Original Article

Impact of pharmacovigilance educational intervention on critical care nurses' performance at cancer hospital, Egypt

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ABSTRACT

This study examined the pharmacovigilance educational intervention impact on critical care nurses' performance at one of the cancer hospitals in Cairo, Egypt. This study used a pretest/posttest quasi-experimental design. A sample of convenience was recruited including 76 Intensive Care Unit nurses. Before and after the training program, three tools were used to gather data pertinent to the current study; a- Pre/Post-test knowledge assessment questionnaire, b- Nurses' Practices Observational Checklist, and c- Adverse Drug Events monitoring sheet. The data was collected for six months. Most of the sample being studied had satisfactory knowledge level, and the majority had satisfactory practice level after implementing the pharmacovigilance program. The most frequently reported signs and symptoms by nurses were rash, itching, fever, tachycardia, and arrhythmias in percentages of 19.2%, 16.7, 14.1, 14.1 10.2, respectively, and the most frequently reported drug category was antibiotics (42.3%). The performance of critical care nurses was markedly improved regarding pharmacovigilance and coincide with an improvement of reporting adverse drug events.

Keywords: Pharmacovigilance, Adverse drug reactions, Adverse drug events, Medication errors, Reporting, Intensive care unit

Introduction

Pharmacovigilance (PV or PhV) is a systematic and structured process that is concerned with Adverse Drug Reactions (ADRs), Adverse Drug Events (ADE) reporting, and medication errors [1]. PhV is an arm in patients' care and surveillance, which is also known as drug safety. It is the science and activities related to assessment, detection, understanding, and prevention of adverse effects or any other drug-related problem. It deals with preventing and minimizing morbidity associated with the use of various medicines [2]. It aims at getting the best outcome from treatment with medications [3]. Adverse Drug Reactions (ADRs) are noxious and unintended responses to a drug [4, 5]. They represent a very important cause of hospitalization and are among the leading causes of death in many countries [6]. They also represent a potentially life-threatening or permanently disabling effect caused directly by a medication, even though the medication is administered at a recommended dose [7]. More specifically. ADRs are important complications of drug therapy in approximately 30% of hospitalized critically ill cancer patients and can be a threat to patients' safety, quality of life, and may impose a lot of costs on the health care systems [8].

An important aspect of ADRs is pharmacovigilance which helps in their recording, evaluation, and prevention [9]. It has the potential to increase drug safety and minimizing medication errors [10]. Medication errors in Intensive Care Units (ICUs) are frequent, serious, and predictable. They can cause patients' death [11]. It is associated with the increasing number of medications, medications for certain disease states, and specific medications (e.g., oncology, musculoskeletal and immune-

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suppression, infections, and cardiovascular). Most errors occur during the administration stage [12]. Lack of adequate knowledge, practice, and attitude among healthcare professionals towards ADR could lead to an underreporting of ADR [13].

Critical care nurses play an essential role in assuring patients' best response to therapy and administering the correct dose of the ordered medications. Monitoring and reporting ADRs is an essential quality assurance activity [14]. To improve reporting rate, it is crucial to upgrade nurses' knowledge and practice [15]. This definitely will help to increase spontaneous reporting [16]. Knowledge and awareness about the effects, adverse effects, and methods of drug administration could help to improve the quality of pharmacotherapy in hospitals [17]. Technological advances as Electronic Health Care Record (EHR) in the critical care setting especially intensive care unit, represents a challenge and give ICU nurses more detailed and relevant patients' information [18]. Advanced care does not function without high technology equipment and skilled nurses [19].

According to the United States (US) Food and Drug Administration (FDA), more than 100000 deaths occur yearly, and 7% of hospitalizations are related to ADRs. In Egypt, according to a study done by Gouda [18] to review spontaneous adverse drug reactions reporting to the Egyptian Pharmaceutical Vigilance Center, 7220 ADRs were reported from 2011 to 2015 [20]. Moreover, through clinical experience, it has been observed that certain patients develop adverse drug reactions. Some of these reactions were fatal such as renal impairment and, even though they could be prevented. So, assessing the pattern of ADRs among critically ill cancer patients will be beneficial in many ways; first, it will help in patients' safety; second, it will improve quality of life; third, it will decrease a lot of costs on the health care systems, and fourth, it will prevent and minimize morbidity associated with the use of various drugs. Therefore, this study was carried out to examine the impact of pharmacovigilance educational intervention on Critical Care Nurses' Performance at one of the cancer hospitals in Egypt.

Research hypotheses

To achieve the aim of the present study, we postulated three research hypotheses. H.I: The post-test mean knowledge assessments scores of ICU nurses who attend the pharmacovigilance educational program will be higher as compared to their mean pre-test knowledge assessment scores; H.II: The post-test mean practice assessment scores of ICU nurses who attend the pharmacovigilance educational program will be higher as compared to their mean pre-test practice assessment score; H.III: The number of reported adverse drug events by critical care nurses who will attend the pharmacovigilance educational intervention will be improved as compared to those reported by other health team members for the same patients at the same time.

Materials and Methods

Study design

In the present study, a quasi-experimental (intervention group) research design was used. It is a type of experimental design that has the same purpose as other experimental designs, which is to test descriptive causal hypotheses about the manipulation of causes and also, many structural details like the frequent presence of pre-test measures.

Setting

This study was carried out at the Intensive Care Unit of one of the Cancer Hospitals in Egypt. This hospital is well equipped with advanced information technology, electronic health care records (Cerner) an integrated IT system that uses the latest technology. It supports the clinical, financial, or operations of a hospital or health care system.

Subjects

A convenience sample consisting of 76 nurses, representing all those who accepted to participate in this study, was considered.

Data collection tools

To gather data pertinent to the current study, three tools were developed and used. These tools are Pre/Post-test knowledge assessment questionnaire, critical care nurses' practice observational checklist, and Adverse Drug Events (ADE) monitoring sheet.

- **Pre / Post-test Knowledge Assessment Questionnaire (K.A.Q)** was developed to assess nurses' knowledge regarding pharmacovigilance. It is a self-administered questionnaire consisting of two parts: a- Critical care nurses' demographic characteristics which covered participants' gender, years of experience, job title, and educational level; and b- Critical care nurses' knowledge assessment regarding pharmacovigilance which entailed a list of 25 Multiple Choice Questions (MCQ). The items were categorized under four main domains: knowledge about pharmacovigilance; adverse drug reactions, reporting, and medication errors. Each question needed only one answer, and some questions needed more than one answer.

Scoring system

One score was allocated for each correct answer and zero for each incorrect answer. Scores of less than 75% were regarded unsatisfactory, and scores of 75 % - 100% (38 – 50 mark) were regarded satisfactory.

- **Critical Care Nurses' Practices Observational Checklist Regarding Parental Medication**

Administration: It entailed a list of 29 items. The items were categorized under four main domains: patient verification, medication verification, asepsis technique, and documentation & follow-up response. Each nurse's performance was written in the checklist as either done or not done.

Scoring system

One score was allocated for each correctly done action and zero for incorrectly done, incompletely done, and not done actions. Scores below 75% were considered unsatisfactory measures, and scores between 75 % - 100% (22 -29 mark) were considered satisfactory.

- **Adverse Drug Events (ADE) Monitoring Sheet:** It was developed to monitor/assess the quality (completeness & accuracy) and the number of reported ADEs by nurses. It consisted of two parts: a- Adverse drug reactions monitoring, which entailed a list of 34 items categorized under 5 main domains: patients' identification, suspected medications, medications and laboratory results assessment, suspected ADR and reporter confirmation, and b- medication errors monitoring, which entailed a list of 15 items. It was categorized under three main domains: patient identifiers, description and categorized medication errors, and reporter confirmation. Each item required only one answer.

Scoring system

One score was given for each correctly complete reported and documented data and zero scores for each not documented or incorrectly and incompletely documented data. Scores less than 75% are considered unsatisfactory practices and scores from 75%-100% (26 - 34 mark for ADR & 12 - 15 mark for M.E) are considered satisfactory.

Pilot study

To examine the objectivity, applicability, and feasibility of data collection tools, a pilot study was done on 20 staff nurses working in an ICU. The researcher gained experience in dealing with the included subjects and using the data collection tools after carrying out the pilot study. No modification is needed considering the results of the pilot study.

Statistical analysis

Data was tabulated and analyzed by Statistical Package for Social Sciences (SPSS) program version 25 after being collected. Results were presented as mean ± standard deviation (SD) for quantitative variables and number with percentages for categorical variables like the demographic characteristics of nurses, level of knowledge and practice domain as well as the category of signs and symptoms, body system, and causative drugs of the ADR reports. Changes in pre-test and post-test scores were analyzed. The Chi-square test was performed to compare the level of knowledge and practice between pre and post-program implementation. The significance level of $P < 0.05$ was used, where the test was relevant.

Procedure and data collection

This research was performed on three phases: the designation, implementation, and evaluation phases. The designation phase includes the construction and preparation of different data collection tools, designing the pharmacovigilance nursing educational program, and setting the timetable to deliver the program's contents. The program schedule consisted of 8 lectures through face-to-face teaching. The overall training hours were ten, divided into four theoretical hours and six practical hours. The researcher approaches the responsible nursing supervisors of the critical care unit to specify a room near the ICU to teach the program contents. Then, the researcher asked for equipping the room with a computer, and data show, as well as obtaining the other managerial agreements to conduct the research. It was done for two months.

The implementation phase was conducted after obtaining official permissions. The data was collected within 6 months, starting from November 2018 to May 2019. The actual implementation of the study was started by obtaining a list of involved nurses in the morning, afternoon, and night shifts from the monthly schedule. There were daily visits to the selected ICU, and during their working shifts, nurses were approached, where the aim and nature of the study were explained. The written agreements were obtained from those who consented to participate in the research. Then involved nurses were asked to fill out the first data collection tool, "Pre / Post-test Knowledge Assessment Questionnaire." The researcher was available to answer any question and to give the required explanations. Then the researcher reviewed the questionnaire to ensure that there are no missing data/items. For each nurse, about 25- 35 minutes was required for filling this sheet.

The involved 76 nurses were divided into small groups according to their schedule. The average number of nurses working in ICU/day/shift was 20 of these 7-10 nurses were scheduled to attend the educational program sessions. Two groups were met daily during the conduction of the program. The Pharmacovigilance program included eight sessions: the first session covered history, definition, scope, and aim of pharmacovigilance; the second session included definitions, types, and classifications of ADR and signs and symptoms of an adverse drug reaction; the third session was concerned with medication errors definition, types and WHO's classifications; the fourth session focused on reporting and under-reporting of ADR, reason, and aim of reporting, how to report ADR and reporting of medication errors; the fifth and six sessions were concerned with practical applications of reporting ADR; the seventh session was about practical reporting of medication errors, and finally the eighth session which was about the

practical application of parenteral medications administration. The overall duration of implementing the pharmacovigilance program was around three months to cover training of all the study samples.

Regarding the evaluation phase, the researcher followed up and documented the set program's outcomes using Pre / Post-test Knowledge Assessment Questionnaire (tool1) and observational Practice Checklist (tool 2) immediately after implementing the pharmacovigilance program. During their practice of different nursing care skills, observation of nurses' practice was performed in the morning and afternoon shifts. Three nurses were observed in each shift. While performing each procedure of the observational checklist, each nurse was observed on three different occasions. Nurses were also assessed and noted for documenting all details of medication administration. They were assessed continuously for three months during the actual period of delivering the educational program. The researcher opened communication channels by creating a WhatsApp pharmacovigilance group to assure continuity of program implementation with feedback and follow up to nurses' reports.

Then the researcher monitored nurses' reporting and the number of ADE for the next 3 months by Adverse Drug Event (ADE) monitoring sheet (Tool 3). This period started from the second week of February to the second week of May. The WhatsApp group remained the channel of communication used by the studied sample to inform the researcher about detected ADE. The hard copies of reporting sheets were kept at the main stations of the ICU, and the researcher received the filled-out reports directly from nurses or the ICU's supervisor. The researcher evaluated the quality (completeness and accuracy) of nurses' ADR reporting and medication errors by comparing the documented data reported by nurses with electronic documentation and comparing the number of nurses' reporting with the total number of ADE reported by other health care team in the same period. The obtained data were changed into numeric data, and the mean of the three observations was documented.

Results and Discussion

Demographic characteristics data

Table 1, explains that the majority of the studied sample was in the age group of 20-29, had a bachelor's degree, and worked as staff nurses in percentages of 77.6%, 69.7%, and 82.9%, respectively. The sample consistedof 61.8% female participant. Around half (56.6%) of the sample being studied had less than five years of experience working as critical care nurses, with average years of experience = 5.99 ± SD= 9.430.

Table 1. Frequency Distribution of the Studied Sample Considering Demographic Characteristics, (N=76).

Socio-demographic data	No	%
Age (years)		
20<30	59	77.6
30<40	13	17.1
40 - 50	4	5.3
M± SD		27.72± 5.137
Gender		
Female	47	61.8
Male	29	38.2
Level of Education		
Master degree	1	1.3
Bachelor degree	53	69.7
Technical nursing institute	12	15.8
Nursing diploma (3 years)	10	13.2
Job Categories		
In- charge nurse	13	17.1
Staff nurse	63	82.9
Years of Experience		
<5	43	56.6
5<10	20	26.3
10 <15	3	3.9
15 <20	3	3.9
20 <25	5	6.6
25 - 30	2	2.6
X± SD		5.99 ± 9.430

Knowledge of nurses

Table 2, indicates that, unsatisfactory knowledge before intervention was in common related to pharmacovigilance, ADRs reporting, and medication errors in percentage of 100%, 96.1%, 89.5%, and 94.4%, respectively, with a subtotal mean knowledge scores of 1.64±SD=0.743, 10.96 ±SD = 4.4, 5.9 ± SD = 2.4, 3.59 ± SD=1.3 respectively and a mean total pre-program implementation knowledge scores of 22.17±SD=7.47.

Table 2. Frequency Distribution of the Studied Sample as Regards Total and Subtotal Knowledge Scores, (N=76)

Pharmacovigilance Knowledge assessment domains	Pre Program					Post Program				
	Satisfactory		Unsatisfactory		X±SD	Satisfactory		Unsatisfactory		X±SD
	No.	%	No.	%		No.	%	No.	%	
Pharmacovigilance	0	0	76	100	1.64±0.743	70	92.1	6	9.7	4.42±0.735
Adverse drug reaction	3	3.9	73	96.1	10.96 ±4.4	63	82.9	13	17.1	20.58 ±3.35
Reporting	8	10.5	68	89.5	5.9+2.4	56	73.7	20	26.3	10.83+2.33
Medication	5	6.6	71	93.4	3.59±1.3	56	73.7	20	26.3	6.16± 0.925
	0	0	76	100		61	80.3	15	19.7	
Total	X±SD		X±SD			X±SD		X±SD		41.91±5.95
	0±0		22.17±7.47		22.17±7.47	44.25±3.25		32.40±4.89		

Immediately post-implementation, the majority of the studied sample who had satisfactory knowledge that in common related to pharmacovigilance and adverse drug reactions in the percentage of 92.1% and 82.9% respectively, with a subtotal mean knowledge score of 4.42±SD = 0.735, 20.58 ±SD = 3.35 respectively and a mean total post-program implementation knowledge score of 44.25±SD=3.25.

Practice of nurses

Table 3, shows unsatisfactory practice (among all of the studied group) before the educational intervention that was in common related to reporting Adverse Drug Reactions (ADRs), and medication errors reporting in the percentage of 100%, with a subtotal mean practice score of 8.22±SD = 2.370, 5.36 ±SD = 1.458 respectively and a mean total pre-program practice scores of 36.86 ±SD = 4.228. Post-program implementation, the majority of the studied group had a satisfactory practice which was in common related to medication errors reporting and medication administration in the percentage of 82.9% and 92.1%, respectively, with subtotal mean practice scores of 13.07±SD = 1.517, and 26.70±SD = 2.355 respectively, and mean total practice scores of 68.63±SD = 4.261.

Table 3. Frequency Distribution of the Studied Sample Considering Total and Subtotal Practice Scores, (N=76).

Pharmacovigilance practice domains	Pre					post				
	Satisfactory		Unsatisfactory		X±SD	Satisfactory		Unsatisfactory		X±SD
	No.	%	No.	%		No.	%	No.	%	
Adverse drug reaction (ADR) reporting	0	0	76	100	8.22±2.370	54	71.1	22	28.9	28.17±3.978
Medication error Reporting	0	0	76	100	5.36 ±1.458	63	82.9	13	17.1	13.07 ±1.517
Medication Administrations	50	65.8	26	34.2	23.1+2.928	70	92.1	6	7.9	26.70+2.355
	0	0	76	100		73	96.1	3	3.9	
Total	X±SD		X±SD		36.68±4.228	X±SD		X±SD		68.18+4.729
	0±0		36.86±4.228			68.63±4.261		57.33±1.155		

Reporting of ADRs

Figure 1, shows that more than half (51%) of adverse drug events reported by the studied sample were medication errors as compared to nearly half (49%) who reported adverse drug reactions.

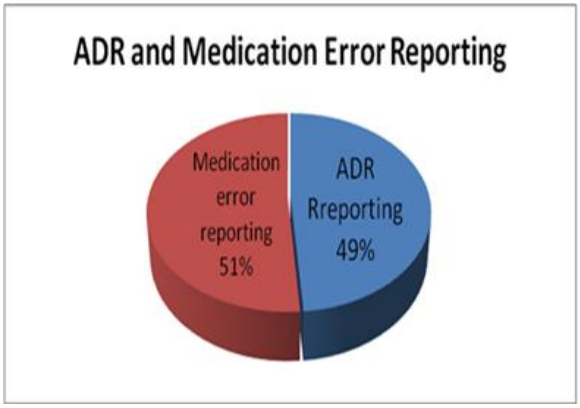

Figure 1. Percentage Distribution of Reported Adverse Drug Events concerning their Type by the studied sample (N=160).

Figure 2, shows that half (50%) of total adverse drug events were reported by the studied sample after program implementation.

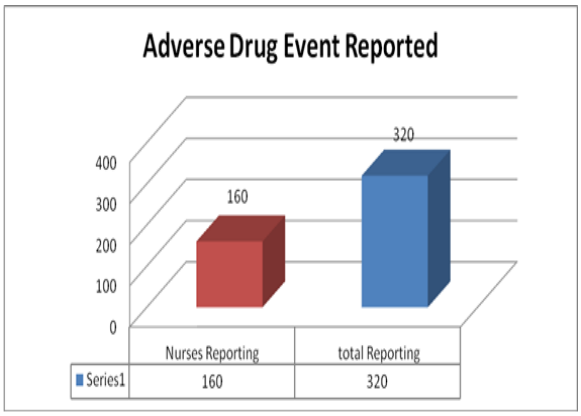

Figure 2. Percentage Distribution of Reported Adverse Drug Events concerning the Total Number of Reporting, (N=320).

Additional correlational findings

Table 4, clarifies that the total and sub-total mean post-test knowledge scores differed significantly as compared to the mean pretest scores concerning pharmacovigilance, adverse drug reactions reporting, and medication errors (t / p: 23.55 / 0.000, 17.01 / .000, 14.67 / 0.000, 15.78 / 0.000 respectively). A significant statistical difference was found between the total pre and post-test mean knowledge scores (t= 21.161, P ≤ 0.05).

Table 4. The Comparison of Mean Pre and Post Knowledge Scores of the studied sample concerning Pharmacovigilance (N = 76).

Pharmacovigilance Knowledge Assessment Domains	Knowledge Score		
	Pre-program	Post-program	Test statistics / P-value
	M±SD	M±SD	
Pharmacovigilance concept	1.64 ± .743	4.42 ± .735	t= 23.55 / .000*

Adverse drug reaction	10.96 ±4.419	20.58 ± 3.352	t= 17.01 / .000*
Reporting & underreporting	5.91 ± 2.492	10.83 ± 2.335	t= 14.67 / .000*
Medication error	3.59± 1.3483	6.16 ± .925	t= 15.78 / .000*
Total	22.17 ± 7.473	41.91 ± 5.956	t= 21.16 / .000*

* Significant at p ≤ 0.05.

Table 5, displays that the total and sub-total mean practice scores differed significantly as compared to the mean pre-practice scores concerning reporting adverse drug reactions, reporting medication errors, and medications administration (t / P: 34.21 / 0.000, 33.41 / 0.000, 11.65 / 0.000 respectively). A significant statistical difference was found in the overall mean pre and post-practice scores (t= 46.47, P ≤ 0.05).

Table 5. The Comparison of Pre and Post Mean Practice Scores among the studied sample, (N = 76).

Pharmacovigilance Practice:	Practice Score		
	Pre	Post	Test of significance / P-value
	M±SD	M±SD	
Adverse drug reaction (ADR) reporting	8.22 ± 2.370	28.17 ± 3.978	t= 34.21 /.000*
Medication errors Reporting	5.36 ±1.458	13.07± 1.517	t= 33.41 /.000*
Medications Administration principles	23.01 ± 2.928	26.70 ± 2.335	t= 11.65 /.000*
Total	36.68 ± 4.228	68.18± 4.729	t= 46.47 /.000*

* Significant at P ≤ 0.05.

Adverse Drug Reactions (ADRs) represent a common and important complication of drug therapy in critically ill cancer patients. Therefore, awareness of pharmacovigilance in patients' management through up-to-date knowledge and refined practical nursing skills can play significant roles in safeguarding critically ill patients against ADRs. Nurses should have the opportunity to practice pharmacovigilance on a day-to-day basis as an integral part of patients' care. Because of this, the present study was carried out. Most of the studied sample was in the age group ranged between 20 to 30 years old. This could reflect the younger age of the studied sample and the subsequent ability to acquire knowledge and change their behaviors in response to exposure to an up to date knowledge and practical skills. In this regard, Hussain *et al.* [21], showed that older age is a significant determinant of lower knowledge levels.

This research evaluated the effect of an educational intervention on the knowledge and practice of nurses towards pharmacovigilance to improve and increase the number of ADE reports. Baseline assessment of nurses' knowledge indicated unsatisfactory knowledge levels among all the studied nurses, while post-intervention, the majority had satisfactory levels. In an attempt to identify areas of knowledge deficit among the involved nurses (who had unsatisfactory knowledge level), they were related to the concept of pharmacovigilance; adverse drug reactions, reporting, and medication errors. On the same line with this finding was that of Palaian *et al.* [22], who found poor baseline knowledge scores among their studied sample in a study about the assessment of pharmacovigilance-related educational intervention on nursing students' knowledge, attitude, and practice: A pre-post study. In this regard, Padmavathi *et al.* [23], showed that nurses have poor basic knowledge of pharmacovigilance, ADR, and its reporting. However, Alshakka *et al.* [24], revealed contradicting findings as they found a relatively good level of knowledge about pharmacovigilance among physicians and nurses.

Besides, more than two-thirds of the current study's sample had a satisfactory knowledge level about ADR reporting after the educational intervention. Knowledge of ADR reporting (from the researcher's point of view) is vital for decreasing the irrational use of an inappropriate pharmacy. Nurses' knowledge about the purpose of ADR reporting increased to more than seventy percent in the post-test after intervention where it differed significantly as compared to pre-test knowledge scores. This finding is in concordance with that of Goka *et al.* [14], who evaluated the effect of educational intervention on pharmacovigilance and ADR reporting among nurses in a tertiary care teaching hospital and revealed increased correct responses from less than one third to more than two thirds after the intervention. So, from what has been introduced, we can conclude that the first stated research hypothesis is supported where training was effective for improving critical care nurses' knowledge as evidenced by higher mean post-test assessment scores as compared to their mean pre-test knowledge assessment scores.

Concerning the assessment of nurses' practice regarding pharmacovigilance, this study demonstrated that, in the baseline assessment, the studied sample had unsatisfactory practice level regarding adverse drug reactions and medication errors reporting. Similarly, studies were done by Datta *et al.* [25], and Bepari *et al.* [26], showed the unsatisfactory practice of adverse drug reaction reporting. Although the overall scores before the intervention were unsatisfactory, around two-thirds of the studied sample had satisfactory scores regarding medication administration. This finding (from the researcher's point of view) reflects the positive role of on job training and strict following of policies and procedures' guidelines in the hospital, and construction supervision.

Besides, this research showed that most of the studied sample had satisfactory practice level considering pharmacovigilance after the educational program concerning adverse drug

reactions reporting, medication errors reporting, and medications administration. The quality and filling out of the ADR and ME reports were improved after the program concerning the data provided according to patients' identifiers, suspected medications, laboratory results, suspected ADR, description, and categorized ME and reporters' confirmation. These results are in agreement with a study done by Alsalimy *et al*. [27], about the characteristics and quality of adverse drug reactions reporting where ADR reports are judged to be of high quality. Approximately the same findings were noticed by Zaveri and Chaudhari [28], who studied the effect of educational training and workshop on knowledge, attitude, and practice of pharmacovigilance in nursing staff of a tertiary care hospital and found the majority of participants had obtained good scores in filling ADR's forms.

Consequently, the current study showed an increased number of ADRs and medication error reporting. The educational program improved the studied nurses' knowledge of pharmacovigilance and enhanced their skills of accurately detecting and filling out reports forms. This result is in concordance with that of Jaiswal [29], who recommended education and training to be the most recognized means of improving ADE reporting. Therefore, including professional nurses in pharmacovigilance services has a significant role in contributing to patients' safety through drug safety analysis and to the prevention, early identification, and communication of ADEs. In this regard, Varallo *et al.* [30], revealed that multidisciplinary teams have a significant role in reporting ADE, and engaging them in educational interventions for pharmacovigilance indicated a considerable enhancement in the prevalence of ADE reporting mainly by the nursing staff. Thus the second research hypothesis can be supported as evidenced by higher mean post-test practice scores of critical care nurses who attended the pharmacovigilance educational program as compared to their mean pre-test practice scores.

As regards affected organ systems, the current study showed that skin was the most frequently reported body system by nurses in the ADR form, followed by renal, cardiovascular, and neurological systems. This result is in agreement with that of Conforti *et al.* [31], who mentioned that the skin was the most affected system. However, Ganachari [32], contradicts the present study's finding and reported that the cardiovascular system was commonly affected by ADRs. Also, Shamna *et al.* [33], found in their study about ADRs of antibiotics in a tertiary care hospital that the most affected body systems were the gastrointestinal tract.

In addition, antibiotics were the most common medications often involved in ADR reporting in the current study. Antibiotics are used for treatment and prophylaxis of various infectious conditions, especially with cancer patients who receive many types at the same time. This goes in line with that of Khan [34], and Silva *et al.* [35], who revealed that antibiotics were the top class of drugs reported ADRs. However, these results contradict those of Shamna *et al*. [33], who reported a low incident rate of reporting antibiotic ADRs. Therefore, efforts are needed not only to empower what nurses know and can do but also correct unsatisfactory practices. Therefore, the third research hypothesis can be supported as evidenced by increasing the number of reported adverse drug events by critical care nurses who attended the Pharmacovigilance educational intervention. However, efforts are still needed to increase the quantity and improve the quality of reports and keep matching with other health care team reports.

Conclusion

The findings of the current study have shown that, despite having satisfactory knowledge and practice levels regarding pharmacovigilance and improved number of reports after the educational program as compared to before, underreporting still found when comparing nurses' reports with other health care professionals. This emphasizes the importance of continuous hands-on training to meet the challenges of critical care nursing practice and achieve better patients outcomes.

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Conflict of interest: None

Financial support: None

Ethics statement: The Human Research and Ethical Committee at the Faculty of Nursing Cairo University approved the current study with ethical number FWA 00026458. The aim and the nature of the study were also explained in Scientific Medical Advisory Committee (SMAC) to gain their acceptance and support. Then the researcher obtained approval from the Institutional Review Board (IRB) at the data collection setting. The medical and nursing directors of the ICU gave official permissions. After explaining the aim and nature of the study, critical care nurses gave their written consent.

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