



Contents lists available at ScienceDirect

Saudi Pharmaceutical Journal

journal homepage: www.sciencedirect.com

Original article

Knowledge, attitude and practice of hospital pharmacists towards pharmacovigilance and adverse drug reaction reporting in Najran, Saudi Arabia



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ARTICLE INFO

Article history:

Received 14 November 2021

Accepted 26 April 2022

Available online 30 April 2022

Keywords:

Pharmacovigilance

ADR reporting

Pharmacists

KAP

Najran

Saudi Arabia

ABSTRACT

Introduction: Pharmacovigilance (PV) is critical in determining the risk–benefit ratio of medicines and encouraging their safe, rational, and effective use, hence enhancing patient safety and care. Pharmacists, as drug experts, share responsibility for ensuring that medicines remain safe.

Objective: The study aimed to assess the knowledge, attitude, and practice of hospital pharmacists towards PV and adverse drug reaction (ADR) reporting and to know factors that discourage them from reporting ADRs in Najran, Saudi Arabia.

Methods: A pre-tested self-administered questionnaire was distributed to all the pharmacists working in government hospitals who consented to participate in the study. Data was collected over three months, from 01 June 2018 to 31 Aug 2018. Data were analyzed using Statistical Package for Social Science (SPSS) software for Windows, version 23. Descriptive statistics such as frequency and percentages, mean \pm standard deviation (SD) were calculated, and the Pearson's Chi-square test was used to examine the relationship between different variables.

Results: A total of 145 questionnaires were distributed, and the response rate obtained was 70.3%. The definition of PV and ADR were correctly identified by 42% and 68.3% of participants, respectively. A noteworthy finding is that 95% of participants were aware of the existence of the ADR reporting system, and 88.9% knew the responsible regulatory agency. Participants showed a positive attitude towards PV and ADR reporting; 90.1% considered ADR reporting a part of professional obligation, and 94.1% believed that there should be collaboration between pharmacists and other healthcare professionals. A majority of participants (86.1%) had identified an ADR during their practice, and 71.3% had reported an ADR. The unavailability of a professional environment to discuss ADR and insufficient pharmacotherapy/clinical knowledge was cited as the main factors discouraging from reporting ADRs.

Conclusions: Overall, the pharmacists had an average to good knowledge of and positive attitude towards PV and ADR reporting and a good ADR reporting practice. The concept of PV and ADR reporting should be further strengthened, and there is a vast potential for the same.

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1. Introduction

World Health Organization (WHO) defines Pharmacovigilance (PV) as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem (WHO, 2002a). The PV plays a vital role in enhancing patient well-being and safety in connection to the utilization of medicines, advancing detection of beforehand unidentified adverse drug reactions (ADRs) and interactions, and increase in the incidence of acknowledged ADRs. Additionally, it

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Peer review under responsibility of King Saud University.



aids in recognizing risk factors for the development of ADRs, adds to the assessment of benefit/risk analysis, and encourages safe, rational, and cost-effective use of drugs. The scope of PV also includes advancing comprehension, instruction and clinical training in PV and its effective correspondence to people in general (WHO, 2002a; Campbell et al., 2014).

As per the WHO definition, an adverse drug reaction (ADR) is any noxious, unintended, and undesired effect of a drug, which occurs at doses usually used in humans for prophylaxis, diagnosis or therapy of disease, or for modification of physiological function (WHO, 2002b). ADRs are common reasons for patient-related morbidity and mortality and are recognized to cause the extended duration of hospital stay and augmented therapy cost (Suyagh et al., 2015; Ali et al., 2018). In 17 of the studies performed in Europe, the share of ADRs leading to acute hospital admissions ranged from 0.5% to 12.8%, and the percentage of hospital patients developing an ADR in 10 studies ranged from 1.7% to 50.9% (Bouvy et al., 2015; Ferner and McGettigan, 2018). Within the United States of America (USA), the ADRs claim 100,000 to 218,000 lives annually and are the third most important reason of death behind heart disease and cancer (Campbell et al., 2014). According to one study, the rate of in-hospital ADRs is at 5.6% in the United States (US) and 3.2% in the United Kingdom (UK) (Stausberg, 2014). A study carried out in the hospitalized internal medicine patients at King Abdulaziz University Hospital, Jeddah, revealed an incidence rate of ADRs at 3.1% in a retrospective study and 5.5% in a prospective study (Khan et al., 2012). Another study carried out in hospitalized pediatric patients from the same hospital revealed an incidence rate of ADRs at 4.50% in retrospective analysis and 8.2% in a prospective study (Khan et al., 2013). In the UK, the total annual expenditure for ADR linked admissions was around 466 million pounds (Pirmohamed et al., 2004), while in the USA, the same in ambulatory care settings was anticipated to go over 177 billion US dollars (Campbell et al., 2014). Many hospitalizations and emergency visits caused by ADRs are preventable (Ahmad et al., 2013; Said and Hussain, 2017).

Prior to marketing authorization, a drug is tested for its efficacy and safety in a relatively small number of carefully selected subjects, and these studies are usually of a shorter duration. Once the drug is approved and released into the market and is used by a larger set of patients having concurrent diseases, special groups such as children, elderly or pregnant women and who may be on other drugs, potentially rare and serious ADRs are detected. Moreover, post-approval monitoring of a drug profile for longer durations allows its off-label use to be explored (WHO, 2002a; Campbell et al., 2014; Gildeeva and Belostotsky, 2017). Thus it is crucial to monitor and report ADRs. Good PV programs are an effective tool to identify drug hazards and assess a drug's benefit-risk ratio in the shortest possible time (WHO, 2002a; Campbell et al., 2014; Gildeeva and Belostotsky, 2017).

There are multiple mechanisms by which ADRs are reported. Spontaneous reporting system (SRS) is the most commonly employed method of reporting ADRs by health care professionals (including physicians, dentists, nurses and pharmacists), pharmaceutical companies and even the patients. SRS is one of the easiest, convenient and cost-effective means of reporting ADRs. One of the main advantages of spontaneous reporting is that it is not limited to a study phase and can be done throughout the life cycle. ADRs that could not have been identified during premarketing clinical trials or even post-marketing surveillance studies can be detected and reported via spontaneous reporting. Hence it can be said that SRS forms a cornerstone of PV activities. However, there are certain limitations associated with SRS, the prominent of which is under-reporting. Low-quality reports are much of a concern, and establishing a causal relationship is tricky (Campbell et al., 2014; Said and Hussain, 2017; Hadi et al., 2017; Alshammari et al., 2017).

A national pharmacovigilance center was established in Saudi Arabia in 2009 by Saudi Food & Drug Authority (SFDA), and the SFDA became the 92nd member of the World Health Organization's Uppsala Monitoring Center with the primary aim of promoting reporting of ADRs by health care professionals. The ADRs can be reported through different platforms such as online reporting systems, email, telephone, fax and post (Alshammari et al., 2017; Alshammari and Almoslem, 2018). A PV program is successful only when participation and co-operation from all the stakeholders involved and timely reporting of ADRs to PV centers (Alshammari et al., 2017).

Pharmacists, the healthcare team member with complete drug therapy knowledge, have a significant role in PV activities. The pharmacists working in hospitals and, in particular, clinical pharmacists with an excellent clinical background are more likely to report ADRs because of their regular interaction with the physicians and other health team members in addition to access to patients' medical records (Hadi et al., 2017).

There is a strong relationship between ADR reporting and healthcare professionals' knowledge, attitude, and practice (KAP) (Ibrahim et al., 2021). Studies have demonstrated that streamlining KAP concerning PV is vital in detailing methodologies to encourage ADR reporting. Certain studies have been conducted in different regions of Saudi Arabia evaluating KAP of pharmacists working in hospital or community pharmacies towards ADR reporting and PV (Al-Hazmi and Naylor, 2013; Khan, 2013; Abdel-Latif and Abdel-Wahab, 2015; Almandil, 2016; Alharbi et al., 2016; Ali et al., 2018; Alshammari and Almoslem, 2018; Tadvi et al., 2018). However, there is no published data from the province of Najran. Therefore, this study was carried out to evaluate KAP towards ADR reporting and PV among hospital pharmacists working in government hospitals in Najran city, Saudi Arabia.

2. Methodology

2.1. Study design, participants and site

This was a cross-sectional questionnaire-based study carried out among the pharmacists working in the government hospitals in Najran city of Saudi Arabia. We used simple convenient sampling technique to recruit the study participants. The duration of the study was for three months, from 01 June 2018 to 31 August 2018. With a margin of error of 5%, a response distribution rate of 50%, and a confidence level of 95%, the minimum sample size was calculated using Raosoft sample size calculator and found to be 108. The study population included all the pharmacists who consented to partake in the survey. The study was conducted at King Khalid Hospital, Najran General Hospital, Najran University Hospital, Maternity and Children Hospital and Armed Forces Hospital in Najran city. The selected hospitals provide a range of general and specialist services.

2.2. Study questionnaire

A self-administered 37-item questionnaire was used to investigate the KAP of hospital pharmacists towards ADR reporting and PV, including the factors that discourage ADR reporting. The survey was created using previously published local and international studies as a guide (Palaian et al., 2011; Al-Hazmi and Naylor, 2013; Gupta et al., 2015; Suyagh et al., 2015; Almandil, 2016; Shamim et al., 2016; Alsaleh et al., 2017; Ali et al., 2018; Alshammari and Almoslem, 2018; Lemay et al., 2018; Nisa et al., 2018; Tadvi et al., 2018).

The questionnaire consisted of five sections. The first section consisted of eight questions that documented a participants'

socio-demographic characteristics. The second part of the survey consisted of ten items that evaluated PV and ADR reporting knowledge and awareness. In the third part of the questionnaire, there were seven questions to assess participants' attitudes towards ADR reporting and PV. The focus of the fourth section of the questionnaire was identifying the practices of respondents about reporting ADRs and included four questions. The fifth and final section of the questionnaire consisted of eight questions and was intended to identify the barriers that might discourage reporting. The questionnaire was in English and included both open-ended and closed-ended questions.

2.3. Validation and reliability of the study questionnaire

The prepared questionnaire was pretested for content conciseness, comprehensiveness, consistency, and validity. A pilot study was done among ten pharmacists of the Najran University hospital pharmacy, who also serve as instructors in college of pharmacy affiliated with Najran University. Six of the ten staff has clinical and research backgrounds, four participants have prior experience in clinical research, PV, healthcare quality, and regulatory sciences. Their remarks were thought about, and the last review was readied with minor changes to the tool post content validity. Data acquired from the pilot study were not included in the revealed investigation results. The questionnaire reliability was checked by a statistician calculating Cronbach's alpha factor (0.71), indicating a good internal consistency of the questionnaire.

2.4. Collection and analysis of data

A hard copy of the pretested questionnaire and survey objective was circulated to the pharmacists and the departmental heads of respective hospitals. The participants were given sufficient time to fill the questionnaire. Data was collected over three months during periodic visits to the hospitals. The pharmacists who responded to the study tool were considered as lending approval to contribute.

The Statistical Package for Social Science (SPSS) software for Windows, version 23, was used to perform statistical analysis. Data obtained from the closed-ended questions were coded, and descriptive statistics such as frequency and percentages, mean \pm standard deviation (SD) were used to analyze data. The association between different variables was calculated and were determined by the Pearson's Chi-square test. When the p-value was < 0.05 , the results were considered significant.

2.5. Ethical approval and considerations

The Institutional Review Board of the Najran University, reviewed and approved the study (Reference No.:442-41-52467-DS). An informed consent form was provided to participants, and the questionnaire ensured the confidentiality of the collected information. All the questions revealing the personal information of the participants, such as name, contact details, the name of the organization, etc., were optional. Finally, the participants were assured that the results obtained from the study would be published anonymously.

3. Results and discussion

The study questionnaire was distributed to a total of 145 pharmacists working in governmental hospitals in Najran city. Of these, 102 questionnaires were completely filled and returned, giving a response rate of 70.3%, which is very close to the calculated sample size. The response rate obtained in our study is comparable to that

of the other studies wherein similar response rates were obtained (Al-Hazmi and Naylor, 2013; AlShammari and Almoslem, 2018; Jose et al., 2014).

3.1. Socio-demographic characteristics

The details of the participants' socio-demographic characteristics are presented in Table 1. A little more than half of the participants (51.6%) were in the age group of 31 to 40 years, followed by (40%) in the age group of 21 to 30 years. The majority of the participants were male (84.5%), which is similar to the finding of the studies conducted in Madina Al-Munawwara (75.7%) (Alharbi et al., 2016) and Majmah (89%) (Tadvi et al., 2018). In contrast, females constituted the majority of the participants in studies conducted in Kuwait (57.7%) (Alsaleh et al., 2017), Jordan (63.9%) (Suyagh et al., 2015) and Syria (64.5%) (Bahnassi and Al-Harbi, 2018). The majority of the participants (85.6%) were Saudi nationals, similar to the study results conducted in Madina Al-Munawwara (Alharbi et al., 2016). Hence the findings of our study represent the opinion of Saudi pharmacists at large. Future studies should target the Saudi pharmacists; findings will give an idea about the status of PV and ADR reporting practices based on which novel interventional strategies can be planned and implemented. Most of the participants (66.3%) had a bachelor degree in pharmacy, similar to the findings of the studies conducted in Madina Al-Munawwara (69.9%) (Alharbi et al., 2016). In our study, 45% of the participants had less than five years, and 41% had 6 to 10 years of professional experience. In a study conducted in Kuwait (Alsaleh

Table 1
Socio-demographic characteristics of the pharmacists (n = 102).

Characteristic	Number (n)	(%)
Age in years[Mean \pm SD = 33 \pm 6.3]		
21 to 30	38	40
31 to 40	49	51.6
41 to 50	7	7.4
51 to 60	1	1
Gender		
Male	82	84.5
Female	15	15.5
Nationality		
Saudi	83	85.6
Non-Saudi ^a	14	14.4
Qualification		
Diploma	28	27.7
Bachelor	67	66.3
Masters	2	2.0
PharmD	4	4.0
Country of graduation/qualification		
Saudi Arabia	79	78.2
Outside Saudi Arabia ^b	22	21.8
Professional pharmacy experience		
<5 years	45	45
5–10 years	41	41
11–15 years	9	9
More than 15 years	5	5
Rank		
Beginner Pharmacist	23	23.7
Pharmacist	58	59.8
Senior Pharmacist	15	15.5
Pharmacy Specialist	0	0
Senior Pharmacy Specialist	0	0
Head of Pharmacy Services	1	1
Type of Setting		
General Hospital	75	74.3
Specialized Hospital	26	25.7

Values are expressed as n (%), unless otherwise indicated. Numbers may not add to the total due to missing data.

^a India (n = 5), Egypt (n = 4), Jordan (n = 3), Pakistan (n = 1), Philippines (n = 1).
^b Egypt (n = 8), India (n = 5), Australia (n = 3), Jordan (n = 3), United Kingdom (n = 2), Philippines (n = 1).

et al., 2017), 40.5% of the pharmacists had 1 to 5 years of experience as qualified pharmacists. More than half of the participants (59.8%) worked as staff pharmacists, 23.7% were beginner pharmacists, and 15.5% were senior pharmacists. In the study conducted in Madina (Alharbi et al., 2016), 51.5% worked as staff pharmacists, and in a Kuwaiti study (Alsaleh et al., 2017), 28.7% of participants worked as beginner pharmacists and 18% as senior pharmacists. About 72.2% of the pharmacists were affiliated with general hospital settings, which is higher when compared to the results of the study conducted in Kuwait (Alsaleh et al., 2017); 59.8% were working in general hospitals. On the other hand, more pharmacists (40.2%) were working in specialized hospitals in Kuwait (Alsaleh et al., 2017) than in our study (27.8%).

3.2. Pharmacists' knowledge about PV and ADR reporting

A total of ten questions were used to evaluate a pharmacist's knowledge and awareness of PV and ADRs. In Table 2, details of the responses to the knowledge-related questions are presented. Results revealed that pharmacists generally had an average to good knowledge of the concept of PV and ADRs. However, pharmacists lacked knowledge and awareness of a few of the questions. Less than half of the study population (42%) knew the correct definition of PV, and 71% correctly identified the purpose of carrying out PV activities. These results are similar to previously reported studies where 40% (Faqihi and Fageehi, 2019), 43.4% (Shamim et al., 2016) and 44.3% (Almandil, 2016) had correctly identified the definition of PV, 66.3% (Gupta et al., 2015) and 74.8% (Alsaleh et al., 2017) knowing the purpose of PV activities. On the other hand, in other studies, a higher proportion of pharmacists at 81.08% (Hussain et al., 2021) and 91% (Alshayban et al., 2020) had rightly identified the definition of PV and 91.89% (Hussain et al., 2021) identifying the purpose of PV. The definition of ADR was correctly identified as any noxious or undesired effect of a drug occurring at normal doses by 68.3%, reflecting the results of other studies (Suyagh et al., 2015; Bahnassi and Al-Harbi, 2018; Faqihi and Fageehi, 2019), while 22.8% defined an ADR wrongly as adverse health outcomes associated with inappropriate drug use.

Out of the given options, 83.3% of the participants concluded that all the physicians, pharmacists, and nurses could report ADRs when asked about the health care professional responsible for reporting ADRs. In our study, 43.6% of participants rightly knew that both HCPs and non-HCPs could report ADRs. Similarly, 40.9% of participants from Turkey (Güner and Ekmekci, 2019) knew that even patients could report ADRs, and 48% from Majmaah (Tadvi et al., 2018) knew the individuals responsible for reporting.

Our research found that 95% of pharmacists know the national ADR reporting system, and 88.9% correctly identified National Pharmacovigilance and Drug Safety Center, run by the Saudi Food and Drug Authority (SFDA), as the regulatory organization responsible for PV activities in Saudi Arabia. In contrast, a low proportion of participants were aware of the existence of ADR reporting centers in Alahsa (10%) (Khan, 2013), Kuwait (7% and 10.6%) (Alsaleh et al., 2017; Lemay et al., 2018) and Syria (19.5%) (Bahnassi and Al-Harbi, 2018), Dammam (26.7%) (Ali et al., 2018), an exception to these is a study from Oman (88.8%) (Jose et al., 2014). The responsible regulatory agency was known by 78.2% of participants in a study from India, 80% of pharmacists from Majmaah (Tadvi et al., 2018) and by 80.8% of pharmacists in a large study carried out in Saudi Arabia (Alshayban et al., 2020) while only 67.5% from Jizan (Faqihi and Fageehi, 2019) knew of it. This can be attributed to the laudable job SFDA is doing in educating and training healthcare professionals at the national level. The awareness of the ADR reporting system and the National Pharmacovigilance and Drug

Table 2
Pharmacists' knowledge of PV and ADR (n = 102).

Item	Number (n)	(%)
Which of the following best defines PV?		
The science of monitoring ADRs occurring in a hospital	36	36
The process of improving of safety of drugs	9	9
The detection, assessment, understanding and prevention of adverse effects (Correct)	42	42
The science of detecting the type and incidence of ADR post marketing	9	9
Do not know	4	4
The purpose of carrying out PV activities (chose the most appropriate answer)		
To enhance patient's safety in relation to use of drugs (Correct)	71	71
To identify predisposing factors to ADRs	20	20
To identify unrecognized ADRs	2	2
To calculate incidence of ADRs	4	4
Do not know	3	3
Which of the following defines an ADR correctly?		
Any noxious or undesired effect of a drug occurring at normal doses, during normal use (Correct)	69	68.3
Adverse health outcomes associated with inappropriate drug use	23	22.8
Harm resulting from the use of substandard/counterfeit drugs	7	6.9
Harm caused by drug overdose	0	0
Adverse outcomes associated with drug impurity	2	2
Other health problems associated with drug use	0	0
The healthcare professional responsible for reporting ADRs is/are		
Physician	7	6.9
Pharmacist	10	9.8
Nurse	0	0
All of the above (Correct)	85	83.3
Can only HCPs report		
Yes	57	56.4
No, even non-HCPs can report (Correct)	44	43.6
Are you aware of the existence of ADR reporting system in Saudi Arabia		
Yes	96	95
No	5	5
An ADR is considered serious, if		
ADR results in death	4	4
It is life threatening	1	1
Leads to hospitalization or prolongs existing hospitalisation	7	7
Causes significant disability/incapacity	7	7
Leads to congenital anomaly	0	0
Requires intervention to prevent permanent impairment or damage	5	5
All of the above (Correct)	75	75.8
Which ADRs should be reported?		
All serious ADRs	26	26.3
ADRs to new drugs	1	1
ADRs to herbal and non-allopathic drugs	4	4
ADRs to vaccines	2	2
Unknown ADRs to old drugs	0	0
All of the above (Correct)	66	66.7
Regulatory agency responsible for carrying out pharmacovigilance activities in Saudi Arabia		
National Pharmacovigilance and Drug Safety Center	88	88.9
Saudi Commission for Health Specialties	9	9.1
Saudi Red Crescent Authority	0	0
National Guard Health Affairs	2	2
Drug withdrawn from the market because of potential cardiotoxicity		
Baycol (Cervastatin)	13	13.4
DBI (Phenformin)	32	33.0
Vioxx (Rofecoxib)	42	43.3
Raptiva (Efalizumab)	10	10.3

Values are expressed as n (%). Numbers may not add to the total due to missing data.

PV: Pharmacovigilance; ADR: Adverse Drug Reaction; HCP: Healthcare professional.

Safety Center (Saudi Vigilance) under the aegis of SFDA has significantly increased among HCPs, especially pharmacists, over the last few years.

The majority of the participants, at 75%, rightly identified the criteria that classify an ADR as serious. 66.7% of pharmacists correctly answered the categories of ADR to report, which is similar to the findings of other studies; Kuwait (66.3%) (Lemay et al., 2018) and Al-Khobar (71.6%) (Almandil, 2016). However, a higher proportion of pharmacists from other studies, 76% (Alsaleh et al., 2017) and 80% (AlShammari and Almoslem, 2018), knew that all the ADRs should be reported.

Only 43.3% of the participating pharmacists identified Vioxx (rofecoxib) as the drug withdrawn from the market due to potential cardiotoxicity, one of the discouraging findings of our study. The drug Vioxx was voluntarily withdrawn worldwide after it was found that patients taking it long-term were at twice the risk of a heart attack than patients receiving a placebo (Sibbald, 2004). This lack of awareness can be ascribed to an individual's level of seriousness, learning interests, and priorities to drug safety-related incidents.

There was no significant correlation between participants' socio-demographic characteristics and their level of knowledge.

3.3. Pharmacists' attitude towards PV and ADR reporting

There were seven attitude-related questions; Table 3 and Fig. 1 provide details of the responses to these. It was encouraging to see participants showing a positive attitude towards ADR reporting and PV; nearly all participants (97%) said that reporting ADR was necessary and would contribute to drug safety. These observations reflect the findings of similar studies with pharmacists; 98.8% from Kuwait (Alsaleh et al., 2017), 100% of them from Majmaah (Tadvi et al., 2018) and another Kuwaiti study (Lemay et al., 2018) deemed reporting necessary. The pharmacists from Kuwait (97.1%) (Alsaleh et al., 2017) and Alahsa (100%) (Khan, 2013) stated that reporting would positively affect healthcare and contribute to drug safety. Reporting of ADRs was accepted as a part of professional obligation by a majority of our participants (90%), similar

Table 3
Pharmacists' attitude towards and practice of PV and ADR reporting (n = 102).

Attitude	Number (n)	(%)
Reporting of ADRs is necessary and will contribute to drug safety	97	97
Reporting of ADRs is part of the professional obligation	91	90.1
Opinion about establishing ADR reporting center in hospitals		
Should be in every hospital	67	66.3
Not necessary in every hospital	3	3
One in a city is sufficient	11	10.9
Depends of the number of bed size in the hospital	20	19.8
Willing to implement ADR reporting in practice	68	67.3
PV should be taught in detail to HCPs	88	87.1
There should be collaboration between pharmacists and other HCPs	95	94.1
Practice	Number (n)	(%)
Ever identified an ADR in the patient during last 6 months	87	86.1
Number of identified ADRs in the patients during last 6 months		
<5	49	49.5
5–10	19	19.2
>10	17	17.2
None	14	14.1
Ever reported an ADR	72	71.3
Trained on how to report an ADR to a reporting center	69	68.3

Values are expressed as n (%). Numbers may not add to the total due to missing data.

ADR: Adverse Drug Reaction; PV: Pharmacovigilance; HCP: Healthcare professional.

to the findings of other studies from Oman (90.6%) (Jose et al., 2014), Kuwait (85.6%) (Alsaleh et al., 2017) and a multi-centric study from Saudi Arabia (86%) (AlShammari and Almoslem, 2018). On the other hand, a lesser proportion of pharmacists from Syria (37.6%) (Bahnessi and Al-Harbi, 2018), Madina (52.4%) (Alharbi et al., 2016) and Pakistan (75.7%) (Husaain et al., 2021) considered ADR reporting an obligation.

When enquired about the preferred method for reporting ADR information (Fig. 1), direct contact was preferred by 36% of the participants, while 23% preferred to report to a designated email or through a website. Around 27% preferred mobile applications. These findings are similar to the results from other studies. Direct contact was preferred by 36.1% (Alsaleh et al., 2017) and 32.1% (Lemay et al., 2018) of participants from two of the studies carried out in Kuwait, respectively, and by a higher share of participants at 62.1% from Pakistan (Nisa et al., 2018). 23.9% and 23.2% of participants from Turkey (Güner and Ekmekci, 2019) and Pakistan (Nisa et al., 2018) preferred to report to a designated email, respectively. The mobile application was preferred by 20.4% from Turkey (Güner and Ekmekci, 2019). Reporting through the post was the least preferred method; only one per cent preferred to use it, similar to findings from two Kuwaiti studies (Alsaleh et al., 2017; Lemay et al., 2018) and Pakistan (Nisa et al., 2018).

A sizeable share of participants (66.3%) believed that every hospital should have an ADR reporting center (Fig. 1), similar to the findings from Majmaah (68.9%) (Tadvi et al., 2018) and south India (74.3%) (Gupta et al., 2015). Despite most pharmacists considering reporting necessary and a professional obligation, simply 67.3% were willing to implement ADR reporting into their practice indicating a possible lack of commitment. This is lower than the results obtained in studies from Kuwait, wherein 81.3% (Lemay et al., 2018) and 88.6% (Alsaleh et al., 2017) of pharmacists were willing to implement ADR reporting. The existing number of PV and ADR reporting centers and PV coordinators should be increased and extended to smaller hospitals in peripheral regions of Saudi Arabia.

When asked if the health care professionals should be taught about PV in detail, 87.1% answered "yes" corresponding to the findings of studies involving pharmacists from Kuwait (92.2% and 93.3%, respectively) (Lemay et al., 2018; Alsaleh et al., 2017) while 96% of pharmacists from Majmaah (Tadvi et al., 2018) having agreed to it. This indicates the pharmacists' positive perception of the importance of PV and its impact on patient safety. Another important finding of our study is an affirmative response from 94% of pharmacists regarding collaboration between other healthcare professionals and pharmacists in the context of ADR reporting and PV, an observation similar to the findings of a study carried out in Pakistan (Shamim et al., 2016). This kind of inter-professional team approach will facilitate clinical knowledge transfer, help in the case and causality assessment, and ultimately lead to increased error-free quality reports.

There was no significant correlation between participants' socio-demographic characteristics and attitudes.

3.4. Pharmacist's practice with PV and ADR reporting

A total of four questions were utilized to assess the actual practice of reporting suspected ADRs. The participants were asked if they had ever reported an ADR, ever identified an ADR in the last six months of practice, number of identified ADRs in the last six months, and received any training regarding reporting of ADRs. The detail of the responses to these questions is presented in Table 3 and Fig. 2.

Concerning practice, most of the participants (86.1%) identified an ADR during the last six months of their practice (Fig. 2). This was as good as results from Jordan (Suyagh et al., 2015) and Australia (Li et al., 2018), wherein 91.2% and 88.4% of participants

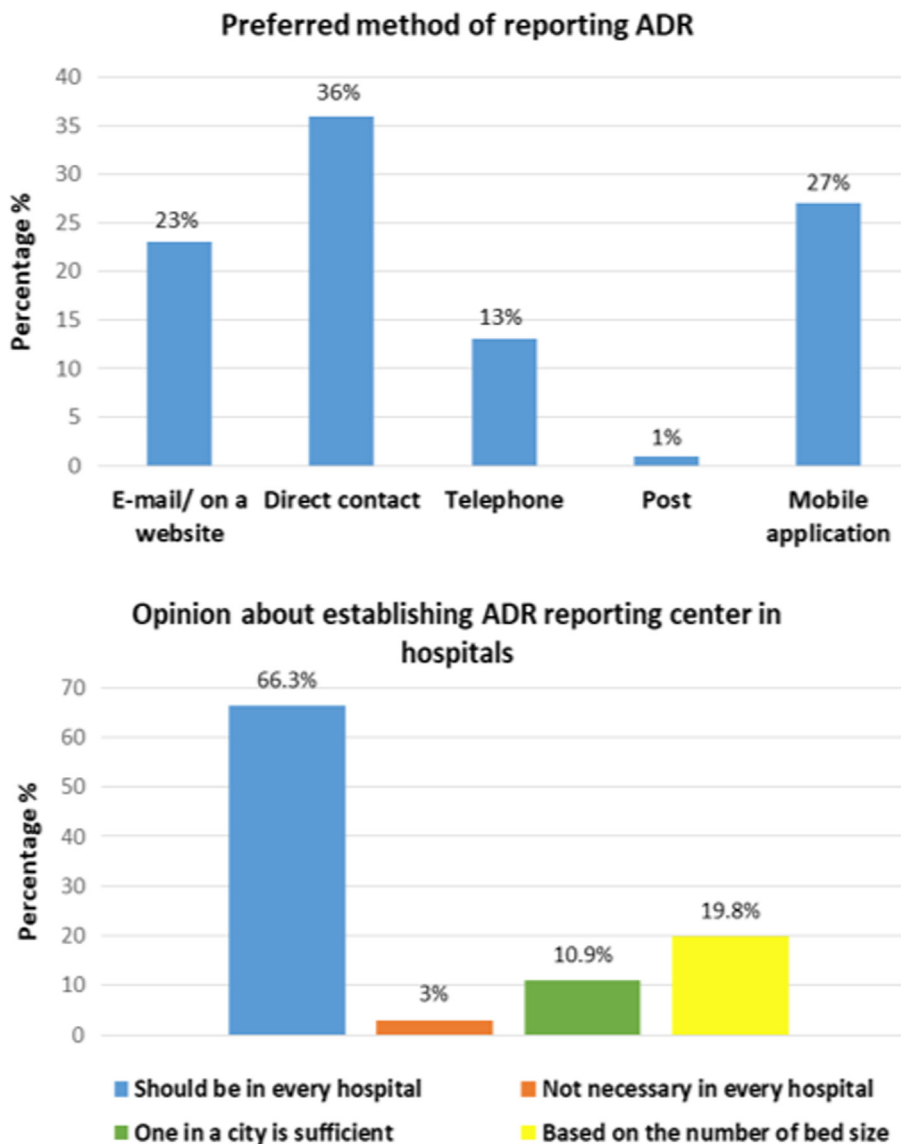


Fig. 1. Pharmacist's preferred method of ADR reporting and opinion about establishing ADR reporting center in hospitals. ADR: Adverse drug reaction.

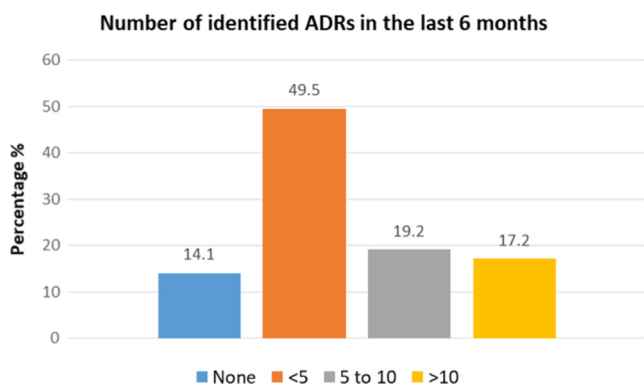


Fig. 2. Number of ADRs identified by pharmacists in last 6 months. ADRs: Adverse Drug Reactions.

had identified an ADR. There wasn't a huge gap between the ADRs identified and ADRs reported, as highlighted in previous studies (Gupta et al., 2015; Suyagh et al., 2015).

About half of the participants (49.5%) had identified less than five ADRs in the last six months of their practice, higher than the findings of Kuwaiti studies (42.6% and 41.8%) (Alsaleh et al., 2017; Lemay et al., 2018), 5 to 10 ADRs were identified by 19.2%; lower than the results of Kuwaiti (27.8% and 30.2%) (Alsaleh et al., 2017; Lemay et al., 2018) and Alahsa (88%) (Khan, 2013) studies. More than 10 ADRs were identified by 17.2%, lesser than the results obtained in Kuwait (29.6% and 28%) study (Alsaleh et al., 2017; Lemay et al., 2018).

Around 71.3% of pharmacists reported an ADR during their practice, similar to the findings of studies from Oman (69.2%) (Jose et al., 2014) and Makkah (70.9%) (Al-Hazmi and Naylor, 2013). The results obtained in the current study are much higher than the outcomes reported in studies from Jizan (6.25%) (Faqihi and Fageehi, 2019), Syria (10.8%) (Bahnessi and Al-Harbi, 2018), Dammam (17.8%) (Ali et al., 2018), Jordan (19.5%) (Suyagh et al., 2015), and south India (22.8%) (Gupta et al., 2015), Kuwait (26.8%) (Alsaleh et al., 2017), a larger study carried out in Saudi Arabia (32.1%) (Alshayban et al., 2020), Pakistan (32.4%) (Hussain et al., 2021) and Majmaah (35.1%) (Tadvi et al., 2018). Another noteworthy finding of our study is participants' positive attitude

reflected in their practice, contrary to previous studies where poor reporting was reported despite positive attitudes (Almandil, 2016; Alsaleh et al., 2017; Lemay et al., 2018).

A sizeable share of participants (68.3%) had received training regarding ADR reporting and is substantially higher than findings of studies conducted in Jordan (Suyagh et al., 2015), wherein only 8.2% had attended a workshop on how to report an ADR, Jizan (14%) (Faqihi and Fageehi, 2019), Oman (32.7%) (Jose et al., 2014) and Makkah (35.2%) (Al-Hazmi and Naylor, 2013). On the other hand, our result was similar to the finding of a study from Majmaah (Tadvi et al., 2018), wherein 72% of pharmacists had received training. In Dammam (Ali et al., 2018), a higher proportion of pharmacists (76.3%) had attended continuing medical education/training on ADR reporting. The participants who had received training had a significantly better-answered definition of PV ($P = 0.00$) and reported ADRs ($P = 0.00$) compared to those without training, similar to the findings of other studies (Gupta et al., 2015). Several studies have established the benefits of regular training and educational interventions on KAP, including actual reporting (Ahmad et al., 2013; Hanafi et al., 2014; Abu Farha et al., 2018; Ibrahim et al., 2021).

It is a need of the hour that PV and ADR reporting is incorporated into the curriculum at undergraduate levels of all the health sciences schools and has been advised in many previous studies (Almandil, 2016; AlShammari and Almoslem, 2018; Güner and Ekmekci, 2019; Faqihi and Fageehi, 2019). In addition, we would like to add that the universities design their syllabus or curriculum about PV and ADR reporting in consultation with the SFDA or get it approved so that all the fundamental and advanced components can be integrated. Furthermore, short term courses or post-graduate diplomas should be initiated in collaboration with SFDA and the Ministry of Health. The industry-academia partnership might also serve as a platform for skill development wherein students can do internships in PV or medication safety units of pharmaceutical industries and tertiary care hospitals. More importantly, outgoing students must be encouraged to take up their higher studies in drug safety sciences. The licensing examinations of healthcare professionals should give more emphasis on PV and drug safety sciences. The healthcare professionals should be provided with periodic training.

3.5. Factors discouraging pharmacists from ADR reporting

Many PV programs worldwide face the problem of ADR under-reporting, even in countries with well-established centers (Lopez-Gonzalez et al., 2009; Herdeiro et al., 2012). In this context, we studied the barriers to ADR reporting. We used a total of 8 closed-ended questions to find the factors discouraging pharmacists from reporting ADRs. The participants were given the option to “agree” or “disagree” with the statements. Fig. 3 provides a graphical representation of factors discouraging pharmacists from ADR reporting.

Absence of a professional environment to discuss an ADR (90.9%) followed by insufficient knowledge of pharmacotherapy/lack of clinical knowledge (78.2%) were cited as the primary reason discouraging participants from reporting. Lack of professional environment was reported as a significant barrier in studies from Alahsa (86%) (Khan, 2013) and Bangladesh (95.5%) (Amin et al., 2016). Lack of or insufficient clinical knowledge was also cited as a barrier, but to a lesser extent in studies from Makkah (64.9%) (Al-Hazmi and Naylor, 2013), Jizan (63.75%) (Faqihi and Fageehi, 2019), Jordan (61.4%) (Suyagh et al., 2015) and a multi-centric study from Saudi Arabia (36%) (AlShammari and Almoslem, 2018). The unavailability of reporting forms (77.2%) and not knowing how and where to report (72.3%) were cited as the next most important reasons. Unavailability of reporting forms was reported

as a barrier with nearly comparable results in Syria (70.2%) (Bahnassi and Al-Harbi, 2018), Jordan (72.5%) (Suyagh et al., 2015) and Jizan (72.5%) (Faqihi and Fageehi, 2019) and at a much higher rate in Alahsa (88%) (Khan, 2013), while not knowing how and where to report was cited as a barrier with nearly similar results in studies from Jordan (66.7%) (Suyagh et al., 2015), Jizan (67.5%) (Faqihi and Fageehi, 2019) and Kuwait (68.9%) (Alsaleh et al., 2017). The fear of legal liability was cited as a barrier by 69.3% of participants. A relatively lesser proportion of participants from Jizan (28.3%) (Faqihi and Fageehi, 2019), Jordan (30.3%) (Suyagh et al., 2015), and Makkah (56.8%) (Al-Hazmi and Naylor, 2013) cited fear of legal liability as a barrier. It was found to be least in Alahsa (12%) (Khan, 2013), Madina Al-Munawwara (12.6%) (Alharbi et al., 2016) and Syria (12.9%) (Bahnassi and Al-Harbi, 2018). The time factor (64.4%), lack of motivation (63.4%) and complex nature of reporting forms (59.6%) were the other barriers cited. The time constraint, to a smaller extent, was cited as a reason in studies from Jordan (32.2%) (Suyagh et al., 2015), Jizan (32.5%) (Faqihi and Fageehi, 2019) and Alahsa (34%) (Khan, 2013). The lack of motivation was reported from Madina Al-Munawwara (24.3%) (Alharbi et al., 2016) and Alahsa (38%) (Khan, 2013) to a lesser degree compared to our study. In the Saudi multi-centric (AlShammari and Almoslem, 2018) and Makkah (Al-Hazmi and Naylor, 2013) studies, 61% and 50.4% of participants found reporting form too complex, while only 18% and 21.4% from Alahsa (Khan, 2013) and Madina Al-Munawwara (Alharbi et al., 2016) found it complex.

Knowledge of pharmacotherapy and clinical aspects of a case report including but not limited to causality assessment, can be enhanced with regular continuing education activities and training in workshops, seminars, and conferences focused on ADR monitoring and reporting. The emphasis should be given to the commonly used causality assessment tools that will help establish a causal relationship between an adverse reaction and a drug. A healthy working environment is related to the productivity and efficiency of employees and motivates them to achieve the set goals and targets in their work. The healthcare professionals should be provided with the right environment and allowed to execute their responsibilities under the scope of their practice. The right professional environment will lead to increased ADR monitoring and reporting. Focus group interviews can help identify the barriers to ADR monitoring and reporting and find solutions to these issues. The latest guidelines, policies and procedures about PV released by the concerned authorities and agencies should be made available to the healthcare professionals to keep themselves informed with the latest developments.

3.6. Suggestions

Above all, the NPC should continue with the tremendous work that it has been doing by educating and providing training to HCPs and the public by conducting workshops, seminars and conferences, initiation of promotional campaigns and periodic meetings with the nationwide network of regional coordinators aimed at improving PV and ADR reporting practices in Saudi Arabia. The patients should be involved in ADR reporting. ADR reporting drop boxes should be placed at strategic locations in the hospitals for both HCPs and patients to increase reporting. Both ADR reporting forms and ADR alert forms should be provided to HCPs so that practitioners with a busy schedule fill the alert forms, which can then be taken up by dedicated personnel. Further KAP studies in the peripheral regions of Saudi Arabia should be taken up to identify knowledge gaps and behavioral patterns, needs and problems, barriers, and design interventions for better outcomes.

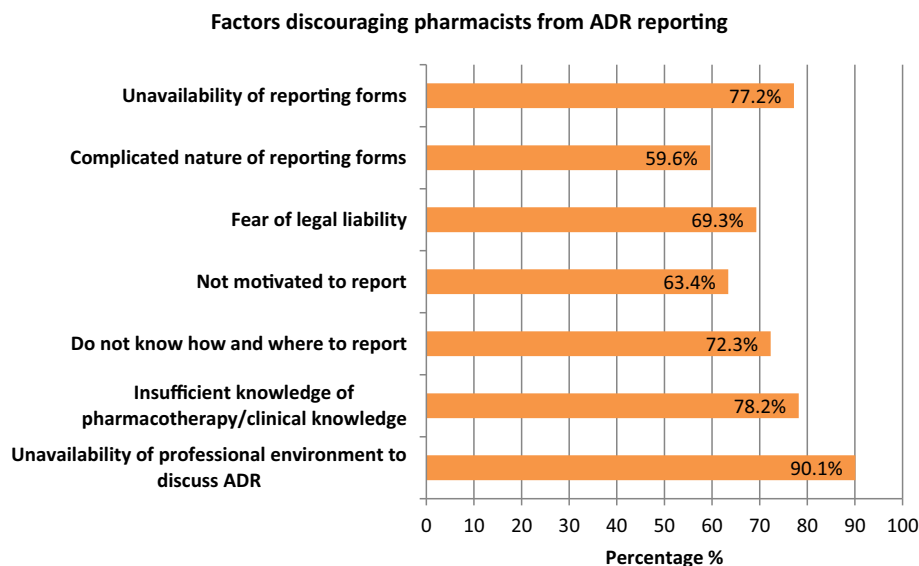


Fig. 3. Factors discouraging pharmacists from reporting ADRs. ADRs: Adverse Drug Reactions.

3.7. Strengths and limitations

To the best of our knowledge, this is the first study undertaken to assess the KAP of pharmacists towards PV and ADR reporting from the province of Najran. The majority of our participants were Saudi nationals, and hence the results primarily depict the KAP of the Saudi pharmacists. Our study has certain limitations. The sample size was relatively small. All our participants were hospital pharmacists working in government institutions; hence our results do not reflect the KAP of pharmacists working in private hospitals, primary healthcare centers and community pharmacies.

Moreover, the study was carried out in Najran city only; thus, the findings cannot be generalized to the entire province. The study involved only pharmacists and did not include other health professionals. The recall bias cannot be excluded as the study included many questions requiring recollecting information, and there could be social desirability bias.

4. Conclusions

The findings of our study revealed average to sound knowledge, positive attitude and reflection of the same into the practice of the pharmacists, and that KAP of pharmacists in Najran is satisfactory. Most pharmacists appreciated the importance of PV and agreed that reporting is obligatory and will contribute to drug safety. Also, the majority believed that PV should be taught in detail to HCPs and that there should be collaboration between pharmacists and other HCPs. There was a significant correlation between PV training and ADR reporting. Unavailability of a professional environment was cited as the primary factor discouraging pharmacists from reporting. Our findings suggest a massive potential for the further development of ongoing PV activities in Saudi Arabia.

Funding

The authors are thankful to the Deanship of Scientific Research, Najran University, Najran, Saudi Arabia, for funding this research through grant research code NU/NRP/MRC/11/19.

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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