Jordan Medical Journal, Volume 56, No.4 2022
DOI: https://doi.org/10.35516/jmj.v56i4.468

Assessment of Knowledge, Attitude, and Practice of Physicians toward Pharmacovigilance in Public and Private Hospitals in Jordan

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Abstract

Knowledge, attitude, and practice toward pharmacovigilance (PV) among healthcare providers is strongly associated with the reporting of adverse drug reactions (ADRs). This study was conducted to evaluate knowledge, attitude, and practice toward pharmacovigilance and to identify barriers for ADR reporting among physicians working in public and private hospitals in Jordan. This study was conducted using an online questionnaire in Arabic, designed by members of the Health Hazard Evaluation Committee of the Jordan Food and Drug Administration (JFDA) between August 2016 to December 2017. The questionnaire was completed using Google Forms online. A total of 341 physicians completed the questionnaire online. The rate of reporting of ADRs is low among physicians as only 4.7% have reported an ADR. The majority of physicians had never heard the term PV before. Respondents also lacked awareness of the existence of a PV center in Jordan and were unaware that ADR monitoring is carried out by the JFDA. Although most of the physicians had never seen the ADR form, many had positive attitudes toward reporting ADRs. According to participant responses, the main barriers to reporting are: 1) not knowing how to report; 2) not knowing the importance of reporting; 3) the unavailability of the ADR form; and, 4) general time pressure in the work environment. Although there is a low rate of ADR reporting among physicians, doctors have a positive attitude toward PV and are willing to implement ADR reporting in their practices. More education and training sessions are needed to raise physician awareness and knowledge of PV, and to enhance ADR reporting.

Keywords: Pharmacovigilance, adverse drug reaction, physicians, reporting, monitoring, Jordan.

(J Med J 2022; Vol. 56 (4):316-327)

Received	*Accepted*
April, 25, 2021	*March, 28, 2022*

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Introduction

Legislation requires the drug marketing authorization holder to monitor continuously the safety of their medicinal products and report adverse drug reactions to the Jordan Food and Drug Administration (JFDA). There are laws regarding the monitoring of adverse drug reactions (ADR) in Jordan; a national Pharmacovigilance Centre linked to the JFDA was established and became a full member of the World Health Organization (WHO) program for international drug monitoring in 2002 [1]. As part of the Pharmacovigilance National Centre Action Plan to increase awareness among healthcare providers of pharmacovigilance as a concept, five regional centers were established. In 2012, the first regional center was founded in Karak governmental hospital, followed by the founding of three regional centers in Amman (Pharmacy College at the University of Jordan, Princess Hamzeh Hospital, and Al-Basher Hospital), and one in the northern region at King Abdullah University Hospital [2].

A drug is registered and marketed according to its benefit-risk balance, based on safety, quality, and efficacy, and risk management considerations [3–5]. Clinical trials are used to assess, evaluate, and confirm the safety and the efficacy of medicinal products [6–7]. When the drug leaves the controlled environment of clinical trials and is made available for consumption by the general population, many unidentifiable and unknown adverse drug reactions may occur [8–9]. An adverse drug reaction (ADR) is defined by WHO (2002) as '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' [10–11]. ADR is considered a major health concern all over the world and represents a serious public health problem [12–13]. ADRs in the USA may cost up to 30.1 billion dollars annually [14], while in Europe ADRs lead to 5% of all hospital admissions and are believed to cause 197,000 deaths annually [15].

Therefore, the reporting of ADRs is considered the cornerstone of pharmacovigilance (PV) [6, 16], which is defined as 'the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine- related problem' **(**WHO, 2002) [17]. Detection of ADRs post-marketing relies mainly on spontaneous reporting by healthcare providers (HCPs) (e.g., physicians, pharmacists, and nurses) [13, 18], but under-reporting is still a major challenge facing pharmacovigilance system worldwide [19–22]. According to the Uppsala Monitoring Centre (WHO), Sweden, which maintains the international database of ADR reports, only 6–10% of ADRs are reported [23].

Studies and observations from many countries show a strong association between ADR reporting and the knowledge, attitudes, and practices (KAP) of HCPs [24–26]. KAP analysis may provide an explanation for the underreporting of adverse drug reactions [26]. Physician knowledge about ADR reporting affects attitudes towards patient care and drug safety. Moreover, positive attitudes enhance physicians' ADR reporting practices [25]. Several studies have been conducted to assess the KAP regarding PV among HCPs in Jordan [27–29]. The present study targets physicians working in different health care sectors, including public governmental and private sectors.

Aim of the study

This study was conducted to assess the knowledge, attitudes, and practices regarding PV and to identify barriers to ADR reporting among physicians working in both public and private hospitals in Jordan.

Methods

Study design, subjects and setting

This cross-sectional study was conducted via an online questionnaire written in Arabic; this was prepared and designed by members of Health Hazard Evaluation Committee of the JFDA. The study targeted physicians working in public and private hospitals in Jordan and was conducted between August 2016 and December 2017.

Questionnaire development, validation and data collection procedures

The questionnaire was developed based on thorough review of the literature and communication between members of the Health Hazard Evaluation Committee of the JFDA [30–31]. The questionnaire was validated by detailed evaluation by two academic professors. In addition, a pilot study was conducted with ten physicians working in public and private hospitals to assess the clarity and consistency of the questions. It was estimated that the questionnaire would take about ten minutes to complete. Minor amendments were recommended. Data obtained from the pilot study were not included in the results. The questionnaire included four sections and was composed of 25 multiple choice questions. The first section consisted of six questions to address the demographics of the respondent physicians. The second contained seven questions to assess knowledge of physicians regarding the definition of PV, existence of PV centers, and the institute responsible for ADR reporting in Jordan. The third section contained six questions that explored participants' knowledge about the ADR reporting form. The fourth part had five questions to evaluate the physicians' attitude toward ADR reporting and knowledge of who is responsible for reporting. The final section consisted of one question that offered a list of options to choose from. This question investigated barriers for ADR reporting and factors having a negative impact on reporting.

Ethical considerations

The study was approved by the Ethics Committee at JFDA. Participation in the study was voluntary and informed consent of the participants was obtained prior to study inclusion and no personal data of the participants are reported; all information regarding participation was provided via the consent form and cover letter, and in compliance with the Declaration of Helsinki.

Sampling technique

A systematic sampling technique was used. Systematic sampling is probability sampling method where the researcher chooses elements from a target population by selecting a random starting point and choosing sample members after a fixed 'sampling interval.' There are about 20,000 physicians working in public and private hospitals in Jordan, and a list of their contact details was obtained from the Jordan Medical Association. The questionnaires were distributed using online Google Forms to the validated email addresses of 400 physicians using a random systematic sampling technique with a fixed 50 sampling periodic interval. The sampling interval was calculated by dividing the entire population size (20,000) by the desired sample size (400).

Results

Demographics of the respondents

A total of 400 physicians received the study questionnaire and 341 agreed to participate,

yielding a response rate of 85%. Most participants were males (84.5%) and 15.5% were females. There were 57 (16.7%) consultants, 111 (32.6%) specialists, 161 (47.2%) residents, 4 (1.2%) general practitioners and 8 (2.3%) postgraduate medical students. Two hundred and ninety-seven (87.1%) of the questionnaires were completed by physicians working in government hospitals, 24 (7%) in teaching hospitals, and 20 (5.9%) in the private sector (**Table 1**).

Table 1
Demographic Characteristics of the Respondents

Category	Sub-category	Number (%) Total =341
Sex	Male	288 (84.5%)
	Female	53 (15.5%)
Age (Years)	24–30	140 (41.4%)
	31–39	114 (33.7%)
	40–49	53 (15.7%)
	50–59	27 (8%)
	≥ 60	4 (1.2%)
Professional Qualification	Consultant	57 (16.7%)
	Specialist	111 (32.6%)
	Resident	161 (47.2%)
	General practitioner	4 (1.2%)
	Postgraduate medical student	8 (2.3%)
Work Experience (Years)	(0–5)	156 (45.8%)
	(6–10)	68 (19.9%)
	(11–15)	51 (15%)
	(16–20)	24 (7%)
	(21–25)	28 (8.2%)
	(26–34)	14 (4.1%)
	> 35	0 (0%)
Workplace	Government hospital	297 (87.1%)
	University hospital	24 (7%)
	Private hospital	20 (5.9%)

Awareness of pharmacovigilance

Most of the respondents 232 (68%) reported that they had never heard the term pharmacovigilance. Physicians were provided with a list of options to choose from, where they could select one or more options for a definition of pharmacovigilance. In the survey, 228 (66.9%) of the participants defined it as detecting, understanding and evaluating ADRs, 204 (59.8%) characterized it as the rational, safe, effective, and economic use of drugs, 139 (40.8%) understood it to mean therapeutic drug monitoring, and 137 (40.2%) answered that pharmacovigilance is detecting post-marketing drug-related problems. When physicians were asked if they were aware of the existence of the PV and ADR reporting center in Jordan, only 66 (19.4%) were aware. The physicians were also asked if they knew that the Jordan Food and Drug Administration (JFDA) is the responsible institution to which they should report ADRs, and 132 (38.8%) of the answers were ‘yes,’ 193 (57.4%) ‘do not know’ and 13 (3.8%) thought that the

reporting institution is 'not the JFDA'.

Awareness of the ADR reporting form

Two hundred and ninety-one (85.6%) of the participants stated that they had never seen the ADR reporting form (distributed to medical facilities on a printed yellow card). The remaining 49 physicians (14.4%) who reported having seen the form before thought it was difficult to obtain one at their workplace. Of these, 35 expressed that it was difficult to fill out the yellow card, and 27 participants described the level of difficulty as high.

Attitude toward ADR Reporting

The majority of the physicians involved in the study (n=297, 87.1%), agreed that ADR reporting is important for patients' health and safety, whether the ADR is listed in the drug insert leaflet or not. When asked about the types of ADRs that should be reported, the responses were as follows: 275 (80.6%) physicians believed that serious ADRs which could be life-threatening or may lead to death should be reported; 220 (64.5%) believed ADRs not already listed in the drug insert leaflet should be reported; 169 (49.5%) believed that if the ADR is rare, it should be reported; and 80 (23.5%) respondents answered that an ADR should be reported even if it is non-serious, as long as it is labelled in the insert leaflet (**Table 2**). Participants were also asked whom they believe should report ADRs, and they were provided with the ability to select one or several options**.** The most common response at 258 (75.7%) was that reporting should be the responsibility of physicians, followed by pharmacists at 202 (59.2%), nurses at 78 (22.9%) and patients at 62 (18.2%).

Table 2: Physicians' attitudes regarding the types of ADRs that they should report (multiple responses were possible)

ADR Type	Number (%)
Serious ADRs that may be life-threatening or may lead to death	275 (80.6%)
Not labelled in the drug insert leaflet	220 (64.5%)
Rare ADR	169 (49.5%)
Labelled non-serious ADR	80 (23.5%)

Practices of and barriers to ADR reporting

When physicians were asked if they had reported an ADR before, only 16 out of 341 (4.7%) answered positively. Barriers to ADR reporting and factors having a negative impact on ADR reporting were investigated by giving the physicians a list of possible reasons for under-reporting, from which they could select one or several options (**Table 3**).

Table 3: Barriers of ADR reporting cited by the physicians participating in the study

	Barrier	Number (%)
1	Not knowing how to report	200 (58.7%)
2	Not knowing the importance of reporting	175 (51.3%)
3	Unavailability of a reporting form	153 (44.9%)
4	Work pressure	149 (43.7%)
5	Lack of continuous training in ADR reporting	127 (37.2%)
6	Lack of time	110 (32.3%)
7	The relationship of the drug to the ADR is uncertain	89 (25.8%)
8	Difficulty identifying the medication responsible for the ADR	88 (25.8%)
9	Difficulty in determining the ADR	79 (23.2%)
10	Ignore the reporting forms from recipients	78 (22.9%)
11	Fear of taking responsibility	68 (19.9%)
12	The reporting format is complex and difficult to complete	35 (10.3%)
13	Incomplete reporting information	35 (10.3%)
14	The ADR is expected and no need to report	28 (8.2%)
15	Reporting the ADR will not change the treatment plan for the patient	16 (4.7%)
16	Institutional barriers	10 (2.9%)
17	Only safe drugs are available on the market	6 (1.8%)

Discussion

To our knowledge, this is the first study to assess the knowledge, attitudes, and practices regarding PV and to identify barriers for ADR reporting among physicians working at government, private, and university hospitals in Jordan.

Knowledge of Pharmacovigilance

Results from this study show that the majority of the physicians had never heard the term PV before. A previous study by Alshammari et al. showed that health care professionals working within 12 Saudi hospitals had limited knowledge of PV, as more than half did not know the correct definition of PV, and only a third of the respondents were aware that the national PV Center is the official authority responsible for monitoring of ADR reporting [32]. Results from previous studies in Jordan have shown that physicians had poor knowledge of PV and ADR reporting, and they have demonstrated that many Jordanian health care providers were unaware of the concept of PV [27–29].

Data from this study show that only 19.6% of physicians were aware of the existence of the PV and ADR reporting center in Jordan, and 57.4% did not know that ADRs should be reported to the JFDA. A cross-sectional study showed that physicians had insufficient knowledge of ADR, with only 16.1% of the sampled general practitioners and 22.8% of the specialists were aware of the existence of a PV center in Egypt [33]. A study by Sharoukh et al. in 2018 found that only half of the physicians (53 out 106) working at health centers of the Jordanian Ministry of Health were aware that the Jordan Pharmacovigilance Centre at the JFDA was responsible for monitoring ADR reporting [27]. Another study by Suyagh et al. reported that pharmacists had inadequate knowledge about PV and ADR reporting, and most were unaware of the presence of the national ARD reporting system in Jordan [34]. These results indicate that large numbers of physicians lack knowledge of the existence of the PV Center in Jordan, and they are unaware that the JFDA is the authority responsible for ADR reporting. Therefore, there is a need to raise awareness and promote

the existence of the National Pharmacovigilance Center among physicians and other health care providers in Jordan.

Knowledge of the ADR Reporting Form

Most physicians in the current study, 85.6%, had never seen the ADR form before. About 14% of the participants had difficulty obtaining the form in their workplace, and 35 participants thought that the form is difficult to complete. This finding is line with a study by Welelaw, who found that two thirds of health care professionals had an inadequate level of knowledge towards PV and the ADR reporting system, and only 16% had reported an ADR during their clinical practice [31]. Another study revealed that half of the sampled doctors and pharmacists in Malaysia did not know about the ADR reporting system and agreed that the ADR form is too complex and difficult to complete [30]. The study by Sharoukh et al. (2018) demonstrated that about 95% of physicians rarely or never used the ADR reporting form [27]. These data indicate that the JFDA has to ensure that the ADR reporting form is available in all hospitals and departments and ensure that healthcare providers have easy access to it. Also, it seems that physicians find it difficult to complete the ADR form. Therefore, the JFDA should conduct more educational and training workshops to train physicians to complete these forms.

Attitude toward ADR Reporting

Many physicians in this study had positive attitudes toward reporting ADRs. About 87% reported that ADRs should be reported, whether the ADR is labelled in the drug insert leaflet or not. Participants also thought that serious and non-serious ADRs, and rare ADRs, should also be reported. The study by Sharoukh et al. (2018) observed a high level of positive beliefs and attitudes towards PV among physicians working at health centers of the Jordanian Ministry of Health [27]. A recent study by Mukattash et al. (2018) reported that 71% of pediatricians and pediatric residents in Jordan had good attitudes towards the reporting of ADRs [28]. Another study by Abu Hammour et al. (2017) found that the majority of the sampled medical doctors in Jordan University Hospital in Amman, Jordan, agreed with the necessity of ADR reporting and participating in training workshops on PV [29]. These findings suggest that a positive attitude towards PV among physicians will encourage them to participate in training sessions and activities designed to improve their knowledge and practices related to PV and ADR reporting.

About two-thirds of the participants in the present study thought that reporting should be the responsibility of physicians, followed by pharmacists, nurses, and patients. Alsaleh et al. (2017) showed that participants believed that pharmacists are responsible for ADR reporting (90%), followed by physicians (72%), and to a lesser extent, other health care providers (e.g., dentists and nurses) and patients [35]. These observations suggest that physicians and pharmacists play a major role in prescribing and dispensing the drugs, and therefore should be more involved in the process of reporting ADRs.

Practices and barriers to ADR reporting

This study found a low rate of reporting among the physicians involved, as only 4.7% of physicians had reported an ADR. Mukattash et al. (2018) reported low rates of reporting among pediatricians and pediatric residents in Jordan [28]. Shroukh et al. (2018) observed that the majority of physicians (95%) working at health centers rarely or never used the ADR form [27]. It is clear from these studies that the rate of ADR reporting by physicians is low in Jordan, and indeed underreporting is a

common phenomenon worldwide [36].

The current study aimed to explore barriers to ADR reporting, and factors having a negative impact on reporting. The main barriers to reporting were: not knowing how to report; not knowing the importance of reporting; and, the unavailability of the ADR form. Other barriers to ADR reporting mentioned by respondents were: work pressure, lack of time, and lack of continuous training in ADR reporting. These results reflect those of the other published studies from Jordan and countries in the Middle East. A study in Kuwait by Alsaleh et al. (2017) found that factors hindering the reporting of ADRs are: not knowing how to report (69%); thinking it is not important to report (35%); managing the patient is more important (30%); and, patient confidentiality issues (26%) [35]. A recent published study conducted by Al Rabayah et al. reported that lack of time and training and not knowing the reporting rules were the major barriers to ADR reporting for health care providers working at the King Hussein Cancer Center in Jordan [37].

Other factors discouraged the participants in the present study from reporting related to the ADR itself, such as: the relationship of the drug to the ADR being uncertain; difficulty identifying the medication responsible for the ADR; difficulty in determining the ADR; and, the ADR being expected and there was no need to report. Alsaleh et al. (2017) reported similar results; these authors found that a lack of both time and awareness among health care professionals on reporting ADRs, and the difficulty of specifying the causes of ADRs, are barriers to ADR reporting [35]. These findings suggest that reporters should be informed and encouraged to report suspected ADRs, even when they are unsure of a causal relationship between the drug and ADR.

Results from this study show that other, less frequently cited factors also discouraged the participants to report ADRs, such as: ignoring the ADR reporting forms from recipients; fear of taking responsibility; incomplete reporting information; and, institutional barriers. According to the results of a study published by Alsbou et al. (2016), the main barriers to reporting ADRs in a new regional PV center for South Jordan were: lack of awareness about the importance of PV and reporting among health care providers; some HCPs' fears that reporting might put them at risk; and, doubts regarding the causal relationship between the drug and suspected ADR [2]. Another study by Shroukh et al. (2018) found that 15% of physicians in Jordanian health centers believed that reporting an ADR might expose them to legal responsibility [27]. Therefore, physicians should be informed that the reporting of ADRs is risk-free and has no legal consequences, and thus they should be encouraged to report suspected ADRs.

Conclusions

The findings of this study suggest that there is low rate of ADR reporting and a lack of training and awareness about the importance of PV and ADR reporting among physicians working in public and private hospitals in Jordan. Therefore, educational programs and training activities are needed to raise the awareness and knowledge of physicians about PV, and to promote ADR reporting in Jordan.

Funding information

The authors received no specific funding for this work.

Data Availability Statement

The data that support the findings of this

study are available from the corresponding author upon reasonable request.

Conflict of interest/ Competing interests

The authors declare that there is no conflict of interest regarding the publication of this article.

Acknowledgements

The authors are extremely grateful to the survey respondents for taking the time to participate.

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تقييم معرفة وموقف وممارسات وعوائق الإبلاغ عن الآثار الجانبية للأدوية بين الأطباء في الأردن

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[6] الخدمات الطبية الملكية.

الملخص

أجريت هذه الدراسة لتقييم المعرفة والموقف والممارسة تجاه اليقظة الدوائية، ولتحديد العوائق التي تحول دون الإبلاغ عن الآثار الجانبية للأدوية بين الأطباء العاملين في المستشفيات العامة والخاصة في الأردن، وأستخدمت الدراسة استبيان يمكن تعبئته عبر الإنترنت باللغة العربية، والذي أعده أعضاء لجنة تقييم المخاطر الصحية للأدوية في المؤسسة العامة للغذاء والدواء بين أغسطس (2016) إلى ديسمبر (2017)، أكمل تعبئة الاستبانة ما مجموعه (341) طبيبًا، وغالبيتهم لم يسمعوا بمصطلح اليقظة الدوائية من قبل، وكان معدل الإبلاغ عن الآثار الجانبية للأدوية منخفضًا بينهم (4.7٪)، وبينت النتائج أن المشاركين في الاستبيان لم يكونوا على علم بوجود مركز لليقظة الدوائية في الأردن، على الرغم من أن غالبية الأطباء لم يروا نموذج رصد الآثار الجانبية للأدوية، وكان لدى العديد منهم مواقف إيجابية تجاه الإبلاغ عن هذه الآثار الجانبية.

ووفقًا لإجابات المشاركين، فإن العوائق الرئيسية أمام الإبلاغ، هي: 1) عدم معرفة كيفية الإبلاغ. 2) عدم معرفة أهمية الإبلاغ. 3) عدم توافر نموذج رصد الآثار الجانبية. 4) ضغط الوقت في بيئة العمل، وخلصت الدراسة إلى أنه على الرغم من وجود معدل منخفض للإبلاغ عن الآثار الجانبية للأدوية بين الأطباء، إلا أن الأطباء لديهم موقف إيجابي تجاه اليقظة الدوائية، ومستعدون لتعبئة تقارير رصد الآثار الجانبية للأدوية في ممارساتهم العملية، وكذلك هناك حاجة ماسة إلى عقد المزيد من ورش العمل والتدريب؛ وذلك من أجل زيادة وعي الأطباء ومعرفتهم حول اليقظة الدوائية، وتعزيز تعبئة تقارير رصد الآثار الجانبية للأدوية.

الكلمات الدالة: اليقظة الدوائية، الآثار الجانبية للأدوية، الأطباء، تقارير الرصد، الأردن.