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Original article

The development of a pharmacovigilance system in Bahrain

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ABSTRACT

Introduction: The pharmacovigilance system is playing a vital role in the process of patient safety through reporting of ADRs and other drug-related problems. Although, the.

Pharmacovigilance system is well established in other Gulf Cooperation Countries (GCC). In Kingdom of Bahrain, the Pharmacovigilance system is still in its early stages. Establishing a successful Pharmacovigilance system in Bahrain requires a collective effort from various stakeholders such as the ministry of health and the National Health Regulatory Authority (NHRA).

Aim: To assess the current status of the Pharmacovigilance system in Bahrain and the feasibility of its development.

Objectives: To investigate the current Pharmacovigilance activities in Bahrain, to explore the attitude / knowledge of healthcare providers towards PV systems and to identify the limitations, and barriers of the PV system in Bahrain.

Methodology: This was a descriptive cross-sectional study utilising an online survey composed of 24 questions. It was distributed to pharmacists, physicians, and nurses working at government and private hospitals in Bahrain through emails and social media. In addition, a telephone interview was performed with a pharmacist working for NHRA in Bahrain. Ethics approval was prior to commencing the study.

Results: More than half of the respondents (69.8%) did not report any ADRs so far in their practice, whereas 30.2% had done so. A total of 95.8% of those who have never reported before were willing to report in the future. Participants who received training regarding reporting ADRs reported lower positive attitudes (3.3 ± 0.8 vs 3.6 ± 0.6). In addition, the participants were more knowledgeable about the ADRs reporting process than the PV system. The results showed the absence of an active PV program. The activity of PV in Bahrain is limited to receiving notifications and periodic safety update records from manufactures or the GHC. Conclusion: Despite the average level of knowledge of healthcare providers towards the PV system, the results indicated a negative attitude. Moreover, some barriers were reported. Establishing a specialised PV centre is the next step to improve the status of PV system in Bahrain.

1. Introduction

1.1. Background

Pharmacovigilance (PV) is a major component in the process of patient safety. Pharmacovigilance is defined as "the process of detection, assessment, understanding and prevention of adverse effects or any other drug-related problems" in order to improve patient safety (World Health Organization, 2022a). One of the Pharmacovigilance system goals is to afford trusted information regarding risks, benefits, and effectiveness of drugs to public healthcare (World Health Organization, 2022b). The PV system was established in 1961 as a preventive action after the Thalidomide tragedy (Fornasier et al., 2018). In the 1950s, Thalidomide was a medicine that is used as a mild sleeping pill to reduce morning sickness, and it was licensed to be used even during pregnancy (Rice, 2019). In 1961, it was discovered that Thalidomide caused sever birth defects; it interfered with the babies' normal development leading to children born with short or absent body limbs. The consumption of Thalidomide by pregnant women resulted in almost 10,000 children born with congenital disorders and the death of approximately 2000 child (Sarwa et al., 2019). This was known as the Thalidomide tragedy. The PV program was established to avoid similar incidents and to obtain information regarding unknown Adverse Drug Reactions (ADRs) (Uppsala Monitoring

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Centre, 2022a). The role of PV systems is not limited to prevente unknown drug related side effects. The PV science covers all aspects of medication safety. Some of PV programme objectives include designing a nation-wide system to collect the ADRs, assist the regulatory authority on making decisions, and spread awareness regarding proper use of medicines (Kumar et al., 2015). Furthermore, the scope of PV continues to broaden to include herbals, traditional products, blood products, biologicals, medical devices, and vaccines (Suke et al., 2015).

Concerning the PV process of collecting medication safety-related information, the WHO collaborate with National pharmacovigilance centres (NPCs) which in turns collect, monitor, analyse reports and give advice in all PV-related aspects (Ampadu et al., 2018). The NPCs of member countries in the WHO Programme for International Drug Monitoring (PIDM) is intended to share reports to the global WHO individual case safety reports (ICSRs) database, which is called VigiBase and managed by Uppsala Monitoring Centre (Uppsala Monitoring Centre, 2022c). WHO together with Uppsala Monitoring Centre (UMC) promotes Pharmacovigilance at a country level (World Health Organization, 2022a).

1.2. Pharmacovigilance system requirements

Uppsala Monitoring Center (UMC) together with WHO had set basic requirements for countries intending to join the WHO international drug monitoring program (UMC, 2021). These requirements include:

- Being familiar with the methods of Spontaneous monitoring.
- Having a system and National Center (NC), to collect ICSRs, which is authorised and recognised by the Ministry of Health or equivalent.
- The NPCs could be part of a national drug regulatory authority and could also be part of a university institution, a hospital department, or integrated with a drug/poison information service.
- Demonstrating the capability of submitting case report in the required format to WHO.
- The submitted ICSRs should be available for analysing by the member countries investigators (UMC, 2021).

Not all the requirements have to be achieved in order to be an associated member. However, a practical procedure should be followed in order to join the WHO program for Drug monitoring (UMC, 2021). The practical procedure is represented in filling an application submitted by the competent health authority of the country to WHO Headquarters in Geneva. The application must identify the institution and the person responsible for representing the country as a NC. By receiving the form, the country will be considered an associated member (UMC, 2021). In order to become a full member country, a sample of 20 ICSRs at least should be collected in the national PV program and sent to UMC (UMC, 2021).

1.3. Pharmacovigilance reporting process challenges

According to (Alnajjar et al., 2019) one of the main challenges facing PV systems regarding the reporting process is the lack of education and training about PV. Factors that act as a barrier towards reporting ADRs and implementing a PV system could vary depending on the country and region. In Pakistan, for example, the absence of a reporting system was found to be the main barrier of the reporting process (Hussain et al, 2020). In low-middle income countries (LMIC), the main challenge was the lack of time because of the shortage of doctors in comparison to the number of patients (Kiguba et al., 2021). Another factor that affects the reporting process in many countries is the limited financial resources which plays an essential role in underreported medicine-related problems (Kaeding et al, 2017). A recent study conducted in the United Arab Emirates (UAE) in which a questionnaire was distributed to a sample of 230 pharmacists for the purpose of investigating the barriers to adverse drug reaction reporting in community practice. The result showed that more than 48.8% of pharmacists in UAE are reporting ADRs, however the authors acknowledged that there were many factors associated with not reporting ADRs. These factors include the place of graduation, unawareness about the reporting process, the intricacy of the reporting process, and the patients' acceptance to talk about adverse drug reactions they are suffering from (Alnajjar et al., 2019). Furthermore, although the electronic reporting system is used in many countries, there are still some barriers that affect the global implementation of this system. According to a study conducted in Kenya about barriers to electronic PV reporting systems, the main challenges were the internet accessibility, the system design, and the usability of the reporting tool (Agoro et al., 2018). In order to minimise the challenges to electronic PV systems, it is crucial to educate people and healthcare providers about the proper techniques of electronic reporting and to provide an internet connection in the workplace.

1.4. The status of PV systems worldwide

The United Kingdom was one of the first countries that implemented an electronic reporting system in 1964; it is known as the Yellow Card scheme (Chaplin, 2019). The Yellow Card scheme is managed by Medicines and Healthcare products Regulatory Agency (MHRA) in the UK and it gathers and monitors all information of any medicine-related incidents such as side effects, fake medicines, medical device issues, electronic cigarette concerns, and defective medicines. These problems can be reported by the healthcare professionals or patients (Medicines and Healthcare products Regulatory Agency [MHRA], 2020). The United Kingdom is developing their PV system regularly. For example, in 2015 the Yellow Card App was created alongside MHRA website to make the reporting process possible through smart phones (See Appendix. A) (Kaeding et al, 2017) The Medicines and Healthcare products Regulatory Agency (2020). With respect to the status of PV system in European countries, the European Union (EU) law obligates each marketing authorisation holder, national competent authority and European Medicines Agency (EMA) to set up a regional Pharmacovigilance system. Moreover, the EU PV system is operating through cooperation between the EU Member State (EMA, 2020).

PV system is well established in many developed countries, yet PV system in low-middle income countries is not receiving much attention (Kiguba et al., 2021). One of the reasons behind this is that medicine is not available for most of the population (Olsson et al., 2015). The aim of the WHO program is to develop a global PV strategy that fulfils the needs of healthcare in low and middle income countries. Nevertheless, the most recent study published in one of the low-middle income countries stated that the majority of physicians are unaware of the reporting system (Hussain et al., 2020). The study was done by interviewing 13 physicians in Pakistan for the purpose of understanding the challenges they faced in terms of acquiring the knowledge and practice needed to report ADRs. However, the accuracy of this study's result is questionable due to the small sample size.

1.5. Pharmacovigilance system in Arab world & Bahrain

Since year 2014, pharmacovigilance started to receive much attention in Arab countries. To illustrate, the first Eastern Mediterranean region and Arab countries meeting of PV was taking place in year 2014, this event included recommendations and plans

regarding the future vision of the PV system in Arab Countries (Bham, 2015). As for the status of the PV system in Arab region, only 45% of Arab nations are members of the WHO Collaborating Centre for International Drug Monitoring, with only 0.6% of reported cases in VigiBase. (Alshammari et al., 2019). According to a study conducted by Qato (2018), an online survey was sent to the national PV official leadership. The purpose of this survey was to evaluate the status of PV system in the middle east. Although Bahrain, Somalia, and Syria did not respond to the survey, a high response rate (82%) was identified from this study with the participation of 20 out of 24 countries. All but four countries including Djibouti, Lebanon, Palestine, and Qatar indicated the absence of a National PV program. By considering the PV program performance, it was concluded that among Arabic countries, the highest performing systems were in Morocco and Egypt (Qato, 2018). According to Alshammari et al. (2019), this observation is reflective as he reported that Morocco and Egypt have a mature PV system. Furthermore, Qato (2018) concluded that it is necessary to create regional collaboration to promote the healthcare professional and public awareness about PV and improve its capabilities. The regional collaboration is required to follow the steps of EU PV system which proved its effectiveness through influencing the public health positively (EMA, 2019).

Gulf Cooperation Council Countries (GCC) is a cooperation between six countries including Bahrain, United Arab Emirates (UAE), Saudi Arabia, Oman, Kuwait, and Qatar (Khoja et al, 2017). The list of UMC indicates that Saudi Arabia, UAE, and Oman are full members of the WHO PIDM. In contrast, Bahrain, Kuwait, and Qatar are associated members (Uppsala Monitoring Centre, 2022b). In 1975 there was a great cooperation in the health sector among GCC countries which resulted in establishing the Gulf Health Council (GHC) in 1976 (Gulf Health Council [GHC], 2020). One of the main goals of GHC is to enhance the health of citizens of all the member states (GHC, 2020). Although so far there are no collective PV activities in GCC, GCC countries are cooperating at all levels including public health (GHC, 2020), Bahrain still has no activated PV system database to collect and monitor the ADRs. Unlike Saudi Arabia, Oman, and UAE, who have fully developed their PV system.

To clarify the details of PV activity in Bahrain, since year 2002 Bahrain was an associated member in WHO PIDM (Uppsala Monitoring Centre, 2022b). However, in 2013, Bahrain's National Health Regulatory Authority (NHRA) provided a guidance document about the management of Serious Adverse Events (SAEs) along with a reporting form. The SAE form included a description of the incident and the measures taken to fix the event. All public healthcare hospitals were required to submit the SAE forms along with the supporting documents, which include the conducted tests and the patient's medical records, within five working days from the occurrence of the event (Alshammari et al, 2019). Moreover, the Medical Complaint Unite (MCU) in NHRA considers every adverse event that happened in healthcare settings and was reported by a healthcare professional (National Health Regulatory Authority, 2020b). Furthermore, According to NHRA strategic plane (2021–2025), one of NHRA's main goals is to deliver safe and trusted health services through establishing a full PV programme by the end of year 2023 (NHRA, 2021). In addition, after approving the Covid-19 vaccines in Bahrain, the Minsitry of Health generated a specific form which is accesible through their website to report the adverse drug events post Covid-19 vaccine (Minisitry of health, 2022).

However, since the current actual activity of the PV system in Bahrain is vague and there is no proof that a database exists to monitor ADRs, this study is aiming to investigate the current status of the Pharmacovigilance system in Bahrain and the feasibility of its development.

1.6. Objectives

- To investigate the current Pharmacovigilance activities in Bahrain.
- To explore the attitude / knowledge of healthcare providers towards PV systems
- To determine the unmet requirements towards being a full member country in the World Health Organization (WHO) program for international Drug monitoring.
- To identify the limitations, and barriers of the PV system in Bahrain.

2. Method

2.1. Data collection and study design:

To expand the sample size efficiently, a descriptive cross-sectional online survey targeting healthcare providers in the Kingdom of Bahrain was made. It was sent to several practitioners working in primary, secondary and tertiary healthcare settings in order to investigate their knowledge (Appendix. C) and attitude (Appendix. D) towards the PV system. The survey was created by using Qualtrics website, an online survey tool designed to be used for conducting researches (Qualtrics, 2020). The online survey was delivered through email and social media platforms such as WhatsApp, Instagram, and Twitter. Hence, the survey followed the snowball sampling with no randomisation. Snowball sampling is characterised as a sampling technique in which the participants of the research recruit other participants for the study (Ochoa, 2017). The data collection took place from April 2020 until June 2020. Moreover, on April 2020 a telephone interview was performed with a pharmacist working at NHRA - Pharmaceutical Products Regulation Office department. The objectives of the interview were to identify the current activity of the PV system in Bahrain, determine the unmet requirements towards being a full member country in the WHO program, and identify barriers/limitations of developing the system. The interview was done through the phone because the Government of Bahrain has implemented social distancing as a regulation to prevent the spread of Coronavirus (Covid-19) (Nasrallah, 2020). Covid-19 is a new fast spreading virus which was declared a pandemic by the WHO (World Health Organization, 2020a).

The participants were enrolled in this study according to the following inclusion and exclusion criteria:

- Inclusion criteria:
- Pharmacists, nurses, and physicians working in the primary, secondary, and tertiary healthcare settings.
- The pharmacist who works in NHRA and was eligible/knowledgeable to answer the interview's questions.
- Exclusion criteria:
- Lab specialists and lab technicians; they are not in direct contact with patients.
- Physiotherapists and Dentists.
- Community pharmacists.

2.2. Survey development

The questionnaire was composed of 24 questions divided into three domains. The first domain included multiple choice questions that are related to the participants' demographics characteristics (Appendex. B). The second domain addressed the knowledge of healthcare providers regarding PV and it consisted of multiple-choice questions. The third domain contained Likert scale and multiple-choice questions that investigated the attitude of health-

care professionals towards PV systems. The questions of the survey were written by referring to different published primary research.

2.3. Telephone Interview

The interview questions were derived from WHO's practical manual for the assessment of PV systems (WHO, 2015). The interview was composed of both closed-ended (Yes/No responses) and open-ended questions. The total number of questions were 12 and it included four structural, four process, and four impact questions. According to WHO (2015), the structural questions assess the existence of key pharmacovigilance structures and basic infrastructures that enable the PV systems to operate. Moreover, the process questions evaluated the PV activities which include the process of collecting the ADRs, analysing, and reporting them to the relevant health agency. The impact questions measured the extent to which the pharmacovigilance system has resulted in changing policies, guidelines, and regulations (WHO, 2015). Detailed information about the questions are included in (Appendix. E).

2.4. Data analysis

The data in the survey was analysed by using Statistical Package for the Social Sciences (SPSS) software version 26. Descriptive statistics were used to analyse the sociodemographic data and knowledge related questions. Mann-Whitney *U* test was used to investigate the relationship between participants' training and willingness to report ADRs and their knowledge/attitude towards PV. Additionally, the Chi-square test was used to determine whether the difference between the percentage of respondents' correct answers and percentage of their incurrent answers was statistically significant or not. A P-value ≤ 0.05 was considered significant. Alternatively, the data from the interview was analysed by using the deductive thematic qualitative analysis method. According to Caulfield (2020), the deductive approach involves creating expected preconceived themes before the analysis is performed, whereas the inductive approach involves allowing the data to determine the research themes. The data were coded according to structural, process, and impact indicators.

2.5. Ethical approval

Regarding the online survey, ethics approval was given by the Health Science Engineering & Technology Ethics Committee with Delegated Authority. Additionally, the survey contained a participant information sheet that was attached to the first page of the online questionnaire in order to inform participants about the aim/objectives and the purpose of the study (Appendix. F). The participant information sheet informs the respondents that their confidentiality is guaranteed, and it explained that participation in this study is voluntary and any participant who does not want to complete the survey can close it at any time. In order to ensure the participants' confidentiality, no personal information was collected from the respondents. At the bottom of the participant information sheet, the contact details of the researcher were written in case of any concerns or questions regarding the survey. Concerning the telephone interview, the interviewee's consent was taken prior to recording the interview.

3. Result

3.1. Survey

To avoid undue influence of missing data, respondents had to proceed to the second domain (Knowledge section) to be included in the data analysis. The total number of respondents was 236, but only 140 responses were analysed for the study. Moreover, out of 140 participants only 136 completed the whole questionnaire. This could be due to the current situation with Covid-19 and the limited capacity of healthcare providers. The response rate of this study was 59.3% (n = 140) which is considered an adequate response rate (Willott, 2019).

3.2. Demographic data

The sample contained 140 participants, of which the vast majority were females (82.1%), with those between the ages of 20 and 40 years representing 90.7% of the total. Three quarters of the sample (72.1%) were working in governmental hospitals, while only 27.9% of them were working in private hospitals. More than half of the participants (53.6%) were physicians along with almost equal numbers of pharmacists and nurses who represent 23.6% and 22.9%, respectively. Two thirds of the participants had work experience between less than one to five years (65%). 70% of the participants graduated from a university located in Bahrain (See Table 1).

3.3. Knowledge about pharmacovigilance

Various items in the questionnaire were asked to assess the knowledge and awareness of participants regarding ADRs report-

Table 1
The sociodemographic data of respondents.

Variable	Categories	N	%
Gender			
	Male	25	17.9%
	Female	115	82.1%
Age group			
	20–30 years old	91	65.0%
	31–40 years old	36	25.7%
	41–50 years old	8	5.7%
	51–60 years old	4	2.9%
	60 years old and above	1	0.7%
Place of work			
	Government hospital	101	72.1%
	Private hospital	39	27.9%
Country of study			
	Bahrain	99	70.7%
	Abroad	41	29.3%
Profession			
	Doctor	75	53.6%
	Pharmacist	33	23.6%
	Nurse	32	22.9%
Healthcare level			
	Primary	71	50.7%
	Secondary	36	25.7%
	Tertiary	25	17.9%
	Primary - tertiary	1	0.7%
	Secondary - tertiary	7	5%
Years of experience			
	<1 year	35	25%
	1–5 years	56	40%
	6–10 years	26	18.6%
	11–15 years	3	2.1%
	15–20 years	11	7.9%
	More than 20 years	9	6.4%

ing. A total of 45.7% indicated "The science and activities of detecting, assessing, understanding & preventing adverse effects or any other drug-related problem" as the definition of PV. In addition, 47.9% stated that the purpose of PV system is to enhance patient safety in relation to the use of drugs. 27.9% and 26.4% chose "Do not know" when asked about the definition and purpose of PV, respectively. 55.7% of the participants selected the correct answer "All of the above" when asked about the PV inclusions, whereas 42.1% of the respondents reported that the PV system only involves drug-related problems (See Table 2).

In addition, a total of 79.3% pointed out that "any noxious or undesired effect of a drug occurring at normal doses, during normal use" is the correct definition of ADRs. Moreover, 7.1% and 2.1% chose "Adverse health outcomes associated with inappropriate drug use" and "Harm caused by drug overdose" as ADRs definition, respectively. 81.4% selected the correct answer when asked which Adverse Drug Reactions should be reported. However, 15% of the participants assume that the reporting process is limited to all the serious ADRs (See Table 3).

Overall, the percentage of choosing the correct answers among the five questions was 59.3%. The two ADR-related questions which were "what is the definition of ADRs" and "Which ADRs should be reported" possessed the highest percentage of the correct answers which were 79.3% and 81.4%, respectively. Whereas the PV inclusion question received the least correct answers (42.1%) (See Table 4).

3.4. Attitude towards Pharmacovigilance system

3.4.1. Participants' practice of reporting ADRs

A total of 69.8% of the participants gave a negative response to the question "Have you ever reported an ADRs?" and only 30.2% provided a positive response. 92% of participants submitted between one to five reports, and 7.5% submitted five to ten forms. No one at all have submitted more than ten reports during the last year (See Table 5).

3.4.2. Participants' attitude towards the reporting process of ADRs

The respondents who reported ADRs before were asked about their experience in filling the ADRs reporting form. The number

Table 2
Knwledge of participants among PV.

Question	Answer's choices	N	%
Which of the following BEST defines Pharmacovigilance?			
1	**The science and activities of detecting, assessing, understanding & preventing adverse effects or any other drug-related problem***	**64**	**45.7%**
2	The science of detecting the type & incidence of Adverse Drug Reactions (ADRs) after a drug is marketed.	32	22.9%
3	The process of improving the safety of drugs	4	2.9%
4	The science of monitoring ADRs happening in a hospital	1	0.7%
5	Do not know	39	27.9%
What is the purpose of Pharmacovigilance?			
1	To identify predisposing factors to Adverse Drug Reactions (ADRs)	17	12.1%
2	To calculate incidence of ADRs	0	0%
3	**To enhance patients' safety in relation to use of drugs***	**67**	**47.9%**
4	To identify unrecognized ADRs	19	13.6%
5	Do not know	37	26.4%
Pharmacovigilance includes			
1	Drug related problems	59	42.1%
2	Blood related products	1	0.7%
3	Herbal products	2	1.4%
4	**All of the above***	**78**	**55.7%**

*Correct answers.

Table 3
Knowledge of participants about ADRs.

Question	Answer's choices	n	%
Which of the following defines an Adverse Drug Reactions (ADRs) correctly?			
1	**Any noxious or undesired effect of a drug occurring at normal doses, during normal use***	**111**	**79.3%**
2	Adverse health outcomes associated with inappropriate drug use	10	7.1%
3	Harm resulting from the use of substandard/counterfeit drugs	9	6.4%
4	Harm caused by drug overdose	3	2.1%
5	Other health problems associated with drug use	7	5%
Which Adverse Drug Reactions (ADRs) should be reported?			
1	All serious ADRs	21	15%
2	ADRs to herbal and non-allopathic drugs	1	0.7%
3	ADRs to new drugs	3	2.1%
4	Unknown ADRs to old drugs	1	0.7%
5	**All of the above***	**114**	**81.4%**

*Correct answer.

Table 4
Participants' knowledge about PV (Expressed as percentage of correct answers).

	Statement	*n*	*%*
Q1	Which of the following BEST defines Pharmacovigilance?	64	45.7%
Q2	What is the purpose of Pharmacovigilance?	67	47.9%
Q3	Pharmacovigilance includes:	59	42.1%
Q4	Which of the following defines an Adverse Drug Reactions (ADRs) correctly?	111	79.3%
Q5	Which Adverse Drug Reactions (ADRs) should be reported?	114	81.4%
	Pooled n(%)	**415**	**59.3%**
	p-value	***<0.0001****	

*Statistically significant difference with Chi square test of independence (X2 = 22.6, df = 1, p < 0.0001).

Table 5
Participants' practice of reporting ADRs.

Question	Category	n(%)*
Have you ever reported an Adverse Drug Reaction?		
	Yes	42 (30.2%)
	No	97 (69.8%)
How many Adverse Drug Reaction reports have you submitted in the last year?		
	1–5	37 (92.5%)
	greater than 5–10	3(7.5%)
	greater than 10	0(0%)

Table 6
Participant experience in filling ADRs form.

Statement	Disagree	Partially disagree	Partially agree	Agree	Mean
The Sentinel Events reporting form is too complicated	4 (10%)	5 (12.5%)	19 (47.5%)	12 (30%)	2
Reporting Adverse Drug Reactions is time-consuming	13 (32.5%)	5 (12.5%)	14 (35%)	8 (20%)	2.5
There should be a specific form to report Adverse Drug Reactions	2 (1.5%)	0 (0%)	14 (10.3%)	120 (88.2%)	3.8
			Grand mean		**3.5**

Table 7
Willingness of participants to report ADRs (For those who never reported).

Are you willing to report adverse drug reaction?		p-value
Yes	92(95.8%)	***<0.0001****
No	4(4.2%)	

of participants who partially agreed and agreed with the statement "The sentinel event reporting form is too complicated" were 19 (47.5%) and 12 (30%), respectively. A total number of 13 (32.5%) disagreed with the statement "Reporting ADRs is time consuming", whereas 35% partially agreed. In addition, most of the sample (88.2%) agreed with the idea of specifying a form to report ADRs (See Table 6).

3.4.3. Are those who had never reported ADRs willing to report in the future?

The vast majority of those who had never reported an adverse drug reaction (95.8%) are willing to report in the future. The statistical difference between the two groups was significantly big (95.8% vs. 4.2%, $p < 0.0001$) (See Table 7).

3.4.4. Effect of reporting process training on attitude/knowledge

Participants who have received training regarding reporting adverse drug reaction reported significantly lower positive attitudes than those who have not been trained (3.3 ± 0.8 vs 3.6 ± 0.6, P-value = 0.025). However, they did not differ significantly in their knowledge level. Conversely, those who were willing to implement adverse drug reaction reporting scored 3.9 ± 0.4 in the attitude score, whereas those who are not willing scored 3.3 ± 1.5. Participants who were willing to implement ADRs in their practice had a high level of knowledge (62 ± 22.4) compared to those who were not willing (20 ± 16.3) (See Table 8).

3.4.5. Responsibility of reporting ADRs

The majority of participants (47.8%) reported that the responsibility of reporting ADRs should be shared between doctors, pharmacists and nurses. However, nearly one fifth of the respondents (17.6%) stated that it should be the doctors' responsibility. In addition, only 3.7% of the sample believed that ADRs should be reported by nurses (See Table 9).

Table 9
Responsibility of ADRs reporting.

Responsibility of reporting	n	%
Doctors	24	17.6%
Pharmacist	13	9.6%
Nurse	5	3.7%
Doctor and pharmacist	14	10.3%
Doctor and nurse	15	11%
Doctor, pharmacist, and nurse	65	47.8%

Table 10
Preferred method to report ADRs.

Means of reporting	n	%
Email	48	34%
Direct telephone	12	8.5%
Post	3	2.1%
NHRA website	22	15.6%
Other	14	9.8%
Email & direct telephone	8	5.7%
Direct telephone & NHRA website	10	7.1%
Email, direct telephone, and NHRA website	13	9.2%
Other combination of means	11	7.8%

3.5. Means of reporting ADRs

Reporting adverse drug reactions by email was the favourite reporting method with a percentage of 34% of the sample preferring it to other means. Reporting through NHRA website came as the second preferred choice with 15.6% of the participants having chosen it. In addition, the least preferred method to submit ADRs reports was through post with a percentage of 2.1% (See Table 10).

Regarding the participants who preferred to use other means to report ADRs; the majority of the respondents suggested the use of the governmental healthcare unified system, which is called Iseha, to report ADRs 4.2% (n = 6). Additionally, using the direct web form, in-patient file, and WhatsApp were preferred by equal numbers of participants 1.4% (See Table 11).

3.6. Educating practitioners on Pharmacovigilance

A total of 95.6% of respondents uniformly agreed with the fact that PV should be taught in detail to healthcare practitioners in

Table 8
Training on PV and participants' attitude/ knowledge.

Statement	Category	Attitudes score		Knowledge score	
		Mean	*±SD*	*Mean*	*±SD*
Have you ever been trained on how to report Adverse Drug Reaction?					
	Yes	3.3	±0.8	60.0	±27.3
	No	3.6	±0.6	60.0	±21.7
	p-value	***0.025****		***0.903***	
Are you willing to implement Adverse Drug Reactions reporting in your practice?					
	Yes	3.9	±0.4	62.0	±22.4
	No	3.3	±1.5	20.0	±16.3
	p-value	***0.553***		***0.001****	

*Statistically significant difference with Mann-Whitney test (U = 1593, Z = -2.2, p = 0.025) at Alpha 0.05.
*Statistically significant difference with Mann-Whitney test (U = 25, Z = -3, p = 0.001) at Alpha 0.05.

Table 11
Other suggested techniques.

Other means of reporting	n	%
Direct web form	1	0.7%
Forms	1	0.7%
I Seha form completion	2	1.4%
In patient file	1	0.7%
Iseha direct to nahra	1	0.7%
No need to send its enough to document in pt file	1	0.7%
OVA or incident report	1	0.7%
Printed out template sent by the facility i work in	1	0.7%
Through electronic medical records	1	0.7%
To add it to iseha system	1	0.7%
Using I-Seha website in SMC	1	0.7%
Whatsapp	2	1.4%
Total	**14**	**100%**

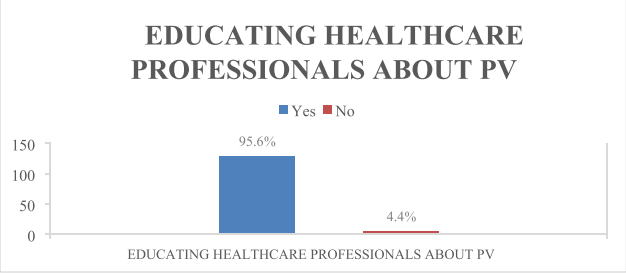


Fig. 1. Educating healthcare professionals about PV.

their undergraduate syllabus. Only 4.4% of the respondents disagreed with this idea (See Fig. 1).

3.7. Telephone interview

The telephone interview was performed on April 2020 and it approximately lasted eight minutes. The interview was done with a senior pharmacist at NHRA, the National Health Regulatory Authority who was eligible to answer all questions. See (Document 1) for more information regarding the interviewee answers.

3.8. Structural indicator performance

As of the time of writing this document, there is no activated pharmacovigilance program in Bahrain. There is also no centre or unit specifically dedicated to Pharmacovigilance activities. The main reason behind the absence of PV program in Bahrain is the lack of financial support. To elaborate, there is no specifically dedicated budget to the Pharmacovigilance entity's activities in Bahrain. In addition, there is no standard Adverse Drug Reaction case reporting form. For those who wish to report any ADRs, the National health regulatory authority (NHRA) asks them to submit the case for the Gulf Health Council (GHC). However, the interviewee has highlighted that there are plans to unify the reporting forms, databases, and PV systems across GCC countries through GHC.

3.9. Process indicator performance

The PV force is not activated yet, even though Bahrain is an associated member in the WHO Program for International Drug Monitoring (PIDM). The activity of PV in Bahrain is limited to receiving notifications and periodic safety update records from manufactures or other trusted authority such as the GHC. In Bahrain, there is no database that collect reports of ADRs, but healthcare workers are required to download reporting applications from GHC website in order to submit any ADR to NHRA.

3.10. Impact indicator performance

In Bahrain, the safety signal issues are communicated regularly to health workers and the public. In addition, the interviewee said, "we send emails to hospitals and clinics around Bahrain to inform healthcare professionals who are working in those facilities about recent safety updates or warnings". Furthermore, all new safety updates are being published on NHRA's website and are made available to the public. Furthermore, over the past two years, NHRA has withdrawn more than 28 medical items (National Health Regulatory Authority, 2020c). Yet, there is still no national PV advisory committee or a clear communication strategy for routine and crisis communication in Bahrain.

4. Discussion

The overall response rate of this study was adequate, however the current Coivid-19 pandemic situation could reflect on the response rate of this study negatively. According to Lamara (2020), the response rate of studies related to the healthcare sector had dropped during Covide-19 pandemic. The participants reported an average level of knowledge about pharmacovigilance. More than half of the sample (59.3%) were able to answer the five PV-related questions correctly. This observation is valid as Bahrain has adopted Continuing Medical Education (CME) for healthcare professionals aiming to communicate an up-to-date knowledge and the recent medical developments (National Health Regulatory Authority, 2020a). This coincides with the study of Shrestha et al. (2020), who reported that healthcare providers who had attended the Pharmacovigilance educational intervention showed a significant increase in their knowledge score. Moreover, during the year 2018, a Pharmacovigilance workshop titled "Early steps in Pharmacovigilance" was performed in Bahrain, which contributed to spreading awareness regarding PV among healthcare providers (Sakheer, 2018). The results indicate that ADRs-related questions received the highest percentage of correct answers when compared to other PV-related questions. This result was expected as the term ADRs is widely used in the healthcare sector and any person with a medicine-related degree would have learned about it during his or her undergraduate study. However, The WHO recently has changed the definition of ADRs into "any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function" (Sakiris et al., 2021). Furthermore, when participants were asked about their opinion regarding educating healthcare workers on PV, most of the participants (95.6%) supported the idea. These positive views were in line with the findings of Gupta et al. (2015). Moreover, the Pharmacovigilance educational interventions that have proven to be effective in other regions such as north Portugal and Spain should be endorsed in the Kingdom of Bahrain (Lopez-Gonzalez et al., 2015).

The majority of participants have not reported any ADR in their practice yet (69.8%), whereas 30.2% have done so. Even among the 30.2%, most of the participants submitted an average of one to five ADR reports during the past year. The main reason that contributes to this result is the absence of a specific reporting form and a database to collect ADR reports in Bahrain. The result of this study is in line with the findings of Hussain et al. (2020) study which highlighted that the absence of a PV system is considered a barrier towards the PV reporting process. In addition, more than half of the participants (77%) agreed or partially agreed with the state-

Structural=4, Process=4, Impact=4

Hello , how are you?
I would like to do an interview with you about the PV system in Bahrain. First, I will introduce myself, my name is . and I am studying Master of Clinical Pharmacy at the university of Hertfordshire in the United Kingdom. Currently, I am working on my final project which is about the development of PV system in Bahrain.

1- Can you introduce yourself please?
, senior pharmacists at NHRA the national health regulatory authority

Before starting out interview, I have to mention some general information about the PV system. The PV is the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems. And the World Health Organization (WHO) established a program for International Drug Monitoring (PIDM) which is operated by Uppsala Monitoring Centre.
A minimum requirement was set to be achieved before establishing any national Pharmacovigilance system. I will ask you several questions in order to detect the existence of these requirements, determine the current Pharmacovigilance activities in Bahrain, and identify the barriers toward developing this system in Bahrain.

S1- . Are you aware of any Pharmacovigilance programme in Bahrain? (a national pharmacovigilance centre)
Currently there is No PV PROGRAM ACTIVATED IN BAHRAIN

P2- Is Bahrain a member of the WHO Program for International Drug Monitoring (PIDM)?
Yes, but as I told you the PV forces is not activated

According to WHO, The PV science covers all aspect of medication safety and includes prevent drug-related side effects medication errors, substandard medicines, lack of drug efficacy, using the medicines for unapproved indications, case reports of poisoning.

S3- In Bahrain, is there a centre, building, or unit specifically dedicated to Pharmacovigilance activities? (a national pharmacovigilance centre)
No

S5- Is there any specific budget for the Pharmacovigilance entity activities (the activities which I mentioned above)? (stable basic funding)
This is the main reason why there is no PV in Bahrain, the budget has not been dedicated yet.

P6- CAN YOU TELL ME MORE ABOUT THE ACTIVITY?
We are not taking it as PV, as a full PV dedicated system and as a dedicated team, we only depending on the notifications, pf yards (periodic safety update records), we are receiving such reports from the different manufactures themselves or any other confident authority

P6- CAN YOU TELL ME MORE ABOUT THE ACTIVITY?
We are not taking it as PV, as a full PV dedicated system and as a dedicated team, we only depending on the notifications, pf yards (periodic safety update records), we are receiving such reports from the different manufactures themselves or any other confident authority or the gulf health council itself, and we are dealing with case by case but not as fully operated system.

S6- Is there a standard Adverse Drug Reaction case reporting form? (the existence of a national spontaneous reporting system)
No,
When there is some case like this, we ask them to report for the gulf health council

P8-How do the healthcare providers report ADRs to the NHRA?
The website on GHC there is a part for PV so there are raising the form on the website and start reporting

P9- Is there a database of reported ADRs cases? (national database for collating ADR reports)
In Bahrain, No.

Safety signal issues are the information on a new or known adverse event that may be caused by a medicine and requires further investigation.

I9-So, in Bahrain Are safety signal issues communicated regularly to health workers and the public? How?
We are doing something similar to this, through our website, we are issuing warning and safety updates on the website in regular basis, so this is the main …. To communicate with the healthcare professionals in addition to this, when we upload it to the website, we also send an email to the hospitals and clinics in Bahrain for them to inform the healthcare professionals working in those facilities about the new safety updates or warnings.

According to the world health organization, the pharmacovigilance advisory committee is able to provide technical assistance on causality assessment, risk assessment, risk management, case investigation and, where necessary, crisis management including crisis communication.

I11- In Bahrain, is there a national pharmacovigilance advisory committee? (a national pharmacovigilance advisory committee).
No

I12- Is there a clear communication strategy for routine and crisis communication with WHO? (A clear communication strategy).
As a clear strategy, No.

How many product recalls?

Anything to add?
Currently, we are working on a project to unify all PV centres among the gulf countries through the gulf health council (GHC), so in the near future there will be an implementation of one unified PV centre through all GCC countries.
System, database, forms, everything will be unified because currently each country is working alone except Bahrain because there is no system right now so this was the discussion that we had in GHC recently, that we need to unified the system, one database, one system, one reporting form, everything will be unified across the GCC countries.

Document 1. The interviewee answers.

ment "Sentinel reporting form is too complicated". This was expected as the sentinel reporting form is not collecting ADRs specific information and is only used to report undesirable incidents and malpractices such as surgical events (Appendix. G). In this case, the obvious recommendation would be to develop a separate form to report the occurrences of any PV-related incident such as medicine side effects, fake medicines, and defective medicines. This was evident in the opinions of participants, in which 98.5% of the respondents agreed that there should be an ADRs specific reporting form. Furthermore, Bahrain should follow the steps of the UK in implementing the Yellow card scheme which has proven its effectiveness (Keading, n.d) (Appendix. H). Most of those who did not report ADRs so far in their practice (95.8%) were willing to perform the reporting process. This finding was closely related to participants' knowledge score. To clarify, those who were willing to implement ADR reporting had a significantly higher level of knowledge when compared to those who stated that they were not (62 ± 22.4 vs 20 ± 16.3) (P-value= <0.005). This finding suggests that the knowledge of pharmacovigilance has a positive impact on participants' willingness to report adverse drug reactions. This is consistent with the conclusion of a study carried out by Güner and Ekmekci (2019), which founds that the familiarity of healthcare providers with PV system plays a key role in their attitude towards the ADRs reporting process. Surprisingly, the attitude score of trained participants was slightly lower than those who had no training on reporting ADRs. This finding suggests that training on the reporting process has no impact on the attitude of healthcare providers. This conclusion can be interpreted by the fact that the absence of a fully activated PV system contributed to preventing healthcare providers from practicing what they were trained on. This result is conflicting with the finding of Upadhyaya et al. (2015), Kaeding et al. (2017), and Alnajjar et al. (2019).

Regarding the responsibility of reporting ADRs, 47.8% of participants agreed that the reporting process is a collective responsibility which is shared by all the healthcare professionals included in

the study (pharmacists, doctors, and nurses). However, only 3.7% of the respondents believed that reporting ADRs is the responsibility of nurses. This response is interpreted by Mueller (2019) who stated that "The role of nurses in Pharmacovigilance (PV) and drug safety is often overlooked, since this unique role is out of the mainstream of traditional healthcare nursing". It is recommended to run awareness lectures about the PV process in order to enhance the healthcare providers' knowledge/attitude regarding ADR reporting procedures. Moreover, a periodic evaluation courses training should be operated for nurses to assess the validity and quality of reported Individual Case Safety Reports.

This study revealed that the participants' preferred two methods for reporting ADRs which were email (34%) and NHRA website (15.6%). Moreover, using the I-seha system of government hospitals in Bahrain was also favoured by participants who suggested other means (4.2%). This suggestion is interesting because it showed that most of the participants were preferring the electronic reporting method rather than using the post or telephone. However, before implementing the computerised reporting system, the best recommendation would be to provide a good internet service in workplaces and to educate the users about the appropriate techniques for using it (Agoro et al., 2018).

The findings suggest that the PV system in Bahrain does not exist. There was no PV program nor centre, and no standard ADR reporting form. This finding is consistent with the result of Qato (2018), who reported that the PV system in the middle east is still in its introductory level. Moreover, the interviewee said that the lack of budget is the main reason behind the absence of a PV program in Bahrain. This result is coherent with Kaeding et al. (2017) findings as lack of financial support is one of the main challenges facing the PV system in many countries. However, it was concluded that there is a serious plan to create a regional PV program that unifies the PV system of GCC countries.

Bahrain is an associated member in the WHO Program for International Drug Monitoring (PIDM) (Uppsala Monitoring Centre, 2022b). However, the activity of collecting and analysing ADRs in Bahrain is not practiced. This is an area of incongruence in which NHRA stated that the medical complaint unit is concerned with the study of reported ADRs (National Health Regulatory Authority, 2020b). The PV entity role is limited to receiving alert and warning notifications from manufactures or the GHC. In addition, the absence of a specific ADR reporting form obligates the healthcare workers wishing to submit reports to download it from the GHC website. Therefore, the recommendation for easier accessibility of reporting forms would be to include a specific ADR reporting form in every healthcare facility system.

Although there was no activated PV program in Bahrain, the impact of its limited activity contributed to the recall of more than 28 medical items throughout the past two years. Moreover, the public and healthcare providers were regularly receiving every new safety signal.

According to WHO, the following minimum requirement has to be met for a functional national PV system:

1- A PV centre with at least one full-time staff and a stable funding.
2- A spontaneous reporting system.
3- A national database for collecting ADR reports.
4- A national Pharmacovigilance advisory committee.
5- A clear communication strategy.

In order to be a full member country in the WHO PIMD, Bahrain must achieve all the requirements stated above. After that, the national PV program must collect a sample of 20 ICSRs at least and send it to UMC (UMC, 2021). Establishing a special national pharmacovigilance centre in Bahrain could be the first step towards developing a PV system. In addition, Bahrain should learn from the successful experience of other neighbouring countries such as Saudi Arabia (KSA).

KSA has made considerable progress with regards to its PV system (Qato, 2018). The Saudi Food and Drug Authority (SFDA) established a National Pharmacovigilance Centre (NPC) which developed three methods for reporting ADRs which were online reporting, paper-based reporting, and traditional methods (fax, telephone reporting) (Alharf et al, 2018). In order to strengthen the PV system in Saudi Arabia, the Vigilance and Crisis Management (VICM) Executive Directorate was established. Since then, Saudi Arabia became a member of UMC (Alshammari et al., 2017). The VICM is responsible for all activities related to pre- and postmarketing assessments of registered medical items and it consists of the NPC, Benefit-Risk Assessment Department, and Medication Errors Department (Saudi Food and Drug Authority, 2020). Another developed Pharmacovigilance system in the Gulf region is Oman's PV. Oman was the first Arab country to obtain full membership in the WHO PIDM (Uppsala Monitoring Centre, 2022b). According to Alshammari et al. (2019), the PV journey in Oman started by establishing a department responsible for ADR reporting and it was called the infection control section. In 1994, a circular conducted to healthcare providers about the importance of ADR reporting was issued. At same year of issuing the circular, Oman became an associated member. Then after one year, it acquired the full membership in the World Health Organization Programme for International Drug Monitoring (Alshammari et al, 2019). In addition, because the UAE has been a full member of the WHO PIDM for nine years, the PV system in the United Arab Emirates is another good example to follow (Uppsala Monitoring Centre, 2022b). The National Pharmacovigilance committee in UAE has issued a guideline in good vigilance practice (GVP) for marketing authorisation holders and pharmaceutical manufacturers (Ministry of Health, 2017a).

The findings of this study can be presented to the Ministry of Health and NHRA aiming to spread awareness regarding the reporting process of ADRs and to increase healthcare providers' knowledge regarding the PV system. This can be achieved by establishing a committee charged to improve healthcare practitioner awareness about the reporting procedure and the importance of the PV system through conducting conferences, lectures, and workshops. Moreover, a valuable recommendation to initiate the PV program in Bahrain would be to allocate a pharmacovigilance task force team that is able to develop plans which ease the launching of the PV system. In addition, hiring a liaison officer to form a working relationship between Bahrain and the Uppsala Monitoring Centre. Furthermore, a good PV practice guideline should be issued by NHRA to marketing authorisation holders, and pharmaceutical companies and factories. In addition to these measures, the healthcare systems in Bahrain could be provided with a notification message which appears just before the patient is discharged; to remind the healthcare provider to record any medicine-related problems.

5. Conclusion

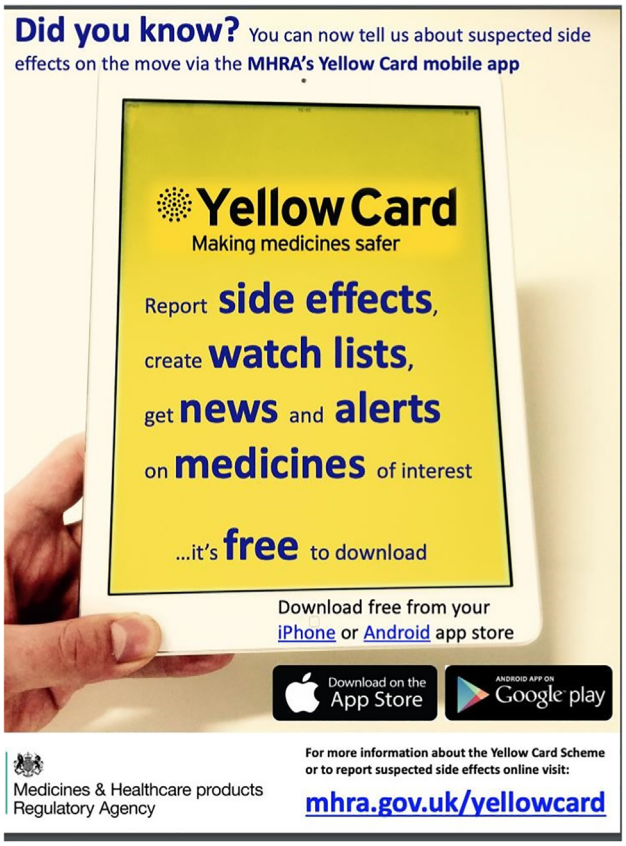
The results indicate that there is an absence of an active PV system in the Kingdom of Bahrain and a limited activity. However, the impact of its limited activity contributed to the recall of more than 28 medical items throughout the past two years. Moreover, the healthcare provider who participate in this study showed an average level of knowledge about Pharmacovigilance and more than half of the sample have not reported any ADR yet. This study found that training on the reporting process has no impact on the attitude of healthcare providers in Bahrain. Establishing a special

national pharmacovigilance centre in Bahrain is the next step to improve the attitude of healthcare practitioners towards PV system.

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.

Appendix A. Reporting process is possible through smart phones in the UK



Appendix B. Demographic questions

Start of Block: Demographic

Q1 Gender:
- Male
- Female

Q2 Age group:
- 20-30 years old
- 31-40 years old
- 41-50 years old
- 51-60 years old
- 60 years old and above

Q3 Current practice setting (you can choose more than one answer):
- Government hospital
- Private hospital

Q4 Country of graduation?
- Bahrain
- Abroad, which country? _____

Q5 What is your profession?
- Doctor
- Pharmacist
- Nurse

Q6 I am working in (you can choose more than one answer):
- Primary health care
- Secondary health care
- Tertiary health care

Q7 Years of experience:
- less than 1 year
- 1-5 years
- 6-10 years
- 11-15 years
- 15-20 years
- More than 20 years

End of Block: Demographic

Appendix C. Knowledge related questions

The following questions assess the knowledge of healthcare professionals toward Pharmacovigilance

Q8 Which of the following BEST defines Pharmacovigilance?

- ○ The science and activities of detecting, assessing, understanding & preventing adverse effects or any other drug-related problem
- ○ The science of detecting the type & incidence of Adverse Drug Reactions (ADRs) after a drug is marketed.
- ○ The process of improving the safety of drugs
- ○ The science of monitoring ADRs happening in a Hospital
- ○ Do not know

Q9 What is the purpose of Pharmacovigilance?

- ○ To identify predisposing factors to Adverse Drug Reactions (ADRs)
- ○ To calculate incidence of ADRs
- ○ To enhance patients' safety in relation to use of drugs
- ○ To identify unrecognized ADRs
- ○ Do not know

Q10 Pharmacovigilance includes:

- ○ Drug related problems
- ○ Blood related products
- ○ Herbal products
- ○ All of the above

Q11 Which of the following defines an Adverse Drug Reactions (ADRs) correctly?

- ○ Any noxious or undesired effect of a drug occurring at normal doses, during normal use
- ○ Adverse health outcomes associated with inappropriate drug use
- ○ Harm resulting from the use of substandard/counterfeit drugs
- ○ Harm caused by drug overdose
- ○ Other health problems associated with drug use

Q12 Which Adverse Drug Reactions (ADRs) should be reported?

- ○ All serious ADRs
- ○ ADRs to herbal and non-allopathic drugs
- ○ ADRs to new drugs
- ○ Unknown ADRs to old drugs
- ○ ADRs to vaccines
- ○ All of the above

End of Block: Knowledge

Appendix D. Attitude related questions

Start of Block: Attitude

The following questions evaluate the attitude of healthcare professionals toward Pharmacovigilance.

Before proceeding, it is important to know that NHRA Issued a form to report all sentinel events that could happen within a maximum of 5 working days from the date of occurrence. These sentinel events could include Adverse Drug Reactions (ADRs)

Q13 Have you ever reported an Adverse Drug Reaction?

- ○ Yes
- ○ No

Q14 How many Adverse Drug Reaction reports have you submitted in the last year?

- ○ 1-5
- ○ 5-10
- ○ >10

The following questions are evaluating the process of ADRs reporting

Q15 The Sentinel Events reporting form is too complicated

- ○ Agree
- ○ Partially agree
- ○ Partially disagree
- ○ Disagree

Q16 Reporting Adverse Drug Reactions is time-consuming

- ○ Agree
- ○ Partially agree
- ○ Partially disagree
- ○ Disagree

Q17 Are you willing to implement Adverse Drug Reactions reporting in your practice?

- ○ Yes
- ○ No

Q18 There should be a specific form to report Adverse Drug Reactions

- ○ Agree
- ○ Partially agree
- ○ Partially disagree
- ○ Disagree

Q19 Have you ever been trained on how to report Adverse Drug Reaction?

- ○ Yes
- ○ No

Q20 Which method do you prefer to use in order to send Adverse Drug Reactions information to the reporting center? (you can choose more than one answer)

- ☐ Email
- ☐ Direct contact telephone
- ☐ Post
- ☐ Using NHRA's website
- ☐ Other, please specify _____

Q21 The healthcare professionals responsible for reporting Adverse Drug Reactions in a hospital is/are? (you can choose more than one answer)

- ☐ Doctors
- ☐ Pharmacists
- ☐ Nurses

Q23 Do you think Pharmacovigilance should be taught to all healthcare professionals?

- ○ Yes
- ○ No

End of Block: Attitude

Appendix E. The telephone interview questions

Telephone interview questions	
Structural Questions Assessing the existence of key pharmacovigilance structures and basic infrastructure that enable the PV systems to operate.	1- Are you aware of any Pharmacovigilance programme in Bahrain? 2- In Bahrain, is there a centre, building, or unit specifically dedicated to Pharmacovigilance activities? 3- Is there any specific budget for the Pharmacovigilance entity activities? 4- Is there a standard Adverse Drug Reaction case reporting form?
Process questions Evaluating the PV activities which include the process of collecting, analysing the ADRs, and reporting them to the relevant health agency.	1- Is Bahrain a member of the WHO Program for International Drug Monitoring (PIDM)? 2- What is the current PV activities in Bahrain? 3- How do the healthcare providers report ADRs to the NHRA? 4- Is there a database of reported ADRs cases?
Impact questions To measure the extent to which the pharmacovigilance system has resulted in changing policies, guidelines, and regulations.	1- in Bahrain Are safety signal issues communicated regularly to health workers and the public? How? 2- In Bahrain, is there a national pharmacovigilance advisory committee? 3- Is there a clear communication strategy for routine and crisis communication with WHO? 4- During the last 2 years, how many drug recall was done?

Appendix F. Participant information sheet.

- We would like to invite you to take part in our research study.
- This research will form the basis of Miss Zainab Abdulrasool's Masters degree.
- This study aims to explore the current status of the Pharmacovigilance system in Bahrain and the feasibility of developing it.
- The objective of this study is to Investigate the attitude and knowledge of healthcare providers (ONLY Doctors, Pharmacists, and Nurses) towards Pharmacovigilance systems in Bahrain.
- Your participation is voluntary, and you may cease to take part in this study at any time.
- If you agree to take part, confidentiality will be guarantee to all participants.
- This research is supervised by Dr. Nkiruka Umaru at the Department of Clinical and Pharmaceutical Sciences, University of Hertfordshire.
- This survey is composed of 19 to 22 questions, it will take about 5 minutes to complete it.
- This survey has ethical approval in accordance with the University of Hertfordshire's Health, Science, Engineering and Technology Ethics committee.

If you have any concerns about the questionnaire or need further information about the study, please contact one of the research team:

Ph. Zainab Abdulrasool, Department of Clinical and Pharmaceutical Sciences, School of Life and Medical Sciences, University of Hertfordshire, College Lane, Hatfield, AL10 9NL, E-mail: z.abdulrasool@gmail.com, Tel: +97333325355 / +447446798369

I freely and voluntary choose to participate in this study.

- ○ Yes, I consent
- ○ No, I do not consent

Appendix G. The sentinel reporting form in Bahrain

Sentinel Event reporting Form

- It is mandatory to report all sentinel events to NHRA within a maximum of 5working days from date of occurrence, kindly the form, print it for your signature, then scan it and send to NHRA via incidents@nhra.bh
- Reporting should include a copy of the medical record, all tests and radiological images and statements from the concerned professionals' involved /in charge of the patient.
- A copy of the full internal investigation report inclusive of the root cause analysis, related policies, action plans for improvement/ prevention of recurrence, training conducted, and any actions taken against involved staff should be sent to NHRA within 45 days of the event.

Facility Information			
Name			
Sector	Governmental □	Private □	Others: ----------
Type	Hospital □	Medical center □	Dental center □
	Alternative medicine center □	Clinic □	Others ----------

Reporter information			
Name (first, middle, last)			
Profession	Doctor □	Nurse □	Others ----------
Position			
Contact Number			
Email			

Patient information					
Name (first, middle, last)					
CPR/Passport number		Age----------	Gender	Male □	Female □

Diagnosis	----------	Unknown □
Department		

Details of the event			
Date of the event	---------/----------/----------	Time of the event ----------	
Category of event	Care management event	Type	Choose an item.
	Surgical event	Type	Choose an item.
	Product/device event	Type	Choose an item.
	Criminal event	Type	Choose an item.
	Environment event	Type	Choose an item.
	Patient protection event	Type	Choose an item.

Description of the event

Information of professionals involved in the event					
Name		Profession	Doctor □	Nurse □	Other ----------
Name		Profession	Doctor □	Nurse □	Other ----------
Name		Profession	Doctor □	Nurse □	Other ----------
Name		Profession	Doctor □	Nurse □	Other ----------

Appendix H. The Yellow Card Scheme

BNF

In Confidence

YellowCard It's easiest to report online at www.yellowcard.gov.uk

COMMISSION ON HUMAN MEDICINES (CHM)

MHRA

SUSPECTED ADVERSE DRUG REACTIONS

If you suspect an adverse reaction may be related to one or more drugs/vaccines/complementary remedies, please complete this Yellow Card. See 'Adverse reactions to drugs' section in BNF or www.yellowcard.gov.uk for guidance. Do not be put off reporting because some details are not known.

PATIENT DETAILS Patient Initials:_____ Sex: M / F Ethnicity:_____ Weight if known (kg):_____

Age (at time of reaction):_____ Identification number (e.g. Your Practice or Hospital Ref):_____

SUSPECTED DRUG(S)/VACCINE(S)

Drug/Vaccine (Brand if known)	Batch	Route	Dosage	Date started	Date stopped	Prescribed for

SUSPECTED REACTION(S) Please describe the reaction(s) and any treatment given:

Outcome
Recovered
Recovering
Continuing
Other

Date reaction(s) started:_____ Date reaction(s) stopped:_____

Do you consider the reactions to be serious? Yes / No

If yes, please indicate why the reaction is considered to be serious (please tick all that apply):

Patient died due to reaction
Life threatening
Congenital abnormality
Involved or prolonged inpatient hospitalisation
Involved persistent or significant disability or incapacity
Medically significant; please give details:_____

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