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Original article

Healthcare professionals' awareness, attitudes and practices towards pharmacovigilance and spontaneous adverse drug reaction reporting in Jazan Province, Saudi Arabia: A survey study

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ABSTRACT

Background: Globally, adverse drug reactions (ADRs) are the foremost cause of morbidity as well as mortality. This necessitates a system of surveillance that can effectively and efficiently monitor the effect of drugs on the general population. The role of pharmacovigilance (PV) is paramount in ensuring drug safety through spontaneous ADR reporting.

Methods: Data collection in the current research was carried out by an anonymous, online 36-item self-report questionnaire amongst a sample of 351 working healthcare professionals (HCPs) across different regions of Jazan Province, Kingdom of Saudi Arabia (KSA). The current sample comprised 54.4% males and 45.6% females, having an age range of 26–57 years, and was conducted between August 21 and October 21, 2022. Participants were recruited using the convenience snowball sampling technique.

Results: The participants' awareness of PV as well as spontaneous ADR reporting, had a significant association with having <40 years of age (χ^2 = 27.40; $p < 0.001$), being pharmacists (χ^2 = 212.20; $p < 0.001$), with more than five years of experience (χ^2 = 40.80; $p < 0.001$), having Masters (or) Doctorate/Fellowship (χ^2 = 171.94; $p < 0.001$), and having their practice located in an urban area (χ^2 = 50.30; $p < 0.001$). It was also observed that most participants with excellent awareness of PV and spontaneous ADR reporting also demonstrated excellent attitudes (χ^2 = 147.70; $p < 0.001$). Similarly, it was also seen that almost all (97%) of the study sample with excellent attitudes towards PV and spontaneous ADR reporting also demonstrated excellent practices (χ^2 = 250.73; $p < 0.001$).

Conclusion: Our results demonstrate a need for designing and conducting educational programs, providing training and conducting workshops for all the HCPs to improve their awareness towards PV and spontaneous ADR reporting while also highlighting the need and importance of having positive attitudes towards spontaneous ADR reporting. Cooperation between different HCPs should be encouraged to improve their practices towards spontaneous ADR reporting.

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1. Introduction

The role of pharmacovigilance (PV) is paramount in ensuring drug safety through spontaneous adverse drug reaction (ADR) reporting (Kumar, 2017). World Health Organization (WHO) defined pharmacovigilance (PV) as the "*science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems*" (WHO, 2002a; 2002b; 2002c). United Kingdom led the way in 1964 by initiating voluntary ADR reporting (van Grootheest et al., 2004). Veeren & Weiss in their study reported a 53% rise in ADR-related emergency admissions between 2012 and 2017 (Veeren & Weiss, 2017). A review of European observational studies reported that 3.5% of ADRs resulted in hospitalization, whereas 10% of ADRs during hospitalization led to extended hospital stays (Bouvy et al., 2015). The rate of ADR-associated hospitalizations in public hospitals in New Zealand was reported to be around 13%. However, a lower incidence rate (3.5%) of ADR-related hospitalizations was reported in a French study (Bénard-Laribière et al., 2015).

A prospective cohort study conducted in Riyadh, Kingdom of Saudi Arabia (KSA), reported a rate of 6.1 ADRs for every 100 hospital admissions (Aljadhey et al., 2016). Globally, the foremost cause of morbidity as well as mortality is the ADR occurrence (Pirmohamed et al., 2004; Silva et al., 2021). This necessitates a system of surveillance that can effectively and efficiently monitor the impact of drugs on the general population (Bouvy et al., 2015). The healthcare professionals (HCPs) play a crucial role in the spontaneous reporting of ADRs (Campbell et al., 2014), which not only reduces the economic burden but also improves the quality of life of the patients (van Grootheest et al., 2005; Güner & Ekmekci, 2019). For this purpose, the United States started the FDA Adverse Event Reporting System (FAERS) in 1998 (Sonawane & Hansen, 2015). Regulatory authorities worldwide have established spontaneous ADR reporting systems that mandate the HCPs and encourage patients to record and report any ADR occurrence (Aagaard et al., 2012).

In KSA, developing a rigorous and robust spontaneous ADR reporting system was imperative. Therefore, the National Pharmacovigilance Centre and Drug Safety Center (Saudi Vigilance) was established by the Saudi Food and Drug Authority (SFDA) in the year 2009 (Alharf et al., 2018). Additionally, in 2009 SFDA became a member of the Uppsala Monitoring Centre in Sweden to contribute to global drug safety efforts (Aljadhey et al., 2015). In order to promote and achieve effective national ADR reporting, the Saudi Pharmacovigilance Guidelines relating to Good Pharmacovigilance Practices (GVP) were put forth by the SFDA in 2015, which illustrate the different roles as well as responsibilities of all stakeholders, including the HCPs (Bin Yousef et al., 2022).

The pharmacovigilance system depends on the effective reporting of the ADRs by the HCPs and the public. Moreover, it is also affected by the level of communication between them and the pharmacovigilance centers (Almandil, 2016). Worldwide, underreporting of ADRs has been the foremost challenge encountered by the pharmacovigilance systems (Alharf et al., 2018; Lopez-Gonzalez et al., 2009; Suyagh et al., 2015). A study from the Arab world indicated that the contribution of ten countries from the Middle East, including Saudi Arabia, was only a meager 0.6% to WHO's global database (Vigibase) (AlShammari et al., 2019; Bham, 2015). Despite persistent efforts by SFDA, there have been concerns regarding ADRs needing to be reported more frequently, mainly owing to the paucity of knowledge as well as training related to pharmacovigilance (Ahmad, 2014; AlShammari et al., 2017; Ibrahim et al., 2021).

A multicenter centre study from the Makkah region in Saudi Arabia reported positive attitudes as well as awareness of HCPs towards the identification of ADRs and the pharmacovigilance. However, the HCPs associated the under-reporting issue with inadequate training and fear of reporting (Al-Hazmi & Naylor, 2013). Another Saudi study conducted among physicians in Riyadh indicated that most physicians were unsatisfied with their pharmacovigilance training (Al-Arifi et al., 2015). Moreover, studies evaluating the Saudi community and hospital pharmacists' awareness of the spontaneous ADR reporting systems did not yield positive findings (Khan & Azhar, 2013; Mahmoud et al., 2014). The HCPs are at the focal point where they handle medications and advise patients regarding their safe and effective usage. For this reason, the HCPs' awareness of spontaneous ADR reporting is imperative for an effective pharmacovigilance system.

An influential role is played by the clinical pharmacists in PV as well as in ADR reporting (Mostafa et al., 2020). The clinical pharmacists' role in the detection, reporting and prevention of medication errors (MEs) was studied by Fawaz et al. who conducted a study in a pediatric surgery department in Cairo, Egypt and reported that clinical pharmacists in a pre-operative setting could play a significant role in markedly reducing MEs. They also recommended that having a clinical pharmacy department in surgery departments is imperative for promoting patient safety (Fawaz et al., 2017).

No previous research has evaluated the awareness, attitudes and practices of PV and spontaneous ADR reporting among all HCPs of Jazan Province. Jazan is a habitat for a variety of medicinal flora owing to an increased rate of herbal as well as complementary medicine use (Abdelmola et al., 2021), a pivotal role can be played by the HCPs in the detection as well as in the spontaneous reporting of the ADRs related to these medicinal products in addition to other prescription medications. Therefore, we aimed to study the HCPs' awareness, attitudes and practices towards pharmacovigilance and spontaneous ADR reporting in Jazan Province, KSA.

2. Methods

2.1. Study design and study population

For data collection an anonymous, web-based cross-sectional survey was carried out amongst a sample of 351 working HCPs across different regions of Jazan Province.

2.2. Inclusion and exclusion criteria

Study participants for being included necessitated (i) working as an HCP (licensed physicians, pharmacists, nurses) as well as pharmacy technicians working in government (or) private institutions, (ii) being 26 years of age (or) above, (iii) understanding Arabic (or) English language (iv) providing informed consent (v) answering the complete survey. Participants failing to meet the inclusion criteria were excluded.

2.3. Data collection tools

Data collection in the current research was carried out by a 36-item self-administered survey (*see Appendix 1*). The questionnaire was validated by face as well as content validation (Ahsan et al., 2021; Elnaem et al., 2021). The self-report questionnaire consisted of four sections. Section one comprised eight questions regarding respondents' sample characteristics/socio-demographics. Section two consisted of 12 questions assessing the respondents' awareness towards PV and spontaneous ADR reporting. Section three comprised eight questions assessing the respondents' attitudes regarding PV and spontaneous ADR reporting. The last section consisted of eight questions assessing the respondents'

practices regarding PV and spontaneous ADR reporting. After careful, methodical deliberation and review of available similar literature (Alshabi et al., 2022; AlShammari & Almoslem, 2018; Almandil, 2016; Alsaleh et al., 2017; Gupta et al., 2015; Lemay et al., 2018; Tadvi et al., 2018) the survey instrument was prepared. Based on these deliberations, the study authors approved the final version of the questionnaire consisting of 36-items.

2.4. Measures

2.4.1. Demographics

Participants recorded their nationality, sex, age group (in years), exact age, job profile, educational qualification, experience, and current practice location as explanatory variables.

2.4.2. Awareness, attitudes and practices

Current research participants also responded to questions evaluating their PV and spontaneous ADR reporting-related awareness, where the questions had responses from 0 (no) to 1 (yes). Additionally, the study participants responded to questions evaluating their PV and spontaneous ADR reporting-related attitudes. The responses to these questions were rated on a four-point Likert scale, ranging from 1 *(strongly disagree)* to 4 (*strongly agree*). While in the last section, the participants also responded to questions evaluating their PV and spontaneous ADR reporting-related practices, and the items had responses from 0 (no) to 1 (yes).

2.5. Validation, translation and piloting of the survey instrument

Forward-backward translation was employed to translate the English version of the questionnaire to Arabic, by an independent professional translator. The Arabic version was later reviewed by a study author (native speaker). Inconsistencies, if found, were subsequently discussed and resolved with the help of the independent translator and the final draft prepared. Another study author who was unaware of the original English version, back-translated the Arabic version into English. All the study authors thoroughly reviewed both the versions (Syed et al., 2020; Syed et al., 2022). Focus group that consisted of 10% of the total estimated sample size (Hertzog, 2008) was used for piloting the approved final version of the survey as well as for assessing the completion time and the ease of using the questionnaire. The pilot sample understood all the questionnaire items relatively easily and completed the survey in around eight minutes. The final study also observed a comparable completion time of around eight minutes. Face and content validation was used for validating the study questionnaire (Elnaem et al., 2021). The internal consistency and reliability of the developed instrument was evaluated by the pilot sample, which was excluded from subsequent analyses.

2.6. Data collection

The self-administered questionnaire was prepared and hosted on *Google Forms*. The invitation to partake in the current research was distributed on social media (Twitter, WhatsApp, and Facebook) on various HCP-related groups covering Jazan Province, KSA. Data was collected between August 21 and October 21, 2022. Sharing the invitation link amongst the professional contacts of the participants was hugely encouraged. Regular reminders for completing the survey were also sent.

2.7. Scoring of the questionnaire

The study questionnaire consisted of three sub-sections covering three domains (i.e. awareness, attitude as well as practices). By adding the score of individual items, a total score for each sub-section was calculated. After a comprehensive review of relevant literature, Bloom's cut-off point was determined to be used (Bloom et al., 1956). Scores below 60% of the total score were considered as poor; while scores ranging from 60 to 80% were deemed moderate, and scores exceeding 80% of the total score were considered excellent. (Bloom et al., 1956; Assiry et al., 2022).

2.8. Sample size

Sample size of the current research was estimated by Raosoft sample size calculator. With a margin of error of 5%, a confidence interval of 95%, an approximate population size of nearly 2000, and a response distribution of 50%, a sample size of 323 was estimated (Raosoft, 2022).

2.9. Ethical considerations

The Standing Committee for Scientific Research at Jazan University, KSA, provided the relevant ethical approval before the start of the study. (HAPO-10-Z-001) (Approval Reference Number: REC42/1/142). Before starting the survey, all the participants provided their informed consent.

2.10. Data analysis

Data analysis was carried out by Statistical Package for the Social Science (SPSS Inc., Chicago, IL., USA) statistical software (version 23). After completing the survey, the *Google Forms* data were exported into Microsoft Excel sheet, coded and transferred to an SPSS file. Sample characteristics were expressed as frequencies, total percentages, mean, and standard deviation. Significant associations across different study variables were evaluated by Pearson's Chi-square test and Fisher's exact test assessed significant associations across variables having a count below five. Significant associations across continuous variables were evaluated by Pearson's correlation coefficient. $p<0.05$ was deemed statistically significant.

3. Results

The study questionnaire was accessed by 460 HCPs, out of which only 351 provided their consent and completed the survey.

Table 1
Socio-demographics / sample characteristics (n = 351).

Variable	*Options*	*Frequency (n)*	*%*
Sex	Male	191	54.4
	Female	160	45.6
Nationality	Saudi	183	52.1
	Non-Saudi	168	47.9
Age Group*(In Years)*	< 30	164	46.7
	31–40	157	44.7
	41–50	22	6.3
	> 50	8	2.3
Exact Age	34.29 (SD ± 7.91)		
Job Profile	Pharmacists	125	35.6
	Physician	115	32.8
	Nurses	90	25.6
	Pharmacy technicians	21	6.0
Educational Qualification	Diploma	24	6.8
	Bachelors	222	63.2
	Masters	72	20.5
	Doctorate / Fellowship	33	9.4
Experience (*In Years)*	< 5	113	32.2
	5–10	202	57.5
	> 10	36	10.3
Location of Current Practice	Rural	187	53.3
	Urban	165	46.7

Based on the sample that accessed the survey, provided their consent, and completed the survey, the response rate was determined as 76.3% (i.e. 351/460).

3.1. Participants' socio-demographics

Table 1 elucidates the socio-demographics of the current sample. Over half of the participants were male (n = 191; 54.4%). A similarly high percentage was also seen for participants' nationality, where more than half of the sample were Saudi (n = 183; 52.1%). The best part of the sample studied was under 40 years of age (n = 321; 91.4%). Participants mean age was 34.29 (SD ± 7.91). Pharmacists contributed the highest percentage of participants (n = 125; 35.6%). Regarding educational qualification, a large proportion of the current sample (n = 222; 63.2%) had a bachelor's degree. Likewise, many participants (n = 202; 57.5%) had 5–10 years of experience. Regarding the location of current practice, it was noticed that just over half (n = 187; 53.3%) of the sample had their practices located in rural areas.

3.2. Reliability analysis

Reliability as well as internal consistency of the developed instrument were tested on the pilot study's sample. Internal consistency of the developed instrument was assessed by Cronbach's alpha. The alpha coefficients of all the sections of the developed instrument were above the required value of 0.70 (*see* Table 2), indicating excellent reliability (Merghani Ali et al., 2022). Data from the pilot study was subsequently excluded from all further analyses (See Table 2).

3.3. Definition and purpose of PV

It was noted that almost the entire current sample (n = 336; 95.7%) knew the correct definition of PV, while around two-thirds of participants (n = 244; 69.5%) knew the correct purpose of PV (Table 3).

3.4. Participants' awareness regarding PV and Spontaneous ADR reporting

With regards to the existence of a national PV program (86.9%), the existence of national PV and Drug Safety Center (Saudi Vigilance) KSA (88.1%), the existence International Drug Monitoring Center of Uppsala, Sweden (71.7%), the presence of PV system at their respective hospitals (81.5%), and of SFDA-ADRs for Health Professional forms (72.4%), majority of participants were aware of their existence. Over three-quarters, (76.9%) of the sample were unaware that "Naranjo" scales were used to establish an ADR's causality. A similarly high percentage (69.5%) was unaware of 'VigiBase', the unique WHO global database comprising medicinal products-related side effects (Table 3).

Table 2
Internal consistency of the questionnaire.

Section	*No of items*	*Cronbach's Alpha*
Participants' awareness regarding PV and spontaneous ADR reporting	12	0.72
Participants attitudes regarding PV and spontaneous ADR reporting	8	0.88
Participants practices regarding PV and spontaneous ADR reporting	9	0.73

Table 3
Descriptives of participants' awareness regarding PV and Spontaneous ADR reporting.

Definition of PV	**Correct Answer**	**Incorrect Answer**
The detection, assessment, understanding and prevention of adverse effects.	95.7	4.3
Purpose of PV	**Correct Answer**	**Incorrect Answer**
To improve public health and safety in relation to the use of medicines.	69.5	31.5
Are you aware:	**Yes%**	**No%**
1. Of the existence of a National Pharmacovigilance Programme in KSA?	86.3	13.7
2. Of the existence of the Drug Safety and National Pharmacovigilance Center (Saudi Vigilance) of SFDA?	88.3	11.7
3. That the International Drug Monitoring Centre is located in Uppsala, Sweden?	71.8	28.2
4. That "Naranjo" scale is used for establishing causality of an ADR?	23.1	76.9
5. Of the existence of the Pharmacovigilance system at your hospitals?	81.5	18.5
6. Of the existence of SFDA-ADRs for Health Professional form?	72.4	27.6
7. Of the existence of the spontaneous ADR reporting system at your practice site?	63.8	36.2
8. Of 'WHO's VigiBase' - Global database of reported potential side effects of medicinal products?	30.5	69.5
9. Of the 'MedWatch' forms for the spontaneous reporting of the ADRs?	34.4	65.6
10. Of the 'Yellow Card Scheme' for the spontaneous reporting of the ADRs?	38.7	61.3

3.5. Participants' attitudes regarding PV and Spontaneous ADR reporting

Table 4 illustrates attitudes of participants regarding PV and spontaneous ADR reporting. For the statement *'Pharmacovigilance is very important for promoting drug safety'*, 95.2% showed a positive attitude by strongly agreeing (36.5%) (or) agreeing (58.7%). With regards to the statement *'As HCPs, spontaneous reporting of ADRs is part of my professional obligations'*, showed negative attitude by strongly disagreeing (20.8%) (or) disagreeing (40.2%). For a negative statement, *'Spontaneous recording and reporting ADRs is solely the responsibility of the Physicians'*, participants strongly agreed (23.4%) (or) agreed (47.6%), thus showing a negative attitude.

3.6. Participants' practices related to PV and Spontaneous ADR reporting

Table 5 depicts practices of participants with regards to PV and spontaneous ADR reporting. For the statements *'Have you ever seen an SFDA-Spontaneous ADR reporting form?', 'Have you ever reported an ADR?', and 'Have you ever used an SFDA-Spontaneous ADR reporting form or the SFDA website for reporting ADRs?'*, more than half of participants (60.4%, 63.5% and 57.3%) responded 'No' respectively, exhibiting poor practices.

3.7. Association between socio-demographics and awareness of participants

Table 6 elucidates the association between socio-demographic characteristics of the participants and their awareness. The respondents' awareness of PV and Spontaneous ADR reporting was significantly associated with having<40 years of age (χ^2 = 27.40; $p < 0.001$), being pharmacists (χ^2 = 212.20; $p < 0.001$), with more than five years of experience (χ^2 = 40.80; $p < 0.001$), having Masters (or) Doctorate/Fellowship (χ^2 = 171.94; $p < 0.001$), and having

Table 4
Descriptives of participants' attitudes regarding PV and Spontaneous ADR reporting.

	Strongly Disagree	Disagree	Agree	Strongly Agree
A1: Pharmacovigilance is very important for promoting Drug Safety.	–	17 (4.8)	206 (58.7)	128 (36.5)
A2: Spontaneous ADR reporting is necessary as it contributes to Drug Safety.	98 (27.9)	89 (25.4)	124 (35.3)	40 (11.4)
A3: As HCPs, spontaneous ADR reporting is part of my professional obligations.	73 (20.8)	141 (40.2)	92 (26.2)	45 (12.8)
A4*: Spontaneous recording and reporting of the ADRs is solely the responsibility of the Physicians.	64 (18.2)	38 (10.8)	167 (47.6)	82 (23.4)
A5: Close collaboration between the different HCPs improves drug safety.	85 (24.2)	109 (31.1)	107 (30.5)	50 (14.2)
A6: Receiving training and attending workshops related to PV and spontaneous ADR reporting is essential for all HCPs.	93 (26.5)	101 (28.8)	123 (35.0)	34 (9.7)
A7: Receiving training and attending workshops related to PV and Spontaneous ADR reporting should be made mandatory for all HCPs.	87 (24.8)	116 (33.0)	100 (28.5)	48 (13.7)
A8: Spontaneous ADR reporting should be made mandatory.	187 (53.3)	52 (14.8)	70 (19.9)	42 (12.0)

A4*: Reverse coded.

Table 5
Descriptives of participants' practices towards PV and Spontaneous ADR reporting.

	Yes	No
P1: Have you ever seen an ADR?	296 (84.3)	55 (15.7)
P2: Have you ever spontaneously reported an ADR as soon as it was observed?	128 (36.5)	223 (63.5)
P3: Have you ever used an SFDA-Spontaneous ADR reporting form or the SFDA website for reporting ADRs?	150 (42.7)	201(57.3)
P4: Have you ever received any training in filling spontaneous ADR reporting forms?	205 (58.4)	146 (41.6)
P5: Have you ever attended any workshops or lectures regarding PV and Spontaneous ADR reporting?	146 (41.6)	205 (58.4)
P6: Do you provide patient counseling about potential ADRs?	199 (56.7)	152 (43.3)
P7: Do you find it difficult to spontaneously report ADRs?	193 (55)	158 (45)

their practice located in an urban area (χ^2 = 50.30; $p < 0.001$). Participants' awareness of PV and Spontaneous ADR reporting had no significant association with their gender and nationality.

3.8. Association between participants' awareness and attitude regarding PV and spontaneous ADR reporting

Table 7 illustrates the crosstabulation results between different categories of awareness of PV and Spontaneous ADR reporting and their attitude towards the same. Most participants with excellent awareness of PV and Spontaneous ADR reporting also demonstrated excellent attitudes towards PV and Spontaneous ADR reporting (n = 74; 89.2%). Similarly, the sample with poor/moderate awareness (n = 181; 83.8%) also showed poor attitude (χ^2 = 147.70; $p < 0.001$).

3.9. Association between participants' attitude regarding PV and spontaneous ADR reporting and practices

Table 8 depicts the crosstabulation results between participants' attitude regarding PV and Spontaneous ADR reporting and their corresponding practices. It was seen that almost all (n = 64; 97%) of the study sample with excellent attitudes towards PV and Spontaneous ADR reporting also demonstrated excellent practices. Similarly, a very high proportion of the sample (n = 189; 78.4%) with poor attitudes regarding PV and ADR also reported poor practices (χ^2 = 250.73; $p < 0.001$).

3.10. Correlation between participants' awareness, attitude and practice scores

Correlation between scores of different sections was evaluated using Pearson's correlation coefficient *'r'*. Positive significant correlations were seen across participants' awareness score and attitude score (r = 0.46; *p < 0.01),* their awareness score and practice score (r = 0.43; *p < 0.01),* as well as their attitude score and practice score (r = 0.64; *p < 0.01)* (Table 9).

4. Discussion

The current research assessed the HCP's awareness, attitude and practices towards PV and Spontaneous ADR reporting. Our results show that almost all participants (95.7%) were aware of the correct definition of PV, demonstrating excellent awareness. These findings starkly contrast with Alshabi et al. (2022), who used the exact definition as our study and reported that less than half (42%) of their sample was aware of the correct definition of PV. Our findings also differ from Faqihi & Fageehi (2019), who observed less than half (40%) of their sample to be aware of the correct definition of PV. More than half (69.5%) of the current sample were aware of the correct purpose of PV and Spontaneous ADR reporting. These findings are consistent with Alsaleh et al. (74.8%), Alshabi et al. (71%), and Gupta et al. (66.3%), who also reported a relatively similar percentage of their sample be aware of the correct purpose of PV, thus demonstrating good awareness towards the purpose of PV (Alsaleh et al., 2017; Alshabi et al., 2022; Gupta et al., 2015).

Most (86.3%) of the current sample were aware of the national pharmacovigilance system. Contrasting findings to our study were reported by Abdel-Latif & Abdul-Wahab (2014), who reported that only 39.6% of the sample was aware of the national pharmacovigilance system. It was also noticed that 86.3% of the current sample was mindful of the national pharmacovigilance center (NPC) presence. A study conducted in 2018 among HCPs working in different hospitals in Saudi Arabia reported nearly two-thirds (67%) of their sample to be oblivious to the presence of NPC in Saudi Arabia (AlShammari & Almoslem, 2018).

Additionally, more than half (63.8%) of the present study sample were aware of the pharmacovigilance system at their practice sites. These observations are similar to that of AlShammari & Almoslem (2018), who also reported that a similar percentage of their sample (73%) were mindful of the pharmacovigilance system at their hospitals. Regarding the Naranjo ADR probability scale, it was observed that over half of the participants (61.3%) of the present study were aware that it is used to assess causality for all ADRs. Kahkashan et al. also reported that just half (51.3%) of their

Table 6
Association between socio-demographics and awareness.

Variables	*Awareness*			*Total n (%)*	*(Chi-square) χ^2*	*p-value*
	Poor	*Moderate*	*Excellent*			
Sex						
Male	80 (56.7%)	47 (52.8%)	64 (52.9%)	191 (54.4%)	0.51	*p = 0.77*
Female	61 (43.3%)	42 (47.2%)	57 (47.1%)	160 (45.6%)		
Nationality						
Saudi	81 (57.4%)	43 (48.3%)	59 (48.8%)	183 (52.1%)	2.67	*p = 0.26*
Non – Saudi	60 (42.6%)	46 (51.7%)	62 (51.2%)	168 (47.9%)		
Age Group (In Years)						
< 30 Years	18 (40.0%)	28 (30.1%)	118 (55.4%)	164 (46.7%)	27.40	*p* < 0.001
31 – 40 Years	19 (42.2%)	60 (64.5%)	78 (36.6%)	157 (44.7%)		
41 – 50 Years	5 (11.1%)	3 (3.2%)	14 (6.6%)	22 (6.3%)		
> 50 Years	3 (6.7%)	2 (2.2%)	3 (1.4%)	8 (2.3%)		
Job Profile						
Pharmacists	1 (2.2%)	5 (5.4%)	119 (55.9%)	125 (35.6%)	212.20	*p* < 0.001
Physician	17 (37.8%)	28 (30.1%)	70 (32.9%)	115 (32.8%)		
Nurse	7 (15.6%)	59 (63.4%)	24 (11.3%)	90 (25.6%)		
Pharmacy Technician	20 (44.4%)	1 (1.1%)	0 (0.0%)	21 (6.0%)		
Experience (In years)						
< 5	22 (48.9%)	17 (18.3%)	74 (34.7%)	113 (32.2%	40.80	*p* < 0.001
5 – 10	22 (48.9%)	75 (80.6%)	105 (49.3%)	202 (57.5%)		
> 10	1 (2.2%)	1 (1.1%)	34 (16.0%)	36 (10.3%)		
Educational Qualification						
Diploma	20 (14.2%)	1 (1.1%)	3 (2.5%)	24 (6.8%)	171.94	*p* < 0.001
Bachelors	114 (80.9%)	76 (85.4%)	32 (26.4%)	222 (63.2%)		
Masters	7 (5.0%)	12 (13.5%)	53 (43.8%)	72 (20.5%)		
Doctorate/Fellowship	0 (0.0%)	0 (0.0%)	33 (27.3%)	33 (9.4%)		
Location						
Rural	35 (77.8%)	71 (76.3%)	81 (38.0%)	187 (53.3%)	50.63	*p* < 0.001
Urban	10 (22.2%)	22 (23.7%)	132 (62.0%)	164 (46.7%)		

Table 7
Association between awareness and attitude.

	Attitude			*Total n (%)*	*(Chi-square) χ^2*	*p-value*
	Poor	*Moderate*	*Excellent*			
Poor Awareness	108 (50.0%)	29 (55.8%)	4 (4.8%)	141 (40.2%)	147.70	*p* < 0.001
Moderate Awareness	73 (33.8%)	11 (21.2%)	5 (6.0%)	89 (25.4%)		
Excellent Awareness	35 (16.2%)	12 (23.1%)	74 (89.2%)	121 (34.5%)		

Table 8
Association between attitudes and practices.

	Practice			*Total n (%)*	*(Chi-square) χ^2*	*p-value*
	Poor	Fair	Good			
Poor Attitude	189 (78.4%)	25 (56.8%)	2 (3.0%)	216 (61.5%)	250.73	*p* < 0.001
Moderate Attitude	43 (17.8%)	9 (20.5%)	0 (0.0%)	52 (14.8%)		
Excellent Attitude	9 (3.7%)	10 (22.7%)	64 (97.0%)	83 (23.6%)		

Table 9
Correlation between different scores.

	Pearson's Correlation Coefficient' r'	*p-value*
Participants' Awareness Score vs Attitude Score	0.46	*p < 0.01*
Participants' Awareness Score vs Practice Score	0.43	*p < 0.01*
Participants' Attitude Score vs Practice Score	0.64	*p < 0.01*

sample were aware of using the Naranjo scale (Kahkashan et al., 2020). 72.4% of the present study's sample was aware of the SFDA-Spontaneous ADR reporting forms. These findings differ from those reported by Kassem et al. who reported that 60% of their sample was unaware of SFDA-Spontaneous ADR reporting forms (Kassem et al., 2021).

Only 30.5% of the current sample was aware of 'Vigibase'(A unique WHO global database containing reported potential side effects of medicinal products). It was reported by Ahmad (2014) that KSA, along with ten other Middle-Eastern countries, contributed only a meager 0.6% to the WHO's Vigibase, thus indicating the under-reporting of ADRs. Lack of awareness of Vigibase among HCPs could contribute to this under-reporting of ADRs. Similar results were shown for awareness towards 'MedWatch' forms (34.4%) and 'Yellow card scheme' (38.7%), where only a small percentage of the study participants were aware of its use. As 'MedWatch' and 'Yellow card scheme' are not commonly used in Saudi Arabia, this could be one of the probable reasons for the current sample to demonstrate poor awareness towards them.

Regarding the participants' attitudes towards PV and Spontaneous ADR reporting, 95.2% of the current sample agreed / strongly agreed that PV is essential for promoting drug safety, thus exhibiting a positive attitude. Similar results were also shown by Alshabi

et al., who reported that 97% of their sample agreed that reporting ADRs is necessary and would promote drug safety (Alshabi et al., 2022). A study among medical students and HCPs of Majmaah, KSA also reported their entire sample to have acknowledged the necessity of reporting ADRs (Tadvi et al., 2018). Only 39% of the current sample agreed / strongly agreed that reporting ADRs was part of their professional obligation, exhibiting a poor attitude. Contrasting findings were reported by Almandil et al. (2016), wherein majority (75.9%) of the HCPs were of the opinion that spontaneous ADR reporting was their professional obligation.

For a negative statement like "Recording and reporting ADRs is the sole responsibility of the physicians", 71% of the current sample agreed / strongly agreed, thus showing a poor attitude. Our findings differ from Moinuddin et al. (2018), who stated that 70% of their sample agreed that reporting ADRs is the responsibility of all the HCPs, not just physicians alone. It was also reported in the present study that well over half of the participants (68.1%) disagreed / strongly disagreed with the statement that "Reporting of ADRs should be made mandatory", thus showing a poor attitude. AlShammari & Almoslem (2018) reported dissimilar findings to the present study, wherein 58% of their sample agreed that spontaneous ADR reporting should be mandatory.

Regarding participants' practices towards PV and Spontaneous ADR reporting, it was noticed in the present study that for the statement 'Have you ever spontaneously reported an ADR as soon as it was observed?', more than half of the sample (63.5%) replied no, thus showing poor practices towards Spontaneous ADR reporting. Almandil et al. (2016) also reported a high percentage, wherein (88.8%) of the participants had not identified and reported an ADR. Just over half of our respondents (55%) found it difficult to spontaneously report ADRs. Consistent findings were also reported by Al-Hazmi &Naylor (2013), wherein they reported that half of their sample to find it challenging to report ADRs. Less than half of our sample (41.6%) reported attending workshops related to PV and Spontaneous ADR reporting. Similar findings were reported by Al-Hazmi & Naylor (2013) (35.2%) & by AlShammari & Almoslem (2018) (25%), who also reported a lower percentage of their sample to have received training regarding Spontaneous ADR reporting.

The findings of the present study showed that more than half of the sample (55.9%) with excellent awareness towards PV and Spontaneous ADR reporting were pharmacists ($p < 0.001$). AlShammari & Almoslem (2018) also reported in their study that pharmacists demonstrated better awareness than other healthcare professionals (p = 0.01). Contrasting findings were reported by Asiamah et al. (2022), who did not find any significant association between being a pharmacist and Spontaneous ADR reporting ($p > 0.05$). However, they reported that nurses were less likely to report ADRs ($p < 0.001$). With regards to participants' age, it was noticed in the present study that almost all (92%) of the study sample with excellent awareness towards PV and Spontaneous ADR reporting were below the age of 40 years ($p < 0.001$). Similar findings were observed by Asiamah et al. (2022), who reported that participants' age below 40 years was significantly associated with Spontaneous ADR reporting ($p < 0.01$).

Participants' gender and nationality were not significantly associated with their awareness of PV and Spontaneous ADR reporting in the present study ($p > 0.05$). Similar findings were reported by John et al. (2012), who conducted a study in UAE and reported that gender was not significantly associated with Spontaneous ADR reporting ($p > 0.05$). Asiamah et al. (2022) also observed no significant association between gender and Spontaneous ADR reporting. One unique finding of this study is that we observed a significant association between practice location and awareness towards PV and Spontaneous ADR reporting ($p < 0.001$).

The current research noticed positive significant correlations between participants' awareness score and attitude score (r = 0.52; $p < 0.01$), their awareness score and practice score (r = 0.61; $p < 0.01$), as well as their attitude score and practice score (r = 0.42; $p < 0.01$). The aforesaid findings show that an increase in the score of one variable results in an increase in the score of other variables (Alnohair et al., 2021; Assiry et al., 2022; Merghani Ali et al., 2022; Syed et al., 2022). Our findings demonstrate the three components (i.e., awareness, attitude and practice) to be correlated. Alhowaymel et al. (2023), also demonstrated that participants' knowledge positively correlates with their attitudes and practices. Similar findings were also reported by Yousaf et al that participants' KAP (knowledge, attitude as well as practice) scores are inter-correlated (Yousaf et al., 2020). A Lebanese study also reported positive correlations among different components of KAP. They concluded that if any component of KAP increases other KAP components would increase as well and vice-versa (Hallit et al., 2020).

A significant percentage of the current sample (89.2%) having excellent awareness also demonstrated excellent attitudes towards PV and spontaneous ADR reporting ($p < 0.001$). Similarly, the majority of the current sample demonstrating excellent attitudes (97%) showed excellent practices as well ($p < 0.001$). HCP's knowledge was significantly associated with their attitude ($p < 0.001$) (Khobrani et al., 2023). Better knowledge of community pharmacists was also significantly associated with better attitudes and practices (Hajj et al., 2019).

Based on our findings, the participants with poor awareness demonstrated poor attitudes, eventually resulting in poor practices. To improve awareness amongst HCPs, we recommend that employers organize professional education, conduct awareness programs, and provide proper hands-on training in filling spontaneous ADR-reporting forms. The HCPs should be encouraged to voluntarily attend educational sessions, lectures, seminars, and workshops relating to PV and spontaneous ADR reporting. Additionally, the employers should improve the work environment where the HCPs are self-motivated, confident and feel safe to record and report all ADRs as and when they occur.

5. Strengths and limitations

The current research according to our best knowledge is the first study in Jazan province to evaluate the awareness, attitudes as well as practices of HCPs towards PV and Spontaneous ADR reporting.

Some potential limitations include the study being conducted only in one province. Hence, the generalizability of the results to other parts of the country could not be claimed. Additionally, questions on the importance of signal and signal calculation were not included. Moreover, the cross-sectional study design makes it extremely difficult to assess causality. Furthermore, the study sample could not be considered representative, due to convenience sampling. Additionally, recall bias is usually associated with self-report surveys, and the potential for selection bias cannot be ruled out owing to snowball convenience sampling.

6. Conclusion

Our findings demonstrate the need for designing and conducting educational programs, providing training and conducting workshops for all the HCPs to improve their awareness of PV as well as Spontaneous reporting of ADRs. Continuous feedback from national and international PV centers in newsletters containing information on new ADRs and other drug safety-related issues should be provided. The national and international PV centres must also share information from periodic safety update reports (PSURs) and also from expedited safety reports to improve awareness about drugs with safety issues. Cooperation between different HCPs should be encouraged to improve their Spontaneous ADR reporting practices.

7. Future prospective

A similar study overcoming all the current study's limitations should be carried out across KSA.

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.

Acknowledgements & Dedications

N.K.S, the corresponding author, dedicates this research to his dearly loved father, Mr. Alhaj Syed Maqbool, who passed away. The authors also thank all the study participants.

Appendix 1. Study questionnaire

SECTION – 1. SOCIO-DEMOGRAPHICS / SAMPLE CHARACTERISTICS

Variable	Options	Tick Here
Sex	1: Male	☐
	2: Female	☐
Nationality	1: Saudi	☐
	2: Non-Saudi	☐
Age Group (In Years)	1: < 30	☐
	2: 31–40	☐
	3: 41–50	☐
	4: > 50	☐
Exact Age		
Job Profile	1: Physician	☐
	2: Pharmacists	☐
	3: Nurses	☐
	4: Pharmacy technicians	☐
Educational Qualification	1: Diploma	☐
	2: Bachelors	☐
	3: Masters	☐
	4: Doctorate / Fellowship	☐
Experience(In Years)	1: < 5	☐
	2: 5–10	☐
	3: > 10	☐
Location of Current Practice	Rural	☐
	Urban	☐

SECTION 2: PARTICIPANTS' AWARENESS TOWARDS PHARMACOVIGILANCE &SPONTANEOUS ADR REPORTING

Aw1: Definition of PV	**Options**	
a. The science detecting the type and incidence of adverse drug reactions after a drug is marketed	☐	
b. The science of monitoring adverse drug reactions occurring in a Hospital	☐	
c. The process of improving the safety of the drug	☐	
d. The detection, assessment, understanding and prevention of adverse effects	☐	
Aw2: Purpose of PV	**Options**	
a. To improve public health and safety in relation to the use of medicines	☐	
b. To calculate the incidence of adverse drug reactions	☐	
c. To identify predisposing factors to adverse drug reactions	☐	
d. To identify previously unrecognized adverse drug reactions	☐	
Are you aware:	**Yes**	**No**
Aw3. Of the existence of a National Pharmacovigilance Programme in KSA?	☐	☐
Aw4. Of the existence of the Drug Safety and National Pharmacovigilance Center (Saudi Vigilance) of SFDA?	☐	☐
Aw5. That the International Drug Monitoring Centre is located in Uppsala, Sweden?	☐	☐
Aw6. That "Naranjo" scale is used for establishing causality of an ADR?	☐	☐
Aw7. Of the existence of the Pharmacovigilance system at your hospitals?	☐	☐
Aw8. Of the existence of SFDA-ADRs for Health Professional form?	☐	☐
Aw9. Of the existence of the spontaneous ADRs reporting system at your practice site?	☐	☐
Aw10. Of 'WHO's VigiBase' - Global database of reported potential side effects of medicinal products?	☐	☐
Aw11. Of the 'MedWatch' forms for the spontaneous reporting of the ADRs?	☐	☐
Aw12. Of the 'Yellow Card Scheme' for spontaneous reporting of the ADRs?	☐	☐

Aw: Awareness.

SECTION 3: PARTICIPANTS' ATTITUDES TOWARDS PHARMACOVIGILANCE & SPONTANEOUS ADR REPORTING

	Strongly Disagree	Disagree	Agree	Strongly Agree
A1: Pharmacovigilance is very important for promoting Drug Safety.	☐	☐	☐	☐
A2: Spontaneous ADR reporting is necessary as it contributes to Drug Safety.	☐	☐	☐	☐
A3: As HCPs, spontaneous ADR reporting is part of my professional obligations.	☐	☐	☐	☐
A4*: Spontaneous recording and reporting of the ADRs is solely the responsibility of the Physicians.	☐	☐	☐	☐
A5: Close collaboration between the different HCPs improves drug safety.	☐	☐	☐	☐
A6: Receiving training and attending workshops related to PV and spontaneous ADR reporting is essential for all HCPs.	☐	☐	☐	☐
A7: Receiving training and attending workshops related to PV and Spontaneous ADR reporting should be made mandatory for all HCPs.	☐	☐	☐	☐
A8: Spontaneous ADR reporting should be made mandatory.	☐	☐	☐	☐

A-Attitude.

SECTION – 4: PARTICIPANTS' PRACTICES TOWARDS PHARMACOVIGILANCE & SPONTANEOUS ADR REPORTING

	Yes	**No**
P1: Have you ever seen an ADR?	☐	☐
P2: Have you ever spontaneously reported an ADR as soon as it was observed?	☐	☐
P3: Have you ever used an SFDA-Spontaneous ADR reporting form or the SFDA website for reporting ADRs?	☐	☐
P4: Have you ever received any training in filling spontaneous ADR reporting forms?	☐	☐
P5: Have you ever attended any workshops or lectures regarding PV and Spontaneous ADR reporting?	☐	☐
P6: Do you provide patient counseling about potential ADRs?	☐	☐
P7: Do you find it difficult to spontaneously report ADRs?	☐	☐

P-Practice.

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