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**Research Article** 

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# STUDY ABOUT KNOWLEDGE, ATTITUDE, AND PRACTICES OF MEDICAL STAFF ON REPORTING OF ADVERSE DRUG REACTIONS IN THE KINGDOM OF SAUDI ARABIA

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### ABSTRACT

Reporting adverse drug reactions (ADRs) are a significant action in any community, and it should be done by healthcare professionals. Although there is much research on this issue all over the world, especially the issues related to: the better reporting of adverse drug reaction, and the developed countries culture, reporting by healthcare professionals. Development of adverse drug reactions databases in most of countries worldwide has been determined in many previous studies, most of these studies have shown prevalence of this issues in developed countries, not in the developing countries. Also, most of these previous studies from different areas in the world, including the kingdom of Saudi Arabia, have focused on the perception and practice of ADR reporting among physicians only, while excluding other medical stuff of healthcare Professionals (physicians, nurses, and pharmacies) in medical field, including hospitals, and pharmacies, in the Kingdom of Saudi Arabia by using a simple survey, and collected from 52 qualified participants. The results were analyzed by the most convenient statistical tests. The study revealed many results, including: a positive attitude, and adequate knowledge and practice towards ADR reporting.

Keywords: Reporting, adverse drug reaction, attitude, Knowledge, practices of hospital staff.

# INTRODUCTION

Adverse drug reactions (ADRs) are an important reason for morbidity and mortality in all over the world.<sup>1</sup> According to World Health Organization (WHO) definition, an ADR is any noxious, unintended, and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or therapy.<sup>2</sup> It is known that, the role of healthcare Professionals in any community in monitoring and reporting ADRs are so important too.<sup>3-6</sup>

Although, there is a better ADR reporting culture in the developed countries, under-reporting is a major issue with spontaneous reporting.<sup>7,8</sup> The predictors of under-reporting have been described several times by many healthcare professionals,<sup>9-</sup> <sup>11</sup> but these vary from study to another study.

Also, although, the socio-economic and health consequences of ADRs have been studied in many previous studies,<sup>10-12</sup> and the importance of healthcare professionals in these issues (reporting of ADRs, and development of ADRs databases) in all over the world has been established before in many previous studies, too,<sup>4,6-8</sup> most of these studies have shown prevalence of this issue in both developed, while in developing countries (including the Kingdom of Saudi Arabia) are not evaluated

sufficiently. Unfortunately, there is a deficiency in data accuracy, and specificity, about these issues, from many developing countries. Also, the previous studies from various areas in the KSA have focused on the perception and practice of ADR reporting among physicians only, while the other various healthcare workers (such as pharmacists, and nurses) are excluded.<sup>13-15</sup>

So, we tried in this study to determine and estimate the attitude, knowledge, and practice of ADR reporting among healthcare Professionals (physicians, nurses, and pharmacists) in various work positions in the Kingdom of Saudi Arabia, by using a simple survey.

## METHODOLOGY

The study was done by a survey (a cross-sectional questionnaire), it was established between the period April and May of 2023, with 35 questions (7 of them are personal questions) from 52 participants, involving physicians, nurses, and pharmacists, who work in various work positions, or various departments of hospitals or pharmacies, medical centers in various regions in the KSA, such as: Sabya, Abha General Hospital, King Fahad Central Hospital). The survey questions can be seen in Tables 1, 2 and 3.

Also, a convenience sampling method was done, and distributed to the participants during their work activities for study. The questionnaire was designed and adapted from similar studies that aimed to evaluate the attitudes, knowledge, and practices of reporting ADRs in the Kingdom of Saudi Arabia.<sup>5</sup>

Then the collected data, which were nominal<sup>16</sup> or ordinal data<sup>17</sup> (such as the Likert scale),<sup>18</sup> were quantified and calculated by convenient statistical tests (such as percentages), and figured by SPSS version 26 at a defined statistical significance (P-value) of less than 0.05.<sup>19,20</sup>

Invalid data were excluded from collection and analysis.

### Ethical approval

Provided by Aseer IRB, Ministry of Health, Directorate of health affairs, Aseer region.

# RESULTS

The questions and their answers were quantified and calculated by convenient statistical tests (such as percentages) and figured by SPSS version 26. at a defined Statistical significance (Pvalue) of less than 0.05. However, the results can be summarized briefly in the following Tables 1, 2 and 3.

Table 1: Demographic characteristics	s of the study participants
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Question/Answer	Frequency	Percent	Valid Percent	Cumulative Percent
What is your gender?				
Male	32	61.5	61.5	61.5
Female	20	38.5	38.5	100.0
Is your hospital/work private or government?				
Government	45	86.5	86.5	86.5
Private	7	13.5	13.5	100.0
Please write the name of your hospital/work?				
King Fahd Central Hospital	1	1.9	1.9	1.9
Abha psychiatric hospital	2	3.8	3.8	7.7
Aasier general hospital	1	1.9	1.9	3.8
Abu Arish general hospital	1	1.9	1.9	9.6
Ahad almasarha general	1	1.9	1.9	11.5
AL ARDAH General hospital	1	1.9	1.9	13.5
Al dawaa pharmacy	1	1.9	1.9	15.4
Al twaoal general hospital	1	1.9	1.9	17.3
Al-nahdi Pharmacy	2	3.8	3.8	21.2
Al.T.G.H	3	5.8	5.8	26.9
Aldawaa pharmacy	1	1.9	1.9	28.8
Aloteab hospital	1	1.9	1.9	30.8
Fahad malitary center	1	1.9	1.9	32.7
GAMA hospital	1	1.9	1.9	34.6
General baish hospital	1	1.9	1.9	36.5
KFCH	7	13.5	13.5	50.0
KFMC	1	1.9	1.9	51.9
King Fahad Cental Hospital	1	1.9	1.9	53.8
King Fahad Central Hospital	4	7.7	7.7	61.5
King salman hospital	1	1.9	1.9	63.5
Mohammed bin nasser hospital	1	1.9	1.9	65.4
National guard hospital	1	1.9	1.9	67.3
Pmbnh	1	1.9	1.9	69.2
Prince Khalid bin sultan cardiac center	1	1.9	1.9	71.2
Respiratory hospital	1	1.9	1.9	73.1
S.G.H	1	1.9	1.9	75.0
Sabya general hospital	4	7.7	7.7	82.7
Sametah general hospital	8	15.4	15.4	98.1
Saudi German hospital	1	1.9	1.9	100.0
Sabya general hospital	4	7.7	7.7	82.7
Sametah general hospital	8	15.4	15.4	98.1
Saudi German hospital	1	1.9	1.9	100.0

# Table 2: Personal experience and Knowledge of HCPs regarding the reporting of suspected ADRs

Question/Answer	Frequency	Percent	Valid Percent	Cumulative Percent	
Have you ever had an adverse drug reaction or sensitivity to any medication?					
Yes	16	30.8	30.8	30.8	
No	36	69.2	69.2	100.0	
Do you have any family member who had an adverse drug reaction or sensitivity to any medication?					
Yes	21	40.4	40.4	40.4	
No	31	59.6	59.6	100.0	
Have you ever come across any patient during your hospital who had an adverse drug reaction or sensitivity to any medication?					
Yes	31	59.6	59.6	59.6	
No	21	40.4	40.4	100.0	

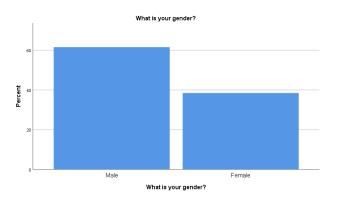
If you answered the last question "YES", have you reported it?							
Yes	26	50.0	50.0	50.0			
No	26	50.0	50.0	100.0			
Adverse drug reaction (ADR) is\are							
Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment	25	48.1	48.1	48.1			
Any noxious change which is suspected to be due to a drug occurs at a dose normally used in a human requires treatment or a decrease in dose, or indicates caution in the future use of the same drug	27	51.9	51.9	100.0			
Adverse drug reactions classification based on							
Onset of occurrence	7	13.5	13.5	13.5			
Type of reaction	9	17.3	17.3	30.8			
Severity	5	9.6	9.6	40.4			
The onset of occurrence, Type of reaction, and severity	31	59.6	59.6	100.0			
The scale used to assess the cause of adverse drug reactions is named							
Probability scale	23	44.2	44.2	44.2			
Causality scale	19	36.5	36.5	80.8			
Severity scale	10	19.2	19.2	100.0			
Hypersensitivity reactions are to adverse drug reactions:	<b>1</b>						
Related	41	78.8	78.8	78.8			
Unrelated	11	21.2	21.2	100.0			
The governmental monitoring agency for adverse drug reactions in Saud			1	1			
Ministry of Health (MOH)	13	25.0	25.0	25.0			
Saudi Food and Drug Authority (SFDA)	36	69.2	69.2	94.2			
Saudi Arabia does not have a monitoring agency for adverse drug reactions	3	5.8	5.8	100.0			
Which type of adverse drug reactions should be reported?			1				
All ADRs should be reported regardless of their severity	45	86.5	86.5	86.5			
Only serious adverse drug reactions should be reported	7	13.5	13.5	100.0			
Adverse drug reactions that should be reported are related to							
Medications, OTC, Vaccines, Herbal products, and Cosmetics	42	80.8	80.8	80.8			
Medication only	4	7.7	7.7	88.5			
Vaccines	3	5.8	5.8	94.2			
Cosmetic	1	1.9	1.9	96.2			
Medications + Over the counter (OTC) products 2 3.8 100.0   Before reporting an adverse drug reaction confirmation that adverse drug reaction is related to a particular drug is							
	0						
Necessary	49	94.2	94.2 5.8	94.2			
Not necessary	5	5.8	5.8	100.0			
<b>Reporting adverse drug reactions make a significant contribution to the</b> Strongly agree	33	63.5	63.5	63.5			
Agree	14	26.9	26.9	90.4			
Neutral	5	9.6	9.6	90.4			
Reporting adverse drug reactions make a significant contribution to pati	5	9.0	9.0	100.0			
Strongly agree	30	57.7	57.7	57.7			
Agree	17	32.7	32.7	90.4			
Neutral	4	7.7	7.7	98.1			
Disagree	1	1.9	1.9	100.0			
Reporting adverse drug reactions is a responsibility of me?							
Strongly agree	25	48.1	48.1	48.1			
Agree	18	34.6	34.6	82.7			
Neutral	9	17.3	17.3	100.0			
Reporting ADRs should be made compulsory for all health care profession	-						
Strongly agree	25	48.1	48.1	48.1			
Agree	13	25.0	25.0	73.1			
Neutral	10	19.2	19.2	92.3			
Disagree	2	3.8	3.8	96.2			
Strongly disagree	2	3.8	3.8	100.0			

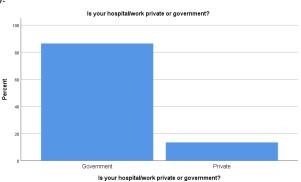
# Table 3: Attitude and Practice of HCPs regarding the reporting of suspected ADRs

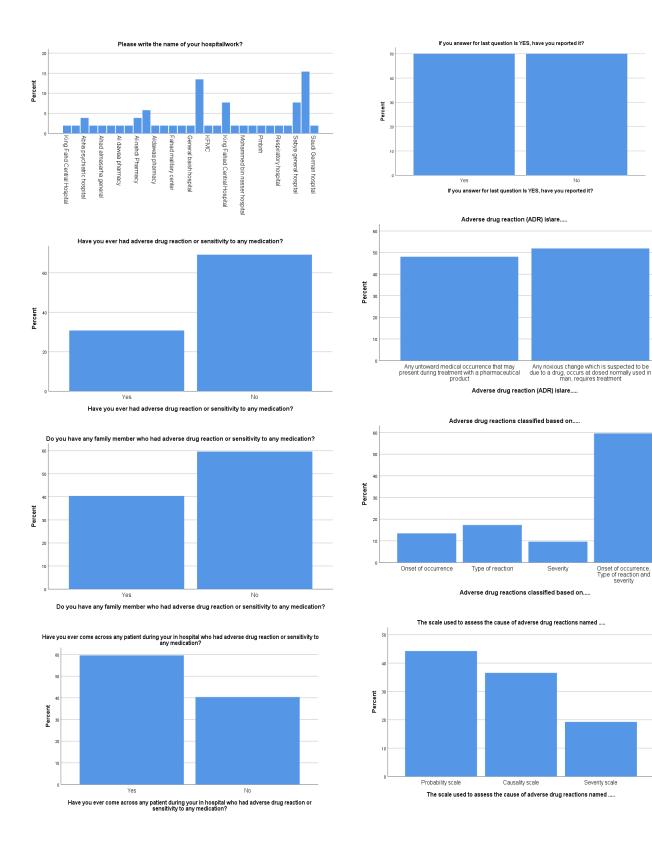
Question/Answer	Frequency	Percent	Valid Percent	Cumulative Percent		
Staff in your hospital are trained on how to report adverse drug reactions?						
Yes	41	78.8	78.8	78.8		
No	11	21.2	21.2	100.0		
Staff in your hospital can perform adverse drug reaction reporting during their clerkship/ internship?						
Yes	35	67.3	67.3	67.3		
No	17	32.7	32.7	100.0		
Are you use the Naranjo scale in your hospital?						
Yes	25	48.1	48.1	48.1		
No	27	51.9	51.9	100.0		
If your answer is "Yes", it is used						
Manual	33	63.5	63.5	63.5		

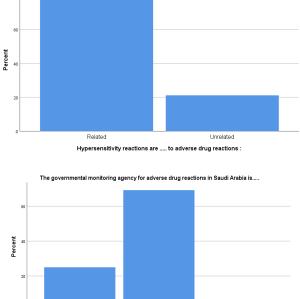
	1.0				
Electronic	19	36.5	36.5	100.0	
The previous conclusive reports on this reaction?					
Yes	14	26.9	26.9	26.9	
No	4	7.7	7.7	34.6	
Don't know	34	65.4	65.4	100.0	
Did the adverse events appear after the suspected dru	ig was given?				
Yes	22	42.3	42.3	42.3	
No	8	15.4	15.4	57.7	
Don't know	22	42.3	42.3	100.0	
Did the adverse reaction improve when the drug was	discontinued or				
Yes	26	50.0	50.0	50.0	
No	9	17.3	17.3	67.3	
Don't know	17	32.7	32.7	100.0	
Did the adverse reaction appear when the drug was re	e-administered	?			
Yes	26	50.0	50.0	50.0	
No	7	13.5	13.5	63.5	
Don't know	19	36.5	36.5	100.0	
Was the reaction more severe when the dose was incr	eased, or less se	vere when the d	lose was decrea	sed?	
Yes	25	48.1	48.1	48.1	
No	7	13.5	13.5	61.5	
Don't know	20	38.5	38.5	100.0	
Have you received some form of ADR education prev	iously?	•	•	· · · ·	
Yes	37	71.2	71.2	71.2	
No	15	28.8	28.8	100.0	
If you answer YES, which form of education did you	have?	•	•	•	
Attend educational session	12	23.1	23.1	23.1	
Social media	7	13.5	13.5	36.5	
Compulsory course in your college curriculum	12	23.1	23.1	59.6	
Reading	21	40.4	40.4	100.0	
If you attend an educational session about adverse dr	ug reaction rep	orting previous		ou receive it?	
University	28	53.8	53.8	53.8	
Hospital	17	32.7	32.7	86.5	
Social meeting	3	5.8	5.8	92.3	
Online	4	7.7	7.7	100.0	
Who conducted that education?		,	, . ,		
My academic teacher	16	30.8	30.8	30.8	
Pharmacists	22	42.3	42.3	73.1	
Medication safety officer	6	11.5	11.5	84.6	
Physician	7	13.5	13.5	98.1	
Nurses	1	1.9	1.9	100.0	
Do you feel you are adequately prepared to report adverse drug reactions in your future practice?					
Yes	34	65.4	65.4	65.4	
No	18	34.6	34.6	100.0	
<b>Do you believe that all medical staff need education about adverse drug reaction reporting systems?</b>					
Yes	43	82.7	82.7	82.7	
No	9	17.3	17.3	100.0	
	/	- ,	- ,	10010	
If the staff in your hospital were offered an opportunity to undertake education in an adverse drug reaction reporting system, would you be willing to participate?					
Yes	44	84.6	84.6	84.6	
No	8	15.4	15.4	100.0	
110	0	1.7.т	1.7.7	100.0	

Also, the results can be presented in the following Figures (Bar Charts):





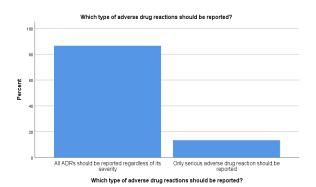




Hypersensitivity reactions are ..... to adverse drug reactions :

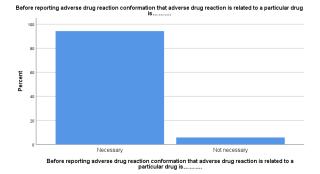
Saudi Food and Drug Authority (SFDA) Saudi Arabia does not have a monitoring agency for adverse drug reactions Ministry of Health (MOH)

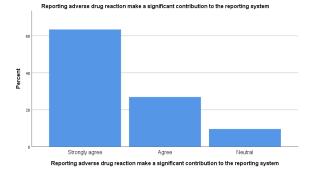
The governmental monitoring agency for adverse drug reactions in Saudi Arabia is.....



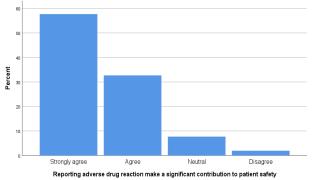
Adverse drug reactions that should be reported are related to. Percent Medications, OTC Vaccines, Herbal products and Cosmetics Medications + Over the counter (OTC) products Medication only Cosmetir

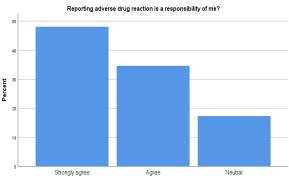
#### Adverse drug reactions that should be reported are related to .....



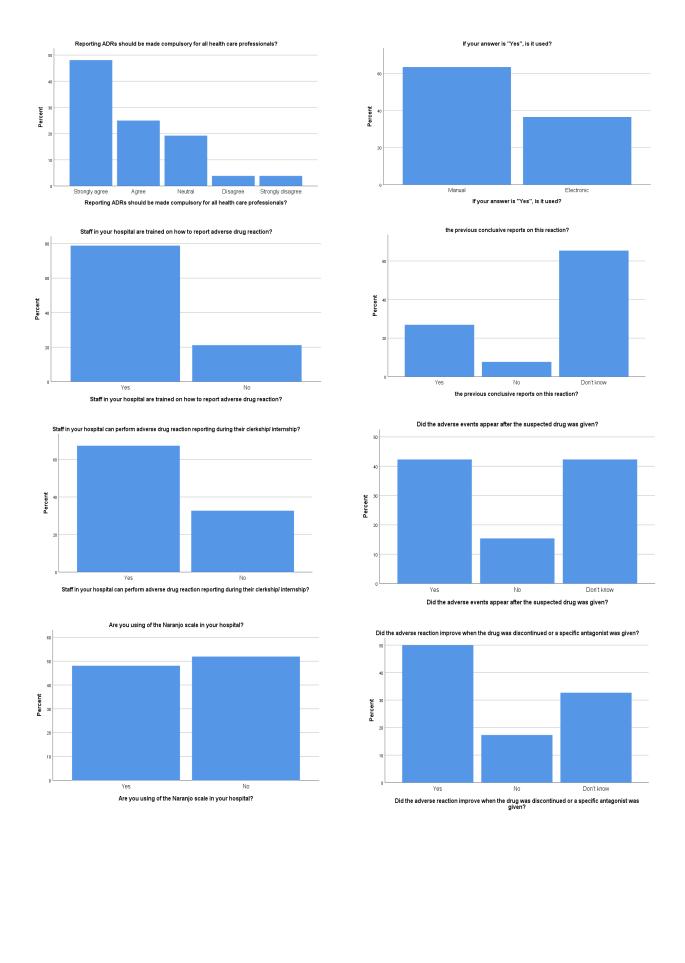


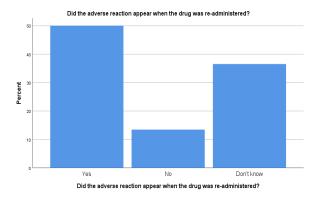
Reporting adverse drug reaction make a significant contribution to patient safety

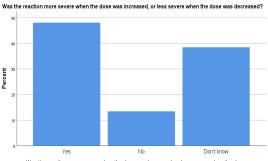




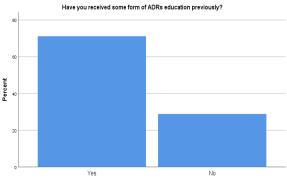
Reporting adverse drug reaction is a responsibility of me?



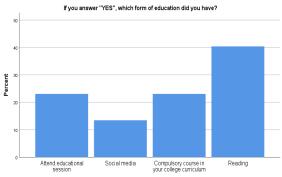


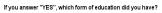


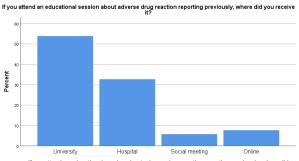
Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?



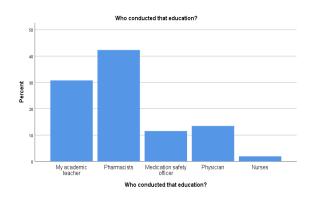
Have you received some form of ADRs education previously?

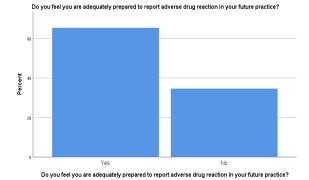




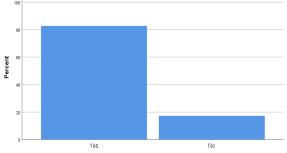


If you attend an educational session about adverse drug reaction reporting previously, where did you receive it?



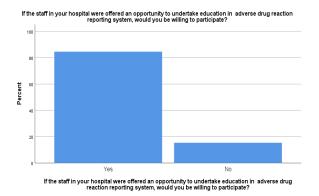


Do you believe that all medical staff need education about adverse drug reaction reporting system?



Do you believe that all medical staff need education about adverse drug reaction reporting system?

# Yazeed Hussein Al-Jmaai et al / Int. J. Res. Ayurveda Pharm. 15 (2), 2024



## DISCUSSION

We can notice in Table 1, about the demographic characteristics of the study participants, that 61.5% are males and 38.5% are females. Regarding their hospital/work, most of them work in a government job (86.5%), with various workplaces.

Also, in Table 2, about personal experience and Knowledge of HCPs regarding the reporting of suspected ADRs, we can notice that: About the question (Have you ever had an adverse drug reaction or sensitivity to any medication?), most of the answers are "No" with 69.2%. Question (Do you have any family member who had an adverse drug reaction or sensitivity to any medication?), most of the answers are "No" with 59.6%. Question (Have you ever come across any patient during your hospital who had an adverse drug reaction or sensitivity to any medication?), most of the answers are "Yes" with 59.6%. Question (If you answered the last question "YES", have you reported it?), the answers are 50% for each. Question (Adverse drug reaction (ADR) is\are.....), most of the answers are (Any noxious change which is suspected to be due to a drug, occurs at dosed normally used in human, requires treatment or decrease in dose or indicates caution in the future use of the same drug), with 51.9%. Question (Adverse drug reactions classification based on.....), most of the answers are (The onset of occurrence, and type of reaction and severity), with 59.6%. Question (The scale used to assess the cause of adverse drug reactions is named .....), most of the answers are (Probability scale), with 44.2%. Question (Hypersensitivity reactions are ..... to adverse drug reactions), most of the answers are (Related), with 78.8%. Question (The scale used to assess the cause of adverse drug reactions is named .....), most of the answers are (Probability scale), with 44.2%. Question (The governmental monitoring agency for adverse drug reactions in Saudi Arabia is.....), most of the answers are (Saudi Food and Drug Authority (SFDA)), with 69.2%. Question (Which type of adverse drug reactions should be reported?), most of the answers are (All ADRs should be reported regardless of their severity), with 86.5%. Question (Adverse drug reactions that should be reported are related to.....), most of the answers are (Medications, OTC, Vaccines, Herbal products, and Cosmetics), with 80.8%. Question (Before reporting adverse drug reactions confirmation that adverse drug reaction is related to a particular drug is.....), most of the answers are (Necessary), with 94.2%. Question (Reporting adverse drug reactions make a significant contribution to the reporting system?), most of the answers are (Strongly agree), with 63.5%. Question (Reporting adverse drug reactions make a significant contribution to patient safety?), most of the answers are (Strongly agree), with 57.7%. Question (Reporting adverse drug reactions are a responsibility of me?), most of the answers are (Strongly agree), with 48.1%. while question (Reporting ADRs should be made compulsory for all

health care professionals?), most of the answers are (Strongly agree), with 48.1%.

In Table 3, bout the attitude and Practice of HCPs regarding the reporting of suspected ADRs, we can notice that: Question (Staff in your hospital are trained on how to report adverse drug reactions?), most of the answers are (Yes), with 78.8%. Question (Staff in your hospital can perform adverse drug reaction reporting during their clerkship/ internship?), most of the answers are (Yes), with 67.3%. Question (Are you use the Naranjo scale in your hospital?), most of the answers are (No), with 51.9%. Question (If your answer is "Yes", it is used......), most of the answers are (Manual), with 63.5%. Question (The previous conclusive reports on this reaction?), most of the answers are (Don't know), with 65.4%. Question (Did the adverse events appear after the suspected drug was given?), most of the answers are (Don't know), with 42.3%. Question (Did the adverse reactions improve when the drug was discontinued or a specific antagonist was given?), most of the answers are (Yes), with 50%. Question (Did the adverse reactions appear when the drug was re-administered?), most of the answers are (Yes), with 50%. Question (Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?), most of the answers are (Yes), with 50%. Question (Have you received some form of ADR education previously?), most of the answers are (Yes), with 71.2%. Question (If you answer "YES", which form of education did you have?), most of the answers are (Reading), with 40%. Question (If you attend an educational session about adverse drug reaction reporting previously, where did you receive it?), most of the answers are (University), with 53.8%. Question (Who conducted that education?), most of the answers are (Pharmacists), with 42.3%, this answer may be due to most of the participants being pharmacists. Question (Do you feel you are adequately prepared to report adverse drug reactions in your future practice?), most of the answers are (Yes), with 65.4%. Question (Do you believe that all medical staff needs education about adverse drug reaction reporting system?), most of the answers are (Yes), with 82.7%. Lastly, question (If the staff in your hospital were offered an opportunity to undertake education in adverse drug reaction reporting system, would you be willing to participate?), most of the answers are (Yes), with 84.6%.

The sample size of this study is quite small, and most of the participants are pharmacists, so, there is some bias in some answers, such as in question (Who conducted that education?), most of the answers were (Pharmacists), with 42.3%. Also, this study cannot be generalized in various areas or other countries.

# CONCLUSIONS

Health care professionals had a positive attitude, they had adequate knowledge and practice towards ADR reporting. But the present study identified lack of good documentation and ADR reporting practice which contributed to underreporting in hospitals to SFDA or MOH. Although most of HCPs (most of them are pharmacists) had favorable attitude towards ADR reporting. Hence, taking into account HCPs' suggestions and the study findings, there is a need for more educational and training programs for HCPs regarding the Adverse drug reactions reporting system.

#### **Recommendations and Limitations**

Because of the small sample size of this study, and most of the participants are pharmacists (about 42.3%), so, this study cannot

be generalized in various areas or other countries. Also, it is recommend designing, and doing much research, in future, about these issues with larger sample sizes, various participants with various medical field, and in various areas in the country, to obtain more better, accurate, and generalized results. Also, to obtain more evidence and more comprehensive knowledge is recommended.

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# ABBREVIATIONS

ADRs: Adverse drug reactions. KSA: the Kingdom of Saudi Arabia. SPSS: Statistical Package for the Social Sciences. HCPs': Healthcare professionals. OTC: Over the counter products. MOH: Ministry of Health. SFDA: Saudi Food and Drug Authority.

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