

Effect of Educational Intervention on Nurses' Knowledge, Attitude and Practice Towards Pharmacovigilance and Adverse Drug Reaction Reporting

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Abstract: Pharmacovigilance (PV) has constantly grown in importance in last 15 years, relating to absolute amount of adverse drug reactions (ADRs) and to the fact that several hospital admissions are due to ADRs. This study was aimed to evaluate the effect of an educational intervention on nurses' knowledge, attitude and practice (KAP) toward pharmacovigilance adverse drug reactions reporting. It was conducted in medical specialist hospital at (Cardiology, Hepatology, Endocrinology and ICU department). Quasi-experimental design was utilized in this study on a convenience sample of (117) nurse in the previous mentioned setting. Two tools were used to collect the data, Tool I: an interviewing questionnaire contained questions related to demographic characteristics, factors that can hinder PV and ADRs reporting and method that can used for PV and ADRs reporting. Tool II: self-administered questionnaire was used to assess nurses KAP toward PV and ADRs reporting. The study found that knowledge, attitude and practice level toward PV and ADRs reporting were deficient among studied nurses before educational training and highly significantly improved ($P < 0.001$) after training. The study concluded that, underreporting of nurses toward PV and ADR was identified on this study. The entire participants' respond to; they did not attend training intervention toward ADR reporting, also they didn't know the proper way to report it and had poor knowledge regarding reporting ADRs and PV. The educational training success to improve nurses KAP related PV and ADRs reporting. This study recommended that, all nurses should be trained for early detection, investigation and management of ADRs to increase their knowledge on ADR reporting.

Key words: Adverse drug reaction • Attitude • Knowledge • Pharmacovigilance • Practice • Reporting

INTRODUCTION

Adverse drug reactions (ADRs) are negative consequences of drug therapy [1]. It affects irrespective of the age group of patients worldwide with varying magnitude of morbidity and mortality [2, 3]. World Health Organization (WHO) defined ADRs as any unintended, noxious and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, cure of a disease and/or for modification of a physiological function. Pharmacovigilance is "the science and activities that permit the detection, assessment, understanding and prevention of adverse effects or any other drug-related

[4]. Pharmacovigilance deals not only with ADRs of new medicines but also with old medicines, ADRs with increased frequency, drug interactions and ADRs resulting from overdose, medication errors and counterfeits [5].

World Health Organization (WHO) established its Program for International Drug Monitoring in response to the thalidomide disaster observed in 1961. Uppsala Monitoring Centre (UMC), Sweden, is maintaining global database of adverse drug reaction reports on behalf of WHO [6]. Egypt became a member in WHO International Program for Drug Monitoring in 2001, yet no solid steps were taken except in 2009 with the establishment of the

Egyptian PV Center (EPVC). It is responsible for receiving ADR reports, detecting safety signals, issuing regular newsletters with pharmacovigilance (PV)-related updates and conducting awareness workshops. In Egypt the Yellow Card is used by EPVC which acts as main points to spread awareness with the ADRs reporting process, each yellow card accounts as an individual case and it is also called Individual Case Safety Report (ICSR) [7].

Spontaneous reporting is cornerstone of ADRs, a pre-requisition for effective pharmacovigilance and is important in maintaining patient safety. It may detect previously unrecognized adverse reactions and identify risk factors that predispose to drug toxicity, investigate causality and identify rare unexpected ADRs more quickly than any other study designs. It is a voluntary process in nature reported by healthcare professionals and members of public. Different factors can discourage reporting such as lack of time, unable to link adverse event to medication and unavailable reporting forms [8].

Nurses, in their distinctive position as drug administrators who record the ascertained effects of drug use, are been found to have an very important role in ADR reporting and represent a potentially valuable source for spontaneous ADR reports in hospitals, because they are close to the patients and have a good knowledge of patient's health status, symptoms, drugs and ADRs. They are typically the sources in alerting the accountable prescriber concerning the attainable ADRs. There's a logical reason to involve nurses and encourage them to contribute in ADR reporting system [9].

Significance of the Study: ADRs are the six leading causes of death within the USA, cause death of many thousand patients annually and hospitalizations for regarding 10%. Additionally to the increased the financial burden for the general public, some countries pay up to 15-20% of their healthcare budget for treatment of drug-related problems. Despite this, only 6-10% of all ADRs are reported worldwide. However there is a lack of information on ADR burden in developing countries like Egypt [10].

Nurses have important role in ADRs reporting, however the number of reports received is insufficient and less frequently occurred for all types of serious ADRs and unexpected reactions. Studies from totally different settings indicate inadequate information regarding PV and ADRs among healthcare professionals as well as attitudes that are accompanied with a high degree of underreporting PV is still in its infancy in Egypt and the

Egyptian national PV program lacks continuity that occurred from lack of awareness and inadequate training regarding drug safety monitoring among Egyptian health care professionals [11]. Therefore this study was conducted to evaluate the effect of educational intervention on nurses' knowledge, attitude and practice towards pharmacovigilance and adverse drug reaction reporting.

Aim of the Study: Evaluate the effect of educational intervention on nurses' knowledge, attitude and practice towards pharmacovigilance and adverse drug reaction reporting.

Research Hypothesis: Level of knowledge, attitude and practice of nurses towards pharmacovigilance and adverse drug reaction reporting will be enhanced after implementing an educational intervention.

MATERIALS AND METHODS

Research Design: A quasi-experimental design was utilized to achieve the purpose of the present study.

Setting: This study was conducted in Medical Specialist Hospital departments (Cardiology, Hepatology, Endocrinology and ICU department) at Mansoura University Hospital, Egypt.

Subjects: Convenience sample of all available number of nurses (117) worked in the previous mentioned setting during the period of the study.

Tools of Data Collection: Two tools were used to collect the data by the researchers as the following:

Tool I: An interviewing Questionnaire: This tool was designed and used by the researchers after extensive review of literature. It included three parts as follows:

Part (1): This part included questions related to demographic characteristics as; sex, age, qualification, years of experience and working unit.

Part (2): This part contained data related to factors that can hinder nurses from reporting PV and ADRs as; don't know where to report, don't know how to report, lack of time to report, poor knowledge and lack of training program, lack of access to the reporting form and fear of negative impact, legal liability issues [12].

Part (3): This part contained data related to method that can be used by nurse for reporting PV and ADRs as; phone call, yellow card and internet [13].

Tool II: Self-administered questionnaire: This tool was developed by the researchers after extensive literature review [14, 15]. It was used to assess nurses KAP toward PV and ADRs reporting. It contained three parts as follows:

Part (1): General Knowledge regarding PV and ADRs reporting and; this section consists of (10) items.

Scoring System: For general knowledge regarding PV and ADRs reporting had two responses, ' correct ' response was given the score of "ONE" and ' incorrect ' response was given the score of "ZERO". The total knowledge score of a subject is the sum of scores obtained for each question, the maximum score for ADR reporting and PV was 10 score. The knowledge level was categorized based upon the scoring system utilized as follows: Poor level is < 50%, Fair level $50 \leq 75\%$ and Good level was $\geq 75\%$.

Part (2): Attitude regarding PV and ADRs reporting; this section consists of (9) items.

Scoring System: Attitude regarding PV and ADRs reporting had three responses, 'agree' response was given score "THREE", 'somewhat agree' was given score "TWO" and 'disagree' response was given the score of "ONE", while question 5 and 6 had reversed score. The total attitude score of a subject is the sum of scores obtained for each question, the total score from 9-27 score. Based upon scoring system utilized, the attitude level was categorized as follows: positive level is more than score $\geq 65\%$ (18) and negative level is less than score <65% (18).

Part (3): General practice regarding PV and ADRs reporting; this section consists of (6) items. It was checked by two responses yes and no.

Validity and Reliability: For validity purposes, the researchers conducted an extensive literature review and developed the questionnaires from the previously used tools and reviewing the pertinent reviews. Panel of five expertise of professors academic nursing, reviewed the tool for feasibility, clarity, relevance, comprehensiveness, applicability and simplicity for implementation and according to their opinion some modification were done.

Reliability analysis was ascertained with Cronbach's alpha to determine the extent to which the items in all instruments are related to each other by using test-retest method and it was ($r = 0.70$).

Pilot Study: A pilot study was conducted to assess the applicability of the instruments, the feasibility of the study and to estimate the time needed for data collection. It was conducted on (12) nurses of the total participants according to the selection criteria. All nurses participated in the pilot study excluded from the study sample.

Fieldwork: This study was carried out through three consecutive phases: interviewing & assessment, implementation and evaluation phase. The data collection period was done for 4 months from the start of Jun 2016 to the end of September 2016.

The Interviewing and Assessment Phase:

- During this phase, the researchers explained the purpose of the study, tools components and steps of (Yellow Card) reporting.
- The time needed for completing the questionnaire was ranged from 30 - 40 minutes for each nurse.

The Implementation Phase:

- Based on the findings of assessment phase, goals and expected outcomes were formulated.
- In this phase the instruction related PV and ADRs reporting were developed by the researcher based on the available instruction presented in the related literature such as national, international books, scientific journal as well as, nurses' needs that carried out in the assessment phase.
- The developed instructions were translated from English to Arabic language, supplemented by photos, illustrations to help the patients to understand of the content.
- The selected nurses who were recruited were interviewed individually by the researchers two times throughout the study.
- The first interview was carried out by the researchers for each participant for collecting baseline data about their demographic, knowledge, attitude, practice, factors that hinder reporting and method that can be used to report about PV and ADRs. The interview carried out at the previously mentioned departments in the hospital during the morning and afternoon shifts. It took about 20 - 30 minute using tool (I and II,) as pretest.

- After that the researchers gives the instructions about Pharmacovigilance and ADRs reporting, using booklet and PowerPoint into two sessions:

First Session: It was provided the nurses with knowledge about definition and importance of PV and ADRs, to whom and where nurses should reporting, PV Centre in Egypt, proper way to discover ADRs, proper way for reporting, factor that can hinder reporting and method of reporting.

Second Session: The researcher refreshed the previous given knowledge and then discussed the details of reporting form.

- The second interview was carried out by the researchers for each participant staff after implementing the educational intervention using the tool II as posttest, the researchers were interviewed each nurse individually for 20 - 30 minute.

The Evaluation Phase: This phase was emphasized on estimating the effect of an educational intervention for improving awareness of pharmacovigilance and ADRs reporting among nurses, through a comparison between pre and post applying educational intervention.

Ethical Considerations:

- An official approval was obtained from administrative authorities to carry out the study after explanation of the purpose of the study.
- Approaches to ensure the ethics were considered in the study regarding confidentiality and informed consent. Confidentiality was attained through the use of closed sheets with the names of the participants changed by numbers. All nurses were informed that their information which provided during the study would be kept confidential and used only for statistical purpose.
- Written informed consent was taken from all participants' staff before being enrolled in the study after explaining the purpose of the study.
- Participants were informed that their participation in the study was voluntary and they could withdraw from the study whenever they decide.
- The findings would be presented as group data with no personal participant's information remained.

Statistical Analysis: Collected data were coded, computed and statistically analyzed using SPSS (statistical package of social sciences), version 21.

Data were presented as frequency and percentages (qualitative variables) and mean \pm SD (quantitative continuous variables). Chi square (χ^2) was used for comparison of categorical variables and was replaced by Mont Carlo Exact test if the expected value of any cell was less than 5. Student's pair f t test was used for comparison of continuous quantitative variables (before and after groups). The difference was considered significant at $P \leq 0.05$.

RESULTS

Table (1) revealed the characteristics of the studied nurses. Out of 117 nurses working in three medical departments; 66.7% of the studied sample was younger in age (21-30 years), with average 28.03 ± 5.97 years. While 75.2% of them were females, in addition to 92.2% of the nurses were qualified from technical institute. Their experience ranged from one to 22 years, with average 7.83 ± 5.66 and median 6 years. According to nurses worked in each department the same table illustrated that 29.9, 28.2, 30.7 and 11.1% for Cardiology, Hepatology, Endocrinology and ICU department respectively.

Table (2) illustrated that; all items of knowledge of the studied nurses about ADRs report were deficient among studied nurses before training and they become significantly improved ($P < 0.001$) after training.

Table (3) Demonstrated that total score of knowledge before training ranges from 0 to 2 with average 1.16 ± 0.74 and median is 1.0. These findings improved after training to become ranges from 4 to 10 with average 9.54 ± 1.13 and median is 10.0.

Fig. 1 showed that; all studied nurses had poor knowledge before training and 93.2% of them reported good knowledge after training with significant difference.

Table (4) showed the attitude of the studied nurses towards ADRs before and after training. Although the percentage of agreement of the studied nurses towards ADRs in most items of the attitude scale is not bad before training, most of these items showed a significant improvement ($P < 0.001$) after training.

Table (5) demonstrated the total score of attitude of the studied nurses before training ranges from 16 to 24 with average 21.62 ± 2.57 and median is 23.0. These findings were significantly ($P < 0.001$) improved after training to become ranges from 24 to 27 with average 26.76 ± 0.65 and median is 27.0.

Fig. (2) showed that after training, all nurses reported positive attitude toward ADRs instead of 84.6% before training with significant difference ($P < 0.001$).

Table 1: Distribution of nurses according to their demographic data (N=117).

Characters	Items	No	%
Age (years)	21 - 30	78	66.7
	31 - 40	33	28.2
	41 - 50	6	5.1
	Min 20		
	Max 42	Mean±SD = 28.03±5.97	Median = 26
Gender	Males	29	24.8
	Females	88	75.2
Qualification	Tech Institute	109	93.2
	Bachelor degree	8	6.8
Experience (years)	< 5	48	41.0
	5 - 10	31	26.5
	>10	38	32.5
	Min. 1		
	Max. 22	Mean±SD = 7.83±5.66	Median = 6
Departments	Cardiology	35	29.9
	Hepatology	33	28.2
	Endocrinology	36	30.7
	ICU	13	11.1

Table 2: Correct knowledge of the studied nurses about ADRs before and after training N=117

Questions	Pre-training		Post-training		Significant test
	No	%	No	%	
1. Define Pharmacovigilance?	0	0.0	110	94.0	$\chi^2=207.58$, P<0.001
2. The healthcare professionals responsible for reporting adverse drug reaction in a hospital?	0	0.0	110	94.0	$\chi^2=207.58$, P<0.001
3. The important purpose of Pharmacovigilance is (Most appropriate one)?	0	0.0	109	93.2	$\chi^2=204.05$, P<0.001
4. The international center for adverse drug reaction monitoring is located in?	0	0.0	113	96.6	$\chi^2=218.53$, P<0.001
5. Systems of reporting ADR s in Egypt use Yellow card?	0	0.0	117	100.0	$\chi^2=234.00$, P<0.001
6. Which one of the following is the 'WHO online database' for reporting ADRs?	0	0.0	113	96.6	$\chi^2=218.53$, P<0.001
7. The major risk factor for the occurrence of maximum adverse drug reactions is one of the following?	50	42.7	115	98.3	$\chi^2=86.84$, P<0.001
8. What is the regulatory center responsible for monitoring of ADR's in Egypt?	43	36.8	117	100.0	$\chi^2=108.22$, P<0.001
9. What type of adverse drug reaction is necessary to report?	19	16.2	114	97.4	$\chi^2=157.21$, P<0.001
10. Adverse drug reaction reports should be sent to AMC within how many hours of suspected ADR?	24	20.5	99	84.6	$\chi^2=96.41$, P<0.001

Table 3: Average knowledge score of the studied nurses before and after training

Knowledge score	Before training	After training	Significant test
Minimum	0.0	4.0	Paired t test
Maximum	2.0	10.0	T = 65.604,
Mean±SD	1.16±0.74	9.54±1.13	P <0.001
Median	1.0	10.0	

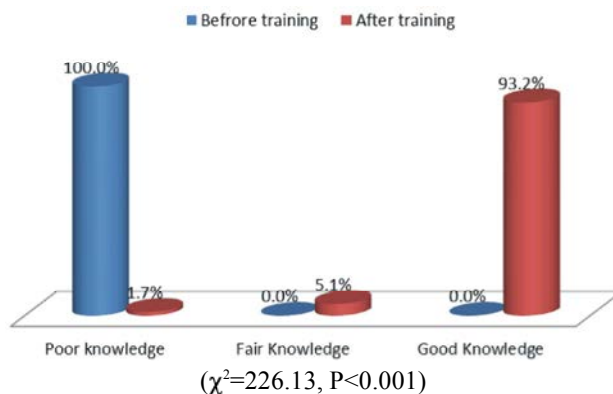


Fig. 1: Knowledge level among studied nurses before and after training

Table 4: Attitude of the studied nurses towards ADR before and after training

Attitude statements	Group	Agree		Somewhat		Disagree		Significant test
		No	%	No	%	No	%	
1. Adverse drug reaction reporting is the professional obligation for you.	Pre	15	12.8	72	61.5	30	25.6	$\chi^2=180.82$,
	Post	117	100.0	0	0.0	0	0.0	$P<0.001$
2. It is necessary to establishing ADR monitoring center in every hospital.	Pre	78	66.7	19	16.2	20	17.1	$\chi^2=36.20$,
	Post	113	96.6	4	3.4	0	0.0	$P<0.001$
3. It is important to report about adverse drug reaction.	Pre	117	100.0	0	0.0	0	0.0	-----
	Post	117	100.0	0	0.0	0	0.0	
4. Pharmacovigilance should be taught in detail to healthcare professionals.	Pre	105	89.7	0	0.0	12	10.3	$\chi^2=12.65$,
	Post	117	100.0	0	0.0	0	0.0	$P<0.001$
5. ADR reporting exposes you to legal matter. (R)	Pre	20	17.1	7	6.0	90	76.9	$\chi^2=30.52$,
	Post	0	0.0	0	0.0	117	100.0	$MEP<0.001$
6. If you report regarding ADR patient's confidentiality will not be maintained. (R)	Pre	80	68.4	0	0.0	37	31.6	$\chi^2=121.56$,
	Post	0	0.0	0	0.0	117	100.0	$P<0.001$
7. ADR reporting by healthcare professionals voluntary.	Pre	68	58.1	25	21.4	24	20.5	$\chi^2=61.98$,
	Post	117	100.0	0	0.0	0	0.0	$P<0.001$
8. ADR reporting by any\ one person can make a significant difference to the community.	Pre	66	56.4	21	17.9	30	25.6	$\chi^2=65.21$,
	Post	117	100.0	0	0.0	0	0.0	$P<0.001$
9. Reporting regarding ADR in the hospital should be financially rewarded.	Pre	90	76.9	0	0.0	27	23.1	$\chi^2=6.92$,
	Post	105	89.7	0	0.0	12	10.3	$P 0.009$

Table 5: Average attitude score among studied nurses toward ADR before and after training

Attitude score	Pre	Post	Significant test
Minimum	16.0	24.0	Paired t test
Maximum	24.0	27.0	$t = 21.793$,
Mean \pm SD	21.62 \pm 2.57	26.76 \pm 0.65	$P<0.001$
Median	23.0	27.0	

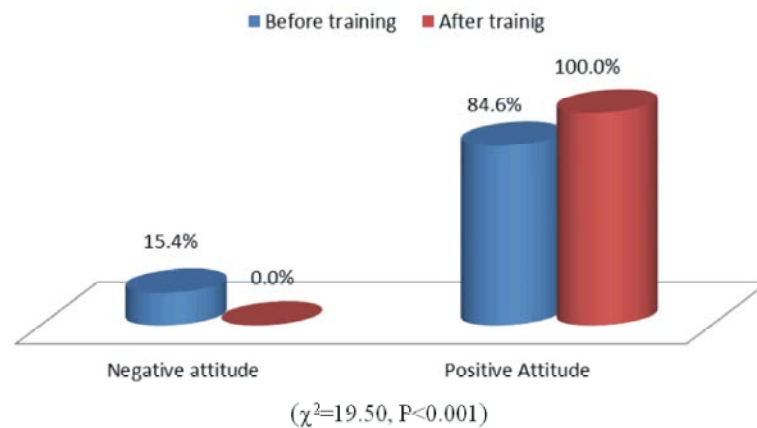


Fig. 2: Attitude level among studied nurses toward ADR before and after training

Table (6) showed that the average scores of knowledge and attitude of studied nurses are not statistically differ after training in relation to age, gender, qualification, experience years and departments where they are working. This means that all nurses have the ability of training to accept knowledge and positive attitude towards ADRs.

Table (7) showed the practice items reported by the studied nurses before and after training. The studied nurses reported that after training, they were improved significantly most of items of ADRs practices ($P < 0.00$).

Table (8) showed that the most frequent factors that can affect nurses' reporting of ADRs were: 100.0% of participants reported for don't know how to report and poor knowledge & lack of training program, followed by 99.3% of them reported for lack of time to report ADR, on the other hand 85.5% of the nurses reported for don't know where to report, while 76.9% of them reported to lack of access to the ADRs reporting form. In addition to 63.5 and 56.4% of the nurses reported for fear of negative impact and legal liability issue respectively.

Table 6: Relationship between characteristics of the studied nurses and average scores of their knowledge and attitude towards ADR reporting after training

Characters	Items	No	Knowledge score Mean±SD	Attitude score Mean±SD
Age (years)	21-30	78	9.67±0.89	26.77±0.66
	31-40	33	9.45±1.30	26.76±0.61
	41-50	6	8.50±2.26	26.67±0.81
Significance test			F=3.224, P 0.043	F=0.068, P 0.934
4Gender	Males	29	9.48±1.06	26.93±0.37
	Females	88	9.57±1.16	26.70±0.71
Significance test			t=0.351, P 0.726	t=1.634, P 0.105
Qualification	Tech Institute	109	9.56±1.12	26.77±0.65
	Bachelor degree	8	9.38±0.92	26.62±0.74
Significance test			t=0.443, P 0.658	t=0.608, P 0.544
Experience (years)	< 5	48	9.62±1.02	26.77±0.63
	5-10	31	9.71±0.69	26.71±0.78
	>10	38	8.32±1.49	26.79±0.58
Significance test			F=1.229, P 0.297	F=0.136, P 0.873
Departments	Cardiology	35	9.50±1.13	26.88±0.45
	Hepatology	33	9.42±1.40	26.78±0.64
	Endocrinology	36	9.72±0.83	26.62±0.81
	ICU	13	9.81±0.73	26.96±0.61
Significance test			F=0.813, P 0.254	F=1.819, P 0.162

Table 7: Practice items reported by the studied nurses before and after training

		Pre		Post		Significant test
		No	%	No	%	
Practice statements	Items					
1. Have you ever come across with an ADR?	Yes	50	42.7	87	74.4	$\chi^2=24.11$, P<0.001
	No	67	57.3	30	25.6	
2. Have you ever been trained on how to report regarding (ADR)?	Yes	0	0.0	117	100.0	$\chi^2=234.00$, P<0.001
	No	117	100.0	0	0.0	
3. Have you ever reported ADR to the Pharmacovigilance centre?	Yes	0	0.0	Not applicable		-----
	No	117	100.0			
4. Have you ever seen the ADR reporting form?	Yes	0	0.0	117	100.0	$\chi^2=234.00$, P<0.001
	No	117	100.0	0	0.0	
5. Have you ever experienced the ADR reporting in your patient during professional practice?	Yes	30	25.6	Not applicable		-----
	No	87	84.4			
6. Your reaction when found adverse drug reactions?	Report to center	15	12.8	117	100.0	$\chi^2=180.82$, P<0.001
	No reaction	102	87.2	0	0.0	

Table 8: Factors affecting nurses' reporting of ADR

Factors	Yes		No	
	No	%	No	%
1. Don't know where to report	100	85.5	17	14.5
2. Don't know how to report	117	100.0	0	0.0
3. Lack of time to report ADR	116	99.3	1	0.7
4. Poor knowledge and lack of training program	117	100.0	0	0.0
5. Lack of access to the ADR reporting form	90	76.9	27	23.1
6. Fear of negative impact	74	63.5	43	36.8
7. Legal liability issues	66	56.4	51	43.6

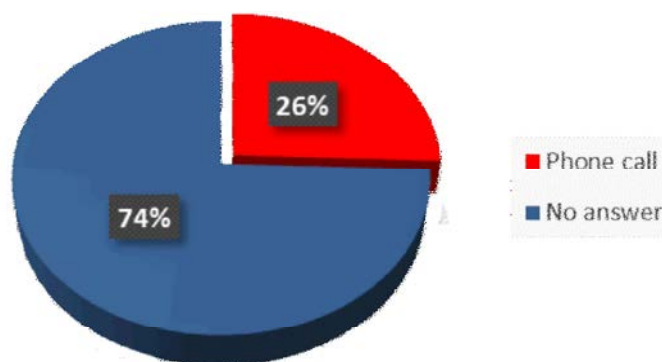


Fig. 3: Methods used for PV and ADR reporting

Fig. (3) revealed that only 26.0% of the studied nurses reported that the method used for ADRs reporting is phone and no other methods.

DISCUSSION

Drug reactions are a major cause of drug related morbidity and mortality. Globally, about 5% of all hospital admissions are due to an ADR and 10 - 20% of inpatients have at least one ADR during their hospitalization. A study by Lazarou, Pomeranz, & Corey [16] described ADRs to be the fourth to sixth largest cause of death in the United States. Therefore, ADRs presented significantly to the burden of a disease by causing drug related hospital admissions, prolonging the hospital stay, plus increasing the visits to emergency wards Sultana, Cutroneo and Trifirò [17].

Hospital nurses play a crucial role in ADRs reporting, as a result of their close observation to the patient and have sensible information of health criteria, symptoms, medication and ADRs. Additional given their unique position in drug administration and recording side effects, nurses are well-placed to observe or monitor the patients' response to medication. They are usually the source in alerting the responsible physician about possible ADRs. There is thus a logical reason to involve nurses and encourage them to contribute in ADR reporting system Toklu and Uysal [18]. The present study was aimed to determine the effect of educational intervention on nurses' knowledge, attitude and practice towards pharmacovigilance and adverse drug reaction reporting.

The findings of this study revealed that about three quarters of the participants were females while two thirds of them were younger in age group (21-30 years) with average 28.03 ± 5.97 years. This finding agrees with De Angelis, Giusti, Colaceci, Vellone and Alvaro [19] who mentioned that most nurses were females with average

age (37.68 ± 8.72). This might be related to the high prevalence of female nurses than male in nursing and according to their younger age, most of them were graduated from technical institute.

As regarding knowledge level of studied nurses, the finding of this study revealed that, knowledge levels about PV and ADRs were deficient among studied nurses before educational training and they become highly significantly improved ($P < 0.001$) after training. This finding is supported by Alraie, Saad, Sabry, & Farid [20] who concluded that knowledge level towards pharmacovigilance is gradually improving among healthcare professionals following an educational intervention of ADRs reporting. This might reflect the nurses' need for information. Once the program is given, the information has improved.

On the same line, Lopez-Gonzalez, Herdeiro and Figueiras [21] found that their participants not only had poor practice, but also had inadequate information regarding ADR reporting. The average knowledge score of the respondents was more than one third of them. On contrary with Indian studies at Gupta and Udupa [22] and Ampadu [23] had shown high knowledge, but poor practice for ADRs reporting, among participants before educational intervention.

In relation to attitude level the present study, revealed that attitude levels about ADR were deficient among studied nurses before educational training and they become highly significantly improved ($P < 0.001$) after educational training. This result is consistent with Gupta, Nayak, Shivananjani and Vidyarthi [24] who stated that attitude towards pharmacovigilance, is gradually improving among studied nurses following an educational intervention of ADRs reporting. In contrast to previous reports Ganesan, Vikneswaran, Reddy, Subrahmanyam and Adithan [25] found that no significant effect on nurses attitude following educational training regarding

ADR reporting. This might be due to, after applying ADRs educational training nurses had a positive attitude towards reporting of ADR because they felt that all ADRs are valuable and must be reported.

As regard to relation between nurses characteristics and average scores of their knowledge and attitude towards ADR reporting after training, the present study showed that the average scores of knowledge and attitude of studied nurses were not statistically different after training in relation to age, gender, qualification, experience years and departments where they are working. In accordance with Johansson, Martin, Fastbom and Jorsäter Blomgren [26] who illustrated in their study, that, in the logistic analysis, adjusting for this factor, as well as workplace, age, nurses working years and specialist nursing degree, did not change the significant association between exposure and self-reported medication competence. This might be means that all nurses have the ability of training to accept knowledge and positive attitude towards ADR.

In relation to nurses practice regarding ADRs reporting, it was found that the practice items about ADRs were deficient among studied nurses before educational training and they become highly significantly improved ($P < 0.001$) after training. This finding in harmony with Rajesh, Vidyasagar and Varma [27] who stated that the practice towards pharmacovigilance is gradually improving among studied nurses following an educational intervention of ADRs reporting. On the contrary, Al-Arifi *et al.* [28] and Lexchin [29] reported that the actual practice of ADRs reporting is still deficient among nurses following educational training. These findings could be the results of unavailability of reporting forms at the hospitals and also inadequate information on the existence of the pharmacovigilance center.

In relation to factors that can hinder nurses from reporting PV and ADRs, this study illustrated that the entire participant respond to; they did not attend training intervention toward ADR reporting, also they didn't know the proper way to report it and had poor knowledge regarding reporting ADRs and PV, while more than half of them reported to the fear of legal liability issues. This might be due to no body of the work previously discussed the important of ADRs reporting with nurses. This is compatible with Bule, Hamido, Chala and Kefeni [30] who found that, more than two third of respondents did not know how to report ADRs.

Similar findings have been reported in Northern India, Rehan, Vasudev and Tripathi [31], Italy, Cosentino, Leoni, Banfi, Lecchini and Frigo [32] and China, Li *et al.*

[33] that majority of the participants were having poor information on ADRs reporting, on the same line with Kamal, Kamel and Mahfouz [34] who found that, less than two third of their participants in the study had not reported ADRs because they did not understand how to report and nearly half of them reported for lack of time. In contrary with the studies conducted at UK, Khalili, Dashti Khavidaki, Mohraz, Etghani and Almasi [35], Green, Mottram, Rowe and Pirmohamed [8] and Okezie and Fawole [10] that reported adequate information on how to report was identified among the health care professionals.

As regard to methods used for reporting ADR and PV, our study revealed that the majority of the study sample had no answer, while less than one third was reported by phone. On the accordance with Evans *et al.* [36] who found that the minority of their participant reported by phone but in contrary with this study the same researchers found that the minority of the participant had no answer regarding methods of reporting. This might be due to our nurses re intervention had poor knowledge regarding ADRs reporting.

In this study, the results showed that, there were highly statistical significant improvement of knowledge, attitude and practice among studied nurses following educational intervention of PV and ADRs reporting. Finally, continuous training interventions are important to increase awareness of PV and ADRs reporting and improvement of knowledge, attitude and practice among healthcare professionals especially nurses. Improving PV and ADRs reporting will decrease the incidence of drug reactions in clinical practice and reduce the cost of health care.

CONCLUSIONS

Underreporting of PV and ADRs by nurses was identified on this study. The entire participant respond to; they did not attend training intervention toward ADRs reporting, also they didn't know the proper way to report it and had poor knowledge regarding reporting ADRs and PV, while more than half of them reported to the fear of legal liability issues.

According to nurses KAP regarding PV and ADRs reporting, the finding of this study revealed that knowledge, practice and attitude level about ADRs were deficient among studied nurses before educational training and they become highly significantly improved ($P < 0.001$) after training. While the average scores of knowledge and attitude of studied nurses were

not statistically differ after training in relation to age, gender, qualification, experience years and departments where they are working.

Recommendation: Based on the findings of this study, it can be recommended that:

- The hospital should ensure that all healthcare professionals especially nurse are trained and instructed regarding PV and ADRs reporting. This has ensured the availability of the forms of reporting by distributing them to the medical offices, stores of drug, hospitals and any other health providing system.
- All nurses should be trained and instructed on the detection, investigation and management of ADRs to increase their information on ADRs reporting.
- Also further researches have to be conducted in other hospitals with larger samples.

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