

Assessing knowledge, attitude, and practices of health-care providers toward pharmacovigilance and adverse drug reaction reporting at a comprehensive cancer center in Jordan

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Abstract

Background and Objective: Cancer patients are more likely to experience adverse drug reactions (ADRs) than other patients, because of both the complexity of the treatment regimens and the severity of disease. The objectives of this study were to determine the knowledge, attitude, and practice of health-care providers toward pharmacovigilance and ADR reporting, barriers to ADR reporting, and the association between the demographics of health-care providers and their knowledge and attitude toward reporting.

Materials and Methods: A cross-sectional survey was conducted at the King Hussein Cancer Center. A self-administered questionnaire was distributed to dispensary pharmacists, clinical pharmacists, physicians, and nurses. Descriptive analysis was used, with testing for associations between variables.

Results: Of the 373 questionnaires, 306 were returned (response rate, 82%). Pharmacists and nurses were more knowledgeable than physicians; however, all participants had a highly positive attitude toward pharmacovigilance and ADR reporting, with a mean score of 3.87 out of 5. The main knowledge gaps were filling in an ADR reporting form, assessing the severity of ADRs, and differentiating between ADRs and adverse events. The main barriers to ADR reporting (37.5% of responses) were considered to be lack of training and of understanding reporting rules. No associations were found with age, gender, years of experience, attitude, or knowledge.

Conclusion and Recommendations: Understanding of pharmacovigilance and ADR reporting could further be improved among health-care providers at our center.

Keywords: Adverse drug reaction reporting, cancer, Jordan, knowledge, pharmacovigilance

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INTRODUCTION

Pharmacovigilance is an essential area of public health, involving the detection, assessment, understanding, and prevention of adverse reactions to drugs and medication-related problems.^[1]

Adverse drug reactions (ADRs) are defined as any unintended noxious response to a drug that occurs at doses used normally in humans for prophylaxis, diagnosis, or therapy or to modify physiological function.^[1]

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Early detection of ADRs can prevent serious clinical outcomes, reduce the associated economic burden, and improve the public safety by signal detection and regulatory actions. Pharmacovigilance systems in hospitals provide essential information about medication use. They establish processes for using reported ADRs to modify, update, or develop therapeutic guidelines, develop risk management plans, and identify educational gaps regarding the use of medicines.

A number of studies have assessed the knowledge, attitude, and practice (KAP) of health-care providers toward pharmacovigilance and ADR reporting. The results vary widely according to the geographical region, type of health-care system, and health-care providers involved.

Limited studies have been conducted in Arabic countries.^[2-4] The previous Jordanian KAP study involved community pharmacists and some hospital pharmacists, but not physicians or nurses.^[3] Furthermore, previous studies did not compare knowledge, attitude, and practice toward ADR reporting among different types of health-care providers. This is considered a limitation for the usefulness of previous KAP study results.

The King Hussein Cancer Center (KHCC) is a leading cancer center in the Middle East, providing adult and pediatric patients with state-of-the-art and comprehensive care for all types of cancer. The Center for Drug Policy and Technology Assessment in the pharmacy department analyzes reported ADRs and submits reports to the hospital pharmacy and therapeutic committee and to the pharmacovigilance center at the Jordanian Food and Drug Administration.

At KHCC, a mean of 600 ADRs are reported per year, only by clinical pharmacists and not by nurses, dispensary pharmacists, or physicians. We aimed to assess the KAP toward pharmacovigilance and ADR reporting of nonreporters at KHCC and to identify the barriers to ADR reporting according to each type of health-care providers.

MATERIALS AND METHODS

A cross-sectional survey was carried out among dispensary pharmacists, clinical pharmacists, physicians, and nurses at KHCC between May 2014 and December 2015. The questionnaire comprised 27 questions, and the content validity was assessed in a pilot study among 10 health-care providers at KHCC. The study team distributed the questionnaire in the various departments of KHCC, explained the purpose of the study, and

gave participants 20 min to fill in the questionnaire and return it.

A 5-point Likert scale was used to measure attitude, and a scoring rule was used to assess knowledge and attitudes. Participants were classified as unknowledgeable if their mean total knowledge score was <0.2, poorly knowledgeable with a score of 0.21–0.40, fairly knowledgeable with a score of 0.41–0.60, intermediately knowledgeable with a mean score of 0.61–0.80, and highly knowledgeable with a score above 0.80.

Participants were classified as having a negative attitude toward pharmacovigilance and ADR reporting if they had a total mean attitude score of <2.33, a positive attitude with a score of 2.33–3.66, and a highly positive attitude with a score above 3.66.

The practice was assessed by determining the weekly mean ADR reporting rate. The questionnaire also included a question about barriers to ADR reporting. The last part of the questionnaire had an open-ended question to collect suggestions from participants to improve ADR reporting at KHCC.

Statistical analysis

Data were analyzed with SAS version 9.4 (SAS Institute Inc, Cary, NC, USA). Descriptive statistics were used to analyze the data. Categorical data were analyzed with a Chi-squared or Fisher's exact tests. All statistical tests were conducted with a two-tailed alpha of 0.05.

Ethical approval

Ethical approval was granted by the Institutional Review Board, KHCC.

RESULTS

Of 372 questionnaires, 306 were returned, for a response rate of 82%. Of the 282 health-care specialists who responded, 154 (50.32%) were nurses, 98 (32%) were physicians, 15 (4.8%) were dispensary pharmacists (4.8%), and 15 were clinical pharmacists. Almost half of the respondents were men (151; 49.34%). The median age of respondents was 28 years, and most had from 1 to 3 or from 5 to 10 years of experience [Table 1].

Knowledge and attitude

Respondents had intermediate knowledge about pharmacovigilance and ADR reporting, with a mean overall knowledge score of 0.66; pharmacist and nurses were considered intermediary knowledgeable. The nurses' mean knowledge score was 0.73, while the combined score

of clinical pharmacists and dispensary pharmacists was 0.62. Clinical pharmacists had the highest knowledge mean score among all health-care providers in the study, with a score of 0.82. Dispensary pharmacists and physicians were considered fairly knowledgeable, with mean knowledge scores of 0.43 and 0.56, respectively.

In the total study population, the knowledge scores for filling in an ADR reporting form, assessing the severity of the ADR, and distinguishing between ADR and adverse events were the lowest [Table 2].

The measure of attitude showed that 64.4% of health-care providers strongly agreed that ADR reporting is necessary for improving clinical practice; 48.4% strongly agreed with the statement that a database of ADR reports can be used for research; 43.5% agreed that pharmacovigilance should be taught at universities; and 42.5% agreed that reporting is necessary even of well-recognized ADRs [Table 3].

In general, health-care providers at KHCC had a highly positive attitude toward ADR reporting, with a mean score of 3.87; clinical pharmacists scored 4.19, dispensary pharmacists scored 3.9, nurses scored 3.81, and physicians scored 3.92.

The results showed no association between knowledge of ADR reporting and attitude toward reporting ($P = 0.2913$), gender ($P = 0.826$), years of experience ($P = 0.314$), or age ($P = 0.7639$); however, a significant association was detected between knowledge and profession ($P = 0$) and between knowledge and participant's service ($P = 0$). No association was detected between attitude and demographic variables.

Practice

In term of practice, 41% of the participants detected at least one ADR per week; however, the mean actual weekly ADR reporting rate was 16%. Of the 306 respondents, 250 (81.7%) had not been trained in pharmacovigilance or ADR reporting. Only 55 (18%) respondents always documented reported ADRs in patients' medical records, while 20 (6.5%) mostly, 40 (13.1%) sometimes, 65 (21.2%) rarely, and 57 (18.6%) never documented ADRs.

Reporting barriers

Table 4 shows the barriers to ADR reporting by health-care providers. Lack of time, difficulty in deciding whether an ADR had occurred, and lack of feedback about previously reported ADRs were the major barriers for pharmacists, while lack of training, lack of time, and not knowing the reporting rules were the main barriers for physicians and nurses.

Table 1: Demographic characteristic of respondents

Demographic variable	n (%)
Gender	
Male	151 (49.34)
Female	126 (41.17)
Experience (years)	
<1	36 (11.76)
1-3	77 (25.16)
3-5	59 (19.28)
5-10	77 (25.16)
>10	30 (9.80)
Service	
Surgery	40 (13.07)
Internal medicine	46 (15.03)
Palliative care	8 (2.61)
Bone marrow transplantation	30 (9.8)
Intensive care (adults)	17 (5.55)
Intensive care (pediatrics)	16 (5.22)
Leukemia	6 (1.96)
Pediatrics	43 (14.05)
Pharmacy	30 (9.80)
Anesthesia	12 (3.92)
Emergency	11 (3.59)
Others	47 (15.35)

Table 2: Responses to questions about knowledge

Question	Population (306)	
	Yes (%)	No (%)
Pharmacovigilance covers both ADRs and other drug-related problems such as medication errors	240 (78.4)	53 (17.3)
The difference between ADR and adverse events is clear to me	175 (57.2)	126 (41.2)
Most of the time I know when an ADR should be reported	240 (78.4)	62 (20.3)
Once I report an ADR, I forward it to the pharmacy department	205 (67.0)	96 (31.4)
I know how to fill in the KHCC ADR reporting form	157 (51.3)	142 (46.4)
I know how to assess the severity of a reported ADR	186 (60.8)	115 (37.6)

ADRs=Adverse drug reactions, KHCC=King Hussein Cancer Center

DISCUSSION

The level of knowledge of ADR reporting was considered intermediate, which is better than in other countries.^[5-12] Nevertheless, our health-care providers had positive attitude toward ADR reporting, as in previous studies.^[13,14]

The level of knowledge about pharmacovigilance and ADR reporting among physicians was lower than that among nurses and pharmacists, as observed in other studies.^[9,14] Pharmacists had intermediate knowledge about pharmacovigilance, although this might be as underestimate because of the inclusion of dispensary pharmacists, who usually do not report ADRs. Nevertheless, the score of pharmacists was better than those reported previously in Iran, India, Nigeria, and Turkey^[11,12,15-17] and similar to these of hospital pharmacists in China.^[18]

Table 3: Responses to attitude questions

Question	Strongly agree (%)	Agree (%)	Neutral (%)	Disagree (%)	Strongly disagree (%)
I believe ADR reporting is necessary for improving clinical practice	197 (64.4)	85 (27.8)	12 (3.9)	6 (2.0)	1 (0.3)
An ADR database can serve as a trigger for research projects	148 (48.4)	111 (36.3)	32 (10.5)	9 (2.9)	1 (0.3)
I believe only serious ADR that result in life-threatening conditions should be reported	57 (18.6)	95 (31.0)	52 (17.0)	46 (15.0)	49 (16.0)
Pharmacovigilance should be taught in detail to all health-care providers	113 (36.9)	133 (43.5)	36 (11.8)	9 (2.9)	3 (1.0)
Even well-recognized ADRs should be reported	121 (39.5)	130 (42.5)	31 (10.1)	12 (3.9)	3 (1.0)

ADRs=Adverse drug reactions

Table 4: Barriers to adverse drug reaction reporting among health-care providers

Barrier	Pharmacists (30)	Physicians (98)	Nurses (154)
I haven't been trained on ADR reporting (%)	33	47	33
I don't know ADRs reporting rules (%)	16.6	45	29
Lack of time to report ADRs (%)	76.6	21	27
Lack of feedback about previously reported ADRs (%)	40	21	19
Difficult to decide whether an ADR occurred or not (%)	43.3	14	2
ADR reporting form is not easily accessible (%)	10	14	7
A single unreported case may not affect clinical practice (%)	3.3	3	6
It is not my responsibility to report (%)	3.3	3	17

ADRs=Adverse drug reactions

We found a low rate of ADR reporting (16%); however, it was within the range reported in other studies (3%–25%).^[5,6,11,19-24]

The most common barriers to ADR reporting were not knowing the reporting rules (37.58%), lack of training (37.58%), and lack of time (30.71%). Lethargy, insecurity, unawareness of reporting rules, and lack of training have been reported as major barriers to ADR reporting in studies in many countries.^[6,13,17,25-28]

As in our study, pharmacists in Iran and China considered doubt about causality, one of the main barriers to ADR reporting,^[12,18] while unawareness of the ADR reporting procedure was the most common barrier among physicians and nurses.^[4,14,23] In a previous study in Jordan,^[3] lack of adequate information about the case and of ADR forms, not knowing how to report, and lack of awareness of the national ADR reporting system were the major determinants of underreporting among pharmacists. The difference from our results may be due to the different settings of the two studies.

Few respondents (8.5%) had been trained in pharmacovigilance or ADR reporting. Variable results have been found regarding the impact of training on ADR reporting. Arici *et al.* showed that training may improve knowledge about pharmacovigilance significantly in the short term, but failed in the long term. Other studies showed that health-care providers trained in pharmacovigilance had more knowledge and practice of pharmacovigilance ($P = 0.001$).^[28-30]

In our study, 80.4% agreed that pharmacovigilance should be taught in detail to health-care providers, and most participants suggested that training and education are required to improve ADR reporting at the center. Similar suggestions have been made in other studies.^[14,18]

We found no difference in knowledge or attitude between males and females or by age group. Similar results were reported for nurses in a teaching hospital in Ajman.^[4]

We found significant associations between knowledge and profession ($P = 0$) and hospital service ($P = 0$). Although we did not measure the impact of the demographic variables on ADR reporting, a KAP study in Nigeria showed significant associations ($P < 0.05$) between previous areas of practice, the respondents' academic qualifications, years of experience, and ADR reporting.^[24] These results suggest that improvement of ADR reporting requires customized interventions according to profession and the area of practice of health-care providers, although our study showed no association between attitude and demographic variables.

Our study had some limitations. First, the results are not considered to be generalizable to other settings. Second, the small number of pharmacists (15 dispensary pharmacists and 15 clinical pharmacists) might have impacted the combined pharmacist scores. We found a relatively high difference in the mean knowledge score between clinical pharmacists (0.82) and dispensary pharmacists (0.43). Nevertheless, this finding is consistent with the reporting trend at our center. Clinical pharmacists, who had the

highest knowledge score, are the only ones who report ADRs at our center. This finding suggests that knowledge has a role in improving ADR reporting, as found in previous studies.^[4] Therefore, innovative strategies are required, in addition to training and education, for consistent improvement in knowledge about pharmacovigilance to improve ADR reporting. Further testing of the relationship between knowledge improvement and real-life ADR reporting is warranted. Our study showed no association between knowledge of ADR reporting and attitude toward reporting; therefore, improving attitude toward ADR reporting is not expected to improve knowledge scores.

CONCLUSION AND RECOMMENDATIONS

Knowledge of pharmacovigilance could further be improved at our center. The results of this study will be used to develop a comprehensive pharmacovigilance campaign at our institution, with multiple strategies, including promotion of reporting rules (what, when, and how to report), customized training for each medical specialty, and facilitation of reporting through electronic means.

Pharmacovigilance systems are essential, and training of health-care providers is a core component. Promotion and the use of technology are necessary to sustain the benefits of training. Further research will be required to assess the impact of the adopted strategies on ADR reporting rate and the quality of the reports.

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Conflicts of interest

There are no conflicts of interest.

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