Risk Management and Healthcare Policy Dovepress

Open Access Full Text Article

ORIGINAL RESEARCH

Knowledge, Attitude, and Practice Regarding Pharmacovigilance and Barriers to Reporting Adverse Drug Reactions Among the General Population in Saudi Arabia

Hind Alshehri[1], Adnan Alharbi[1], Noof Alqethami[2], Mohammed Alnuhait[1], Abdullah Alshammari[1], Abdulmalik S Alotaibi[1]

[1]Pharmaceutical Practices Department, College of Pharmacy, Umm Al-Qura University, Makkah, Saudi Arabia; [2]Clinical Pharmacy Department, Taif Health Cluster, King Faisal Medical Complex, Taif, Saudi Arabia

Correspondence: Abdulmalik S Alotaibi, Email assalotaibi@uqu.edu.sa

Background: Pharmacovigilance (PV) is an essential part of the healthcare system's framework. In Saudi Arabia, pharmacovigilance is still a relatively new concept though it is well established in many countries.

Study Aim: In this study, we aim to evaluate knowledge, attitude, and practice regarding pharmacovigilance and barriers to reporting adverse drug reactions (ADRs) among the general public in Saudi Arabia.

Methods: This is a cross-sectional study that used a self-administered online questionnaire to assess knowledge, attitude, and practice of PV and ADRs. The study included only the adult population in Saudi Arabia. A scoring system was generated with a scale from 0 to 100, where 80% was set as a cut-off point, as any higher score resembled adequate knowledge, a positive attitude, and good practice. We used the Statistical Package for Social Sciences (SPSS) version 26 for performing the statistical analysis, where para-normal tests were used to associate scores with the socio-demographic characteristics of participants.

Results: The study collected 1098 complete responses. The mean age (±SD) of participants was 37.9±11.2 years. Females comprised 68.9% of the participants. The average knowledge score among participants was 37.8±18.5, where only 4.3% of respondents had adequate knowledge. The average attitude score was 90.1±19.2, where 83.4% had a positive attitude. The average practice score was 70.4±18, and 34.5% of participants had good practice.

Conclusion: The study found that the majority of participants had inadequate knowledge, a positive attitude, and poor practice. Individuals holding a master's degree or higher and those working in the healthcare sector had the highest knowledge scores, whereas the group aged 31 to 50 years old, participants from the Al Jawf region, participants who are married with children, holders of a master's degree or higher, and healthcare workers had the best attitude scores. Higher practice scores were seen among married individuals with children and those who work in the healthcare sector.

Keywords: pharmacovigilance, adverse drug reactions, knowledge, attitude, practice, Saudi Arabia

Introduction

Pharmacovigilance is widely acknowledged as an important component of the healthcare system.[1] According to the World Health Organization, pharmacovigilance is

> the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other potential drug-related problems.

[1] Maintaining patient safety, which is critical in healthcare systems, is one of the key goals of pharmacovigilance.[2] While pharmacovigilance is a well-established concept in many countries, it is still relatively new in Saudi Arabia.[3] However, it is clear that in many countries, the general public has only a minimal understanding of adverse drug reactions (ADRs)

Received: 7 August 2024
Accepted: 22 October 2024
Published: 29 October 2024

and pharmacovigilance.[4,5] When it comes to the importance of ADRs, they have a significant impact not only on clinical results but also on the economic burden on the healthcare system; the cost of ADRs in the United States (US) might be as high as $30.1 billion per year.[6] According to a study conducted in the United Kingdom (UK), patients are not receiving adequate information regarding ADRs associated with their prescriptions.[7] In Saudi Arabia, ADRs are the most common drug-related problem reported in the emergency department.[8] According to a previous meta-analysis, the rate of ADRs in primary care settings was 8.32%, with nearly 22% of them being preventable.[9] 3.5% of hospital admissions in Europe could be attributed to ADRs.[10] It is also typical for people not to notify their physician or pharmacist when they experience an ADR.[11,12] About 15% of patients will stop taking their medications due to ADRs without informing their physician, indicating that they lack the knowledge or awareness to recognize ADRs. As a result, patients should be provided with the skills and knowledge to recognize and report ADRs.[13] This includes information on the drug's adverse reactions as well as what to do if they occur.[13] In Saudi Arabia, more information about the population's actual knowledge, attitude, and practice regarding pharmacovigilance is lacking.[14,15] Also, ADRs reporting barriers have not been addressed until now. However, when compared to studies conducted outside of Saudi Arabia, there is a dearth of studies on the general public's understanding of PV and ADRs.[16] Surveillance is necessary for identifying uncommon and underreported ADRs, as well as for improving clinical outcomes and lowering mortality rates.[6] As important as it is, ADRs are considered a priority for recently approved drugs as uncommon ADRs are not always discovered in pre-marketing surveillance.[17] The ADRs reporting system in the United States is divided into two parts: voluntary reporting for patients and medical practitioners and mandatory reporting for pharmaceutical companies.[18] The yellow card system in the UK is based on non-mandatory reporting by health workers (physicians, pharmacists, nurses, and midwives) and patients.[19] Patients play a vital role in pharmacovigilance systems and should be involved in all areas of them.[20] According to available literature,[21–23] there is a significant underreporting of ADRs among medical personnel, pharmaceutical manufacturers, and pharmaceutical trading companies in Saudi Arabia. As a result, expanding the spectrum of probable ADRs reported directly by patients can help improve reporting and assist in the early detection of critical ADRs signals.[5] Patients are frequently aware of their health condition and prescribed treatment options.[24] As a result, they are quite well placed to engage in the reporting of ADRs and improve treatment safety.[24] In the Netherlands, they considered ADRs reported by patients to be valued equally with the ones reported by healthcare professionals.[20] In Saudi Arabia, the National Pharmacovigilance and Drug Safety Center (NPC) has made it possible for the wider public to report ADRs in a variety of ways, including Internet, faxing, and calls.[25] A variation within the provinces of Saudi Arabia has also been noticed in understanding ADRs, ADRs prevalence, reporting rate, and reporting barriers.[16] Possible reasons for underreporting are the difficulty of the reporting process and the lack of realization of ADRs reporting importance.[26,27] The purpose of this study is to assess the knowledge, attitudes, and practices (KAP) of the general public in Saudi Arabia regarding pharmacovigilance, as well as to identify the barriers to reporting adverse drug reactions (ADRs). Pharmacovigilance is a critical component of ensuring drug safety, yet there is limited data on how well the public understands and engages with these practices. By evaluating the general population's awareness and behavior in relation to pharmacovigilance, this study aims to highlight potential gaps in knowledge and practices, which can inform future public health initiatives. The primary objective is to assess the current state of knowledge, attitude, and practice regarding pharmacovigilance and to explore the factors that hinder the reporting of ADRs, offering insights that may guide improvements in public education and reporting systems in Saudi Arabia.

Methods

Study Setting

A cross-sectional design was chosen as it enables the collection of data at a single point in time to assess knowledge, attitudes, and practices (KAP) regarding pharmacovigilance across different demographics using an electronic survey (Google Forms) distributed through different social media platforms targeting the adult population living in Saudi Arabia. The study aims to collect responses on the online data collection tool, where the obtained data will be processed, analyzed, and presented to fulfill the study objectives.

Study Subjects

Participants were recruited through various social media platforms using convenience sampling. The inclusion criteria were adults aged 18 and older residing in Saudi Arabia. Participants who could not provide consent were excluded.The sample consisted of adults aged 18 years or more. The sample was not limited to any specific gender.

Sample Size

The sample size was calculated using the following formula:

The minimum sample size for this study was decided according to the formula:

$$n = \frac{Z^2 \times P \times Q}{D^2}$$

Where n: calculated sample size, Z: The z-value for the selected level of confidence = 1.96, P: The assumed proportion of the general population with satisfactory knowledge, attitude, and practice on pharmacovigilance and barriers to the reporting ADRs = 50% = 0.5, Q: (1 – P) = 0.5, and D: The maximum acceptable error [precision level] = 0.05. The estimated sample size was at least 384 individuals.

Sampling Technique

The data collection tool was distributed online, targeting the Saudi population using an initial eligibility screening checklist to ensure that every participant is eligible for participation in compliance with the aforementioned study selection criteria. Distribution of the data collection tool stopped on reaching up to 20% more than the estimated sample size in order to cover for missing data and invalid inputs.

Data Collection methods, Instruments Used, Measurements

The survey instrument was refined from prior studies to meet the study's aims.[4,5,27] The questionnaire was translated from English to Arabic by a language expert. The focus of the translation was not solely on the literal translation but also the conceptual meaning of the contents. The questionnaire was evaluated, validated, and pilot tested for clarity and content validity in various populations, along with faculty professionals. The validation process of our survey instrument was conducted in a systematic manner to ensure both clarity and relevance. This involved multiple stages, including pilot testing and thorough validity assessments aimed at refining the survey content. Reliability testing was an integral part of the process, confirming the internal consistency of the instrument. Feedback gathered from 10 participants during the pilot phase played a pivotal role in enhancing the design and structure of the questionnaire. To ensure broad accessibility and inclusivity, the final survey was made available in both Arabic and English. The survey included five parts: 1. socio-demographic characteristics, 2. participants' knowledge of pharmacovigilance, 3. participants' practices towards pharmacovigilance, 4. participants' attitude towards pharmacovigilance, and 5. ADRs reporting barriers.

Data Management and Analysis Plan

Descriptive statistics, including frequency and percentage, were used to summarize the data. Scores for knowledge, attitude, and practice were calculated as for each question, every correct response counted for a score of 1, and incorrect responses counted for a 0. A sum of all items in each domain was obtained, where the minimum score was 0, and the maximum was 7, then the total score for the respondents in the knowledge and attitude domains was converted into a percentage score; in the knowledge domain, a total correct score > 80% was assigned as "adequate" general knowledge of PV and ADRs. In the attitude domain, a total ranked score > 80% signified a "positive" attitude towards PV and ADRs, while a total ranked score ≤ 80% was classified as a "negative" attitude. The cut-off for the overall percentage score in the knowledge and attitude domains was adapted from related studies.[4,5] Data analysis was conducted using Statistical Package for Social Software (SPSS) version 65. The determinant factors for the scores were determined using non-parametric tests for quantitative variables. We used the Kruskal–Wallis test and the Mann–Whitney test for associating socio-demographic characters with calculated scores, where the p-value was considered significant if $P < 0.05$.

Ethical Considerations

Ethical approval was obtained from the Ethics Committee of Umm Al-Qura University (Approval No. HAPO-02-K-012-2022-04-1053). Confidentiality and privacy were guaranteed for all participants. This study was conducted in full compliance with the Declaration of Helsinki. All participants provided informed consent prior to their involvement in the study. Before participation, all respondents were provided with an informed consent form outlining the study's purpose, risks, and confidentiality measures. All participants provided written informed consent prior to their involvement in the study, in accordance with ethical standards and institutional guidelines.

Results

Socio-Demographic Characteristics of the Population

A total of 1172 questionnaires were collected. After excluding individuals under the age of 18, 1098 valid responses were finally included in this study with a response rate of (93.7%). The mean age of the respondents was 37.93 years (SD=11.185). The gender distribution was higher among female respondents, with a total of 756 responses (68.9%) compared to male respondents (n=342, 31.1%). The majority of respondents were Saudis (n=1047:95.3%) with Makkah region having the highest responses (n=623; 56.7%) followed by Riyadh region (n=193; 17.6%). The marital status of the respondents was mainly married with children (n=672; 61.2%), 281 (25.6%) were single, and 87 (7.9%) were married with no children. Of all survey respondents, more than 60% had a bachelor's degree. The proportion of individuals who visit the Ministry of Health or Health Centers and National Guard or Military Hospitals for medical appointments account for 47.1% (n=517) and 29.6% (n=325), respectively, while those who visit Private Hospitals account for 19% (n=212). Only 21.6% of the study participants had chronic diseases, with which diabetes (6.6%) and hypertension (4.3%) accounted for the highest proportion (Table 1).

Knowledge Levels Regarding PV and ADRs

Overall, the general public had low knowledge scores regarding PV and ADRs.

Greater than 70% (n=782) of participants had never heard of PV, and for those who had, social media was the main source from which they learned about PV. Hail (44%), Al Jawf (42%), and Makkah (31%) were the regions that had the highest percent of people who had heard of PV.

In addition, a significant number of respondents (n=968; 88.2%) did not know about NPC. More than 80% of respondents selected "Any effect of a medication", representing inadequate understanding of ADRs, compared with only 16% (n=130) showing adequate understanding of ADRs. Although 67.1% (n=737) of participants agreed that not all the drugs marketed are safe, only 31.4% (n=345) were aware of the reporting procedure; among them, people who have children (33%) were more aware of the reporting procedure than others. In contrast, almost 70% of healthcare workers know that not all marketed medications are safe. The average knowledge score among participants was 37.8±18.5, where only 4.3% of respondents had adequate knowledge (Table 2 and figure 1).

General Public's Attitude Towards PV and ADRs

Positive attitudes were found for all questions related to attitudes toward PV and ADRs. More than 95% (n=1054) of respondents agreed to inform their healthcare provider if they experience ADRs. 21% and 14% of participants did not know whether PV helps improve drug safety or the importance of reporting ADRs to the NPC, respectively. More respondents (n=1038, 94.5%) demanded relevant departments carry out public-oriented activities to highlight the importance of reporting ADRs. Nearly all respondents (n=1029, 93.7%) agreed that the pharmacist and physician should inform patients about ADRs also as their responsibility in reporting ADRs. 92.4% (n=1015) of respondents urged the government to open channels for patients to report directly. The average attitude score was 90.1±19.2, where 83.4% had a positive attitude (Table 3 and figure 1).

General Public's Practice Toward ADRs

Almost half of the respondents (n=597, 54.4%) have a family or personal history of ADRs. Among them, 50% discontinued the medication that caused the ADRs, 38% informed a healthcare professional, 3% changed the medication,

Table 1 Socio-Demographic Characteristics of the Population

	Mean	SD
Age	37.93	11.185
	Number	**(%)**
Gender		
Male	342	31.1
Female	756	68.9
Nationality		
Saudi	1047	95.3
Non-Saudi	51	4.6
Region		
Riyadh	193	17.6
Makkah	623	56.7
Eastern Region	63	5.7
Madinah	21	1.9
Al Baha	11	1.0
Al Jawf	26	2.4
Northern Borders Region	5	0.5
Al Qassim	15	1.4
Hail	9	0.8
Tabuk	20	1.8
Asir	75	6.8
Jizan	23	2.1
Najran	14	1.3
Marital Status		
Single	281	25.6
Married with children	672	61.2
Married with no children	87	7.9
Widowed	19	1.7
Divorced	39	3.6
Level of education		
Elementary school	21	1.9
Middle School	37	3.4
High school	229	20.9
Bachelors	688	62.7

(*Continued*)

Table 1 (Continued).

	Mean	SD
Master's degree or higher	123	11.2
Healthcare worker		
Yes	136	12.4
No	962	87.6
Which of the following sectors do you visit in your medical appointments?		
Ministry of Health and Health Centers	517	47.1
National Guard and Military Hospitals	325	29.6
Medical Cities	44	4.0
Private Hospitals	212	19.3
Do you suffer from chronic diseases?		
Yes	237	21.6
No	861	78.4

Table 2 General Public's Knowledge About Pharmacovigilance and ADRs

	Number	(%)
Are you familiar with the term pharmacovigilance?		
Yes	316	28.8
No	782	71.2
If yes, from where have you heard about it?		
Social media	200	18.2
Healthcare providers	100	9.1
Family and friends	74	6.7
I have not heard about it before	724	65.9
Have you heard about the Saudi National Pharmacovigilance Center (NPC)?		
Yes	130	11.8
No	968	88.2
What your understanding of ADRs?		
Any effect of a medication	413	37.6
Unexpected reaction after taking the normal dose	177	16.1
Expected reaction after taking the normal dose	235	21.4
Any effect after taking high dose	149	13.6
I do not know	124	11.3

(*Continued*)

Table 2 (Continued).

	Number	(%)
Who is the major source for reporting an ADR?		
Physician	577	52.6
Pharmacists	204	18.6
Drug Companies	317	28.9
Do you think all the drugs marketed are safe?		
Agree	128	11.7
Disagree	737	67.1
I do not know	233	21.2
Are you aware of the ADR reporting procedures?		
Yes	345	31.4
No	753	68.6
Knowledge score (Mean±SD)	37.8±18.5	
Adequate knowledge	47	4.3
Inadequate knowledge	1051	95.7

5% did nothing, and only 2% reported ADRs to NPC. Drug leaflet was the main source of information about ADRs for 79.7% (n=875) of respondents. Nearly 70% of female respondents report reading the drug leaflet compared to 50% of male respondents. More than half of the respondents (n=576, 52.5%) would not ask healthcare providers about ADRs. Most respondents (n=954, 86.9%) would actively report ADRs if they were familiar with the reporting procedure. 45.6% (n=501) preferred reporting ADRs directly to the healthcare providers, 31.1% (n=341) preferred telephone calls, and 23.3% (n=256) would like to report ADRs via the internet. The average practice score was 70.4±18, and 34.5% of participants had a good practice (Table 4 and figure 1).

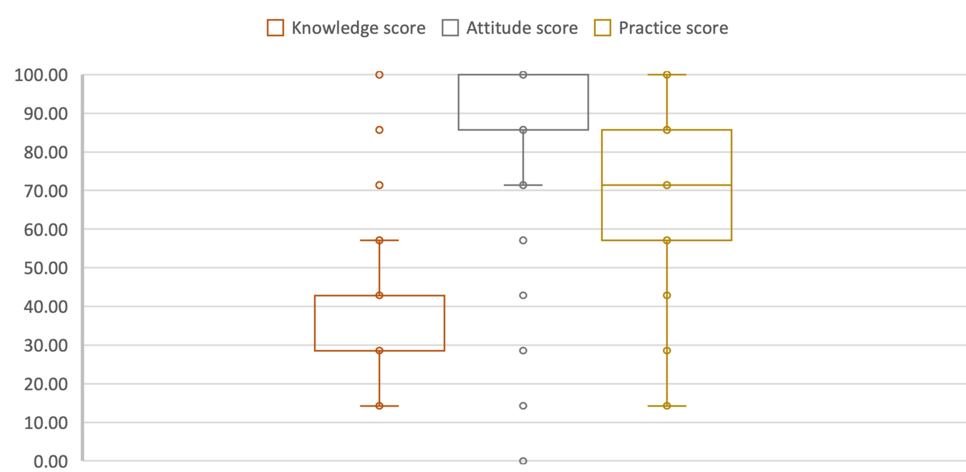

Figure 1 Boxplot of PV & ADR knowledge, attitude, and practice scores among participants (n=1098).

Table 3 General Public's Attitude Towards Pharmacovigilance and ADRs

	Number	(%)
Do you think pharmacovigilance contributes to improving drug safety?		
Yes	849	77.3
No	14	1.3
I do not know	235	21.4
Do you think it is important to report ADRs to the NPC?		
Yes	918	83.6
No	23	2.1
I do not know	157	14.3
Physicians and pharmacists need to inform consumers (patients) about ADRs		
Yes	1029	93.7
No	23	2.1
I do not know	46	4.2
I will inform my physician/pharmacist about any ADRs experienced with the medications used		
Yes	1054	96.0
No	16	1.5
I do not know	28	2.6
Medical personnel are required to report ADRs in patients.		
Yes	1021	93.0
No	18	1.6
I do not know	59	5.4
The government should open channels for patients to directly report ADRs		
Yes	1015	92.4
No	31	2.8
I do not know	52	4.7
Relevant departments should hold activities for the public highlighting the importance of reporting ADRs.		
Yes	1038	94.5
No	19	1.7
I do not know	41	3.7
Attitude score (Mean±SD)	90.1±19.2	
Positive attitude	916	83.4
Negative attitude	182	16.6

Table 4 General Public's Practice Towards ADRs

	Number	(%)
Have you/you family ever experienced ADRs?		
Yes	597	54.4
No	281	25.6
I do not remember	220	20.0
Would you read the medication's leaflet?		
Yes	693	63.1
No	60	5.5
Sometimes	345	31.4
Sources of obtaining information about ADRs		
Drug leaflet	875	79.7
Pharmacist	58	5.3
Physician	64	5.8
Internet	56	5.1
Family and friends	45	4.1
Would you ask healthcare provider about ADRs?		
Yes	522	47.5
No	576	52.5
Action taken in the case of ADRs		
Informed a healthcare professional	341	31.1
Reported to the NPC	34	3.1
Stopped the drug	468	42.6
Changed to another medication	33	3.0
Nothing was done	46	4.2
I have not experienced ADRs before	176	16.0
If you are familiar with the reporting procedure, would you report ADRs?		
Yes	954	86.9
No	32	2.9
I do not know	112	10.2
Which way do you prefer to report ADRs?		
Directly to healthcare providers	501	45.6
By telephone	341	31.1
By Internet	256	23.3

(*Continued*)

Table 4 (Continued).

	Number	(%)
Practice score (Mean±SD)	70.4±18	
Good practice	379	34.5
Poor practice	719	65.5

ADRs Reporting Barriers

For almost 90% (n=969) of respondents, unfamiliarity with the reporting process was the barrier to reporting ADRs. This was followed by a lack of adequate publicity of the ADRs reporting importance by the authorities for 87.1% (n=956) of respondents. Lack of knowledge about drugs or their effects and the uncertainty of the ADRs were almost equally a barrier for 82.4% and 85.0% of respondents, respectively. Lack of time to complete a report is seen as an obstacle to reporting ADRs by half of the respondents (n=560, 51.0%). Only 25.4% (n=279) of respondents felt that reporting well-documented ADRs was unnecessary (Table 5).

Table 5 ADRs Reporting Barriers

	Number	(%)
Lack of knowledge regarding drugs and their effects		
Yes	905	82.4
No	184	16.8
Unaware of the reporting procedure		
Yes	969	88.3
No	120	10.9
Lack of time to fill in a report		
Yes	560	51.0
No	529	48.2
The uncertainty of the ADRs		
Yes	933	85.0
No	156	14.2
No feedback from the authorities		
Yes	497	45.3
No	592	53.9
No need to report a recognized ADRs		
Yes	279	25.4
No	810	73.8

(*Continued*)

Table 5 (Continued).

	Number	(%)
Lack of proper advertisement by the authorities		
Yes	956	87.1
No	133	12.1
After knowing the importance of the NPC, in case that I or a member of my family experiences ADRs, I will:		
Report ADRs to healthcare providers	197	17.9
Report ADRs to NPC	814	74.1
Stop the medication	87	7.9

Factors Associated with Knowledge, Attitude, and Practice

As shown in table 6, knowledge score was significantly associated with the level of education (p=0.004) and working in the healthcare sector (p=0.000). The highest knowledge score was among holders of master's degrees or higher (45.2 ±24.3) and those working in healthcare sectors (53.6±25.8). Attitude score was significantly associated with age (p=0.000), residency region (p=0.034), marital status (p=0.000), level of education (p=0.003), and working in the healthcare sector (p=0.002). The highest attitude scores were observed among the group aged 31–50 years (91.6 ±17.8), participants from Al Jawf (99.5±2.8), participants who are married with children (92.3±15.9), holders of master's degrees of higher (92.3±15.9), and healthcare workers (93.2±18.1). Practice scores were significantly associated with marital status (p=0.020), as a higher score was among those who are married with children (71.7±17.4) and working in healthcare sectors (74±18.8) (p=0.014).

Discussion

This study is believed to be the first to examine knowledge, attitude, and practice of PV and ADRs reporting barriers covering all regions within Saudi Arabia, unlike the other similar studies that focused on only certain regions.[4,5,14,27,28] Studies in this area have tended to target HCPs rather than the general public. This study aimed to assess the general population's knowledge, attitude, and practice towards pharmacovigilance and ADRs reporting. With an 80/100 score threshold for adequate knowledge, we found that the majority of participants had inadequate knowledge (95.7%). Our

Table 6 Knowledge, Attitude, and Practice Scores in Association with Socio-Demographic Characters

Parameter		Knowledge score	P-value	Attitude score	P-value	Practice score	P-value
Age	**19–30**	38±19.4	0.481	87.3±21.5	0.000	69.6±18.1	0.419
	31–50	37.9±17.9		91.6±17.8		70.9±17.9	
	51–87	36.8±19.7		89.9±19.9		70.3±18.9	
Sex	**Female**	37.6±17.6	0.632	90.5±18.7	0.375	71±17.1	0.195
	Male	38.3±20.5		89.2±20.5		69.2±19.9	
Nationality	**Non-Saudi**	40.7±19.5	0.290	84.6±29.2	0.573	69.2±21.3	0.905
	Saudi	37.7±18.5		90.4±18.6		70.5±17.9	

(*Continued*)

Table 6 (Continued).

Parameter		Knowledge score	P-value	Attitude score	P-value	Practice score	P-value
Region	**Al Baha**	32.5±9.3	0.836	70.2±45.9	0.034	54.6±23.8	0.129
	Al Jawf	41.3±20.8		99.5±2.8		76.4±18.5	
	Northern Borders Region	40±25.6		77.2±43.6		74.3±34.2	
	Riyadh	37.6±18.1		90.4±15.8		69.9±16.8	
	Al Qassim	39.1±19.1		94.3±10.6		72.4±19.9	
	Madinah	36.1±20.1		84.4±27.5		76.9±20.5	
	Eastern Region	37±21.6		91±16.5		69.4±18.9	
	Tabuk	39.3±15.3		72.9±37.7		66.5±20.4	
	Jizan	31.7±14.3		87.6±22.6		70.9±20	
	Hail	46.1±28.4		68.3±47.8		74.6±22.4	
	Asir	36.6±17.8		87.3±24.7		67.3±19.8	
	Makkah	38.1±18.5		91.4±16.6		70.9±17.4	
	Najran	37.8±18.3		88.8±14		68.4±17.9	
Marital status	**Widowed**	31.6±12.3	0.089	89.5±20.7	0.000	74.5±13.2	0.020
	Single	37.9±18.5		85.9±23.3		68.4±19.2	
	Married with children	38.5±18.7		92.3±15.9		71.7±17.4	
	Married without children	33.5±17.7		87.2±25		66.2±19.2	
	Divorced	37.4±19.9		89.1±19.6		71.1±18.4	
Level of education	**Elementary school**	36.8±17.9	0.004	76.9±33.1	0.003	68.8±22.5	0.237
	High school	35.5±17.4		88.9±19.4		68±18.4	
	Bachelors	37.6±17.6		90.3±18.9		71±17.4	
	Master's degree or higher	45.2±24.3		94.6±14		72.2±18.7	
	Middle school	32.5±15		86.5±25.5		69.9±21.8	
Healthcare worker	**No**	35.6±16.1	0.000	89.7±19.4	0.002	70±17.9	0.014
	Yes	53.6±25.8		93.2±18.1		74±18.8	
Healthcare sectors	**National Guard and Military Hospitals**	37.6±18.2	0.706	89.6±19.1	0.565	70.6±17.6	0.965
	Medical Cities	42.3±22.5		88.4±23		71.5±19.3	
	Private Hospitals	37.6±18.3		91.3±18.2		69.5±18.4	
	Ministry of Health and Health Centers	37.7±18.5		90.1±19.5		70.7±18.2	
Chronic Disease	**No**	37.6±18.5	0.529	90.2±18.7	0.440	70.1±17.5	0.092
	Yes	38.6±18.8		90±21.1		71.7±20.1	

knowledge results are consistent with a study that assessed the PV awareness of healthcare students.[29,30] Despite a positive perception of PV's importance and a positive attitude toward PV and ADR reporting, PV knowledge was poor. According to Reumerman et al, many factors can influence PV competencies, including the type of education, academic level of study, and previous training.[29] According to our results, the level of education (p=0.004) and working in the healthcare field (p=0.000) were both significantly associated with knowledge scores. Individuals holding a master's degree or higher (45.2±24.3) and those working in the healthcare sector (53.6±25.8) had the highest knowledge scores.

In one study where they assessed knowledge of ADRs among the general public, only around third of respondents had a good knowledge of ADRs reporting.[31] In line with Wang et al findings, our study found that respondents' knowledge of ADRs and reporting was poor.[31] Moreover, PV was largely made known to participants through social media. By utilizing online sources, we can raise awareness associated with PV and ADRs, which will eventually improve public knowledge. On the other hand, social media has enabled patients and clinicians to share their experiences with medications, creating a valuable public database of information that has the potential to provide insights into medicinal product safety concerns.[32] In addition to regulatory authorities, signals identified through social media could be used by pharmaceutical manufacturers, the healthcare system, or healthcare researchers.[33]

NPC was unknown to almost 90% of participants which is comparable to the study's findings conducted in Malaysia, where most participants did not know that their country had an ADRs reporting center.[27] Despite the huge effort made by the NPC in delivering promotional campaigns to the general public,[3] this study suggests that gaps exist in which people have low awareness of NPC and further exploration is recommended. Only 16% of participants had properly understand what are ADRs. In the absence of understanding the nature of ADRs, people may not be able to recognize them, therefore not reporting them. 52% of respondents considered physicians to be the major source for reporting ADRs, which indicates that people in Saudi Arabia might not understand the pharmacist's role regarding PV. The pharmacy profession is considered patient-oriented, so it is vital for pharmacists to gain their patients' and customers' trust in order to deliver effective communication that impacts the overall outcome of patients.[34]

In our study, levels of positive attitude were high as 83.4% had an attitude score that is higher than 80%. Similarly, respondents of the general population in a study that took place in China showed a positive attitude toward ADRs reporting.[5] Age (p=0.000), residency region (p=0.034), marital status (p=0.000), amount of education (p=0.003), and working in the healthcare industry (p=0.002) all had a significant relationship with attitude score. The group aged 31 to 50 years old (91.6±17.8), participants from Al Jawf (99.5±2.8), Participants who are married and have children (92.31 ±5.9), holders of a master's degree or higher (92.3±15.9), and healthcare workers (93.2±18.1) had the best attitude scores. Another study showed that the level of education of a patient was associated with the patient's willingness to report ADR directly.[35] These findings emphasize that respondents with a higher education level would report ADRs than those with lower education levels. Also, we found that most respondents in our study recognized the importance of PV and ADRs reporting; furthermore, they agreed that ADRs should be reported to NPC. Approximately 90% of respondents agree that relevant departments should hold public activities emphasizing the importance of ADR reporting. The same result was found in another study where people believed that HCPs and awareness campaigns seem to play a key role in increasing awareness of the PV and the importance of ADRs reporting.[27] A Saudi study regarding the use of technology to increase PV awareness and gain information about ADRs concluded that people are welcoming the idea.[36]

According to our findings, 34.5% of respondents had good practice scores (>80%). Higher practice scores were seen among individuals who are married and have children (71.7±17.4) and those who work in the healthcare sector (74±18.8) (p=0.014). Almost half of the participant (52.5%) would not ask their HCPs about ADRs and 42.6% would discontinue treatment once they experience an ADR instead of reporting it, which may indicate that HCPs do not give the required attention to ADRs as one study shows that HCPS did not encourage their patients to report ADRs.[14] A recent review described the medication information relevant to patients and showed that patients particularly desired safety-related information including ADRs and drug-drug interactions.[37] HCPs should give ADR-related information to help patients establish safe medication practices and urge them to report ADRs to a health professional in a timely manner if an ADR occurs. Different measures need to be considered to improve the communication between HCPs and patients which would improve the overall health outcome such as communication skills training to health care professionals.[38] In one study, more than half of the HCPs were unaware of the existence of NPC.[22] Another study found that even with the good knowledge and positive attitude HCPs had, the majority of them had never reported ADRs before.[39] Due to under-reporting of ADRs by HCPs, direct reporting by patients to the national PV center should be encouraged.[35]

The majority of respondents in this poll responded that if there was a simple way to report ADRs, they would do so. Direct ADRs reporting to HCPs was the preferred way to report ADRs, which aligns with several studies.[4,40] Although the NCP made a free contact number to receive ADRs reports plus the availability of reporting forms on their website, most participants were not aware of their existence, which necessitates more publicity of communication means from authorities. Interestingly, over 70% of respondents agreed to report even the previously recognized ADRs, in contrast to another study in which participants believed that only major ADRs that disrupt daily life or necessitate hospitalization are worth reporting.[41] More than 60% of participants would read the patient information leaflet which aligns with the findings of a study conducted in Spain.[42] The ADRs section was most commonly read, and the information in this section was the most common specific reason given for reading the patient information leaflet according to one study.[43] More than 80% of participants feel that uncertainty about the ADRs is a barrier to whether to report ADRs or not. This is a higher percentage than a previous study where only 12.1% of respondents were uncertain about the ADRs.[44] Further development and wider availability of ADR-related information from HCPs plus reliable internet information, controlled by the authorities, could facilitate the general public in assessing suspected ADRs. Large number of respondents also claimed that the lack of proper advertising is the additional factor responsible for under-reporting ADRs. We recommend that direct patient ADRs reporting should be further promoted within the routine practice to support the existing spontaneous ADR reporting system.

Strengths and Limitations

Studies to explore the knowledge, attitude and practice regarding PV are limited in Saudi Arabia. Most studies in this regard were oriented toward HCPs rather than the general public. The strength of this study stems from the methodology as the study carefully constructed a questionnaire and developed a scoring system in order to perform inferential statistics to quantitatively investigate determinants of PV and ADRs knowledge, attitude, and practice. Also, the large number and diversity of participants improve the reliability of the results. However, the limitations of this study are that there was a higher risk of recall bias. A small sample in some regions makes generalization difficult because the participants may not represent the population of these regions.

Conclusion

This cross-sectional study was conducted among the general public and found that the majority of participants had inadequate knowledge, a positive attitude, and poor practice. Individuals holding a master's degree or higher and those working in the healthcare sector had the highest knowledge scores, whereas the group aged 31 to 50 years old, participants from Al Jawf region, participants who are married with children, holders of a master's degree or higher, and healthcare workers had the best attitude scores. Higher practice scores were seen among individuals who are married with children and those who work in the healthcare sector. We recommend future emphases on public education of pharmacovigilance and on how and when to report ADRs.

Disclosure

The authors report no conflicts of interest in this work.

References

1. Organization WH. The importance of pharmacovigilance. 2002:48p.
2. Thomas D, Klika C. Pharmacovigilance systems. In: *Clinical Pharmacy Education, Practice and Research: Clinical Pharmacy, Drug Information, Pharmacovigilance, Pharmacoeconomics and Clinical Research*. Elsevier; 2018:215–225.
3. Alshammari TM, Alshakka M, Aljadhey H. Pharmacovigilance system in Saudi Arabia. *Saudi Pharm J*. 2017;25(3):299–305. doi:10.1016/j.jsps.2016.09.008
4. Adisa R, Omitogun TI. Awareness, knowledge, attitude and practice of adverse drug reaction reporting among health workers and patients in selected primary healthcare centres in Ibadan, southwestern Nigeria. *BMC Health Serv Res*. 2019;19(1). doi:10.1186/s12913-019-4775-9
5. Chen Y, Wang Y, Wang N, et al. Knowledge, attitude, and practice regarding pharmacovigilance among the general public in Western China: a cross-sectional study. *Curr Med Res Opin*. 2021;37(1):101–108. doi:10.1080/03007995.2020.1846171

6. Sultana J, Cutroneo P, Trifirò G. Clinical and economic burden of adverse drug reactions. *J Pharmacol Pharmacother*. 2013;4(SUPPL.1). doi:10.4103/0976-500X.120957
7. Carrigan N, Raynor DK, Knapp P Adequacy of Patient Information on Adverse Effects An Assessment of Patient Information Leaflets in the UK. Vol 31.; 2008.
8. Al-Arifi M, Abu-Hashem H, Al-Meziny M, Said R, Aljadhey H. Emergency department visits and admissions due to drug related problems at Riyadh military hospital (RMH), Saudi Arabia. *Saudi Pharm J*. 2014;22(1):17–25. doi:10.1016/j.jsps.2013.01.001
9. Insani WN, Whittlesea C, Alwafi H, Man KKC, Chapman S, Wei L. Prevalence of adverse drug reactions in the primary care setting: a systematic review and meta-analysis. *PLoS One*. 2021;16(5 May). doi:10.1371/journal.pone.0252161
10. Bouvy JC, De Bruin ML, Koopmanschap MA. Epidemiology of Adverse Drug Reactions in Europe: a Review of Recent Observational Studies. *Drug Saf*. 2015;38(5):437–453. doi:10.1007/s40264-015-0281-0
11. Blendon RJ, Schoen C, DesRoches C, Osborn R, Zapert K. Common concerns amid diverse systems: health care experiences in five countries. *Health Aff*. 2003;22(3):106–121. doi:10.1377/hlthaff.22.3.106
12. Kalisch LM, Caughey GE, Roughead EE, Gilbert AL. The prescribing cascade. *Aust Prescr*. 2011;34(6):162–166. doi:10.18773/austprescr.2011.084
13. Gilbert AL, Roughead EE, Beilby J, Mott K, Barratt JD. Collaborative medication management services: improving patient care. *Med j Aust*. 2002;177(4):189–192. doi:10.5694/j.1326-5377.2002.tb04730.x
14. Sales I, Aljadhey H, Albogami Y, Mahmoud MA. Public awareness and perception toward Adverse Drug Reactions reporting in Riyadh, Saudi Arabia. *Saudi Pharm J*. 2017;25(6):868–872. doi:10.1016/j.jsps.2017.01.004
15. MdA I, Al-Karasneh AF, Naqvi AA, et al. Public Awareness about Medicine Information, Safety, and Adverse Drug Reaction (ADR) Reporting in Dammam, Saudi Arabia. *Pharmacy*. 2020;8(4):222. doi:10.3390/pharmacy8040222
16. Almubark RA, Aljadani RH, Alqahtani AS, Alshammari TM, BinDhim NF. National Cross-Sectional Study of Community-Based Adverse Drug Reactions in Saudi Arabia. *Drugs Real World*. 2020;7(2):161–170. doi:10.1007/s40801-020-00186-8
17. Barry AR, Koshman SL, Pearson GJ. Adverse drug reactions: the importance of maintaining pharmacovigilance. *Can Pharm J*. 2014;147(4):233–238. doi:10.1177/1715163514536523
18. Rabbur RSM, Emmerton L. An introduction to adverse drug reaction reporting systems in different countries. *Int J Pharm Pract*. 2010;13(1):91–100. doi:10.1211/0022357055821
19. Bracchi RC, Tseliou F, Copeland L, et al. Public awareness in Wales of the UK Yellow Card scheme for reporting suspected adverse drug reactions. *Br J Clin Pharmacol*. 2021;87(8):3344–3348. doi:10.1111/bcp.14726
20. De Langen J, Van Hunsel F, Passier A, De Jong-Van Den Berg L, Van Grootheest K. Adverse Drug Reaction Reporting by Patients in the Netherlands Three Years of Experience. 2008;31.
21. Ali MD, Ahmad A, Hassan YAM, Ghosn SA, Banu N, Alzahrani MG. Community Pharmacist's Knowledge, Practice and Barrier towards Reporting of Adverse Drug Reactions in Dammam, Saudi Arabia: a Cross-Sectional Survey Based Study. *J Young Pharm*. 2020;12(1):81–85. doi:10.5530/jyp.2020.12.16
22. AlShammari TM, Almoslem MJ. Knowledge, attitudes & practices of healthcare professionals in hospitals towards the reporting of adverse drug reactions in Saudi Arabia: a multi-centre cross sectional study. *Saudi Pharm J*. 2018;26(7):925–931. doi:10.1016/j.jsps.2018.04.012
23. Ali S, Egunsola O, Al-Dossari DS, Al-Zaagi IA. Adverse drug reaction reporting in a large tertiary hospital in Saudi Arabia: results of an incentive strategy. *Ther Adv Drug Saf*. 2018;9(10):585–590. doi:10.1177/2042098618790209
24. Van Hunsel F, Talsma A, Van Puijenbroek E, De Jong-Van Den Berg L, Van Grootheest K. The proportion of patient reports of suspected ADRs to signal detection in the Netherlands: case-control study. *Pharmacoepidemiol Drug Saf*. 2011;20(3):286–291. doi:10.1002/pds.2092
25. Alharf A, Alqahtani N, Saeed G, et al. Saudi Vigilance Program: challenges and lessons learned. *Saudi Pharm J*. 2018;26(3):388–395. doi:10.1016/j.jsps.2018.01.002
26. Al dweik R, Stacey D, Kohen D, Yaya S. Factors affecting patient reporting of adverse drug reactions: a systematic review. *Br J Clin Pharmacol*. 2017;83(4):875–883. doi:10.1111/bcp.13159
27. Mohammad A, Bheemavarapu H, Khan MU, et al. A cross-sectional survey to assess the knowledge, attitudes and common barriers to the reporting of adverse drug reactions by the general public in Malaysia. *J Pharm Pract Res*. 2018;48(4):348–355. doi:10.1002/jppr.1412
28. Patsuree A, Krska J, Jarernsiripornkul N. Experiences relating to adverse drug reactions in the community: a cross-sectional survey among patients and the general public in Thailand. *Expert Opin Drug Saf*. 2016;15(3):287–295. doi:10.1517/14740338.2016.1135127
29. Reumerman M, Tichelaar J, Piersma B, Richir MC, van Agtmael MA. Urgent need to modernize pharmacovigilance education in healthcare curricula: review of the literature. *Eur J Clin Pharmacol*. 2018;74(10):1235–1248. doi:10.1007/s00228-018-2500-y
30. Alshayban D, Mahmoud MA, Islam MA, Alshammari S, Alsulaiman D. Pharmacovigilance perception and knowledge among pharmacists and interns in Saudi Arabia. *Risk Manag Healthc Policy*. 2020;13:55–61. doi:10.2147/RMHP.S241265
31. Wang N, Chen Y, Ren B, et al. A cross-sectional study: comparison of public perceptions of adverse drug reaction reporting and monitoring in eastern and western China. *BMC Health Serv Res*. 2022;22(1). doi:10.1186/s12913-022-07720-0
32. van Stekelenborg J, Ellenius J, Maskell S, et al. Recommendations for the Use of Social Media in Pharmacovigilance: lessons from IMI WEB-RADR. *Drug Saf*. 2019;42(12):1393–1407. doi:10.1007/s40264-019-00858-7
33. Sarker A, Ginn R, Nikfarjam A, et al. Utilizing social media data for pharmacovigilance: a review. *J Biomed Inform*. 2015;54:202–212. doi:10.1016/j.jbi.2015.02.004
34. LoCurto J, Berg GM. Trust in healthcare settings: scale development, methods, and preliminary determinants. *SAGE Open Med*. 2016;4:205031211666422. doi:10.1177/2050312116664224
35. Hariraj V, Aziz Z. Patient Reporting of Adverse Drug Reactions (ADRs): survey of Public Awareness and Predictors of Confidence to Report. *Ther Innov Regul Sci*. 2018;52(6):757–763. doi:10.1177/2168479017745025
36. Kassem LM, Alhabib B, Alzunaydi K, Farooqui M. Understanding patient needs regarding adverse drug reaction reporting smartphone applications: a qualitative insight from Saudi Arabia. *Int J Environ Res Public Health*. 2021;18(8). doi:10.3390/ijerph18083862
37. Kusch MKP, Haefeli WE, Seidling HM. How to meet patients' individual needs for drug information-A scoping review. *Patient Prefer Adherence*. 2018;12:2339–2355. doi:10.2147/PPA.S173651

38. Rosenstein AH. Emotional Intelligence: a Critical Tool to Understand and Improve Behaviors That Impact Patient Care. *Journal of Psy Clinical Psyc*. 2015;2(2). doi:10.15406/jpcpy.2015.02.00066
39. Alsaleh FM, Alzaid SW, Abahussain EA, Bayoud T, Lemay J. Knowledge, attitude and practices of pharmacovigilance and adverse drug reaction reporting among pharmacists working in secondary and tertiary governmental hospitals in Kuwait. *Saudi Pharm J*. 2017;25(6):830–837. doi:10.1016/j.jsps.2016.12.004
40. Jha N, Rathore DS, Ravi Shankar P, Gyawali S. Pharmacovigilance knowledge among patients at a teaching hospital in Lalitpur district, Nepal. *J Clin Diagn Res*. 2014;8(3):32–34. doi:10.7860/JCDR/2014/7378.4097
41. Krska J, Jones L, Mckinney J, Wilson C. Medicine safety: experiences and perceptions of the general public in Liverpool. *Pharmacoepidemiol Drug Saf*. 2011;20(10):1098–1103. doi:10.1002/pds.2178
42. Salgueiro E, Gurruchaga C, Jimeno FJ, Martínez-Múgica C, Martín Arias LH, Manso G. What can we learn from the public's understanding of drug information and safety? A population survey. *Int J Pharm Pract*. 2019;27(1):96–104. doi:10.1111/ijpp.12458
43. Raynor DK, Silcock J, Knapp P, Edmondson H. How do patients use medicine information leaflets in the UK? *Int J Pharm Pract*. 2010;15(3):209–218. doi:10.1211/ijpp.15.3.0008
44. Narumol J, Arunrot P, Krska J. Survey of patients' experiences and their certainty of suspected adverse drug reactions. *Int J Clin Pharm*. 2015;37(1):168–174. doi:10.1007/s11096-014-0060-5