Saudi Pharmaceutical Journal 31 (2023) 1197–1201

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Saudi Pharmaceutical Journal

journal homepage: www.sciencedirect.com

Original article

Jordanians' knowledge, attitude and practice regarding adverse drug reactions reporting

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ARTICLE INFO

Article history:
Received 5 April 2023
Accepted 13 May 2023
Available online 18 May 2023

Keywords:
Pharmacovigilance
Jordan
Adverse drug reaction
Knowledge

ABSTRACT

Objectives: The purpose of the current study was to evaluate the general public knowledge, attitudes, and practice regarding Adverse Drug Reactions (ADRs) reporting and pharmacovigilance in Jordan.
Methods: A cross-sectional study was conducted between July 16, 2022, and July 30, 2022, in Jordan. During the study period, an electronic survey consisting of 4 sections was administered to a convenience sample of Jordanians (aged 18 or above) using 2 social media platforms (Facebook and WhatsApp). Logistic regression analysis was used to screen the predictors of ADRs reporting by the participants.
Results: A total of 441 participants completed the survey. The majority of the participants (67.6%) were females, 53.1% between 26 and 45 years old. Almost all participants (96.3%) were always aware of the indication of the medications they take, the time and frequency (87.8%), and the duration of medications (84.4%). Nearly one-third of the participants (37.4%) asked about their medications' ADRs. However, the drug information leaflet was the most frequently used source of ADR information (33.3%). The majority of responders believed that both healthcare providers and consumers should report ADRs (93.4% and 80.3%, respectively). Only one-quarter of respondents (27.2%) believed that consumers could directly report ADRs through the Jordan pharmacovigilance program. The majority of patients who had experienced ADRs (70.3%) were aware that ADRs should be reported, and among them, 91.9% had reported the ADRs to healthcare providers. Furthermore, few participants (8.1%) reported it to the Jordan National Pharmacovigilance Centre (JNCP). Linear regression revealed that none of the demographic characteristics (age, gender, education, job, and social status) were affecting public reporting practice of the ADRs ($P > 0.05$ for all).
Conclusion: Respondents showed fair knowledge about adverse drug reactions and their reporting. However, there is a need to initiate educational activities and intervention programs to raise awareness about the JNPC, which will have a positive impact on public health and ensure safe medication use in Jordan.

1. Introduction

Keeping the pharmaceutical industry in business requires ensuring patient safety. Despite the importance of randomized controlled trials (RCTs) in assessing the therapeutic and safety profile of potential medications, the design of such studies makes it challenging to track ADRs because RCTs are typically carried out in a strictly defined population for a short period of time (Inácio et al., 2017; Silverman, 2009; Alves et al., 2013; Pal et al., 2013; Hammour and Jalil, 2016; Farha et al., 2018.). Thus, it is essential

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Peer review under responsibility of King Saud University.

Production and hosting by Elsevier

https://doi.org/10.1016/j.jsps.2023.05.016
1319-0164/

to continue monitoring for safety once the drug has received regulatory approval for usage to maximize any potential benefits and assure the effectiveness of the treatment (Pal et al., 2013).

The identification of adverse drug reactions (ADR) through spontaneous reporting is one of the most crucial parts of post marketing surveillance (Inácio et al., 2017). Patient reports are important as a reliable source of information on the safety of novel medications, according to the evidence that is currently available (Inácio et al., 2017). This spontaneous mechanism allow early detection of ADRs that haven't been previously reported. These ADRs could be uncommon and potentially fatal (Inácio et al., 2017; Härmark and Van Grootheest, 2008; Hazell and Shakir, 2006).

Pharmacovigilance is described by the World Health Organization (WHO) as "the science and actions connected to the identification, assessment, understanding, and prevention of adverse effects or any other medicine-related problem" (WHO, 2012). This spontaneous reporting approach has been adopted on a global scale since 1960 (Inácio et al., 2017; WHO, 2012). Data collection is one of the main aspects of spontaneous reporting which, depending on a nation's legislation, may be mandatory or optional (WHO, 2012). Since 2012, ADRs reporting has included patient participation in nations within the European Union (Inácio et al., 2017; Scurti et al., 2012). ADRs reporting was restricted in the past to professionals only. Today, both the European Union and the World Union is aware of how crucial direct patient reports are (Inácio et al., 2017; Härmark and Van Grootheest, 2008; WHO, 2012).

The JNPC, was established in March 2001 by the Jordanian Food and Drug Administration (JFDA). Later, in December 2002, JFDA was admitted as a full member within the WHO's Uppsala Monitoring Centre (UMC). The Jordanian public pharmacies, medical facilities, and healthcare professionals all have access to the system. Data showed that there was a rise in the number of reports submitted through the system between 2010 and 2021. Nevertheless, under-reporting remains a problem in Jordan despite these figures (Alsbou et al., 2017). Low understanding of the reporting system, lack of training, reliance on other health professionals for reporting, and failure to recognize ADRs are a few significant causes of underreporting of ADRs (Alharf et al., 2018; Robertson and Newby, 2013; Tandon et al., 2015; Klopotowska et al., 2013).

Evidence demonstrates that people use pharmaceutical information from a variety of sources, including drug information leaflets (DILs), online sources, and healthcare professionals, to identify potential ADRs (Narumol et al. 2015). How thoroughly patients are informed about the medications, their safety, and the function of JNPC is unknown. Furthermore, there is little research on the Jordanian public's attitudes about ADRs reporting. Thus, this study sought to evaluate Jordanians' knowledge and attitude regarding the medications, and practices of reporting of ADRs.

2. Methods

2.1. Study design, population, and ethics

Between July 16, 2022 and July 30, 2022, a cross-sectional survey was undertaken to determine the Jordanians' knowledge, attitude and practice regarding adverse drug reactions reporting in Jordan.. A convenience sample of Jordanian individuals (aged 18 years or above) was invited to fill-out an electronic survey during the study period utilizing two social media sites (Facebook and WhatsApp). Prior to enrolment, the participants received a thorough explanation of the study's objectives as well as a disclaimer concerning their voluntary involvement and the survey's anonymity. The present study was approved by the Jordan University Hospital's institutional review board (decision number https://doi.org/10/2022/8379).

2.2. Study instruments

After a thorough review of the literature, an Arabic survey was created (Saleset al., 2017; Adisa et al., 2019; Adisa and Omitogun, 2019). Two authors (both PhD holders) with experience in this area of research reviewed the questionnaire. To analyze its structure, clarity, and length as well as the participants' overall impressions of the questionnaire, "it was then pilot tested on ten adult volunteers from the general public of varied ages, gender, backgrounds, and educational level". As a result, the original questionnaire was slightly modified. The final version of the questionnaire was composed of 4 sections: (1) demographic sections, (2) knowledge of medication information, (3) attitude towards ADRs reporting, and (4) practice of ADRs reporting.

2.3. Sample size calculation

The minimum acceptable sample size needed for this investigation was determined using the common Cochran method: n = P (1 - P) z2/d2 (22). This formula is used to compute sample sizes in situations where the population is infinite. The most cautious percentage of participants' willingness to report the ADRs (P = 50%), the desired precision of 5%, and 95 percent confidence intervals were used to calculate the sample size. A minimal sample size of 385 individuals was determined to be representative for this study using this formula.

2.4. Statistical analysis

Statistical Package for Social Science (SPSS) version 22.0 was used to analyze the data (IBM Corp, Armonk, NY). Frequencies and percentages were used to present categorical variables. Logistic regression was used to screen the predictors of ADRs reporting by the participants. Significant variables (p-value $\leq$ 0.250) resulting from the univariate logistic regression were eligible to enter into a multiple logistic regression model, using enter analysis. Results with a p-value $\leq$ 0.05, with a 95% confidence interval, were considered significant.

3. Results

3.1. Respondents sociodemographic characteristics

A total of 441 responses were received. Nearly half of the participants (n = 234, 53.1%) were between 26 and 45 years old andthe majority (n = 298, 67.6%) were females. All of the participants were educated but with different levels, where 81.9% of them (n = 361) had a bachelor's degree or higher. Also, around 42% of the respondents had health-related degree (n = 186, 42.2%). More information about the participant demographics can be found in Table 1.

3.2. Respondents' knowledge regarding medication

The participants were assessed for their knowledge about the medications they take (Table 2). The majority (n = 424, 96.3%) were always aware of the indication, time and frequency (n = 387, 87.8%), and duration of medications (n = 372, 84.4%). Nearly half of them (n = 202, 45.8%) indicated that they always read the drug information leaflet. Nearly one-third of the participants (n = 165, 37.4%) asked about their medication ADRs Drug information leaflet was the most commonly used source of information about ADRs

Table 1
Respondents' sociodemographic characteristics (n = 441).

Characteristic	Frequency (*n*)	Percent (%)
Age		
o 18–25 years	111	25.2
o 26–45 years	234	53.1
o 46–64 years	90	20.4
o Older than 65 years	6	1.4
Gender		
o Male	143	32.4
o Female	298	67.6
Level of education		
o Diploma	80	18.1
o Bachelors level or higher	361	81.9
Having health-related degree		
o Yes	186	42.2
o No	255	57.8
Social Status		
o Married	261	59.2
o Others (Single, divorced, widowed)	180	40.8

Table 2
Respondents' knowledge regarding medication information (n = 441).

Questions	Frequency (*n*)	Percent (%)
Before the administration of medication, I know it's indication		
o Yes	424	96.3
o No	1	0.1
o Sometimes	16	3.6
Before the administration of medication, I know it's time and frequency		
o Yes	387	87.8
o No	9	2.0
o Sometimes	44	10.0
Before the administration of medication, I know for how long should I take it		
o Yes	372	84.4
o No	27	6.1
o Sometimes	42	9.5
I ask about my medications' adverse drug reactions		
o Always	165	37.4
o Sometimes	212	48.1
o Rarely	44	10.0
o Never	20	4.5
Source of information about adverse drug reaction		
o Asking a physician	51	11.6
o Asking the pharmacist	90	20.4
o Internet	131	29.7
o Drug information leaflet	147	33.3
o I did not search about it.	22	5.0

(n = 147, 33.3%) followed by the internet (n = 131, 29.7%), and the pharmacists (n = 90, 20.4%).

3.3. Respondents' attitudes towards ADRs reporting

Most of the study participants believed that both health care providers and consumers should be responsible to report ADRs (n = 413, 93.4%, and n = 354, 80.3%, respectively). Nearly one-quarter of respondents (n = 120, 27.2%) believed that consumer can directly report suspected ADR through the Jordan pharmacovigilance program. They also believed that public should receive more information about ADRs reporting (n = 407, 92.3%) (Table 3).

3.4. Respondents' practices of reporting ADRs

Nearly one-third of the participants had a previous ADR experience (n = 158, 35.8%) (Table 4). Among them around two-third hadreported the experienced ADRs (n = 111, 70.3%). Among those who reported ADRs, reporting was mainly to the healthcare providers (n = 102, 91.9%), while few participants did report it to the JNCP (n = 9, 8.1%).

Table 3
Respondents attitudes towards ADRs reporting (n = 441).

Statements	Agreed participants	
	Frequency (*n*)	Percent (%)
I think that healthcare providers should be responsible for reporting possible ADR from medications	413	93.4
I think that consumers should be responsible for reporting possible ADR from medications	354	80.3
Consumer can directly report suspected ADR through the Jordan pharmacovigilance program	120	27.2
Public should receive more information about ADR reporting	407	92.3

Table 4
Respondents practices of ADRs reporting (n = 441).

Questions	Frequency (*n*)	Percent (%)
Have you ever experienced an ADR?		
o Yes	158	35.8
o No	227	51.5
o I don't know	56	12.7
Have you ever reported any experienced ADRs?[#]		
o Yes	111	70.3
o No	47	29.7
Who did you report to, if you have experienced an ADR?$		
o Health care provider	102	91.9
o Jordanian pharmacovigilance centre	9	8.1

[#] Percentage calculated out of 158. $ percentage calculated out of 111.

3.5. Factors affecting respondents' practice of reporting ADRs

Simple logistic regression revealed that none of the studies demographic characteristics (age, gender, education, job, and social status) were affecting public reporting practice of the ADRs (P > 0.05 for all) (Table 5).

Table 5
Assessment of factors associated with the reporting of adverse drug reactions by the study participants (n = 441).

Parameters	Reporting of ADRs [0: No, 1: Yes]	
	OR	p-value[#]
Age		
o 45 years or lower	Reference	
o Older than 45 years	1.714	0.338
Gender		
o Male	Reference	
o Female	2.270	0.240
Level of education		
o Diploma	Reference	
o Bachelors level or higher	1.110	0.873
Having health-related degree		
o Yes	Reference	
o No	1.858	0.300
Social Status		
o Married	Reference	0.510
o Others (Single, divorced, widowed)	0.628	

[#] Using simple logistic regression analysis.

4. Discussion

This study's primary objective was to assess Jordanians' ADR reporting knowledge, attitudes, and practices. The reporting system for the ADR was only accessible to healthcare professionals (HCPs), according to a number of reports from various nations (Inácio et al., 2018). A global trend in recent years has been toward direct patient involvement in the reporting of adverse drug effects (Inácio et al., 2018). Instead of replacing HCP reports, patient reports are meant to enhance them (Adisa and Omitogun, 2019). Direct patient reporting is valued by pharmacovigilance authorities because it permits the quick gathering of ADR knowledge, according to studies from other regions of the world (Paola and Claudio, 2020). Additionally, patients are more likely than HCPs to indicate how ADRs affect their daily life, providing a more thorough description of reactions. The majority of patients who had experienced ADRs in our study had reported these ADRs (70.3%), and among them, 91.9% had reported the ADRs to healthcare providers. The impact of direct patient reporting of ADRs was evaluated in previous studies in the literature (Matos et al.,2019; Li et al., 2014). A study from China revealed that more information from patients about ADRs could help in preventing underreporting and identifying new issues in a minority of patients (Li et al., 2014). However, it was more disturbing to know that only 8.1% of the study participants reported ADRs to the JNPC, which necessitates a greater emphasis on promoting the centre, its activities, and the impact of public participation.

Nowadays, there is a variety of drug information sources that patients can use to get ADR details (Ho et al., 2009). Among these sources, our study found drug information leaflets to be the most commonly used source of information about ADRs (33.3%), which is lower than that reported from several countries (Nathan et al., 2007; Krska and Morecroft, 2013; Raynor et al., 2007). Researchers in Spain pointed out that nearly two-thirds (61.4%) of the participants always read the drug information leaflet (Krska and Morecroft, 2013; Salgueiro et al., 2019). Moreover, another study in England reported that around half (41.9%) of the participants always read the drug information leaflet (Krska and Morecroft, 2013). Additionally, researchers in United States (US) documented that 49.2% of the participants always read the drug information leaflet (Nathan et al., 2007). The drug information leaflet 's section on adverse effects, however, is the most often read part, according to other studies (Nathan et al., 2007; Krska and Morecroft, 2013; Salgueiro et al., 2019). Only one-third (37.7%) of the participants read the drug information leaflet section on side effects, according to a research conducted in England (Krska and Morecroft, 2013).The same section of the drug information leaflet was read by approximately two-thirds (60.7%) of the respondents, according to a survey conducted by US researchers (Nathan et al., 2007). On the other hand, Raynor et al. mentioned that two-thirds of the participants in the United Kingdom (UK) read the section related to side effects (Raynor et al., 2007).

The majority of the participants said that both healthcare professionals and consumers were responsible for reporting ADRs. Thus, it is crucial that consumers and healthcare professionals are informed about the ADR reporting system. The necessity for developing initiatives to increase Jordanians' awareness of the ADR reporting system was emphasized in previous literature in Jordan (Hammour and Jalil, 2016; Abu Hammour et al., 2017; Farha et al., 2018). Workshops could be used to raise awarenessof Jordanianpharmacovigilance center among healthcare professionals (Hammour and Jalil, 2016; Abu Hammour et al., 2017; Abu Farha et al., 2018). Furthermore, better communication would result from the creation of regional committees to promote knowledge sharing between pharmacovigilance center and healthcare professionals (WHO, 2012). Additionally, educating patients about the Jordanian pharmacovigilance center and ADRs reporting procedure during counselling with healthcare professionals could be effective way to increase ADR reporting. The majority of respondents (92.3%) in this survey had a positive attitude towards taking pharmacovigilance educational courses to learn how to report ADRs.

The results of our study showed that the studied demographic characteristics (age, gender, education, job, and social status) were not associated with affecting the public reporting practices of the ADRs. Earlier studies have found either no effect or a clear correlation between age, gender, and knowledge (Wilbur, 2013; Sanaa et al., 2016; Jose and Rao, 2006). A study conducted in Saudi Arabia, reported that females were more motivated to gather information related to ADRs (Saleset al., 2017). According to the ADR monitoring centre, differences in physiology between men and women make women more susceptible to adverse drug responses. Another study from China reported an inverse relationship between age and ADR reporting, although the prevalence of ADR is higher in elderly patients. Thus, it is important to educate and inform this age group about ADR and its reporting (Chen et al., 2021).

Even though our study didn't find a link between education level and ADR reporting, previous research has shown that a higher education level is associated with a higher awareness score (Fortnum et al., 2012). Thus, educational intervention in pharmacovigilance is needed to increase public awareness and reporting practice.

However, one of the limitations of this study is sampling because there were limited inclusion of older adults. The inclusion of those individuals' comments would have increased the study's representativeness and perhaps explained the results even more. Since the study was done on a convenience sample rather than a random sample, the lack of generalizability is another restriction that should be taken into consideration when drawing conclusions. In spite of this, the sample size and statistical methods chosen to elaborate the results from this group are robust enough to highlight the occurrence with relevance. Furthermore, the questionnaire has the advantage of being able to be repeated at regular intervals and at a minimal cost to evaluate public knowledge.

5. Conclusion

These results suggest that Jordanian population have adequate knowledge about their medications and positive attitude toward the process of pharmacovigilance and spontaneous ADRs reporting system. However, the studied demographic characteristics (age, gender, education, job, and social status) were not associated with affecting the public reporting practices of the ADRs. Educational programs are needed to increase Jordanians' role and their knowledge about the reporting process and its requirements, and thus to have a positive impact on patient caring process.

Authors' contributions

FD, KAH, RA contributed to all aspects of this manuscript, including conception and design; acquisition, analysis, interpretation of data and drafting of the manuscript. QM, AA, AM, and RKH contributed to the design, acquisition, analysis, interpretation of data. All authors read and approved the final manuscript.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not for- profit sectors.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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