

# Knowledge, Attitude and Practices of Pharmacovigilance and Adverse Drug Reaction Reporting Among Pharmacists Working at Alkarak Governorate, Jordan

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Pharmacovigilance (PV) is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problem. Since adverse drug reactions (ADRs) are considered worldwide as one of the most common public health problems that affect all groups of patients; the assessment of healthcare providers' knowledge, attitude, and practice of PV and ADRs reporting will provide an in-depth look at the reasons behind the lack of reports. This study aims to assess the overall knowledge, attitude, and practice of PV and ADRs reporting among pharmacists working at Alkarak Governorate, Jordan. Methods: A cross-sectional study was conducted during the period from 20th February till 20th April 2021. All employed pharmacists working at Alkarak Governorate were eligible to participate using a structured-interview based-questionnaire. The Bivariate correlation test with the Pearson's (r) was used to assess the correlations between metric variables, independent samples t-test and the one-way ANOVA tests were also applied. The SPSS IBM program version 21 and the Stand-Alone FACTOR program were used for the statistical data analysis. The level of significance was set to be = 0.050. The majority of the pharmacists were females (74.4%), most of respondents (84.9%) had a Bachelor's degree in pharmacy. The pharmacists showed a moderately overall knowledge of PV (58.7%), positive attitudes toward their perceived ADRs reporting importance (78%), and toward selective ADRs reporting (62.8%), a moderate effort exerted by those pharmacists regarding the practice of ADRs reporting process (55.8%). The main barrier was that pharmacists did not know how to report (72.1%). Pharmacists had a moderate PV and ADRs reporting knowledge on average. Positive attitudes toward perceived ADRs reporting importance and moderate level of agreement on focusing on the well-known and serious ADRs. The result denotes a moderate effort exerted by those pharmacists on ADRs reporting practices. Pharmacists faced a moderately high perceived difficulties and extra burden (barriers).

**Keywords:** Attitude; ADRs; Jordan; Knowledge; Practice; PV; Reporting.

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Pharmacotherapy seeks to develop patient safety by enhancing medication efficacy and improving the quality of life. However, pharmacotherapy cannot attain this goal always,

particularly when a patient has a bad drug reaction, i.e. adverse drug reactions (ADRs). World Health Organization (WHO) defines ADRs as "A response which is unintended and noxious and happens at

normal doses used in humans for prophylaxis, diagnosis, treatment of disease, or the modification of physiological function”<sup>1</sup>.

Zawiah et al. (2019) emphasized that these ADRs are considered worldwide as one of the most common public health problems that affect all groups of patients irrespective of their age, country, inpatients, and outpatient<sup>2</sup>. ADRs may range from minor to potentially life-threatening ones<sup>3</sup>. These reactions are associated with increased mortality, morbidity, leading to an economic burden on society and patients<sup>2</sup>. In some countries WHO found that the cost of the reaction resulting from a drug exceeds the cost of drug itself<sup>4</sup>.

ADRs are also associated with a high prevalence of hospital admission reaching about 6.5% with great economic burdens in which the annual total cost for medication-related admission is around £466 million in the United Kingdom<sup>5</sup>. Beijer and DeBlaey (2002) showed through meta-analysis in 2002 that the worldwide incidence of ADRs leading to emergency hospitalization ranges from 0.2 to 41.3%<sup>6</sup>. In 2012, another meta-analysis showed that 52% of ADRs associated with emergency hospitalizations, and 10.9% of inpatients estimated to experience ADRs during hospitalization<sup>7</sup>. In the United State and according to the Institute of Medicine report, about 7000 or more people die annually from medication errors and/or ADRs, and the cost varies from 17 to 29 billion dollars/year<sup>8</sup>. In Jordan, it was found that approximately about 5 to 20% of hospital admissions are due to ADRs<sup>9</sup>.

According to the WHO (2008), The majority of the ADRs (as many as 60%) are preventable, that may be occurred due to a variety of reasons some of them are: patient’s self-medication, patient is not following the instructions for taking the medication, and the use of counterfeit drugs with inappropriate ingredients or no active ingredients which can be fatal or dangerous<sup>4</sup>. Akici and Oktay (2007) focused on another preventable reason that contributes to ADRs: the preference for poly-pharmacy by both patients and physicians<sup>10</sup>. Beijer and DeBlaey (2002) also showed through meta-analysis in 2002 that there is about 28.9% of the ADRs were preventable<sup>6</sup>. In 2012, another meta-analysis showed that the percentage of these preventable reactions in inpatients was 45%<sup>7</sup>.

Suyagh et al. (2015) stated that reporting

of ADRs is an essential step in achieving and maintaining safe drug therapy use<sup>5</sup>. Seid et al. (2018) described that this system of reporting is voluntary in nature called: Spontaneous reporting systems (SRS) and it can be done either by healthcare professionals or consumers (patients or their relatives) as soon as they become suspicious of any adverse reaction that is related to any medications<sup>11</sup>.

The collection and reporting of information about adverse reactions commence from the primary stages of the drug development process to the clinical trials and then continuous post-marketing surveillance activities are carried out to obtain complete drug safety information<sup>12</sup>. Zawiah et al. (2019) illustrated that because it is not easy to discover all ADRs before drugs’ approval, post-marketing monitoring and spontaneous reporting of less common and serious ADRs is crucial to achieve safe use of drugs and to understand the risks of medications<sup>2</sup>. This importance of SRS owned to the cost-effectiveness of this system<sup>13</sup>, and the ease of detection of serious and suspected ADR i.e. simplicity<sup>14</sup>.

Since the SRS is a universal phenomenon, it is considered the cornerstone and the best source of information in pharmacovigilance activities<sup>15</sup>. WHO defined pharmacovigilance (PV) as “the activities and science related to the detection, assessment, understanding, and prevention of possible drug/vaccine related reactions or problems”<sup>16</sup>.

The initiatives of international awareness in detecting, monitoring, assessing, and reporting ADRs increased clearly in the last four decades. It came in the wake of the thalidomide disaster in 1961<sup>17</sup>. In 1978 Uppsala monitoring center (UMC) was established as a global response to this tragedy to support and enhance the WHO Program for drug monitoring internationally, this program sought to gather information about the adverse effects of medicines from several sources around the world, to ensure that any first possible signs of danger from medicines would not be missed<sup>18, 19</sup>.

Akici and Oktay (2007) illustrated that PV seeks to optimize the risk-benefit ratio of the marketed drugs at the population level (i.e. Informing the prescribers of its potential risks, removal or maintenance of the drug in the market, etc.) and at the individual level (i.e. the choice of

the most appropriate treatment for a given patient). It was also emphasized that the prevalence of drug-related mortality and morbidity increase in correlation with the increase in drug use<sup>10</sup>.

Despite the importance of ADRs reporting in the improvement of PV system; the problems of underreporting of ADRs, inadequate ability to calculate the incidence of ADRs, and bad quality of reports in many countries. Of these factors, underreporting of ADRs is the major problem experienced globally, and addressing this issue of underreporting is not easy as its extent is unknown and variable. A better understanding of the causal factors for underreporting can be accomplished by encouraging the practitioners to establish ways to promote the reporting culture<sup>13</sup>.

Leporini et al. (2014) in a study about the relationship between ADRs and adherence to therapy demonstrated that consistent drug adherence, is difficult to be achieved and it is considered an important public health problem from a clinical and economic point of view. ADR is one of the most common barriers that's linked to patients' medication-taking behavior, another barrier such as, medication cost, lack of medication understanding, low health literacy, and a poor physician-patient relationship should be taken into consideration, all of them can lead to poor health outcomes and waste of resources that could have been avoided<sup>20</sup>.

#### **Importance of PV**

According to the Guidelines for Detecting & Reporting ADRs; PV has many benefits as:

Improvement on the quality of care offered to patients. Reduction of medicine related problems leading to better treatment outcome. Improved patient confidence in professional practice. Access to feedback information on medicine related problems reported within the country and internationally.

#### **Rationale of the study**

Under-reporting of ADRs is a common inherent health problem encountered in many countries. Since the knowledge, attitudes, and practices (KAP) of PV and ADRs reporting among healthcare providers are still underrepresented in Jordan, this study was conducted to assess the overall Knowledge, attitude, and practices of PV and ADRs reporting among pharmacists working at Alkarak Governorate, Jordan.

#### **Research objectives**

To determine the extent of knowledge, attitude, and practice (KAP) of ADR reporting and PV among pharmacists working at Alkarak Governorate. To determine the main factors that may discourage pharmacists from reporting ADRs. Also, to detect any significant difference in socio-demographic characteristics and each of (knowledge, attitude, practice, and barriers of PV) among pharmacists working at Alkarak Governorate.

### **METHODOLOGY**

A cross-sectional study was conducted to assess the extent of PV and ADR reporting among pharmacists working at Alkarak Governorate, Jordan. A structured interview based-questionnaire was used. The questionnaire was reliable and valid. The questionnaire consists of five main parts: Part A: socio-demographic section, Part B: Knowledge domain, Part C: Attitude domain, Part D: Practice domain, Part E: factors that may discourage pharmacists to report ADRs (Barriers). Therefore, all the pharmacists who work at the study locations were enrolled. A structured interview based-questionnaire was used<sup>5,21</sup>. It consists of 50 closed-ended questions with predetermined answers that were used to obtain data on ADR reporting and PV among pharmacists working at Alkarak Governorate who will give consent to participate voluntarily in this study.

#### **Statistical Data Analysis**

The Person-fit statistics (WMSI and Rp) were applied to identify people with single response categories and rushed responses. However, to ascertain the factorial validity of these questionnaires they were subjected to an Exploratory Factor Analysis (EFA) tests coupled with Parallel Analysis to assess the dimensionality and existing factors within these questionnaires particularly because they were hybridized questionnaires tailored by the researchers. Salient loading was defined as an item-factor loading value of 0.30 and above and items that swayed or cross loaded were eliminated from the yielded factor analysis pattern matrices. The Unidimensionality tests of Unidimensional Congruence (I- Unico), and the ECV test (Explained Common Variance) plus the test of MIREAL (Mean of Item Residual

Absolute Loadings) and I-REAL (Item Residual Absolute Loadings) were applied to the attitudes, practice and barriers questions to ascertain whether they comprised one dimension. The Bivariate correlation test with the Pearson's (r) was used to assess the correlations between metric variables and the independent samples t-test and the One-way ANOVA tests were applied. The SPSS IBM commercially available statistical analysis program Version 21 and the Stand-Alone FACTOR program were used for the statistical data analysis. The alpha significance Level was considered at 0.050 Level<sup>22</sup>.

#### Ethical approval

The research protocol was approved by the Research Ethics Committee of the Faculty of Medicine; Mutah University, Jordan (Ethics Committee Number: 232017). Moreover, informed Verbal and written consent were obtained from all participants after explaining the aim of the study.

#### Confidentiality

The names of the participants are not mentioned either, in the questionnaire, or during entering the data.

## RESULTS

Socio-demographic results revealed that most of the pharmacists (74.4%) were females. The mean age for the pharmacists was  $32.89 \pm 8.14$  years. Also, the mean clinical experience for the pharmacists was equal to  $7.43 \pm 6.51$  years. Regarding their area of pharmacy practice, most of the pharmacists (73.5%) worked in community-based pharmacies, another 10.9% of them worked in public hospital. Most of the pharmacists about 85%, had a Bachelor's degree in Pharmacy.

Regarding their knowledge; the results showed that most of the pharmacists 58.8% had correctly defined the concept of PV. Most of the Pharmacists 71.8% had correctly indicated the purpose of PV, and most of them 73.1% had defined the ADRs correctly. Also, about 73% of pharmacists agreed that the reporting process should be done for all of ADRs and not confined to specific reactions. Nonetheless most of the pharmacists 44.5% had incorrectly inferred regarding the destination of the adverse drug reaction reporting; although 55.5% of

**Table 1.** Descriptive analysis of the pharmacists measured indicators of PV and ADRs reporting Knowledge

Question	Frequency (Percentage)	
	Incorrect	Correct
Which of the following best define PV?	98 (41.2)	140 (58.8)
The purpose of PV is?	67 (28.2)	171 (71.8)
Which of the following defines ADRs correctly?	64 (26.9)	174 (73.1)
Which ADRs should be reported?	65 (27.3)	173 (72.7)
To whom should you report the ADRs?	106 (44.5)	132 (55.5)
ADR reporting is done through email?	134 (56.3)	104 (43.7)
ADR reporting is done through filling ADR form?	164 (68.9)	74 (31.1)
ADR reporting is the responsibility of?	63 (26.5)	175 (73.5)
In Jordan, are there legal provisions in medicines act that provide for pharmacovigilance activities?	104 (43.7)	134 (56.3)
In Jordan, is there pharmacovigilance center?	105 (44.1)	133 (55.9)
In Jordan, is there an official standardized form for reporting ADRs?	111 (46.6)	127 (53.4)

**Table 2.** The pharmacists' sources of information about ADR

Source	Frequency	Percentage
1. Advertisement brochures / leaflet	118	49.6
2. Search engine (internet)/ journal articles	83	34.9
3. Standard text books	81	34
4. Health care professionals	31	13
5. Pharmaceutical company representatives	24	10.1

them had indeed correctly inferred about the right destination for ADR reports, as shown in Table 1.

Pharmacists sources of ADR information were as follows: the top source of information was drug advertisement brochures and leaflets 49.6% ,

the second from the top used source of ADR for the pharmacists was search engines and journal papers periodically according to 34.9% of the pharmacists , then standard pharmacy textbooks 34% of the pharmacists, but 13% of the pharmacists relied

**Table 3.** Descriptive and Relative Importance (RII) analysis of the pharmacists measured attitudes toward PV and ADR reporting

Attitudes	Mean $\pm$ SD	RII%	Rank
I believe that PV should be included as a core topic in curriculum	4.06 $\pm$ 0.68	81.2	2
I believe that ADRs reporting improve the quality of patient care.	4.20 $\pm$ 0.69	84.0	1
I believe that unserious adverse reaction should be reported.	3.87 $\pm$ 0.82	77.4	6
I believe that only reactions for new products should be reported.	3.11 $\pm$ 1.09	62.2	11
I believe that serious and unexpected reactions that are not fatal or life-threatening during clinical trials must not be reported.	3.04 $\pm$ 1.21	60.8	12
I believe that Reporting of well-known ADRs makes no significant contribution to the reporting system.	3.26 $\pm$ 1.01	65.1	10
I believe that one report can make a difference.	3.87 $\pm$ 0.85	77.3	8
I believe that ADRs should be reported spontaneously at regular base.	3.90 $\pm$ 0.67	78.0	5
I believe that as a member of professionals, it's my responsibility to report ADRs.	3.93 $\pm$ 0.74	78.7	3
I believe that I am sufficiently knowledgeable to report ADRs in my practice.	3.50 $\pm$ 0.94	70.0	9
I believe that ADRs reporting should be made compulsory for all health care professionals.	3.92 $\pm$ 0.66	78.3	4
There is a need to be sure that ADRs is related to the drug before reporting	3.87 $\pm$ 0.81	77.4	7

**Table 4.** Descriptive and Relative Importance (RII) analysis of the pharmacists measured practice of PV and ADRs reporting

Practice	Mean $\pm$ SD	RII%	Rank
Have you ever identified ADRs in any patient?	2.47 $\pm$ 0.90	61.8	1
Have you ever report an ADR to ADR monitoring center?	1.96 $\pm$ 1.01	48.9	6
Have you ever used the adverse drug reactions reporting form in your work place?	2.13 $\pm$ 1.06	53.4	4
Do you usually check the Jordanian food and drug administration website?	2.44 $\pm$ 1.02	60.9	2
Have you ever had a course/attended a workshop about PV?	2.04 $\pm$ 0.96	50.9	5
Have you had a habit of reading article about ADRs?	2.32 $\pm$ 0.95	58.1	3

**Table 5.** Overall mean of pharmacists' (KAP) domains toward PV and ADR reporting

KAP Domains	Mean $\pm$ SD	Score Range	Percentage
Knowledge			
Knowledge of PV and ADRs reporting	6.46 $\pm$ 2.47	0-11 points	58.7
Attitude			
1. Perceived PV and ADR reporting importance/benefit	3.90 $\pm$ 0.50	1-5 points	78
2. Perceived selective/purposive ADR reporting	3.14 $\pm$ 0.95	1-5 points	62.8
Practice			
PV and ADRs reporting practice	2.23 $\pm$ 0.82	1-4 points	55.8

on information from healthcare professionals and 10.1% learned from Pharmaceutical companies representative persons as shown in Table 2.

Table 3 showed the descriptive and relative importance index analysis of the pharmacists' perceived attitudes toward PV and ADR reporting. To put simply the findings, the pharmacists top perceived attitude toward PV was their belief in the ADR reporting ability to enhance patients' quality of care, which had a relative importance index (RII) score of 84%, the pharmacists' belief in the importance of incorporating PV in core pharmacy curriculum was ranked secondly (RII=81.2%).

The third top pharmacists attitude toward PV was their agreement on their responsibility for ADR as specialized clinicians in pharmacy (RII=78.7%), and the fourth was given to making ADR reporting compulsory for all health care

workers/professionals (RII=78.3%), as shown in Table 3.

Table 4 revealed that that Pharmacists' top self-rated PV practice was a previous experience of identifying an ADR in patients, which had received a substantive self-rated rate, RII=61.8%. The second from the top self-rated practice according to the pharmacists was checking the Jordanian Food and Drug association website for information, which had received a significant self-rated frequency of website visits, RII=60.9%, but also the third top PV and ADRs reporting practice was reading journal and periodical articles concerning these reactions, RII=58.1%. The lowest self-rated PV and ADRs reporting practice was attended a dedicated PV course and reporting an ADR for known ADR monitoring entity outside workplace (monitoring center), RII=50.9% and 48.9 respectively.

**Table 6.** Descriptive and Relative Importance (RII) analysis of the pharmacists measured barriers of PV and ADRs reporting

Barriers to ADR	Mean $\pm$ SD	RII%	Rank
Level of clinical knowledge makes it difficult to decide whether or not an ADR has occurred.	3.60 $\pm$ 0.81	72.0	2
Association between the drug and the adverse reaction is Unclear.	3.35 $\pm$ 0.89	67.0	8
The ADR is Unimportant to report.	2.71 $\pm$ 1.15	54.2	11
Concern that a report will generate extra work.	3.53 $\pm$ 0.79	70.6	5
Pharmacist's adverse drug reaction form is not available when needed.	3.49 $\pm$ 0.87	69.8	6
Lack of time to fill in a report.	3.55 $\pm$ 0.86	70.9	3
Unaware of the existence of a national ADR reporting system.	3.54 $\pm$ 0.82	70.8	4
Did not know how to report.	3.61 $\pm$ 0.78	72.1	1
Fear of legal liability.	3.49 $\pm$ 0.82	69.7	7
Lack of financial incentives.	3.30 $\pm$ 0.94	66.0	10
Consider it the doctors' responsibility.	3.32 $\pm$ 0.99	66.4	9

**Table 7.** Descriptive bivariate correlations test (Pearson's r) between the pharmacists' ADR overall perceptions

Domain	Knowledge	Attitudes Attitude 1	Barriers Attitude 2	Barrier 1	Barrier 2
<b>Attitudes</b>					
Attitude1: Perceived ADR reporting importance	0.228**				
Attitude 2: Perceived selective ADR reporting	-0.270**	0.155*			
<b>Barriers</b>					
Barriers 1: Perceived PV and ADR reporting difficulties	-0.098	0.128*	0.211**		
Barriers 2: Perceived PV and ADR reporting burden	-0.155*	0.154*	0.318**	0.513**	
<b>Practice</b>					
PV and ADR reporting practice	0.293**	0.423**	0.174**	0.076	0.084

\*\* P-value is  $\leq$  0.01 (2-tailed), \* p-value is  $\leq$  0.05 level (2-tailed)

Table 5 clarified the pharmacists overall knowledge of PV and ADRs reporting was measured with  $6.46 \pm 2.47$  points out of 11 maximum points, and as a percentage it would be equivalent to  $(6.46/11) * 100 = 58.7\%$  knowledge, denoting that those pharmacists had a moderate PV and ADRs reporting knowledge on average.

Regarding attitudes: the Pharmacists mean perceived PV and ADR reporting importance/benefit (attitude 1) was measured with 3.90/5 points, which highlights a positive and high perceived ADRs reporting importance in general for those pharmacists, also the pharmacists collective mean perceived selectivity/purposive of ADR reporting focusing on serious and new appearing adverse occurrence (attitude 2) was measured with 3.14/5 points, which indicates a positive and moderate level of agreement among those pharmacists on focusing the ADR of new drugs, and on the serious and life-threatening ADRs.

Regarding practice: The collective mean level of pharmacists perceived PV and ADRs reporting practice was measured with 2.23 points out of 4 maximum points, which is equivalent to 55.8% PV and ADRs reporting practice; which denotes moderate effort exerted by those pharmacists on ADRs reporting practice.

The Pharmacists top perceived barriers for PV and ADRs reporting was lacking knowledge on the way of reporting, which had received a significant relative agreement level, RII=72.1%. Also, the second from the top perceived barrier to ADR was the low level of the pharmacists' clinical experience that may make it hindering to know whether an ADR event had occurred or not, RII=72%, but the third from the top agreed barrier to ADR reporting was lack of time by the pharmacists to make reports, RII=70.9%. The lowest ranked barriers to PV and ADR reporting were their belief in the worthlessness of ADR to be reported which indeed had received a substantive relative importance, RII=54.2% but it ranked the lowest among the indicators of reporting barriers denoting that those pharmacist do conversely believe in the usefulness of ADR, the second from the bottom agreed upon barriers to PV and ADRs reporting was their belief of the lack of financial incentives for reporting, RII=66%, as shown in Table 6.

Table 7 described that Pearson's correlations were significant for the following factors: The pharmacists measured "PV and ADRs reporting knowledge" was positively correlated with their perceived "PV and ADR reporting importance", ( $r=0.228$ ,  $pd^*0.010$ ), also the pharmacists perceived "PV and ADRs reporting knowledge" had correlated negatively with their perceived "Selective ADR reporting" score, ( $r=-0.270$ ,  $pd^*0.010$ ), and the pharmacists "PV and ADRs reporting knowledge" had correlated significantly negatively with their perceived "ADR reporting burden" ( $r=-0.155$ ,  $pd^*0.05$ ). However, the pharmacists perceived "selective ADR reporting" had correlated significantly and positively with each of their perceptions of ADR reporting (PV and ADR Reporting difficulties ( $r=0.211$ ,  $pd^*0.010$ ), PV and ADR Reporting burden ( $r=0.318$ ,  $pd^*0.010$ ), and PV and ADR reporting practice ( $r=0.174$ ,  $pd^*0.010$ )). Moreover, the Pharmacists "perceived PV and ADR reporting difficulty" had correlated positively with "ADR reporting burden perception" ( $r=0.513$ ,  $pd^*0.010$ ).

## DISCUSSION

To our knowledge, this is the first study in Jordan regarding PV and ADRs reporting among pharmacists working in the general and private sector. The goal of this study was to evaluate the pharmacists' knowledge, attitude and practices with regard to PV and ADRs reporting.

It is noteworthy that a substantial proportion of the pharmacists in the current study lacked knowledge on the presence of PV legislation, centers and reporting forms and process. Finally, the issue of moderate PV and ADRs reporting knowledge level should be tackled, which is the need to promote the Jordan PV center (JPC) among health care providers. It is vital for all health care providers to know about the existence of a national PV center, to which they can report any new adverse drug reaction, PV regulations, and from where they can get updates on information related to drug safety.

Good PV practice will be reflected positively on public health through promoting rational use of drugs and ensuring patient safety. This could be achieved through encouraging the education, understanding, and clinical training

in PV programs among all healthcare workers, particularly in teaching hospitals<sup>8</sup>.

Underreporting of ADRs considered a global reality revealed by different recognized studies which were executed in different countries<sup>9</sup>. It was found in these studies that knowledge and attitude deficiency regarding PV and ADRs reporting is responsible for the problem of underreporting in both developing and developed countries (Farha et al., 2015). In another study done by Varallo et al. (2014) showed that uncertainty and ignorance considered being the main reasons attributed to HCPs' decreased knowledge with regard to the activities of drug safety analysis<sup>23</sup>.

The current study includes pharmacists working in Alkarak Governorate to evaluate their baseline knowledge, attitude, practice toward PV and ADRs reporting and the barriers that might be faced during the process of reporting. This evaluation considered to be the first step in designing interventions that can be an initiative to the optimum functioning of the Jordanian pharmacovigilance program and particularly in Alkarak Governorate.

The overall mean knowledge toward PV and ADRs among pharmacists working at Alkarak Governorate was 58.7%; this indicates that they had a moderate PV and ADRs reporting knowledge. Adisa and Omitogun (2019) showed that more than 80% of healthcare professionals had adequate knowledge regarding ADRs reporting which is higher than the current study findings (58.7%)<sup>15</sup>. On the other hand, Shroukh et al. (2018) found that the overall PV and ADRs reporting knowledge score was poor PV knowledge among participants<sup>21</sup>. Any disparity in ADR knowledge among respondents from different studies may be linked primarily to the possible variations in the criteria for determining the study settings, population<sup>15</sup>.

Unexpectedly the pharmacist's educational level in this study didn't differ significantly on their mean of PV and ADRs reporting knowledge, unlike Farha et al. (2015) who reported the higher knowledge among pharm. D students compared to BSC students (5.4±2.3 and 3.2±1.7, respectively)<sup>9</sup>.

The current study found that pharmacists with prior awareness of PV, previous experience of ADRs reporting, with prior awareness from where they can get ADRs reporting form, and

previous awareness of the minimum requirement for reporting; had a significant impact on PV and ADRs reporting and this result was similar with the finding of several previous studies<sup>2,8,9,15,17,24,25</sup>.

The overall perceived PV and ADRs reporting importance of the whole participants was 78% and the overall perceived selective ADRs reporting was 62.8% this denotes that the majority of pharmacists in this study showed a positive and favorable attitude toward PV and ADRs reporting. A pattern is similar to other studies<sup>5,9,21</sup>.

Pharmacists should exert a leadership in the ADRs program development, sustainability, and evaluation. They should adopt a formal endorsement of these programs through suitable committees (such as the pharmacy and therapeutic committee (PTC) and executive committee of medical staff). Any inputs to the programs should be taken from nursing staff, medical staff, quality improvement staff, risk managers, and medical records staff

Responses to questions exploring the pharmacists' attitudes toward PV and ADRs reporting, pharmacists in this study agreed that reporting process improve the quality of patient care (as a top perceived attitude with a substantial relative importance index score of 84% out of hundred). This result confirmed what Kassa and Biru (2019) assessed in their study that about 94.74% of healthcare professionals agreed on this perception<sup>26</sup>.

Farha et al. (2015) and Abu Hammour et al. (2017) reported that significant proportions of healthcare professionals agreed on the importance of PV in pharmacy education (84.9% and 80% respectively). And these findings were close to what was found in the current study, in which the pharmacists ranked this attitude as second from the top agreed one (relative importance index score of 81.3%)<sup>8,9</sup>.

One of the highest pharmacists' self-rating attitude is believing that ADRs reporting have to be a part of their duty, this attitude had a relative importance index score of 78.7% with third ranking, and this is in the line with the results from similar studies with a percentage of (77.6%, 87.7%, and 77.6%, respectively)<sup>8,9,26</sup>. Based on their perception, this duty should be a compulsory duty for them (relative importance index score of 78.3%, rank four), this result is similar to what



was shown in (Farha et al., 2015; Abu Hammour et al., 2017; Kassa & Biru, 2019) who reported that (73.2%, 76.32%, and 78.2% respectively) of participants was agreed on this statement<sup>8,9,26</sup>.

Spontaneous reporting of ADRs considered as an indication of PV awareness and knowledge because they are effective for differentiating serious unexpected ADRs, therapeutic inefficiency, medication errors, and quality, besides its low cost. In spite of the fact that PV practice varies between countries, the primary responsibility of pharmacists is the benevolence of each one, so they are more likely to detect ADRs earlier than other healthcare providers<sup>9</sup>. Lack of knowledge about PV is considered as starting point to deal with the insufficient practice of reporting since it was previously demonstrated that pharmacists' knowledge strongly influences ADRs reporting<sup>5</sup>.

Alsaleh et al. (2017) showed that about two-thirds of pharmacists stated having identified ADRs during their course practice<sup>24</sup>. Several studies reported that there is a significant variation in the identification of ADRs by pharmacists<sup>27</sup>, from less than 20% to more than 65%<sup>28,29</sup>. Kassa and Biru (2019) reported that only a small number of participants (29.82%) in northeast Ethiopia in contrast with [38% in Specialized Hospital (TASH) in Addis Ababa<sup>26</sup>, 65% in Turkish, and 55.9% in Gondar] identified patients with ADRs in their clinical practice<sup>11,28,30</sup>.

Adisa and Omitogun (2019) reported that nearly 60% of participants had encountered a case of adverse drug reactions in their site of practice, and most of them who had come across these reactions took many measures such as referral the case to the secondary healthcare setting, while others engaged in treating these adverse drug reactions symptoms with another drug<sup>15</sup>. Hanafi et al. (2012) reported that the reactions of respondents while facing ADRs as (87.1%) of respondents reported that they would announce/report the reactions to the physicians, (1.8%) report ADRs to the adverse drug reaction center in the hospital, (1.8%) handling the patient condition, and (1.3%) they wouldn't take any reactions<sup>17</sup>. Kassa and Biru (2019) also reported that 50% of the respondents claimed that they have never reported any ADRs<sup>26</sup>. Shroukh et al. (2018) showed that reporting of any new ADRs was never or almost rarely done by

92.4% of HCPs<sup>21</sup>. Suyagh et al. (2015) also reported that about majority of respondents (80.5%) never had a habit of reporting, therefore if we assume that those pharmacists reported just a few reactions during their working practice, this means that the overall reporting rate of actual and serious reactions is still relatively low but higher than past studies as which showed that only of participants ever reported ADRs<sup>5</sup>.

The unavailability of ADRs reporting forms when needed, fear of legal liability, considering that reporting process is a doctors' responsibility, lack of financial reimbursement, thinking that the adverse drug reaction is too trivial to report, are the other pharmacists' perceived factors that hinder them to report ADRs with relative importance indexes (69.8% sixth self-rated rank, 69.7% with seventh self-rated rank, 66.4% with ninth self-rated rank, 66% with tenth self-rated rank and 54.2% with eleventh self-rated rank (lowest perceived barriers), respectively. Adisa and Omitogun (2019) pointed out that ensuring the proper distribution and availability of reporting forms across healthcare settings from time to time may be one of the measures that improve the reporting rate<sup>15</sup>.

Very often, the uncertainty about the causal relationship between the adverse drug reaction and the drug itself was one of the major reasons for the problem of under-reporting of ADRs<sup>31</sup>. In the current study, this obstacle was perceived as eighth self-rated rank, with RII= 67%, this necessitates that healthcare providers should be aware of the causality assessment on ADRs. Palaian et al., (2011) also explained that the Naranjo algorithm is one of the common scales used for causality assessment, he found only 30.3% of the healthcare providers were aware of the Naranjo algorithm<sup>31</sup>. In order to take convenient initiatives towards adverse drug reaction management, there must be a need to study the severity of the ADRs. The Hartwig scale is used for this purpose widely. This scale classifies the reported ADRs into different levels as mild, moderate, or severe depending on the treatment and whether or not hospitalization was needed for the management of the ADRs. Palaian et al. (2011) found that only 28.1% of the healthcare providers were aware of the scale for the assessment of severity. So, it becomes mandatory

for the educational activities to focus on both the causality as well as severity assessment of the ADRs<sup>31</sup>.

An overview of these several barriers in the present study showed similarities to other studies. Hammour et al. (2017) showed that those barriers were a lack of information about the process of ADRs reporting and the timeline for reporting, as well as where to report<sup>8</sup>. On the other hand, Okechukwu et al. (2013) reported that the respondents considered the time constraint as one of the major challenging factors to the efficient adverse drug reactions reporting process<sup>32</sup>. Li et al. (2018) found that the lack of time was the major barrier to reporting ADRs in Australia and the result was expected since community pharmacists in Australia are providing several professional services such as dose administration aids, clinical interventions, home medicine review, as well as their traditional role in dispensing and supplying medications<sup>12</sup>.

Some of these discussed barriers can be resolved and managed through proper advertisement campaigns about the reporting process and improving any approaches that make the professionals able to communicate the information related to adverse drug reactions. Other obstacles can be resolved also by correspondence post-graduation mandatory training courses and extensive workshops to enhance the process of the reporting systems. Unfortunately, many factors in the current study were found to discourage pharmacists from making ADRs reporting. The pharmacists' top perceived barrier for reporting was lacking knowledge on the way of reporting,

Knowledge of the ADR reporting process and sources of reporting forms didn't differ significantly with the pharmacists' ADR reporting difficulties. Pharmacists with a prior idea about the PV concept measured significantly higher mean perceived ADR reporting difficulty than those unaware of the PV concept on average, and those pharmacists aware of the minimum ADR reporting requirements measured significantly lower mean perceived ADR reporting difficulties than those unaware of the ADR reporting minimum requirements

## CONCLUSION

The overall knowledge of PV and ADRs reporting among the pharmacists denote that pharmacists had moderate PV and ADRs reporting knowledge on average. Concerning attitudes; the overall perceived PV and ADR reporting attitudes for their perceived PV and ADRs reporting importance (attitude 1); and for perceived selective ADRs reporting (attitude 2) were moderately graded, which means that those pharmacists had positive attitudes toward PV and ADRs reporting. Regarding their perceived PV and ADRs reporting practice it was found that the overall level of practice was below average grade, which illustrated the moderate effort exerted by them in the reporting process and this can be justified through ADRs reporting barriers; where the pharmacists perceived difficulties of ADR reporting (barriers 1), and their perceived burden (barriers 2) denoting a moderately high level of barriers encountered by those pharmacists with regards to adverse reactions reporting in general. This deficit in reporting practice resulted in ADRs underreporting despite the majority of the pharmacists had positive and favorable attitudes toward ADRs reporting.

However, through optimizing the awareness and enhancing PV and ADRs reporting process by health care providers which could be achieved by adopting PV interventional programs that highlight on the significance and procedures of ADRs reporting to encourage the active, voluntary participation of pharmacists in drug safety monitoring. Also, Jordan Food and Drug Administration (JFDA) in a collaboration with the Ministry of Health, training institutions and other relevant stakeholders should provide educational campaigns and training regarding ADRs reporting to all pharmacists in the country that is in turn can change the level of knowledge, attitude, and practice among them.

The issue of communication among healthcare professionals must be emphasized and encouraged because effective communication will facilitate signal detection and reporting of ADRs cases. Moreover, since a major part of ADRs are related to the use of herbal medicines; there is a need to strength the national regulation,

registration, quality assurance and control of herbal medicines. Finally, Jordan PV center (JPC) has to ensure that there is continued support to all trained pharmacists in the country in terms of ensuring that reporting tools (guidelines and reporting forms) are available and easily accessible, and to incorporate PV into pharmacists' educational curriculum to make them more oriented in ADRs reporting.

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