CAHIERS MAGELLANES-NS
Volume 07 Issue 1
2025

ISSN:1624-1940
http://magellanes.com/

KNOWLEDGE, ATTITUDE, AND PRACTICE REGARDING PHARMACOVIGILANCE AMONG HEALTHCARE PROFESSIONALS IN SAUDI ARABIA

Adil Ali Ayed[1], Sadeem A. Alzahrani*[2], Sarah A. Alghamd[3], Meshal M. Alorainan[4], Maram S. Bawazir[5], Sarah A. Alzahrani[6], Fay F. Alotaibi[7], Hajar T. Almutairi[8], Norah Y. Asiri[9], Khames T. Alzahrani[10]

[1]Consultant Family Medicine, King Khalid University Medical City, Abha, Saudi Arabia.
[2]Pharmacy, Tamer Health Care Group, Jeddah, Saudi Arabia.
[3]Pharmacist, King Fahad university hospital, Al-khobar, Saudi Arabia.
[4]Pharm.D Intern, University of Hail, Hail, Saudi Arabia.
[5]Pharmacist, international medical Center, Jeddah, Saudi Arabia.
[6]Pharmacy Student, Al Baha university, Al Baha, Saudi Arabia.
[7]Pharmacy Intern, Shaqra University, Riyadh, Saudi Arabia.
[8]Pharmacist, Dr. Sulaiman Al Habib Medical Group, Riyadh, Saudi Arabia.
[9]Pharmacist, King Khalid University, Abha, Saudi Arabia.
[10]BDS, PGD Endo from Stanford University, Saudi Board of Endodontic SR, King Faisal Specialist Hospital & Research Centre, Riyadh, Saudi Arabia.

***Corresponding author**: Sadeem A. Alzahrani; **Email**: sadeemanz@gmail.com

Abstract

Introduction: Pharmacovigilance is the science of monitoring and preventing adverse drug reactions (ADRs) to enhance patient safety and improve healthcare outcomes. Established around 170 years ago, this field has evolved significantly, with key contributions from the World Health Organization's Uppsala Monitoring Centre and national initiatives like Saudi Arabia's National Pharmacovigilance Center. Studies highlight healthcare providers' and patients' varying knowledge, attitudes, and practices regarding ADR reporting, emphasizing the need for increased awareness and training. Addressing the under-reporting of ADRs is crucial to improving global drug safety and patient care. The study set out to evaluate the knowledge, attitude, and practice of pharmacovigilance among healthcare professionals in Saudi Arabia.

Methodology: This observational cross-sectional study recruited healthcare professionals in Saudi Arabia via social media from July to December 2024. Participants, including those with at least one year of experience and direct patient contact, completed an online self-administered questionnaire. The target sample size of 384 was determined using a 95% confidence level and a 5% margin of error. The questionnaire, adapted from similar studies, covered demographics, knowledge of pharmacovigilance, attitudes toward ADR reporting, and reporting procedures

Results: The study assessed the knowledge, attitudes, and practices regarding pharmacovigilance among 452 healthcare professionals in Saudi Arabia. Notably, 59.7% demonstrated a foundational understanding of pharmacovigilance, yet only 56.2% recognized its purpose in enhancing patient safety, revealing a significant knowledge gap. Despite a positive attitude toward reporting adverse drug reactions (ADRs), with 70.4% acknowledging its importance for public health, only 37.2% reported observed ADRs, indicating a discrepancy in proactive engagement. Furthermore, 71.2% exhibited a low level of practice in pharmacovigilance, emphasizing the need for enhanced training to bridge the gap

ISSN:1624-1940
http://magellanes.com/

between knowledge, attitudes, and actual practices.

Conclusion: The mixed levels of awareness, positive attitudes, and concerning reporting practices underscore the importance of continuous efforts to promote pharmacovigilance and enhance patient safety.

Keywords: Pharmacovigilance, Healthcare professionals, Saudi Arabia, Adverse drug reactions.

Introduction:

Pharmacovigilance (PV), which is defined by the World Health Organization (WHO), is the science and practices involved in identifying, evaluating, learning, and avoiding side effects from drugs or any other possible drug-related issues [1]. The WHO also defines Adverse Drug Reactions (ADRs) as a hazardous and unanticipated reaction to medications at recommended dosages used for prevention, diagnosis, treatment, or to modify bodily functions [2]. Thus, pharmacovigilance is a crucial active and successful reporting mechanism for adverse drug reactions (ADRs).

Roughly 170 years ago, pharmacovigilance began, focusing on drug safety and risk-benefit monitoring. This commentary reviews its evolution from early reports to advanced electronic systems, highlighting milestones and challenges [3]. The Uppsala Monitoring Centre, the first WHO center for pharmacovigilance, and Saudi Arabia's National Pharmacovigilance Center, established in 2009, are key contributors [4]. Healthcare providers are crucial for detecting and reporting adverse drug reactions (ADRs) [5].

Recent studies in Saudi Arabia have provided valuable insights into the knowledge, attitudes, and practices of healthcare professionals and students regarding pharmacovigilance (PV) and adverse drug reaction (ADR) reporting. Understanding these aspects is crucial for improving drug safety and efficacy in the healthcare system. Research conducted among pharmacy students at King Khalid University revealed adequate knowledge and positive attitudes toward PV, with statistically significant results (p-value < 0.05) [6]. In contrast, findings from Princess Nourah bint Abdulrahman University highlighted a gap in awareness and practical skills among healthcare students, even though they held positive views on PV [7].further investigation among physicians in Saudi Arabia uncovered a deficiency in ADR reporting knowledge [8]. More recent studies, including those conducted in 2022 among community pharmacists from various regions, showed a strong grasp of ADR reporting and PV, alongside positive attitudes [9]. However, research conducted in Qassim in 2023 identified a low rate of ADR reporting, which was attributed to a lack of knowledge about reporting procedures [10]. A 2024 study that focused on oncology healthcare professionals across Saudi hospitals found that only 38.5% were familiar with formal ADR review processes and highlighted methotrexate and paclitaxel as drugs frequently associated with ADRs [11]. Together, these studies reveal a spectrum of awareness and knowledge regarding PV and ADR reporting, pointing to significant knowledge gaps alongside some positive attitudes among healthcare professionals and students in Saudi Arabia.

Adverse Drug Reactions (ADRs) significantly impact illness rates, mortality, hospitalizations, and healthcare costs, contributing to 28.9% of emergency admissions. However, only 6-10% of ADRs are reported [12], often due to a lack of awareness and training among healthcare providers. This study aims to address these issues by enhancing pharmacovigilance practices, ultimately improving national drug safety and patient outcomes.

ISSN:1624-1940
http://magellanes.com/

Objectives:

This study aims to assess knowledge, attitude, and practice regarding Pharmacovigilance among Healthcare professionals in Saudi Arabia.

Methodology:

Study Design and Setting:

This is an observation cross-sectional study conducted between July 2024 and December 2024 in Saudi Arabia. Healthcare professionals were recruited through social media platforms to participate in a cross-sectional survey. This survey was conducted using an online self-administered questionnaire specifically designed for Saudi healthcare professionals.

Sample size:

From July 2024 to December 2024 was the beginning of data collecting. Data collection involved a target sample of 384 patients (confidence level: 95%; margin of error: 5%). The sample size was estimated using the formula:

n = P(1-P) * Zα 2 / d 2 with a 95% confidence level.

n: Calculated sample size.

Z: The z-value for the selected level of confidence (1- a) = 1.96.

P: An estimated prevalence of knowledge.

Q: (1 – 0.50) = 50%, i.e., 0.50.

D: The maximum acceptable error = 0.05.

Therefore, the calculated minimum sample size was: n = (1.96)2 X 0.50 X 0.50/ (0.05) 2 = 384.

Inclusion and Exclusion Criteria:

Inclusion and Exclusion Criteria The study includes healthcare providers, such as physicians, nurses, and pharmacists, who agree to participate. Participants must have at least one year of experience working in various healthcare settings in Saudi Arabia. The study excludes healthcare professionals who do not agree to participate, or have less than the required minimum of one year of experience. The questionnaire distributed and collected through Google Forms to ensure easy access and submission by participants.

Method for data collection, instrument, and score system:

This cross-sectional study is a questionnaire-based survey used from similar studies with little modifications [13,14]. Conducted in Saudi Arabia among health care providers (Medicine, pharmacy, dentistry, and nursing). The questionnaire was divided into three sections. Six questions in Section (A) asked about the sample characteristics and sociodemographic of the respondents. Section (B) examines the participant's knowledge of the meaning of pharmacovigilance and its related basic concepts. In section (C), the participants asked about their attitudes toward pharmacovigilance and ADR reporting.

ISSN:1624-1940
http://magellanes.com/

Finally, section (D) evaluates the respondents' reporting procedures for spontaneous ADRs and pharmacovigilance.

Scoring system:

In the current study, the prepared 30-item self-administered survey was made available on Google Forms to collect data. An offer to participate in the current study was shared with several HCP-related groups in the Kingdom of Saudi Arabia. The original Bloom's cut-off points are 80.0%-100.0%, 60.0%-79%, and 59.0%, Based on their ratings, the participants split up into three groups.

Part 1: Examine the participant's knowledge about the meaning of pharmacovigilance and its related basic concepts in addition to the questions about the processes of reporting ADR by choosing the right answer through multiple-choice questions, the right response received a score of 1, and the incorrect answer received a score of 0. Thus, the total score ranged from 0 to 15 points. The maximum response 15 points, while the minimum response equal to 0 points. Pharmacists were categorized as having acceptable knowledge or poor knowledge based on their responses to 15 questions about pharmacovigilance and ADR reporting. Those who scored equal to 9 and less were considered to have a low level of knowledge, people who scored 10 to 11 were considered to have a moderate level of knowledge, and people who scored 12 or above 12 were considered to have a high level of knowledge.

Part 2: the participants asked about the attitude questions constructed into a 5-point Likert scale (Strongly agree= 2, Agree= 2, I do not know= 1, Disagree= 0, Strongly disagree= 0). 16 points was the maximum response, while 0 points was the minimum. Individuals with a score of 9 or lower were classified as having a Negative attitude score, those with a score of 10 to 12 as having a moderate level of attitude, and those with a score of 13 or higher as having a high level of attitude.

Part 3: had 7 practice skills questions, The correct response is yes with a score of 1, and No answer with a score of 0. The maximum response is equal to 7, while the minimum response was 0 score. Those who get 4 points or less exhibit poor practice, those with a score of 5 - 6 have a moderate level of practice, and those with a score of 7 have a high level of practice.

Pilot test:

Twenty people were given the questionnaire and asked to complete it. This was done to assess the study's viability and the ease of use of the questionnaire. The pilot study's results were not included in the study's final data.

Analyzes and entry method:

Using the "Microsoft Office Excel Software" application (2019) for Windows, data was entered into the computer. After that, the data was transferred to version 20 of the Statistical Package of Social Science Software (SPSS) application for statistical analysis.

Results:

Table (1) displays various demographic parameters of the participants with a total number of (452). Notably, the mean age of participants is 27.7 years, with a substantial proportion (56.2%) under the age

ISSN:1624-1940
http://magellanes.com/

of 26 and a majority (59.3%) identifying as female. This suggests a young workforce, likely indicative of a dynamic and evolving healthcare environment. Regarding professional experience, most participants (52.2%) reported having only one year of experience, which may reflect the entry-level status of many in the profession. The majority of respondents are pharmacists (65.5%), highlighting the critical role they play in the health system, while a small percentage are nurses and physicians. Additionally, a significant majority (70.8%) reported being single, which may impact workforce stability and career development. Geographically, participants predominantly hail from the southern and eastern regions of Saudi Arabia, and an overwhelming majority are Saudi nationals (91.2%), emphasizing the localized nature of the healthcare workforce. Educationally, most participants hold a bachelor's degree, reinforcing a well-qualified demographic contributing to the healthcare sector.

Table (1): Sociodemographic characteristics of participants (n=452)

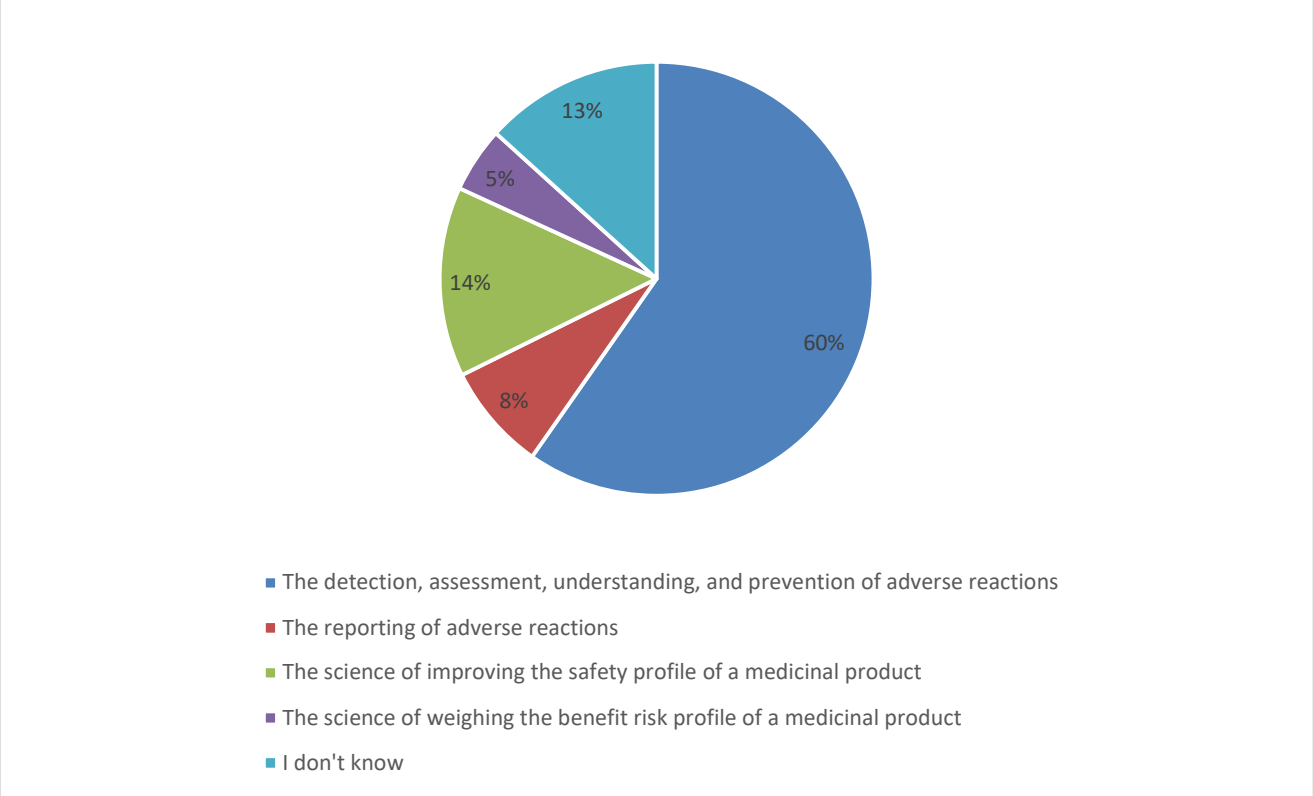
Parameter		**No.**	**Percent (%)**
Age (Mean: 27.7, STD:6.9)	23 years or less	118	26.1
	24 to 25	136	30.1
	26 to 30	94	20.8
	more than 30 years	104	23.0
Gender	Female	268	59.3
	Male	184	40.7
Experience in years (Mean: 3.9, STD:5.3)	1 year experience	236	52.2
	1.5 to 5 years	129	28.5
	6 to 10 years	36	8.0
	more than 10 years	51	11.3
What's your job?	Pharmacist	296	65.5
	Physician	82	18.1
	Nurse	16	3.5
	Other	58	12.8
Marital Status	Single	320	70.8
	Married	124	27.4
	Divorced	8	1.8
Geographic area in Saudi Arabia	Northern region	56	12.4
	Southern region	128	28.3
	Center Region	62	13.7
	Eastern region	112	24.8
	Western region	94	20.8
Nationality	Saudi	412	91.2
	Non-Saudi	40	8.8
Educational Qualification	Diploma	16	3.5
	Bachelor	378	83.6
	Higher than Bsc.	58	12.8

As shown in figure 1, The data on the understanding of the definition of pharmacovigilance reveals mixed levels of awareness among healthcare professionals. The majority, 270 respondents (59.7%), correctly identified pharmacovigilance as "the detection, assessment, understanding, and prevention of

ISSN:1624-1940
http://magellanes.com/

adverse reactions." However, 36 respondents (8%) incorrectly defined it as solely "the reporting of adverse reactions," while 64 participants (14.2%) associated it with "improving the safety profile of a medicinal product." Furthermore, 22 respondents (4.9%) believed it to be "the science of weighing the benefit-risk profile of a medicinal product," and 60 participants (13.3%) admitted they did not know the definition.

Figure (1): Illustrates the definition of pharmacovigilance among participants.



As illustrated in table (2), The data highlights the level of knowledge regarding pharmacovigilance among healthcare professionals, encompassing a sample size of 452 individuals. A significant 59.7% of participants accurately defined pharmacovigilance as the detection, assessment, understanding, and prevention of adverse reactions, indicating a foundational awareness of the subject. However, concerning the purpose of pharmacovigilance, only 56.2% recognized its role in enhancing patient safety related to drug use, suggesting a gap in understanding among some respondents. Notably, 73.5% provided a correct definition of adverse drug reactions, yet there remains a concerning percentage (67.7%) unaware of the International Drug Monitoring Center's establishment in Uppsala, Sweden. This lack of knowledge extends to the awareness of the Naranjo scale, with half of the respondents being uninformed. Additionally, while a majority (69.9%) acknowledged the existence of a National Pharmacovigilance Program in Saudi Arabia, a substantial number had not encountered reporting forms nor were aware of the nearest pharmacovigilance center.

ISSN:1624-1940
http://magellanes.com/

Table (2): Parameters related to knowledge regarding Pharmacovigilance among Healthcare professionals (n=452).

Parameter		***No.***	***Percent (%)***
The definition of pharmacovigilance is	The detection, assessment, understanding, and prevention of adverse reactions	270	59.7
	The reporting of adverse reactions	36	8.0
	The science of improving the safety profile of a medicinal product	64	14.2
	The science of weighing the benefit risk profile of a medicinal product	22	4.9
	I don't know	60	13.3
The purpose of pharmacovigilance is	To calculate incidence of Adverse drug reaction	14	3.1
	To enhance patients' safety in relation to use of drugs	254	56.2
	To identify predisposing factors to Adverse drug reaction	54	11.9
	To identify unrecognized Adverse drug reaction	66	14.6
	I don't know	64	14.2
The definition of Adverse drug reaction is	Adverse health outcomes associated with inappropriate drug use	44	9.7
	Any noxious or undesired effect of a drug occurring at normal doses, during normal use	332	73.5
	Harm caused by drug overdose	6	1.3
	Harm resulting from the use of substandard/counterfeit drugs	42	9.3
	I don't know	28	6.2
The pharmacovigilance center wants medical providers to report the following adverse medication reactions are	All adverse reactions regardless of seriousness and expectedness	208	46.0
	Expected adverse reactions	18	4.0
	Non-serious adverse reactions	22	4.9
	Serious and unexpected adverse reactions	142	31.4
	I don't know	62	13.7
Reports of adverse medication reactions are accepted by the pharmacovigilance center from	Consumers and patients only	36	8.0
	Healthcare professionals only	46	10.2
	Hospital networks only	6	1.3
	All of the above	306	67.7
	I don't know	58	12.8
The most adverse drug reaction	Phase I clinical trials	38	8.4

ISSN:1624-1940
http://magellanes.com/

information gathered across	Phase II clinical trials	42	9.3
	Phase III clinical trials	54	11.9
	Phase IV clinical trials and post marketing surveillance	220	48.7
	I don't know	98	21.7
Are you aware that the International Drug Monitoring Center is in Uppsala, Sweden?	No	306	67.7
	Yes	146	32.3
Do you have any idea that "Naranjo" scale is used for establishing causality of an ADR?	No	226	50.0
	Yes	226	50.0
For reporting purposes, the minimal set of information needed is	Adverse drug reaction type	12	2.7
	Only the names of the suspected drug need to be reported	44	9.7
	Reporter, suspected drug, adverse drug reaction type, patients info	254	56.2
	Suspected drug, adverse drug reaction type	56	12.4
	I don't know	86	19.0
Do you know if Saudi Arabia has a National Pharmacovigilance Program?	No	136	30.1
	Yes	316	69.9
Do you know about the Drug Safety and National Pharmacovigilance Center (Saudi Vigilance) of the SFDA?	No	116	25.7
	Yes	336	74.3
Have you ever seen a form for reporting adverse drug reactions?	No	186	41.2
	Yes	266	58.8
Are you familiar with reporting adverse drug reactions?	No	196	43.4
	Yes	256	56.6
Do you know where the closest pharmacovigilance center is located from your working place?	No	300	66.4
	Yes	152	33.6
Have you taken any courses about Drug safety or Adverse drug reaction reporting?	No	214	47.3
	Yes	238	52.7

As shown in figure (2), The data shows strong support among healthcare professionals for the idea that reporting adverse drug reactions (ADRs) can improve public health. A significant majority, 318 respondents (70.4%), strongly agree with this statement, while 100 respondents (22.1%) agree. Together, 92.5% of participants demonstrate a positive outlook on the importance of ADR reporting in safeguarding public health. Only 18 respondents (4%) neither agree nor disagree, while a minimal percentage, 10 respondents (2.2%) and 6 respondents (1.3%), disagree or strongly disagree, respectively.

ISSN:1624-1940
http://magellanes.com/

Figure (2): Illustrates the importance of reporting ADR to improve public health according to participants

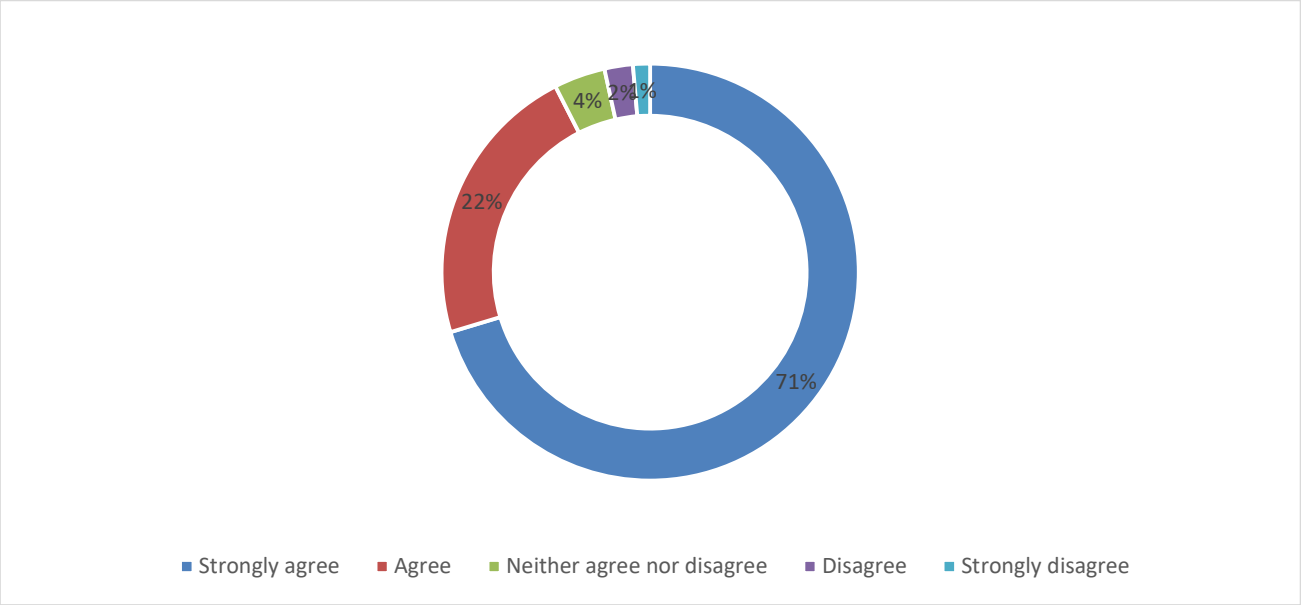


Table (3) reveals insights into healthcare professionals' attitudes toward pharmacovigilance, specifically regarding the reporting of adverse drug reactions (ADRs). A commendable majority of participants, accounting for 70.4%, strongly agree that reporting ADRs is instrumental in enhancing public health; this underscores the recognized importance of pharmacovigilance in ensuring patient safety. Furthermore, while 41.6% of respondents strongly believe that a single report can impact drug safety, a combined 77.9% agree or strongly agree with this assertion, indicating a shared conviction in the value of each individual contribution to the pharmacovigilance database. Interestingly, the perception of the safety of all marketed medications appears more divided, with 44.7% disagreeing with the notion that all medicines are inherently safe. Furthermore, only 20.8% of participants support the idea that ADR reporting should be voluntary, suggesting a preference for a more structured approach in pharmacovigilance practices. Notably, 77.5% of respondents agree on the necessity for detailed pharmacovigilance training for healthcare professionals.

Table (3): participants' attitude regarding Pharmacovigilance among Healthcare professionals (n=452).

Parameter		***No.***	***Percent (%)***
Is it possible to report adverse drug reactions to improve public health?	Strongly agree	318	70.4
	Agree	100	22.1
	Neither agree nor disagree	18	4.0
	Disagree	10	2.2
	Strongly disagree	6	1.3
Can a single report have an impact?	Strongly agree	188	41.6
	Agree	164	36.3
	Neither agree nor disagree	60	13.3

ISSN:1624-1940
http://magellanes.com/

	Disagree	32	7.1
	Strongly disagree	8	1.8
Does reporting adverse drug reactions improve the safety of drugs?	Strongly agree	308	68.1
	Agree	100	22.1
	Neither agree nor disagree	38	8.4
	Disagree	2	.4
	Strongly disagree	4	.9
Are all medications sold on the market safe?	Strongly agree	56	12.4
	Agree	96	21.2
	Neither agree nor disagree	98	21.7
	Disagree	118	26.1
	Strongly disagree	84	18.6
Herbal products are safe because they don't cause any adverse drug reaction	Strongly agree	52	11.5
	Agree	42	9.3
	Neither agree nor disagree	46	10.2
	Disagree	122	27.0
	Strongly disagree	190	42.0
Should HCPs receive detailed instruction in pharmacovigilance?	Strongly agree	178	39.4
	Agree	172	38.1
	Neither agree nor disagree	82	18.1
	Disagree	12	2.7
	Strongly disagree	8	1.8
Should reporting of adverse drug reactions be done voluntarily?	Strongly agree	120	26.5
	Agree	148	32.7
	Neither agree nor disagree	94	20.8
	Disagree	70	15.5
	Strongly disagree	20	4.4
Is it required to verify that adverse drug reaction is associated with a specific drug before reporting it?	Strongly agree	156	34.5
	Agree	186	41.2
	Neither agree nor disagree	72	15.9
	Disagree	34	7.5
	Strongly disagree	4	.9

The data presented in Table 4 offers intriguing insights into the practice of pharmacovigilance among healthcare professionals, as reflected by a sample of 452 participants. A significant 60.6% of respondents indicated they have encountered Adverse Drug Reactions (ADRs), yet only 37.2% have spontaneously reported these cases upon observation, highlighting a potential gap in proactive reporting behavior. This discrepancy is further emphasized by the finding that 73.0% have not utilized the SFDA website or reporting forms for ADRs, suggesting barriers to reporting that may stem from a lack of familiarity or motivation. Furthermore, while 45.1% reported not receiving instruction on completing ADR reporting forms, training appears necessary to enhance compliance and reporting rates. Importantly, an impressive 70.8% of participants indicated they engage in patient counseling regarding possible ADRs, reflecting a proactive approach to patient safety despite the noted shortcomings in reporting practices.

ISSN:1624-1940
http://magellanes.com/

Table (4): Participants' practice towards pharmacovigilance among healthcare professionals (n=452).

Parameter	*No*	*Yes*
Are there any ADRs you have seen?	178 39.4%	274 60.6%
Have you ever spontaneously reported an ADR as soon as it was observed?	284 62.8%	168 37.2%
Have you ever reported an ADR via the SFDA website or an SFDA-Spontaneous ADR reporting form?	330 73.0%	122 27.0%
Have you ever been instructed on how to complete forms for spontaneous ADR reporting?	248 54.9%	204 45.1%
Have you ever gone to any seminars or courses on pharmacovigilance and Spontaneous ADR reporting?	278 61.5%	174 38.5%
Regarding possible ADRs, do you offer patient counseling?	132 29.2%	320 70.8%
Do you find it difficult to spontaneously report ADRs?	250 55.3%	202 44.7%

The data presented in Table (5) highlights a significant gap in pharmacovigilance knowledge among healthcare professionals. With 57.1% of respondents falling into the low knowledge category. Only 19.0% of professionals demonstrated a high level of knowledge, while 23.9% displayed moderate understanding. This imbalance indicates that a large portion of healthcare professionals may not be adequately equipped to engage in effective pharmacovigilance practices.

Table (5): Shows knowledge towards pharmacovigilance among healthcare professionals score results.

	Frequency	**Percent**
High knowledge Level	86	19.0
Moderate knowledge	108	23.9
Low knowledge level	258	57.1
Total	452	100.0

The data in Table (6) reflects a generally positive attitude towards pharmacovigilance among healthcare professionals. A majority, 56.2%, demonstrated a moderate attitude, while 27.4% exhibited a high attitude, indicating that most professionals recognize the importance of pharmacovigilance. However, 16.4% showed a low attitude towards it, which may suggest a lack of engagement or understanding of its significance in ensuring drug safety.

ISSN:1624-1940
http://magellanes.com/

Table (6): Shows attitude towards pharmacovigilance among healthcare professionals score results.

	Frequency	**Percent**
High attitude	124	27.4
Moderate attitude	254	56.2
Low attitude level	74	16.4
Total	452	100.0

The data in Table (7) reveals a concerning trend in the practice of pharmacovigilance among healthcare professionals. A significant majority, 71.2%, reported a low level of practice, indicating that despite knowledge and attitude, actual engagement in pharmacovigilance activities remains insufficient. Only 10.2% of respondents demonstrated a high level of practice, while 18.6% reported moderate involvement.

Table (7): Shows practice towards pharmacovigilance among healthcare professionals score results.

	Frequency	**Percent**
High practice level	46	10.2
Moderate practice level	84	18.6
Low practice level	322	71.2
Total	452	100.0

Table (8) shows that knowledge level towards pharmacovigilance among healthcare professionals has statistically significant relation to age (P value=0.0001), experience in years (P value=0.0001), job (P value=0.0001), marital status (P value=0.008), and educational qualifications (P value=0.0001). It also shows statistically insignificant relation to gender, region of residence and nationality.

Table (8): Relation between knowledge level towards pharmacovigilance among healthcare professionals and sociodemographic characteristics.

Parameters		***Knowledge level***		***Total (N=452)***	***P value****
		High or moderate knowledge	**Low knowledge level**		
Gender	Female	120	148	268	0.336
		61.9%	57.4%	59.3%	
	Male	74	110	184	
		38.1%	42.6%	40.7%	
Age	23 years or less	54	64	118	0.0001
		27.8%	24.8%	26.1%	
	24 to 25	62	74	136	
		32.0%	28.7%	30.1%	
	26 to 30	52	42	94	
		26.8%	16.3%	20.8%	
	more than 30 years	26	78	104	
		13.4%	30.2%	23.0%	
Experience in	1 year	120	116	236	0.0001

ISSN:1624-1940
http://magellanes.com/

years	experience	61.9%	45.0%	52.2%	
	1.5 to 5 years	58	71	129	
		29.9%	27.5%	28.5%	
	6 to 10 years	6	30	36	
		3.1%	11.6%	8.0%	
	more than 10 years	10	41	51	
		5.2%	15.9%	11.3%	
Job	Pharmacist	168	128	296	0.0001
		86.6%	49.6%	65.5%	
	Physician	12	70	82	
		6.2%	27.1%	18.1%	
	Nurse	0	16	16	
		0.0%	6.2%	3.5%	
	Other	14	44	58	
		7.2%	17.1%	12.8%	
Marital status	Single	152	168	320	0.008
		78.4%	65.1%	70.8%	
	Married	40	84	124	
		20.6%	32.6%	27.4%	
	Divorced	2	6	8	
		1.0%	2.3%	1.8%	
Geographic area in Saudi Arabia	Northern region	18	38	56	0.061
		9.3%	14.7%	12.4%	
	Southern region	46	82	128	
		23.7%	31.8%	28.3%	
	Center Region	28	34	62	
		14.4%	13.2%	13.7%	
	Eastern region	56	56	112	
		28.9%	21.7%	24.8%	
	Western region	46	48	94	
		23.7%	18.6%	20.8%	
Nationality	Non-Saudi	16	24	40	0.696
		8.2%	9.3%	8.8%	
	Saudi	178	234	412	
		91.8%	90.7%	91.2%	
Educational Qualification	Diploma	4	12	16	0.0001
		2.1%	4.7%	3.5%	
	Bachelor	178	200	378	
		91.8%	77.5%	83.6%	
	Higher than Bsc.	12	46	58	
		6.2%	17.8%	12.8%	

P value was considered significant if ≤ 0.05.

ISSN:1624-1940
http://magellanes.com/

Table (9) shows that the attitude level towards pharmacovigilance among healthcare professionals has statistically significant relation to gender (P value=0.013), experience in years (P value=0.049), job (P value=0.015), geographical region (P value=0.005) and educational qualification (P value=0.0001). It also shows statistically insignificant relation to age, marital status, and nationality.

Table (9): Attitude level towards pharmacovigilance among healthcare professionals in association with sociodemographic characteristics.

Parameters		***Attitude level***		***Total (N=452)***	***P value****
		High attitude level	**Moderate or low attitude**		
Gender	Female	62	206	268	0.013
		50.0%	62.8%	59.3%	
	Male	62	122	184	
		50.0%	37.2%	40.7%	
Age	23 years or less	30	88	118	0.437
		24.2%	26.8%	26.1%	
	24 to 25	34	102	136	
		27.4%	31.1%	30.1%	
	26 to 30	32	62	94	
		25.8%	18.9%	20.8%	
	more than 30 years	28	76	104	
		22.6%	23.2%	23.0%	
Experience in years	1 year experience	62	174	236	0.049
		50.0%	53.0%	52.2%	
	1.5 to 5 years	43	86	129	
		34.7%	26.2%	28.5%	
	6 to 10 years	12	24	36	
		9.7%	7.3%	8.0%	
	more than 10 years	7	44	51	
		5.6%	13.4%	11.3%	
Job	Pharmacist	78	218	296	0.015
		62.9%	66.5%	65.5%	
	Physician	20	62	82	
		16.1%	18.9%	18.1%	
	Nurse	10	6	16	
		8.1%	1.8%	3.5%	
	Other	16	42	58	
		12.9%	12.8%	12.8%	
Marital status	Single	86	234	320	0.890
		69.4%	71.3%	70.8%	
	Married	36	88	124	
		29.0%	26.8%	27.4%	

ISSN:1624-1940
http://magellanes.com/

	Divorced	2	6	8	
		1.6%	1.8%	1.8%	
Geographic area in Saudi Arabia	Northern region	24	32	56	0.005
		19.4%	9.8%	12.4%	
	Southern region	34	94	128	
		27.4%	28.7%	28.3%	
	Center Region	14	48	62	
		11.3%	14.6%	13.7%	
	Eastern region	20	92	112	
		16.1%	28.0%	24.8%	
	Western region	32	62	94	
		25.8%	18.9%	20.8%	
Nationality	Non-Saudi	6	34	40	0.065
		4.8%	10.4%	8.8%	
	Saudi	118	294	412	
		95.2%	89.6%	91.2%	
Educational Qualification	Diploma	10	6	16	0.0001
		8.1%	1.8%	3.5%	
	Bachelor	106	272	378	
		85.5%	82.9%	83.6%	
	Higher than Bsc.	8	50	58	
		6.5%	15.2%	12.8%	

P value was considered significant if ≤ 0.05.

Table (10) shows that practice level towards pharmacovigilance among healthcare professionals has statistically significant relation to gender (P value=0.0001), age (P value=0.037), job (P value=0.001), and educational qualification (P value=0.008). It also shows statistically insignificant relation to experience in years, marital status, geographical region, and nationality.

Table (10): Practice level in association with sociodemographic characteristics.

Parameters		***Practice level***		***Total (N=452)***	***P value****
		High or moderate practice	**Low practice level**		
Gender	Female	56	212	268	0.0001
		43.1%	65.8%	59.3%	
	Male	74	110	184	
		56.9%	34.2%	40.7%	
Age	23 years or less	26	92	118	0.037
		20.0%	28.6%	26.1%	
	24 to 25	34	102	136	
		26.2%	31.7%	30.1%	
	26 to 30	36	58	94	
		27.7%	18.0%	20.8%	

ISSN:1624-1940
http://magellanes.com/

	more than 30 years	34	70	104	
		26.2%	21.7%	23.0%	
Experience in years	1 year experience	60	176	236	0.091
		46.2%	54.7%	52.2%	
	1.5 to 5 years	48	81	129	
		36.9%	25.2%	28.5%	
	6 to 10 years	10	26	36	
		7.7%	8.1%	8.0%	
	more than 10 years	12	39	51	
		9.2%	12.1%	11.3%	
Job	Pharmacist	104	192	296	0.001
		80.0%	59.6%	65.5%	
	Physician	16	66	82	
		12.3%	20.5%	18.1%	
	Nurse	2	14	16	
		1.5%	4.3%	3.5%	
	Other	8	50	58	
		6.2%	15.5%	12.8%	
Marital status	Single	84	236	320	0.115
		64.6%	73.3%	70.8%	
	Married	42	82	124	
		32.3%	25.5%	27.4%	
	Divorced	4	4	8	
		3.1%	1.2%	1.8%	
Geographic area in Saudi Arabia	Northern region	20	36	56	0.378
		15.4%	11.2%	12.4%	
	Southern region	36	92	128	
		27.7%	28.6%	28.3%	
	Center Region	12	50	62	
		9.2%	15.5%	13.7%	
	Eastern region	34	78	112	
		26.2%	24.2%	24.8%	
	Western region	28	66	94	
		21.5%	20.5%	20.8%	
Nationality	Non-Saudi	10	30	40	0.582
		7.7%	9.3%	8.8%	
	Saudi	120	292	412	
		92.3%	90.7%	91.2%	
Educational Qualification	Diploma	10	6	16	0.008
		7.7%	1.9%	3.5%	
	Bachelor	106	272	378	
		81.5%	84.5%	83.6%	
	Higher than Bsc.	14	44	58	
		10.8%	13.7%	12.8%	

ISSN:1624-1940
http://magellanes.com/

P value was considered significant if ≤ 0.05.

Discussion:

Pharmacovigilance is very important field for detecting, assessing and understanding adverse drug reactions (ADRs) to improve the safety of the patients and the quality of healthcare [15]. With the view to appraise the knowledge, attitude and practice of pharmacovigilance amongst healthcare professional in Saudi Arabia, this present cross-sectional study was carried out. The limitations of the present investigation as well as the findings of this current study are presented and compared to previous research on similar topics.

The study also indicated that about half of Saudi Arabia's healthcare workers, especially ones with little experience, are deficient in pharmacovigilance awareness. While 59.7% of respondents answered correctly the definition of pharmacovigilance, only 56.2% correctly interpreted the purpose of pharmacovigilance in improving patient safety [16,17]. This finding is consistent with Saudi Arabia and other country reports that health care professionals have insufficient knowledge on pharmacovigilance concepts [18, 19].

Dealing with attitudes towards pharmacovigilance, the majority (70.4%) of the participants stated that reporting of ADR is important for public health [20,21]. Yet perceptions of the safety of all marketed medications were more divided, with 44.7 percent disagreeing that all medications are inherently safe. The implication is that additional education is needed to correct misconceptions regarding drug safety [22,23].

For practice, the study showed a worrying tendency: 60.6 % of the experts had encountered ADRs, but only 37.2 % have reported. A well-documented challenge within the field of pharmacovigilance is this gap between knowledge/attitude and reality [24,25]. Some previous studies conducted in Saudi Arabia and in other countries have identified barriers to ADR reporting including lack of time, unfamiliarity with the reporting mechanisms, and doubts about the quantity of reported medication errors [26,27].

Moreover, the study independently demonstrated strong correlations between levels of knowledge, attitude, and practice with age, professional experience, job role, and educational qualification. These findings are consistent with previous research which has identified the need for targeted educational interventions and training programs aimed at closing the knowledge practice gap among health care practitioners [28,29].

Further work should consider the limitations that the present study has. The cross-sectional design precludes the ability to establish causal relationships between the variables studied. Longitudinal studies would contribute in assessing the long-term impact of educational interventions on the knowledge, attitude and practice regarding pharmacovigilance [30,31]. Furthermore, this was a study in Saudi Arabia and the findings may not be generalizable directly to other healthcare settings. It would be beneficial to have comparative studies of pharmacovigilance knowledge, attitudes, and practices in different countries or regions in order to better understand the wider context of pharmacovigilance knowledge, attitudes, and practices [32,33].

Conclusion:

The present cross-sectional study emphasizes the necessity for training purposes as well as for targeted educational interventions to bridge the gap between knowledge, attitudes, and practice of pharmacovigilance among the healthcare professionals in Saudi Arabia. Continuous efforts in pharmacovigilance and safety of the patient are essential because levels of awareness, attitudes are mixed and reporting practices are concerning. Future research should incorporate objective measures

ISSN:1624-1940
http://magellanes.com/

and examine longitudinal approaches in order to have a more complete understanding of this important issue.

Acknowledgement:

We acknowledge all of the volunteers who provided samples for this research.

Ethical approval:

After fully explaining the study and emphasizing that participation is optional, each participant gave their informed consent. The information gathered was safely stored and utilized exclusively for study.

Funding:

This study was not supported by any outside sources.

Conflict of interests:

The authors declare no conflict of interest.

Informed consent:

Written informed consent was acquired from each individual study participant.

Data and materials availability:

All data associated with this study are present in the paper.

References:

1. Chaudhary, Aswani & Gupta, Arvind & Kc, Balaram & Sah, Niraj & Sarraf, Deependra. (2022). Assessment of knowledge, attitude and practice of pharmacovigilance among people working in community pharmacy: a cross-sectional study at Banke district in Nepal Corresponding author. Nepal Medical College Journal. 24. 164-169. 10.3126/nmcj.v24i2.46042.
2. Ryamukuru D, Mukantwari J, Munyaneza E, Twahirwa TS, Bagweneza V, Nzamukosha A, et al. Pharmacovigilance: Awareness and Practice of Nurses and Midwives in Monitoring and Reporting Adverse Drug Reactions in a Selected University Teaching Hospital, Rwanda. Rwanda Journal of Medicine and Health Sciences. 2022;5(2):233–45.
3. Fornasier G, Francescon S, Leone R, Baldo P. An historical overview over Pharmacovigilance. Int J Clin Pharm [Internet]. 2018;40(4):744–7. Available from: https://doi.org/10.1007/s11096-018-0657-1
4. Khardali A. Exploring the knowledge, perception, and practice of community pharmacists in Saudi Arabia toward pharmacovigilance and adverse drug reaction reporting. A nationwide survey. Sci Rep. 2024 Dec 1;14(1).

ISSN:1624-1940
http://magellanes.com/

5. Abu Assab M, Alhamad H, Albahar F, Abu Dayyih W, Echarif S, Abu Assab H. Pharmacovigilance Concept Knowledge, Perspectives and Attitudes: A Cross-Sectional Study Among Community Pharmacists. Inquiry (United States). 2024;61.
6. Siddiqua A. Evaluation and assessment of the knowledge , attitude and practice of pharmacy students with respect to pharmacovigilance in a Saudi pharmacy school : a cross-sectional study . 2019;1–15.
7. Bepari A, Assiri RA, AlYahya MA, AlGhamdi SJ, AlGhamdi AM, AlOnazi AA. The comparative assessment of awareness, perspective, and basic practice skills about the Saudi pharmacovigilance system among students of different health-care professionals of a Saudi Female University. Saudi Pharmaceutical Journal. 2020;28(7):828–36.
8. Alomi YA, Alamoudi NH, Almasoudi AH. Physician's Knowledge of Adverse Drug Reaction in Saudi Arabia. International Journal of Pharmacology and Clinical Sciences. 2021;10(1):6–12.
9. Alsheikh MY, Alasmari MM. A National Survey of Community Pharmacists' Viewpoints About Pharmacovigilance and Adverse Drug Reaction Reporting in Saudi Arabia. Front Pharmacol. 2022 May 26;13.
10. Abdulsalim S, Farooqui M, Alshammari MS, Alotaibi M, Alhazmi A, Alqasomi A, et al. Evaluation of Knowledge, Attitudes, and Practices about Pharmacovigilance among Community Pharmacists in Qassim, Saudi Arabia. Int J Environ Res Public Health. 2023;20(4).
11. Alkofide H, Almalag HM, Alromaih M, Alotaibi L, Altuwaijri N, Al Aloola N, et al. Pharmacovigilance Practices by Healthcare Providers in Oncology: A Cross-Sectional Study. Pharmaceuticals. 2024;17(6):683.
12. Shrestha A, Jha N, Shankar PR, Madhikarmi NL. Knowledge, Attitude and Practice of Pharmacovigilance and Adverse Drug Reaction Reporting among Dental Students. KDC. 2020;3(1):6–11.
13. - CMV, - DrACR. Knowledge, Attitude, and Practice on Adverse Drug Reactions and its Reporting Among Nursing Students. International Journal For Multidisciplinary Research. 2024;6(1).
14. Alqahtani SS, Ahmad S, Alam N, Kashan Syed N, Syed MH, Khardali A, et al. Healthcare professionals' awareness, attitudes and practices towards pharmacovigilance and spontaneous adverse drug reaction reporting in Jazan Province, Saudi Arabia: A survey study. Saudi Pharmaceutical Journal [Internet]. 2023;31(6):979–88. Available from: https://doi.org/10.1016/j.jsps.2023.04.021
15. Almandil, H. "Healthcare professionals' awareness and knowledge of adverse drug reactions and pharmacovigilance." Saudi Medical Journal (2016). doi:10.15537/smj.2016.12.17059.
16. Abdel-Latif, M. M., & Abdel-Wahab, A. "Knowledge and awareness of adverse drug reactions and pharmacovigilance practices among healthcare professionals in Al-Madinah Al-Munawwarah, Kingdom of Saudi Arabia." Saudi Pharmaceutical Journal (2015). doi:10.1016/j.jsps.2014.07.005.
17. Farha, A. et al. "Effect of educational intervention on healthcare providers knowledge and perception towards pharmacovigilance: A tertiary teaching hospital experience." Saudi Pharmaceutical Journal (2018). doi:10.1016/j.jsps.2018.03.002.
18. Nasir, A. et al. "Acquaintance, approach and application of pharmacovigilance: questionnaire based study at a tertiary care teaching hospital in Dhaka." International Journal of Basic & Clinical Pharmacology (2020). doi:10.18203/2319-2003.ijbcp20203994.

ISSN:1624-1940
http://magellanes.com/

19. Hammour, A. et al. "Health care professionals knowledge and perception of pharmacovigilance in a tertiary care teaching hospital in Amman, Jordan." Journal of Evaluation in Clinical Practice (2017). doi:10.1111/jep.12683.
20. Nazakat, A., & Sajid, M. "Revealing Insights: Investigating Pharmacovigilance Knowledge, Attitudes, and Practices at a Leading Tertiary Care Hospital in Faisalabad." (2023). doi:10.53350/pjmhs2023175267.
21. Suyagh, M. et al. "Pharmacist's knowledge, practice and attitudes toward pharmacovigilance and adverse drug reactions reporting process." Saudi Pharmaceutical Journal (2015). doi:10.1016/j.jsps.2014.07.001.
22. Aljadhey, H. et al. "A qualitative exploration of the major challenges facing pharmacovigilance in Saudi Arabia." Saudi Medical Journal (2015). doi:10.15537/smj.2015.9.12125.
23. Jha, A. et al. "Effect of an educational intervention on knowledge and attitude regarding pharmacovigilance and consumer pharmacovigilance among community pharmacists in Lalitpur district, Nepal." BMC Research Notes (2017). doi:10.1186/s13104-016-2343-5.
24. Schutte, T. et al. "Pharmacovigilance Skills, Knowledge and Attitudes in our Future Doctors – A Nationwide Study in the Netherlands." Basic & Clinical Pharmacology & Toxicology (2017). doi:10.1111/bcpt.12712.
25. Kobayashi, Y. et al. "Knowledge, Attitudes, and Practice of Hospital Pharmacists Regarding Pharmacovigilance and Adverse Drug Reaction Reporting in Japan." Hospital Pharmacy (2019). doi:10.1177/0018578719851455.
26. Adenuga, A. et al. "Optimizing spontaneous adverse drug reaction reporting in public healthcare setting in Namibia." Basic & Clinical Pharmacology & Toxicology (2019). doi:10.1111/bcpt.13325.
27. El-Dahiyat, F. et al. "The impact of educational interventional session on healthcare providers knowledge about pharmacovigilance at a tertiary Jordanian teaching hospital." Journal of Pharmaceutical Policy and Practice (2023). doi:10.1186/s40545-023-00561-0.
28. Datta, S., & Sengupta, S. "An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting in a tertiary care teaching hospital of Sikkim." Perspectives in Clinical Research (2015). doi:10.4103/2229-3485.167096.
29. Chandrakapure, I. et al. "Pharmacovigilance: a study to evaluate knowledge, attitude, and practices of and impact of educational intervention among doctors in teaching hospital, in rural area of Jalna, India." International Journal of Basic & Clinical Pharmacology (2015). doi:10.18203/2319-2003.ijbcp20150008.
30. Reumerman, M. et al. "Urgent need to modernize pharmacovigilance education in healthcare curricula: review of the literature." European Journal of Clinical Pharmacology (2018). doi:10.1007/s00228-018-2500-y.
31. Palaian, S. et al. "Health professionals' knowledge, attitude and practices towards pharmacovigilance in Nepal." Pharmacy Practice (2011). doi:10.4321/s1886-36552011000400008.
32. Shrestha, S. et al. "Knowledge, attitude and practice of pharmacovigilance among Nepalese health professionals." Journal of Pharmacovigilance and Drug Research (2022). doi:10.53411/jpadr.2022.3.3.07.
33. Catic, T., & Begovic, M. "The attitudes of pharmacists and physicians in Bosnia and Herzegovina towards adverse drug reaction reporting." Journal of Health Sciences (2016). doi:10.17532/jhsci.2016.327.

ISSN:1624-1940
http://magellanes.com/