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Pharmacovigilance Knowledge and Attitude of Health Professionals: A Pre- and Post-intervention Study

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ABSTRACT

Objective: The objective of the current study was to evaluate healthcare professionals' knowledge and attitude towards pharmacovigilance in Ribat University Hospital, Sudan.

Methods: This was a pre and post-intervention study conducted at the National Ribat University Hospital in Khartoum, Sudan. The sample size was calculated as 98. The phases of the study were as follow: Pre- intervention phase: Knowledge and attitude of health professionals towards Pharmacovigilance were assessed by using a pre-tested questionnaire after obtaining ethics approval and a written informed consent.

Intervention phase: The health professionals were divided into four subgroups. Each group had the same number and categories of the sample. Each subgroup received structured information about Pharmacovigilance by either lecture sessions, pamphlets, mobile phones (SMS) or posters. The sessions were conducted by the researcher.

Post-intervention phase: Reassessment of knowledge and attitude of health professionals towards Pharmacovigilance took place by using a pre-tested questionnaire. Assessment of Knowledge and Attitude was based on Likert scale. Descriptive and inferential analysis was performed by SPSS version 21.

Results: The mean respondents' pharmacovigilance knowledge was improved from 45% to 64% between pre and post-intervention phases (p=0.007). The mean respondents' pharmacovigilance attitude was improved from 78% to 84.3% between pre and post-intervention phases (p=0.254).

Conclusion: The study concluded that, pharmacovigilance knowledge of health professionals in Ribat University Hospital, Sudan is inadequate. Most health professionals have positive attitude towards pharmacovigilance. Health professionals' knowledge of pharmacovigilance significantly improves after intervention. Pharmacists showed higher level of pharmacovigilance knowledge (92.9%) compared to physicians (66%) and nurses (25%). Healthcare professionals with less years of experience showed higher pharmacovigilance knowledge (69.6%) compared to the more experienced (42.6%).

Key words: Knowledge, Attitude, Health professionals, Pharmacovigilance

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INTRODUCTION

Pharmacovigilance is defined as "the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems" [1]. The concern of Pharmacovigilance is extended recently to include herbs, complementary and alternative medicine practices, medical devices, blood products and vaccines [2-6].

Adverse drug reaction (ADR) is "anxious, undesirable and unintended effect occurs due to drug treatment at doses normally used in man for diagnosis, prophylaxis and treatment" [7].

ADRs are one of the leading causes of mortality and morbidity around the world [8-10]. In the UK, 6.5% of hospital admitted patients were due to an adverse drug reaction, and 15% of patients have experience ADRs during their hospital admission [10]. Reporting of ADRs is inadequate, it has been estimated that only 6-10% of ADRs are reported [11]. However, poor results of monitoring ADRs was found in many counties around the world [12].

Studies showed knowledge gap of health professionals and medical students about adverse drug reactions and their reporting in Afghanistan, Saudi Arabia, Malaysia and Egypt [13-16].

In Sudan, the National Medicines and Poisons Board (NMPB) was formed in 2001, a law of drugs and poisons was introduced in 2009. A pharmacovigilance committee was introduced; the aim is to aware health professionals about pharmacovigilance and ADRs. The committee members visit the health facilities for this purpose, and they utilize the social media and others means of communication to achieve their objectives. In Sudan, Pharmacovigilance studies were scanty. ADRs awareness among health professionals is inadequate due to lack of knowledge on how to report ADRs [17].

Many studies conducted among health professionals elsewhere showed lack of knowledge about pharmacovigilance and ADRs reporting, so there is a need to study the knowledge of health professionals regarding PhV as they are responsible to report ADR during their practice. Attitude of health professionals towards pharmacovigilance will encourage them to report and follow ADRs. Hence this study was designed to evaluate health professionals' knowledge and attitude towards pharmacovigilance among health professionals in Ribat University Hospital, Sudan and to assess the impact of an intervention.

METHODS

The design was a pre- and post-intervention to study knowledge and attitude of health professionals in Ribat University hospital, Sudan about Pharmacovigilance. The sample Size was calculated by the formula: $n=Z^{2*}P\ (1-P)/d^2$ (estimate proportion=0.10, error=0.05, CI= 0.90, Z=1.64). Sample size=98, included pharmacists, physicians, and nurses. One hundred and fifty questionnaires were distributed and 100 responded giving response rates as 77%.

Pre-intervention phase

Knowledge and attitude of health professionals towards Pharmacovigilance were assessed by using a pre-tested questionnaire after obtaining ethics approval and a written informed consent (Annex 1). The questionnaire was pre-tested in Khartoum Teaching Hospital. It included questions about pharmacovigilance and ADRs definitions, PhV purpose and components, ADRs treatment, what are the health professionals supposed to report ADRs etc.

Intervention phase

The health professionals were divided into four subgroups. Each group had the same number and categories of the sample. Each subgroup received structured information about Pharmacovigilance by either lecture sessions, pamphlets, mobile phones (SMS) or posters (Annex 2). The information disseminated was about pharmacovigilance and ADRs definitions, components, objectives, importance, who is to report ADRs and reasons behind not reporting ADSs. Two sessions were given separated by seven days and conducted by the researcher. Pamphlets were given twice in the hospital separated by one-week time. Posters were in place for one week and SMS were sent twice separated by one week. All the materials given in the intervention were prepared by the researcher.

Post-intervention phase

Reassessment of knowledge and attitude of health professionals towards Pharmacovigilance took place by using the same pre-tested questionnaire. Assessment of Knowledge and Attitude was based on Likert scale. Ten questions of knowledge were asked. If the respondent scored from five to ten correct answers was considered as having good knowledge and if scored less than five correct answers was considered as having poor knowledge. Six questions of Attitude were asked to the respondents. If the respondent scored more than three correct answers was considered as having positive attitude and if scored less than four correct answers was considered as having a negative attitude. The data were analyzed by Statistical Package of Social Sciences (SPSS)

software, version 20. Descriptive and inferential statistics were used. Comparison between qualitative variables was made by using the person's chi-square to test significance; $p<0.05$ was considered significant.

RESULTS

One hundred and fifty questionnaires were distributed among the health professionals and 100 responded (response rate was 66.7%). Table (1) shows the socio-demographic characteristics of the respondents. Males and females were 16% and 84% respectively. Physicians, nurses and pharmacists were 50%, 36% and 14% respectively. Less than two years of working experience was reported by 44% of the respondents, whereas 22% had experience 2-5 years and 34% had working experience more than five years.

DISCUSSION

This research was conducted to study the

Table 1: Socio-demographic factors (n=100).

Factor	Number	%
Gender		
Male	16	16
Female	84	84
Specialty		
Physicians	50	50
Nurses	36	36
Pharmacist	14	14
Years of experience		
Less than two	44	44
2 to 5	22	22
More than 5	34	34

Table (2) shows the comparison of the respondents' knowledge about Pharmacovigilance in the pre and post-intervention phases. The mean pharmacovigilance knowledge in the pre-intervention phase was 45% and in the post-intervention phase was 64% (p=0.007).

Table 2: Comparison of Pharmacovigilance Knowledge in pre and post interventions

Knowledge	Pre	post	p
	number (%)	number (%)	
PV definition	40 (40%)	77 (77%)	0.007
PV purpose	55 (55%)	75 (75%)	
PV contents	71 (71%)	80 (80%)	
PV benefits	48 (48%)	68 (68%)	
ADR definition	47 (47%)	76 (76%)	
Treatment of independent ADR	53 (53%)	58 (58%)	
Important information in reporting	69 (69%)	84 (84%)	
Location of ADR reporting center	9 (9%)	48 (48%)	
US agency for drug safety	37(37%)	48 (48%)	
Responsibility for reporting ADR	21 (21%)	29 (29%)	
Mean pharmacovigilance knowledge in pre-intervention=45%, in post intervention=64%.			

Table (3) shows the comparison of the respondents' attitude towards Pharmacovigilance between pre and post-intervention phases. The mean healthcare professionals' attitude towards pharmacovigilance in the pre-intervention phase was 78.0%, and in the post-intervention phase was 84.3% (p=0.254).

Table 3: Comparison of respondents' attitude towards pharmacovigilance in the pre and post-intervention phases

Attitude	Pre	post	p
	number (%)	number (%)	
Discourage from reporting	50 (50%)	63 (63%)	0.254
Reporting obligation	81 (81%)	90 (90%)	
Presence of monitoring for ADR center	82 (82%)	80 (80%)	
Reporting necessary	91(91%)	97 (97%)	
PV teaching in detail	97(97%)	98 (98%)	
Reporting by non-medical personnel	67(67%)	78 (78%)	
Mean attitude in the pre-intervention phase= 78.0%, and in the post-intervention phase= 84.3%.			

Table (4) shows the relation between pharmacovigilance knowledge before intervention and social factors. Nurses, physicians and pharmacists with good knowledge were 25%, 66% and 92.9% respectively, p<0.0001. Healthcare professionals with less than 2 years of experience and had good knowledge were 69.6% and those with experience of two years and more and had good knowledge were 23 (42.6%), p=0.0001.

Table 4: Relation between pharmacovigilance knowledge and social characteristics.

Social characteristics	Level of knowledge		Total	P
	Good No. (%)	poor No. (%)		
Specialty				
Nurse	9 (25%)	27 (75%)	36	<0.001
Physician	33 (66%)	17 (34%)	50	
Pharmacist	13 (92.9%)	1 (7.1%)	14	
Experience/years				
Less than 2	32 (69.6%)	14 (30.4%)	46	0.0001
2 and more	23(42.6%)	31(57.4%)	54	

Table (5) shows relation between pharmacovigilance attitude before intervention and social factors. Pharmacists who had more positive attitude towards pharmacovigilance (92.9%) compared to nurses (77.8%) and physicians (62.0%), p<0.001. Health professionals with less than 2 years of experience and had positive attitude towards pharmacovigilance were 65.2% and those with experience more than two years and had negative attitude were 42 (77.8%), p=0.048.

Table 5: Relation between pharmacovigilance attitude and social characteristics

Social characteristics	Level of knowledge		Total	p
	Positive No. (%)	Negative No. (%)		
Specialty				
Pharmacist	13 (92.9%)	01(7.1%)	14	<0.001
Nurse	28 (77.8%)	08 (22.2%)	36	
Physician	31 (62.0%)	19 (38.8%)	50	
Experience/years				
Less than 2	30 (65.2%)	16 (34.8%)	46	<0.048
2 and more	42(77.8%)	12 (22.2%)	54	

knowledge and attitude of Pharmacovigilance among health professionals in Ribat University Hospital, Sudan. The sample size was calculated as 98 and 100 responded giving response rates as 77%. The baseline healthcare professionals' pharmacovigilance mean knowledge was low (47%). This finding is consistent with studies conducted in Egypt, Sudan, Ethiopia, Turkey, Nepal and China [17-22]. However, our findings are not in line with studies conducted in India, Kuwait, Lebanon, Yemen and Jordan where adequate knowledge of pharmacovigilance was observed [23-27]. According to our findings, pharmacists had better PhV knowledge followed by the physicians, the nurses acquired the least level of knowledge. This may be explained by the fact that pharmacist main goals and work experience is about drugs followed by the physicians [28].

In the current study, Pharmacovigilance mean knowledge showed significant improvement after interventions from 45% to 64% (p<0.001). These findings are consistent with studies conducted in Iran and China [29,30]. The significant improvement in Pharmacovigilance knowledge may reflect the readiness of respondents and their interest to improve their knowledge. The directions of knowledge may be different. Fang, et al. reported that both physicians and nurses had good knowledge regarding PhV: However, Physicians had better understand of what to report regarding ADRs while nurses know where to report [31]. In a study conducted in India, Rehan, et al. reported that nurses acquired better knowledge compared to physicians and pharmacists in methods of drug disposal [32]. The subjects with short experience (less than two years) had better knowledge than those with long experience (two years and more). This may be explained that the knowledge of respondents with short experience is still fresh due to short time of leaving classes, those with long experience were far from formal education and hence may forget much of their knowledge. This fact is also aggravated by the economic crises of the country which forces health professionals to work double shifts daily to be enabled to live in a good economic standard.

Our study showed that the attitude of health professionals towards pharmacovigilance was positive (78%). Health professionals with positive attitude in our study is consistent

with findings from Pakistan and India [33,34]. Negative attitude towards pharmacovigilance was found among health professionals in Ethiopia and Saudi Arabia [18,35].

Insignificant improvement of attitude towards pharmacovigilance was seen after intervention, this may be due to the need for long time to change attitude not like knowledge which can be acquired in short duration. Our results reported more positive attitude of pharmacists towards pharmacovigilance compared to nurses and physicians ($p<0.001$) [36,37].

Positive attitude towards Pharmacovigilance was more among pharmacists (92.9%) compared to physician and nurses, 62.0% and 77.8%, $p \leq 0.001$. It is also more among senior compared to junior health professionals (77.8%), 65.2%, $p<0.048$) [38]. Studies of knowledge and attitudes towards pharmacovigilance studies in Sudan are very few, these findings may help to establish strategies to strengthen PhV and ADRs in the country and in the other similar settings. The author observed that after collection of data the policy makers in the hospital started to hold meetings in order to strengthen PV and ADRs [39].

CONCLUSION

The study concluded that pharmacovigilance knowledge of health professionals is inadequate. Health professionals' knowledge of pharmacovigilance significantly improves after intervention. Most health professionals have positive attitude towards pharmacovigilance. The pharmacists have better knowledge and more positive attitude towards pharmacovigilance compared to physicians and nurses. Pharmacovigilance knowledge is higher among junior health professionals: however, positive attitude towards Pharmacovigilance was more among senior health professionals. The study pointed towards an urgent need for enforcement of pharmacovigilance policies in Sudan National Health System. The authors encouraged hospitals managements and colleagues at other hospitals to implement PhV which is not difficult but needs commitment.

LIMITATIONS

The limitation is that, the study was conducted in one setting, so the findings can't be generalized.

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AUTHORS CONTRIBUTIONS

Proposal development, data collection and writing the draft- Tayseer Elsadig Albadawi. Proofreading the manuscript and supervising the work-Tarig Mohamed Hassan, Nahid Osman Ahmed Eisa and Sawsan Mustafa Abdalla, Data analysis- Elsadig Yousif Mohamed. All authors contributed and approved the final manuscript.

CONFLICTS OF INTEREST

All authors have none to declare.

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ANNEX 1

Pharmacovigilance knowledge and attitude of health professionals: a pre-and post-intervention study

Gender: Male ☐ Female ☐

Qualification: Nurse ☐ Physician ☐ Pharmacist ☐

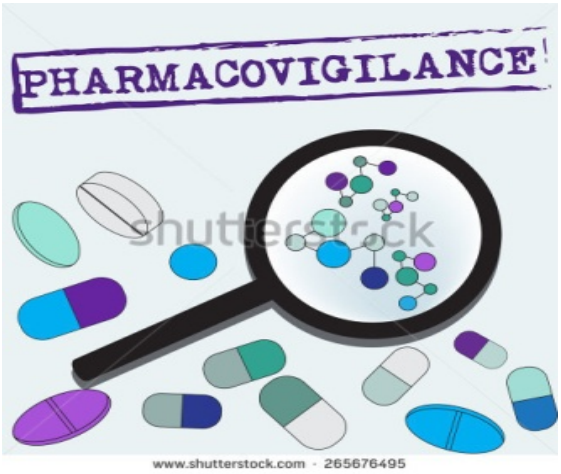
Department: _____

1	Define Pharmacovigilance?
a	The science of detecting the type and incidence of ADR after drug is marketed
b	The science of monitoring ADRs occurring in a Hospital
c	The detection, assessment, understanding, and prevention of adverse effects
d	The process of improving the drug safety
2	The most important purpose of Pharmacovigilance is:
a	To identify the drug safety
b	To calculate incidence of ADRs
c	To identify predisposing factors to ADRs
d	To identify previously unrecognized ADRs
3	Pharmacovigilance includes:
a	Drug related problem
b	Herbal products
c	Medical devices and vaccines
d	All the above
4	Adverse Drug Reactions (ADRs) can be defined as:
a	Intended reaction of the drug
b	A reaction that produces the therapeutic effect of the drug
c	Response to a medicine used in humans or animals, which is anxious and unintended
d	None of the above
5	ADRs which are independent can be treated:
a	By withdrawing the drug
b	By reducing the dose
c	Replacing the medications
d	All the above
e	None of the above
6	Where the international center for adverse drug reaction monitoring is located?
a	Unites States of America
b	Australia

c	France
d	Sweden
7	One of the following is the agency in Unites States of America involved in drug safety issues:
a	American Society of Health System Pharmacists (ASHP)
b	United States food and drug administration (US FDA)
c	American Medical Association (AMA)
d	American Pharmaceutical Association (APA)
8	Which of the following scales is most commonly used to establish the causality of an ADR?
a	Hartwig scale
b	Naranjo algorithm
c	Schumock and Thornton scale
d	Karch & Lasagna scale
9	Which one of the following is the 'WHO online database' for reporting ADRs?
a	ADR advisory committee
b	Medsafe
c	Vigibase
d	Med watch
10	The healthcare professionals responsible for reporting ADR in a hospital is/are:
a	Nurse
b	Senior Nurse
c	Pharmacist
d	Senior Pharmacist
e	Physician
f	All the above
g	None of the above
11	Which among the following factors discourage you from reporting Adverse Drug Reactions?
a	Non-remuneration for reporting
b	Lack of time to report ADR
c	A single unreported case may not affect ADR database
d	Difficult to decide whether ADR has occurred or not
12	Do you think reporting of ADR is a professional obligation for you?
a	Yes
b	No
c	Don't know
d	Perhaps
13	What is your opinion about establishing ADR monitoring center in every hospital?
a	Should be in every hospital
b	Not necessary in every hospital
c	One in a city is enough
d	Depends on number of bed size in the hospitals.
14	Do you think reporting of adverse drug reaction is necessary?

a	Yes
b	No
c	Can't say
d	Maybe
15	Do you think Pharmacovigilance should be taught in detail to healthcare professionals?
a	Yes
b	No
16	Do you think Non-medical person can report ADR to a nearby Health care professional?
a	Yes
b	No
17	Have you anytime read any article on prevention of ADRs?
a	Yes
b	No
18	Have you ever attended an educational session about Pharmacovigilance?
a	Yes
b	No

ANNEX 2



"Pharmacovigilance (PV or PhV), also known as drug safety, is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects, or any other drug-related problem".

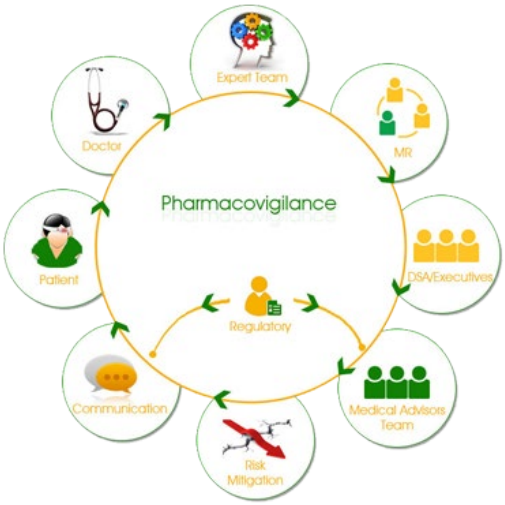
PV function is to identify Drug Safety.
PV includes

a) Drug related problem
b) Herbal products

c) Medical devices and vaccines

The agency of drug safety issues in USA is Food and Drug Administration (FDA).

Adverse Drug Reaction (ADR) is "a response to a drug which is anxious and unintended, and which occurs at doses normally used in man or animal for the prophylaxis, diagnosis, or therapy of disease".



Reporting ADRs is important for treatment and prevention.
Reporting ADR should be done by all health care providers.
International center for ADR monitoring is in Sweden.
WHO database for reporting ADR is Vigibase.