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Original article

Effect of educational intervention on healthcare providers knowledge and perception towards pharmacovigilance: A tertiary teaching hospital experience

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ABSTRACT

Objective: Based on the theory on planned behavior, perception or attitude is found to be a well-established predictor of healthcare providers' intentions to perform different behaviors. Also, improving knowledge was proposed to affect their practice as well. In Jordan, many studies have been conducted to evaluate healthcare providers' knowledge and perception towards pharmacovigilance but no intervention or training was provided. Thus, the aim of this study was to evaluate the impact of an educational workshop on the knowledge and perception of healthcare providers towards pharmacovigilance in a Jordanian tertiary teaching hospital.

Methods: An interventional study conducted in Jordan University Hospital on various healthcare providers to assess their pre- and post-knowledge and perception towards pharmacovigilance and adverse drug reactions (ADRs) reporting via questionnaire before and after an educational workshop.

Results: Among the 200 invited healthcare providers, 150 attended the educational workshop (response rate 75.0%). Pre-workshop, healthcare providers showed an overall low knowledge score (7.8/19), where only 8.7% could define pharmacovigilance correctly. On the other hand, they showed a favorable perception score (33.6/39).

Results: Following educational workshop, knowledge scores significantly improved by 67.9% (P-value <0.05). A similar finding was obtained for perception scores, where perception scores significantly improved by 10.1% following workshop (P-value <0.05).

Conclusion: Continuous efforts are needed to implement different strategies including education modules and the provision of appropriate training programs to increase awareness and improve perception towards pharmacovigilance among healthcare providers. Future study is needed to evaluate the impact of improving knowledge and perception on ADRs reporting practice.

1. Introduction

Pharmacovigilance is defined according to the World Health Organization (WHO) as "the science and activities related to the detection, assessment, understanding, and prevention of adverse drug reactions (ADRs) or any other drug related problems" (WHO, 2002). It has been reported that ADRs are nearly the 5th largest cause of mortality in the United States of America (Lazarou et al., 1998). Jordan, with around 130 other countries, is part of the WHO pharmacovigilance program. This program started in Jordan in the year 2001 with a goal to safeguard the health of the Jordanian population through providing effective and safe medications. However, despite the best efforts, reporting of ADRs is still low (Suyagh et al., 2015). Thus, detection of serious ADRs may be delayed and consequently have a major negative impact on the health status of individuals.

The knowledge of health care providers pertaining to pharmacovigilance had major impact on the practice of pharmacovigilance. If trained, there could be a positive drive towards an

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increase in reporting and thereby could positively influence the safety profiles of medications. Also, perception plays an important role in affecting healthcare providers' reporting of ADRs. Previous studies revealed that inadequate awareness and perception towards ADRs reporting may ultimately affect the rate of reporting (Abu Farha et al., 2015; Suyagh et al., 2015; Abu Hammour et al., 2017).

Up to the researchers' knowledge, no interventional study was conducted in Jordan to improve healthcare providers' knowledge and perception towards pharmacovigilance and ADRs reporting process, although these interventional educational workshops were found to improve knowledge in several health issues (Figueiras et al., 2006; Shuval et al., 2007; Tabali et al., 2009; Rajesh et al., 2011). Thus, the aim of the present study was to evaluate the impact of the educational workshop on the knowledge and perception of healthcare providers towards pharmacovigilance in a Jordanian tertiary teaching hospital.

2. Methods

2.1. Settings and study subjects

This is a pre-post interventional study that was conducted at Jordan University Hospital (JUH) located in Amman-Jordan. JUH is considered as one of the first teaching hospitals at the level of the Arab World and the Middle East. It includes more than 25 specialized medical units, and has 64 specialties and subspecialties in different medical fields, with a bed capacity of 550. The study was conducted by the department of pharmacy that was running a safety program as a part of hospital continuous medical education. The aim of the program is to educate healthcare providers about different drug-safety related services, which was conducted between September-October 2016.

During the study period, and after obtaining ethical approval from the institutional review board at JUH (Reference number: https://doi.org//10/2015/20650), five educational workshops were conducted to educate healthcare providers about pharmacovigilance and ADRs reporting process, each workshop aimed to serve 40 healthcare providers with a target of 200 healthcare providers to be included. Healthcare providers include medical doctors, nurses and pharmacists working throughout different departments in the hospital.

2.2. Sampling and sample size calculation

A sample size calculation was performed using the following formula:

$$n = (Z\alpha/2 + Z_\beta)^2 * (p_1(1-p_1) + p_2(1-p_2))/(p_1 - p_2)^2$$

where

$Z\alpha/2$ is the appropriate value from the normal distribution for the desired confidence interval
$Z\beta$ is the critical value of the normal distribution for the power β
p_1 is the expected pre-intervention sample proportions
p_1 is the expected post-intervention sample proportions.

Using $Z\alpha/2 = 1.96$ (95% confidence level), $Z_\beta = 1.645$ (95% power), $p_1 = 62.5\%$ and $p_2 = 82.25\%$ (Selvan et al., 2016), a minimum sample size of 127 healthcare providers was considered sufficient to obtain a significant difference between pre-intervention and post-intervention awareness about pharmacovigilance. A target sample size of 200 healthcare providers was approached to account for any drop-out after conducting the workshop session.

2.3. Study questionnaire

The study questionnaire was developed and extracted from previous research studies that evaluated healthcare providers knowledge, attitude and practice towards pharmacovigilance, with specific modifications performed to achieve the aim of this study (Suyagh et al., 2015; Abu Hammour et al., 2017). The questionnaire was peer reviewed by two academics with long experience in this research area. The questionnaire was assessed for completeness and clarity of content (content validity).

The questionnaire was structured into four sections, and each section consisted of either close-ended questions or 3-points Likert-scale statements (agree, neutral and disagree). Sections included: (1) demographic characteristics of healthcare providers, (2) knowledge about pharmacovigilance and it's reporting process, (3) perception towards who holds responsibility in reporting ADRs, and (4) perception of healthcare providers towards the importance of ADRs reporting.

2.4. Scoring system

Respondents' knowledge about pharmacovigilance and ADRs reporting process was evaluated using 19 questions. Each response was evaluated to be either correct or incorrect. Healthcare providers were given 1 point for each correct answer and zero points for each wrong answer. A final knowledge score was calculated for each healthcare provider out of 19.

Regarding participants' attitude, the scoring system used was: agree = 3, neutral = 2, and disagree = 1. There were 7 statements for assessing healthcare providers' perception towards the responsibility in reporting ADRs, and 6 statements assessing their perception towards the importance of ADRs reporting. A maximum perception score of 39 and a minimum score of 13 could be obtained for each healthcare provider.

2.5. Conduct of the study

Two hundred selected healthcare providers were divided into five groups, each of 40. Healthcare providers were selected by hospital employee affairs. Accordingly, five educational workshop sessions were scheduled to cover the five groups. The study session was conducted under the supervision of five trained PharmD students, who were trained on how to administer the study questionnaires.

Prior to the beginning of each workshop session, healthcare providers were requested to fill out the study questionnaire, and were allowed 10 min to complete it and give it back to the PharmD student. This represented the baseline pre-intervention data. Following the intervention session, post-intervention questionnaires were administered immediately to healthcare providers and they were also allowed for another 10 min to complete and return the form.

2.6. Educational workshop

The pharmacovigilance educational workshop was a one-hour session. The workshop included a power-point presentation prepared and presented by the head of pharmacy department at JUH. The primary aim of this workshop was to enhance the awareness and knowledge among healthcare providers about pharmacovigilance and ADRs reporting process. The educational workshop covered an introduction about the definition of pharmacovigilance, ADRs definition and how to identify them, types of ADRs, and the yellow form used to report ADRs and explanation of the reporting process. This educational session was followed

Table 1
Demographic characteristics of the study sample (n = 150).

Parameter	N (%)
Age	
• 24–29	80 (53.3)
• 30–39	50 (33.3)
• 40–49	13 (8.7)
• 50–59	7 (4.7)
Gender	
• Males	60 (40.0)
• Female	90 (60.0)
Healthcare provider category	
• Medical doctors	93 (62.0)
• Pharmacists	24 (16.0)
• Nurses	33 (22.0)

by a time period during which participants were allowed to ask questions.

2.7. Ethical considerations

The study was conducted following the ethical standards outlined in the World Medical Association Declaration of Helsinki guideline (World Medical Association, 2013). Verbal informed consents were obtained from all participants before conducting the study. Participants were informed that their participation in the study was voluntary and they have the right to quit from the study before completing the post-workshop questionnaire. Also, they were informed that their responses would be kept confidential and analyzed only as part of a cohort.

2.8. Statistical analysis

Data was analyzed using statistical package for social science (SPSS) version 22 (SPSS Inc., Chicago, IL, USA). The descriptive analysis was done using mean and standard deviation (SD) for continuous variables and percentage for qualitative variables. Checking for normality was carried out using Shapiro-Wilk test (with P-value >0.05 indicating a normally distributed continuous variable). Paired t-test was used to evaluate pre-post changes in knowledge and perception scores (continuous data). McNemar's test was used to evaluate differences in categorical variables between pre and post workshop data.For all statistical analysis, a P-value of less than 0.05 was considered statistically significant and all tests were two tailed.

3. Results

From the 200 healthcare providers that were invited to the different sessions of the workshop, only 150 attended the educational workshop (response rate = 75.0%). Among them, 93 were doctors (62.0%), 33 were nurses (22.0%) and 24 were pharmacists (16.0%). Table 1 shows healthcare providers' demographic characteristics, where 40% (n = 60) were female, and the majority (n = 130, 86.7%) were below the age of 40 years.

In terms of knowledge regarding pharmacovigilance prior to workshop, only few healthcare providers were able to define pharmacovigilance correctly (n = 13, 8.7%). Less than one third of participants knew about the existence of legal provisions that regulate pharmacovigilance activities (n = 36, 24.0%), while 22.7% (n = 34) knew about the existence of a pharmacovigilance center in Jordan. Furthermore, 32% (n = 48) knew about the presence of an official standardized form for reporting ADRs, approximately 17% (n = 26) knew from where they can get the ADR reporting form and 18.7% (n = 28) were aware of how to report ADRs. Better knowledge was achieved when participants were asked about the ADRs reporting process. Details about healthcare providers' knowledge about pharmacovigilance and ADRs reporting process is presented in Table 2.

Table 2 also shows responses to various questions given pre and post-intervention to the healthcare providers. The knowledge of healthcare providers had improved significantly for all questions/statements except for three where there were no significant differ-

Table 2
Healthcare providers' knowledge about pharmacovigilance and the ADRs reporting system pre and post the educational workshop (n = 150).

Questions	Correct answer		
	Pre-workshop	Post-workshop	P-value‡
What is the definition of pharmacovigilance?[1]	13 (8.7)	65 (43.3)	<0.001
In Jordan, are there legal provisions that provide for pharmacovigilance activities?[2]	36 (24.0)	135 (90.0)	<0.001
In Jordan, is there pharmacovigilance center?[2]	34 (22.7)	140 (93.3)	<0.001
In Jordan, is there an official standardized form for reporting ADRs?[2]	48 (32.0)	141 (94.0)	<0.001
Do you know from where can you get the ADR reporting form?[2]	26 (17.3)	137 (91.3)	<0.001
To whom do you report the ADRs?[3]	28 (18.7)	60 (40.0)	<0.001
Patient information is required while reporting ADRs[2]	101 (67.3)	142 (94.7)	<0.001
Adverse reactions description is required while reporting ADRs[2]	105 (70.0)	145 (96.7)	<0.001
Information related to the suspected drug(s) is required while reporting ADRs[2]	97 (64.7)	143 (95.3)	<0.001
Information on management of the ADRs is required while reporting ADRs[4]	11 (7.3)	10 (6.7)	1.000
Information about the reporter is required while reporting ADRs[4]	18 (12.0)	10 (6.7)	0.096
What is the definition of adverse drug reaction?[5]	45 (30.0)	56 (37.3)	0.052
ADRs should be reported only if they are of a serious nature[4]	73 (48.7)	91 (60.7)	0.013
ADRs should be reported only if the reaction is unusual[4]	77 (51.3)	103 (68.7)	<0.001
ADRs should be reported only for non-established new pharmaceutical products. [4]	85 (56.7)	102 (68.0)	0.027
ADRs for well-established products should be reported[2]	110 (73.3)	131 (87.3)	0.001
ADRs associated with herbal drug should always be reported[2]	90 (60.0)	124 (82.7)	<0.001
ADRs should not be reported until the particular drug responsible for it is identified[4]	61 (40.7)	72 (48.0)	0.228
All suspected ADRs associated with drug-food interactions should be reported[2]	105 (70.0)	137 (91.3)	<0.001

‡ Using McNemar test.
[1] Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.
[2] Yes.
[3] The Jordanian food and drug administration.
[4] No.
[5] ADR: is a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function.

Table 3
Healthcare providers' perception towards whom responsibility in reporting ADRs (n = 150).

Questions	Participants who agreed		
	Pre-workshop	Post-workshop	P-value‡
Reporting adverse drug reactions (to authorities) is among the responsibility of medical doctors	103 (68.7)	134 (89.3)	<0.001
Reporting adverse drug reactions (to authorities) is among the responsibility of hospital pharmacists	103 (68.7)	133 (88.7)	<0.001
Reporting adverse drug reactions (to authorities) is among the responsibility of community pharmacists	94 (62.7)	132 (88.0)	<0.001
Reporting adverse drug reactions (to authorities) is among the responsibility of drug companies	97 (64.7)	126 (84.0)	<0.001
Reporting adverse drug reactions (to authorities) is among the responsibility of nurses	78 (52.0)	124 (82.6)	<0.001
Reporting adverse drug reactions (to authorities) is among the responsibility of dentist	89 (59.3)	122 (81.3)	<0.001
Reporting adverse drug reactions (to authorities) is among the responsibility of patients	80 (53.3)	109 (72.7)	<0.001

‡ Using McNemar test.

Table 4
Healthcare providers' perception towards the importance of ADRs reporting (n = 150).

Questions	Participants who agreed		
	Pre-workshop	Post-workshop	P-value‡
Pharmacovigilance is necessary to enable safe drugs to be identified	110 (73.3)	146 (97.3)	<0.001
Pharmacovigilance is necessary to measure the incidence of ADRs	106 (70.7)	144 (96.0)	<0.001
Pharmacovigilance is necessary to identify factors that might predispose to an ADR	99 (66.0)	144 (96.0)	<0.001
Pharmacovigilance is necessary to compare ADRs of the same drug from different drug companies	98 (65.3)	141 (94.0)	<0.001
Pharmacovigilance is necessary to compare ADRs for drugs in similar therapeutic classes	101 (67.3)	136 (90.7)	<0.001
Pharmacovigilance is necessary to evaluate the unusual lack of efficacy of pharmaceutical product	96 (64.0)	132 (80.0)	<0.001

‡ Using McNemat test.

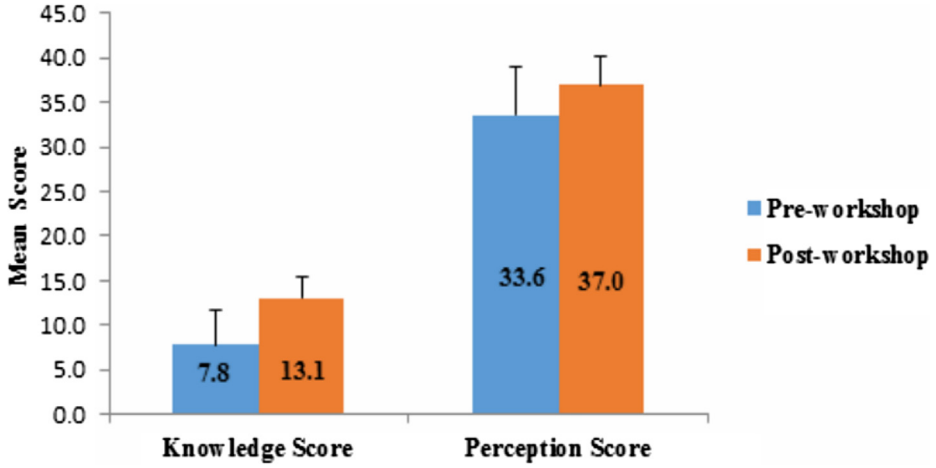

Fig. 1. Effect of educational workshop on healthcare providers on the improvement of knowledge and perception towards pharmacovigilance and ADRs reporting (mean knowledge score was significantly improved from 7.8 (SD = 4.0) pre-workshop to 13.1 (SD = 2.3) immediately post-workshop, while mean perception score significantly improved from 33.6 (SD = 5.4) to 37.0 (SD = 3.1) post-workshop, p-value <0.05 for both using paired sample t-test).

ences between the pre- and post-workshop response. These questions/statements include: information on management of the ADRs is not required while reporting an ADR, information about the reporter is not required while reporting ADRs and the definition of an ADR (P-value >0.05).

Table 3 shows healthcare providers' perception towards who is responsible in reporting ADRs. Most of them believed that reporting of ADRs is a responsibility of doctors and hospital pharmacists (n = 103, 68.7% for both). Since all healthcare providers must contribute (in collaboration with patients) in the reporting process, the educational workshop resulted in a significant improvement in healthcare perception towards the involvement of all parties in the reporting process (P-value <0.05 for all, Table 3).

Regarding the importance of ADRs reporting (Table 4), more than 60% of participants showed positive perceptions towards the benefit of reporting ADRs, which increased significantly to more than 90%in most of the statements following the educational workshop (P-value <0.05).

Regarding the overall knowledge and perception scores, the mean knowledge score among healthcare providers significantly improved from 7.8 (SD = 4.0) pre-workshop to 13.1 (SD = 2.3) immediately post-workshop (P-value <0.05). A similar finding was obtained for mean perception score, where it significantly improved from 33.6 (SD = 5.4) to 37.0 (SD = 3.1) post-workshop (P-value <0.05) (see Fig. 1).

4. Discussion

Pharmacovigilance has grown in importance recently as a key element of effective drug regulation systems, clinical practice and public health programs (Jeetu and Anusha, 2010). Health care professionals play an important role in reporting ADRs, where spontaneous reporting remains an essential tool in detecting and reporting ADRs to avoid harm as much as possible (Jha et al., 2014). For that, it was vital to conduct comprehensive studies to

explore and evaluate healthcare providers' roles and contributions in the pharmacovigilance system activities.

In Jordan, many studies have been conducted to evaluate healthcare providers knowledge and perception towards pharmacovigilance but no intervention or training was provided (Abu Farha et al., 2015; Suyagh et al., 2015; Abu Hammour et al., 2017).

The knowledge score of the participating health care providers in this study before the workshop was low (score = 7.8/19). Similar findings were observed in previous research, where most healthcare professionals were not aware of the concept of pharmacovigilance (Mahmoud et al., 2014; Suyagh et al., 2015; Upadhyaya et al., 2015; Abu Hammour et al., 2017). Our respondents were least knowledgeable in terms of defining pharmacovigilance. Only 8.7% had a correct answer. These results contrasted with what was found in a study conducted in Kuwait. Researchers assessed pharmacists' knowledge and perception of pharmacovigilance and ADRs reporting and showed that the majority of pharmacists had good knowledge regarding the concept of pharmacovigilance and ADRs in terms of their definitions and purposes (Alsaleh et al., 2017). On the other hand, results from a study in Saudi Arabia reported that most of healthcare professionals were unfamiliar with the availability of a national pharmacovigilance system (Abdel-Latif and Abdel-Wahab, 2015).

The importance of ADRs reporting should also be emphasized. According to previous research, reporting of ADRs could be encouraged through building strategies that target optimizing both knowledge and practices with regard to pharmacovigilance (Ahmad et al., 2013). Previous study clearly showed that Jordanian healthcare providers had poor practice in ADRs reporting which was expected since practice is affected by knowledge and awareness with the whole pharmacovigilance system (Suyagh et al., 2015). These findings are mirrored in the fact that the existing pharmacovigilance programs in the Middle East region are still in their infancy stages (Wilbur, 2013). It is also worth mentioning that the number of health employees with competencies related to drug safety is very low in low- and middle-income countries with the scarcity in allocating financial resources to support attendance at professional development courses in pharmacovigilance (Olsson et al., 2015). This eventually led to limited numbers of professionals in developing countries capable of practicing drug safety assessment and improving risk management (Pérez García and Figueras, 2011; Olsson et al., 2015).

The present study showed a significant improvement in healthcare providers' knowledge scores immediately after conducting an intervention (workshop). It wasn't surprising since assessment of both knowledge and perception was done directly after providing the respondents with the necessary information regarding pharmacovigilance. With only a difference in time frame, similar findings were reported by previous studies (Li et al., 2004; Rajesh et al., 2011; Osakwe et al., 2013). Furthermore, a study conducted in Nigeria showed that training healthcare professionals regarding pharmacovigilance had a significant impact on their knowledge and practice scores (P-value = 0.001). Also, another study conducted in India showed that doctors who attended continuous medical education on pharmacovigilance showed better awareness regarding the ADRs reporting system than those who did not (Bisht et al., 2014).

Additionally, healthcare providers showed a positive perception towards the responsibility of reporting ADRs and the importance of this reporting pre-workshop. This educational workshop resulted in an additional significant improvement and increased their perception score in all aspects. Perception is the degree to which individuals showed positive or negative value towards certain behavior or practice (Gavaza et al., 2011). Based on the theory of planned behavior, perception is among the most important constructs affecting individuals' behaviors other than intention, subjective norm and perceived behavioral control (Godin and Kok, 1996). Perception or attitude is also found to be a well-established predictor of healthcare providers' intentions to perform different behaviors (Meyer, 2002; Ko et al., 2004; Bercher, 2008; Shoham and Gonen, 2008). This well-established understanding on the influence of perception on healthcare providers planned behaviors can justify the importance of focusing on healthcare providers' attitude to improve their intention to report ADRs.

Despite the initial increase of healthcare providers' knowledge and perception towards pharmacovigilance system following the educational intervention, the influence of this educational intervention on the practice of ADRs reporting was not studied, which represents a major limitation in this study. A previous report from India showed that educational intervention on pharmacovigilance resulted in adequate knowledge and positive attitudes about pharmacovigilance and ADRs reporting, but ADRs reporting practice was still neglected by healthcare providers (Bisht et al., 2014). Also, a study conducted in Germany revealed that the effect of educational intervention on pharmacovigilance showed only temporary effect on healthcare providers' ADRs practice (Tabali et al., 2009). On the other hand, a previous report from Nigeria showed that the completion of lecture-based educational workshops resulted in a mild increase in the number of reported ADRs (Rajesh et al., 2011). Knowledge and attitudes are considered modifiable factors that appear to be strongly associated with reporting practice (Herdeiro et al., 2005; Osakwe et al., 2013; Ganesan et al., 2017).

Finally, among the main limitations of this study is the use of a self-rated assessment tool, where healthcare providers may have overestimated their perception level. Also, the influence of the educational workshop was studied immediately after workshop, which may not reflect the actual effect on the long term. Thus, further studies may be necessitated to evaluate the impact of educational workshops on the long-term effect after implementing the intervention. Additionally, this study was conducted among healthcare providers in a single institution. Hence, the result of this study may not be generalizable to all other institutions in Jordan.

5. Conclusion

Continuous efforts for increasing the awareness and improving the perception towards pharmacovigilance among healthcare providers should be prioritized by implementing different strategies, education modules and the provision of appropriate training programs at regular intervals for ADRs reporting to encourage adherence to appropriate pharmacovigilance practices among healthcare providers in pharmacovigilance services, as well as those involved in designing educational interventions (Molokhia et al., 2009; Gonzalez-Gonzalez et al., 2013; Pagotto et al., 2013).

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Conflict of interest

None of the authors have any conflict of interest.

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