, and facilitate the attainment of universal health coverage. So, the most popular therapeutic approach in medicine to enhance patient outcomes is pharmacovigilance. Even though pharmaceuticals are intended to help patients, there are many situations in which ineffective drug use procedures and practices compromise their efficacy and put patients' health at risk (Donaldson, et al., 2021).

Significance of the study:

Pharmacovigilance is rapid identification of adverse drug events. Ensuring patient safety while providing healthcare is rational medication therapy is predicated on two fundamental parameters safety and efficacy. Adverse effects are practically inevitable in drugs; nonetheless, the use of these drugs must be accompanied with a manageable risk-benefit ratio. One of the main factors contributing to morbidity and death is ADRs. Up to 35% of hospitalized patients encounter an adverse drug reaction (ADR) during their stay, accounting for about 2.9% to 5.6% of all hospital admissions. Thus, regardless of whether a patient is receiving care in a wealthy or developing nation, patient safety is a global health priority (Veena, et al., 2021).

Research from various contexts show that healthcare professionals lack knowledge about PV and ADRs, and that attitudes toward PV are associated with a high degree of underreporting PV is still prevalent in Egypt; additionally, over half of them express fear of potential legal consequences (Abou Elmaati, et al., 2016). Therefore, the purpose of this study is to assess how staff nurses' involvement in pharmacovigilance programs affects patient safety (Abou Elmaati, et al., 2016). So, evaluate role of implementing pharmacovigilance program for staff nurses and its effect on patients' safety is the aim of this study.

Aim of the study:

Evaluate role of implementing pharmacovigilance program for staff nurses and its effect on patients' safety.

Research hypothesis:

Patients' safety improves after applying pharmacovigilance program for staff nurses.

Subject & Methods

Design: The design was quasi-experimental.

Setting:

The study was carried out at all inpatient departments of Chest Diseases Hospital, Dekerenes Center, Dakhalia Governorate, Egypt. The hospital was affiliated to Ministry of Health. The total number of beds was 34 beds.

It consists of one building and two floors, the first floor contained ICU, and reception. The second floor contains the departments of; " isolation, tuberculosis, chest and respiratory diseases for men and chest and respiratory diseases for woman".

Subject (Participants):

A convenience participant (111) of staff nurses was available at the time of data collection with at least one year of experience who agreed to participate in the study at the time of collection of data.

Tools of data collection:

Three tools were used in the study to collect data; Pre /Post-test Knowledge Assessment Questionnaire, Staff Nurse Pharmacovigilance Attitude Questionnaire and Patient Safety Scale.

1st tool: Pre / Post-test Knowledge Assessment Questionnaire: It includes two parts as follow:

1st part: This part contained" participants' age, gender, marital status, years of experience, and educational level" as personal characteristics.

2nd part: Pre / Post-test Knowledge Assessment Questionnaire: It was established by the researcher guided by World Health Organization (2023), and Coleman& Pontefract (2016), to assess staff nurses' knowledge regarding pharmacovigilance. It consisted of 30 questions (11) Multiple Choice Questions (MCQ) and (19) true and false. The items contained knowledge about pharmacovigilance; adverse drug reactions and its reporting, encouraging and discouraging factors for report adverse drug reaction, and general instruction to avoid adverse drug reaction and keep drug safety. Each question needed only one answer, the correct answer took one point and zero for incorrect answer.

Scoring system:

The total scoring was classified into three levels according to cutoff point as; poor (<50%), fair (50 – <75%) and good (≥75%)

2nd tool: Staff Nurse Pharmacovigilance Attitude Questionnaire: This questionnaire was established

by **Hussain, et al., (2021)**, for assessing the attitude of staff nurse about pharmacovigilance. It includes 12 items. Staff nurse rated their responses on a 5-point Likert scale, ranging from (1) strongly disagree to (5) strongly agree.

Scoring system:

The total scoring was categorized into three levels according to cutoff point as; negative (<50%), moderate (50 – <75%) and positive ($\geq 75\%$).

3rd tool: Patient Safety Scale: This scale was established by the Agency for Healthcare Research and Quality (AHRQ) (2019), to assess patient safety among staff nurse. It consists of 30 items divided into three domains as follows; unit/work area (14 items), think about your supervisor, manager, or clinical leader (3 items), think about communication (7 items) and think about reporting patient safety events (6 items). Staff nurses rated their responses on a 5-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree).

Scoring system:

The total scoring was classified into three levels according to cutoff point as; low (<50%), moderate (50 – <75%) and high ($\geq 75\%$).

Validity and reliability

Five experts in the field of academic nursing administration examined the research tools' face and content validity in order to determine the items' relevance as well as the validity of the complete instrument, as well as comprehensive and appropriate to test what they wanted to measure and then the modifications were made. The Cronbach's alpha test was used to assessed the reliability of the study tools Pre-/Post-test Knowledge Assessment Questionnaire, Staff Nurse Pharmacovigilance Attitude Questionnaire, and Patient Safety Scale. The results showed that the three tools had reliability scores of (85.3%, 89.1%, and 84.6%) respectively.

Pilot study:

10% (12 staff nurses) from 123 study participants participated in a pilot study to test the tools' applicability and clarity as well as the amount of time required to complete the questionnaires. The pilot participants were excluded from total study participants.

Field work:

This study was conducting via three following phases: interviewing & assessment, implementation and evaluation phase. The data collection period lasted four months, starting on (2/9/2024) and ending on (17/12/2024) during morning shift. To assess changes in knowledge of staff nurse regarding pharmacovigilance using tool (1) responding time was (35) minutes used by staff nurse pre, post and follow up after three months of program implementation. To assessing the attitude of staff

nurse about pharmacovigilance used (tool II) which is taken 20 minutes to complete. To assess patient safety among staff nurse used (tool III) which is taken 20 to 25 minutes to complete in presence of researcher.

Interviewing and assessment phase:

In this phase, the researchers clarified the aim of the study. In addition, time table, teaching session, teaching method are designed and handout produced, tool (I) which took about (35) minutes to finished used for staff nurse pre the program implementation, tool (II) which took about (20) minutes to finished used for staff nurse pre the program implementation and tool (III) which took (20 to 25) minutes used by staff nurse preprogram to assess patient safety among staff nurse.

Implementation Phase:

- The program related the pharmacovigilance was designed and applied to all staff nurses by the researchers based on the literature review.
- Staff nurses distributed into seven groups, every group contain (16 nurses) and just one group (15 nurses).
- The pharmacovigilance program completed on three sessions each session (2 hours). Every group took (6) hours. Total time of the program (42) hours.
- The third sessions categorized as; first includes knowledge about definition and importance of pharmacovigilance and adverse drug reaction, second includes its reporting, encouraging and discouraging factors for report adverse drug reaction, and third includes general instruction to avoid adverse drug reaction and keep drug safety.
- The researchers implemented the program by utilizing accessible assets for each group appropriate content and instructional tactics lectures, group discussion; brain storming was all used as instructional approaches.
- The researchers provided the program handout to all participants at the first day.

Evaluation Phase:

The current phase was emphasized on evaluate the role of implementing pharmacovigilance program for staff nurses and its effect on patients' safety through a comparison between pre and post applying program.

Ethical considerations:

The study was approved ethically by the research ethics committee at the Faculty of Nursing, Mansoura University (NO. 0628). Before the study; written informed consent gained from all staff nurses after explaining the nature and aim of the study. Every participant was made aware that their involvement in the study was entirely voluntary and that they might leave at any moment. Throughout the entire study, confidentiality, safety, privacy, and anonymity were all guaranteed. The result is utilized as part of the research that is required for publication and education.

Statistical Analysis:

The computer was fed data, and IBM SPSS software package version 20.0 was used for analysis. (IBM Corp., Armonk, NY). Numbers and percentages were used to describe the qualitative data. The distribution's normality was confirmed using the Kolmogorov-Smirnov test. Range (minimum and maximum), mean, standard deviation, and median were used to describe quantitative data. Significance

of the obtained results was judged at the 5% level. For comparing more than two periods, the Friedman test for abnormally distributed quantitative variables was employed. To compare between more than two periods, use an ANOVA with repeated measures for quantitative variables that are normally distributed. In order to correlate two quantitative variables that are normally distributed, use the Pearson coefficient.

Results:**Table (1): Personal characteristics of nurses (n = 111)**

Characteristics	No.	%
Age years		
▪ 20<30	42	37.8
▪ 30<40	52	46.8
▪ 40 – 50	17	15.3
Mean±SD	32.45 ± 6.41	
Gender		
▪ Male	1	0.9
▪ Female	110	99.1
Marital status		
▪ Single	18	16.2
▪ Married	88	79.3
▪ Divorce	4	3.6
▪ Widow	1	0.9
Level of education		
▪ Secondary School of Nursing	38	34.2
▪ Bachelor of Nursing	14	12.6
▪ Technical Nursing Institute	58	52.3
▪ Others	1	0.9
Experience years:		
▪ < 5	7	6.3
▪ 5-10	41	36.9
▪ 10<15	20	18.0
▪ 15< 20	17	15.3
▪ 20< 25	18	16.2
▪ ≥25	8	7.2
Mean±SD	12.50 ± 7.40	

Table (2): Overall knowledge levels of studied nurses toward pharmacovigilance (n = 111)

Overall Knowledge levels	Pre program		Immediate post program		Post program after three months		Test of Sig.	p
	No.	%	No.	%	No.	%		
▪ Poor (<50%)	25	22.5	0	0.0	0	0.0	Fr= 150.027*	<0.001*
▪ Fair (50 – <75%)	86	77.5	30	27.0	67	60.4		
▪ Good (≥75%)	0	0.0	81	73.0	44	39.6		
Total Score (0 – 30)								
Min. – Max.	4.0 – 21.0		18.0 – 28.0		17.0 – 28.0		Fr= 586.620*	<0.001*
Mean ± SD.	16.39 ± 3.0		23.59 ± 2.04		21.86 ± 2.33			
Average Score (0 – 1) (Mean ± SD)	0.55 ± 0.10		0.79 ± 0.07		0.73 ± 0.08			

SD: Standard deviation

p: p value for comparing between the studied periods

F: F test (ANOVA) with repeated measures

*: Statistically significant at $p \leq 0.05$

Table (3): Overall attitude levels of studied nurses toward pharmacovigilance (n = 111)

Overall attitude levels	Pre program		Immediate post program		Post program after three months		Test of Sig.	p
	No.	%	No.	%	No.	%		
▪ Negative (<50%)	8	7.2	6	5.4	7	6.3	Fr= 6.100*	0.047*
▪ Moderate (50 – <75%)	48	43.2	43	38.7	46	41.4		
▪ Positive (≥75%)	55	49.5	62	55.9	58	52.3		
Total Score (12 – 60)								
Min. – Max.	20.0 – 59.0		29.0 – 60.0		28.0 – 60.0		Fr= 13.107*	<0.001*
Mean ± SD.	46.82 ± 6.46		47.75 ± 6.01		47.24 ± 6.24			
Average Score (1 – 5)(Mean ± SD.)	3.90 ± 0.54		3.98 ± 0.50		3.94 ± 0.52			

Table (4): Overall patient safety levels perceived by studied nurses (n = 111)

Overall safety levels	Pre program		Immediate post program		Post program after three months		Test of Sig.	p
	No.	%	No.	%	No.	%		
▪ Low (<50%)	17	15.3	11	9.9	12	10.8	11.231*	0.004*
▪ Moderate (50 – <75%)	86	77.5	89	80.2	88	79.3		
▪ High (≥75%)	8	7.2	11	9.9	11	9.9		
Total Score (30 – 150)								
Min. – Max.	42.0 – 136.0		51.0 – 134.0		50.0 – 134.0		6.102*	<0.001*
Mean ± SD.	104.1 ± 14.55		106.4 ± 13.22		105.5 ± 13.44			
Average Score (1 – 5)(Mean ± SD.)	3.47 ± 0.49		3.55 ± 0.44		3.52 ± 0.45			

Table (5): Correlation between PV nurses' knowledge, attitude and patients' safety pre, immediate and post program (n= 111)

		Pre program	Immediate post program	Post program after three months
▪ PV Knowledge vs. Attitude	r	0.439*	0.298*	0.260*
	p	<0.001*	0.001*	0.006*
▪ PV Knowledge vs. patients' safety	r	0.357*	0.347*	0.269*
	p	<0.001*	<0.001*	0.004*
▪ PV Attitude vs. patients' safety	r	0.520*	0.452*	0.475*
	p	<0.001*	<0.001*	<0.001*

Table (1): Shows personal characteristics of nurses. The table shows nearly half of staff nurses (46.8 %) aged from 30–<40 years with mean score 32.45 ± 6.41 , the most of them (99.1%) were female, and majority (79.3%) of them were married. One third (36.9) having experience from 5 to <10 year with mean score 12.50 ± 7.40 . Over half (52.3%) of nurses had Technical Nursing Institute.

Table (2): Shows overall knowledge levels of studied nurses toward pharmacovigilance. The table reveals that the studied nurses improved knowledge from (0.0%) good knowledge preprogram to (73.0%) good knowledge immediate program with Mean±SD 23.59 ± 2.04 and become improved highly statistically significant at $<0.001^*$.

Table (3): Shows overall attitude levels of studied nurses toward pharmacovigilance. The table reveals that the studied nurses improved from negative attitude level toward PV (7.2%) preprogram to over half (55.9 %) positive attitude immediate program

with Mean ± SD 47.75 ± 6.01 and become improved statistically significant at 0.047^* .

Table (4): Shows overall patient safety levels perceived by studied nurses. The table reveals that the studied nurses improved from moderate level (77.5%) preprogram to (80.2% and 79.3%) immediate and post program respectively with total Mean ± SD 106.4 ± 13.22 and 105.5 ± 13.44 and improved highly statistically significant at 0.004^{**} .

Table (5): Illustrates correlation between PV nurses' knowledge, attitude and patients' safety pre, immediate and post program. According to this table, there was highly statistically significant relationship among nurses' PV knowledge vs. attitude, knowledge vs. patient' safety and attitude vs. patient' safety pre, immediate and post program.

Discussion:

Regulations concerning PV have been changed and reorganized to expand the opportunity of post-marketing surveillance and improve patient care

recently. In order to contribute to the safe and efficient use of medications for the benefit of patients and public health, the main objective of initiatives to improve communication about drug-related issues is to facilitate medication error reporting and subsequently learn from those errors (Varallo, et al., 2017). Consequently, PV and patient safety are two essential yet linked aspects of healthcare. Patient safety is the practice and discipline of keeping patients safe when they receive health services, while medication safety and effectiveness monitoring and evaluation are the science of pharmacological safety. To assurance that patients obtain safe and effective medicines, the relationship between these two concepts must be understood (Benton, 2023).

The present study aims to evaluate the role of implementing pharmacovigilance program for staff nurses and its effect on patients' safety.

The findings of the present study revealed that nurses improved knowledge from zero good preprogram to over three-quarter good knowledge immediate program and become improved highly statistically significant. This result due to Egypt joined WHO International, allowing for the detection, evaluation, comprehension, and development related to drug monitoring that facilitates program understanding. In the same result Acharya, et al., (2022) showed that the majority of participant had good knowledge of PV after training. Also, Sneha Prakash, et al., (2023) showed that majority of the healthcare practitioners understood the importance of reporting and had good knowledge of PV and ADR reporting.

Contrast to the result Khan, et al., (2023) find that the majority of healthcare providers had poor knowledge and practice after training. As well as Adu-Gyamfi, et al., (2022) concluded that nurses lack of PV training caused the majority of nurses in the study to believe that the information they report about ADRs may be inaccurate, hence they lacked sufficient knowledge of PV and its reporting process.

As regard attitude of studied nurses toward PV the study revealed that attitude level improved from negative attitude preprogram to positive attitude immediate program with highly statistically significant. Due to training are crucial to raising healthcare professionals' knowledge about PV and improving their attitude toward it, particularly nurses. In the same vein Sneha Prakash, et al., (2023) showed that overall, all healthcare professionals had a positive attitude regarding the PV procedures generally and ADRs monitoring following program, Also, Acharya, et al., (2022) found that the nurses reported positive attitude towards PV and ADR reporting after awareness of program. In contrast to study Manasa, et al., (2023) found that the responder

had positivity attitude regarding PV but remained largely unchanged following the educational module. The finding revealed that the studied nurses reported moderate level of patient safety immediate and post program respectively and improved highly statistically significant. This may be due to integrated PV programs for healthcare providers enhance awareness of understanding of PV's role in protecting patient safety. In the end, the relationship is essential to guaranteeing that patients receive high quality, safe cures.

This result match with Abdel-Razik, et al., (2024) clarified that, staff nurses reported moderate level of patient safety at post program and follow up program phases, moreover, there was a highly statistically significant difference improvement of staff nurses perceived patients' safety level through post and follow up program phases compared with preprogram phase. Also, Shashamo et al., (2023) indicated that the responder had good patient safety and stated that patient safety is essential to delivering high-quality care, preventing mistakes, and minimizing negative patient outcomes related to the delivery of healthcare. On the other hand, Kaware, et al., (2022) demonstrated that the crucial areas of patient safety needed to be improved; as a result, action is advised to reduce avoidable patient injury and healthcare expenditures. Ayyad et al., (2024) found that the degree of patient safety among hospital nurses is acceptable and recommended that is necessary to implement patient safety education programs and training.

The result revealed that there was highly statistically significant relationship among nurses PV knowledge. Attitude and patient safety pre, immediate and post program. Due to PV program help to enhance patient outcomes by producing useful data that may be safely and effectively used to enhance medication use and improve patient outcomes.

This study match with Benton, (2023) concluded that PV play a major part in guaranteeing patient safety and the two are intimately intertwined. Through the early identification of potential safety hazards and the implementation of appropriate preventive measures, PV activities, including signal detection, risk assessment, and risk minimization, help to better protect patients. Furthermore, PV contributes to better healthcare quality by guaranteeing the safety, efficacy, and high quality of the medications used in healthcare. As well as, Khan, et al., (2023) found that there was a statistically significant difference in the PV knowledge, attitude, and practices scores between healthcare professionals.

In addition, Zaveri & Chaudhari (2019) showed that significant improvement in PV knowledge and attitude in post-test after educational intervention and

also shows improvement in ADR form filling and concluded that training workshop, detail of PV program useful to improve knowledge and attitude among nursing professionals which is helpful for patient safety through PV program. Also, **Abou Elmaati, et al., (2016)** showed that, the knowledge, attitude, and practice of the nurses under study improved in a highly statistically significant way after they received educational intervention about PV and ADR reporting. Ultimately, enhancing PV and ADRs reporting will lower healthcare costs and the frequency of medication reactions in clinical practice.

Conclusion:

Applying pharmacovigilance program on staff nurses improves patients' safety.

Recommendations:

- Improve awareness among health care providers, particularly those in the nursing and pharmacy fields, which work closely with patients.
- In-service training for nurses, consider their critical role in reporting adverse medication reactions and participating in PV activities.
- Integrate electronic reporting, providing feedback and ADR reporting performance can be improved.
- Implement of obligatory reporting regulations is essential to enhancing the PV knowledge, attitudes, and practices of healthcare personnel as well as the safety and PV activities of patients
- Nurse managers should regularly assess and monitor the safety culture of their nursing staff to provide a safe and healthy atmosphere for patients.

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