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RESEARCH ARTICLE

ASSESSMENT OF COMMUNITY PHARMACIST AWARENESS ON ADVERSE DRUG REACTION (ADR) AND PHARMACOVIGILANCE REPORTING SYSTEM IN KHARTOUM LOCALITY, SUDAN

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Abstract

Introduction: Adverse drug reactions resulting from the use of a medicinal product and were harmful or unpleasant reaction. Pharmacovigilance is related pharmaceuticals product after marketing and associated with collection, detection, assessment, monitoring and prevention of adverse effects. The aim of study is to recognize the awareness of pharmacists regarding pharmacovigilance and adverse drug reactions reporting.
Methodology: Descriptive cross-sectional study conducted to 237 pharmacists working in Khartoum's locality pharmacies from August 2019 to March 2020 selected by simple randomization. The data were collected by face to face interview using self-administrated Questionnaire and analyzed by SPSS version 23.
Results: Total 57.4% from the sample size never seen adverse drug reactions reporting form, 76.4% never receive training on how to report it and only 10.5% from the pharmacists in the study report it to pharmacovigilance center. Total 79% from pharmacists in the study were not aware about existence of pharmacovigilance program in Sudan. Total 51.5% from pharmacists have good attitude about adverse drug reactions and pharmacovigilance in Sudan while 48.5% had poor attitude.
Difficulty in communicating with pharmacovigilance centre in Sudan and how to write the report were the factors discourage pharmacists from reporting of adverse drug reactions.
Conclusions: Community pharmacists have insufficient knowledge about the concept of pharmacovigilance and spontaneous ADRs reporting while they had positive attitudes toward pharmacovigilance, despite their little experience with ADRs reporting, this can be strengthened by educational trainings and workshops.
Keywords: Assessment, pharmacovigilance, reporting.

INTRODUCTION

Adverse Drug Reactions:

There is no therapy devoid from adverse effects[1]. Safety significance measures for drugs based on experiences related to ADRs. New drugs approval based on a benefit-risk assessment but in post marketing survey, unexpected, rare and serious ADRs have been detected[2]. Adverse drug reactions are harmful or unpleasant reaction which can result from an intervention related to use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dose regimen or withdrawal of the product.
Adverse drug reactions considered as toxicity and the incidence and severity of it vary according to demographics of patient and by drug factors (e.g. type of drug, administration route, treatment duration, dosage, and bioavailability). Adverse drug reactions incidence is usually higher in advanced age patients and polypharmacy[3].

Pharmacovigilance:

Pharmacovigilance is associated with collection, detection, assessment, monitoring and prevention of adverse effects of the pharmaceuticals product after marketing and essential part of healthcare systems worldwide[4]. Most countries e.g. China and Japan operate national pharmacovigilance systems as part of their public health and healthcare policies. The World Health Organization international drug monitoring program through the Uppsala Monitoring Centre (UMC) aims to facilitate the collaboration of the national pharmacovigilance systems[5]. Pharmacovigilance objective is safe use of drugs, patient safety, and

ultimately, safeguarding public health and to achieve it, the national regulators and international organizations rely on the reporting of adverse drug reactions (ADRs). National, regional, and global data on ADRs are working to inform regulators, healthcare professionals, and the public about safety concerns with pharmaceutical products[5].

Adverse event reporting:

1. Individual Case Safety Report (ICSR)[6,7]
2. Coding of adverse events[6,7]
3. Seriousness determination[6,7]
4. Expedited reporting[6,7]
5. Clinical trial reporting[6,7]
6. Spontaneous reporting

Relies on vigilant physicians and other healthcare professionals who do not only generate a suspicion of an ADR, but also report it. It is an important source of regulatory actions such as taking a drug off the market or a label change due to safety problems. Spontaneous reporting is the core data-generating system of international pharmacovigilance, relying on healthcare professionals (and in some countries consumers) to identify and report any adverse events to their national pharmacovigilance centre, health authority (such as EMA or FDA), or to the drug manufacturer itself[8].

One of the major weaknesses of spontaneous reporting is that of under-reporting, where, unlike in clinical trials, less than 100% of those adverse events occurring are reported. In view of this, medical personnel may not always see reporting as a priority, especially if the symptoms are not serious[9,10].

Aggregate reporting

Aggregate reporting, also known as periodic reporting, plays a key role in the safety assessment of drugs. Aggregate reporting involves the compilation of safety data for a drug over a prolonged period of time (months or years), as opposed to single-case reporting which, by definition, involves only individual reports. The advantage of aggregate reporting is that it provides a broader view of the safety profile of a drug.

Other reporting method:

Some countries legally oblige spontaneous reporting by physicians. In most countries, manufacturers are required to submit, through its qualified person for pharmacovigilance (QPPV), all of the reports they receive from healthcare providers to the national authority. Others have intensive, focused programmers concentrating on new drugs, or on controversial drugs, or on the prescribing habits of groups of doctors, or involving pharmacists in reporting. All of these generate potentially useful information. Such intensive schemes, however, tend to be the exception. A number of countries have reporting requirements or reporting systems specific to vaccine-related events[11]. Hale. M. K. *et al.*, found (17.2%) of pharmacists had knowledge about pharmacovigilance, (21%) had report adverse drug reaction to concern organization in the previous 12 months and 7% report to national pharmacovigilance centre[12]. Ghazal Vessel. Z. M. *et al.*, found that the Iranian pharmacists have little knowledge regarding the operation, purposes, and usefulness of adverse drug reaction reporting system[13]. Total 55% of community pharmacies in Lagos state have ever heard the word 'Pharmacovigilance' out of which only 18% of all respondents could define the term 'Pharmacovigilance'. Lack of knowledge about how to report ADRs (44.6%) is the most important reason for poor reporting, meanwhile, 90% of respondents believed that the role of the pharmacists in ADR reporting was important. Most community pharmacists were willing to practice pharmacovigilance if they were trained[14]. Arul Prakasam *et al.*, stated that (34.6%) pharmacists could define the term 'pharmacovigilance' and (34.3%) knew about the National Pharmacovigilance Program in India. Pharmacists have poor knowledge, good perception and negligibly low reporting rates. (15) Maysa Suyagh stated that majority of pharmacists have insufficient awareness and lack of knowledge about pharmacovigilance and ADRs reporting[16]. Jimmy j. KM *et al.*, concluded that number of community pharmacist had no enough knowledge about adverse drug reaction reporting and need training course to improve their knowledge and attitude about adverse drug reaction reporting system[17]. Mansour Adam. Y. T. *et al.*, stated that majority of a community pharmacist in Riyadh have a poor knowledge about ADR reporting system and need for interventional program to improve it[18]. A study conducted in India stated that few pharmacists knew about Central Drugs Standard Control Organization (CDSCO) as a centre for reporting ADRs. Majority of pharmacists would direct the patients to the physician, in case of occurrences of ADR. According to 26.67% of the pharmacists in the study, busy schedule is considered as a vital factor for under-reporting an ADR[19]. Yasser MWY *et al.*, found that Pharmacists had a better knowledge than pharmacy technicians regarding pharmacovigilance.

So, educational interventions and training is very important for community pharmacists and pharmacy technicians to increase their awareness and participation in adverse drug reaction reporting[20]. M. Elmusbah and H. Elkheir found that there are poor knowledge of health care professionals about pharmacovigilance[21].

Justification:

The aim of this study to recognize awareness of community pharmacist regarding pharmacovigilance and adverse drug reactions reporting, assess knowledge of community pharmacist about reporting system regarding (to who will report, international centre and reporting form of adverse drug reaction) and assess attitude of community pharmacist regarding pharmacovigilance and assess barriers of adverse drug reaction reporting. In health systems and maintaining the rational and safe use of medicines pharmacist play crucial roles while pharmacovigilance mainly targets safety of medicine that are specifically trained in this field. Improve the outcome of the pharmacotherapy, increase patient safety, improve quality of life and decrease medication cost in Sudan will be improved by effective use of pharmacist's workforce (patient counseling). Sudan became an official member of WHO for drug monitoring, in Uppsala 2008, to promote the role of pharmacovigilance and community pharmacist should also play an important role.

METHODS

Descriptive cross-sectional study conducted in Khartoum's locality pharmacies selected through simple randomization. A validated self- administered questionnaire was distributed in Khartoum locality pharmacies during the period August 2019 to March 2020, 237 were filled the questionnaire during this period. The data were collected by direct interview using self-administrated Questionnaire and analyzed by SPSS version 23 (IKM SPSSInc., Chicago, IL) and STATA 11. In practice area of adverse drug reactions, 61.2% from pharmacists reading articles on prevention of adverse drug reaction, 51.5% ever experienced adverse drug reactions during professional practice, 57.4% never seen the form of adverse drug reactions reporting, 76.4% never receive training on how to report adverse drug reaction and only 10.5% from the pharmacists in the study report adverse drug reaction to pharmacovigilance centre as presented in Figure 1.

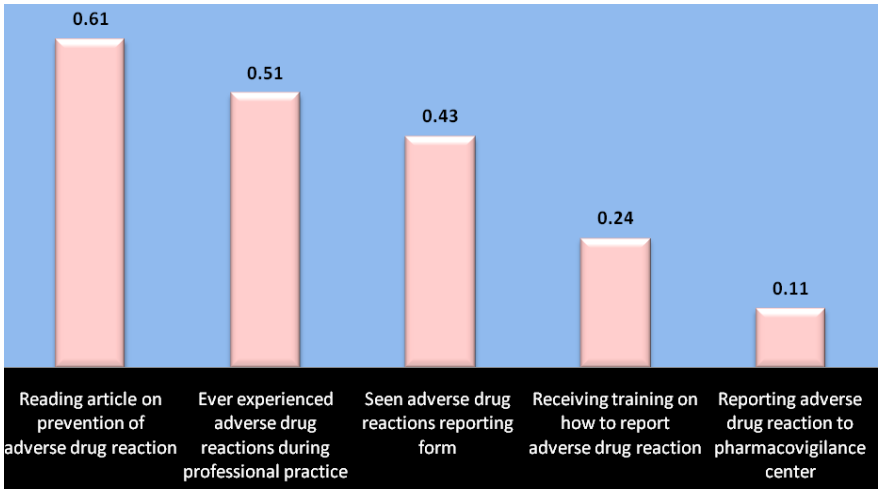

Figure 1: Practice of the pharmacists towards adverse drug reactions.

Table 1: Demographic data Practice variables.

Demographic Data	Variable	Percent %
Sex	Male	43
	Female	57
Age	Less than 30 years	68
	30 – 40 years	24
	More than 40 years	8
Educational level	Bachelor holders	73
	Master holders	24
	PhD holders	3
Years of experience	Less than 2 years	14.8
	2 – 5 years	51.5
	6 – 10 years	22.4
	More than 10 years	11.4

Total 33.8% from pharmacists in the study define the pharmacovigilance as the detection, assessment, understanding and prevention of adverse effects, 31.6% define it as the science detecting the type and incidence of adverse drug reactions (ADR) after drug is marketed while 23.6% don't know the definition of pharmacovigilance as presented in Table 1. Total 29.1% from pharmacists stated that the goal of pharmacovigilance is identifying previously unrecognized ADRs, 27% stated the goal is identifying safety of the drugs while 20.3% didn't know the goal of pharmacovigilance as presented in Figure 2. Total 79% from pharmacists in the study were not aware about existence of pharmacovigilance program in Sudan represented in Figure 3. Total 62.9% from respondents didn't know where the international center for monitoring adverse drug reactions represented in Figure 4. Total 24.9% from the respondent didn't know the regulatory body responsible for monitoring adverse drug reactions, 39.2% know that the responsible body in Sudan is the National Medicine and Poisons Koard (NMPK) as presented in Figure 5. Total 69.6% from the respondents had no knowledge about filling an adverse drug reaction report form as presented in Figure 6. About the duration of reporting serious adverse event in Sudan 51.9% from respondents agreed that the reporting should be within one day, 29.5% don't know while 14.3% stated that should be within seven calendar days as presented in Figure 7. From the previous results, 64.6% from the respondents in the study had poor knowledge score about adverse drug reactions and pharmacovigilance system in Sudan as presented in Figure 8.

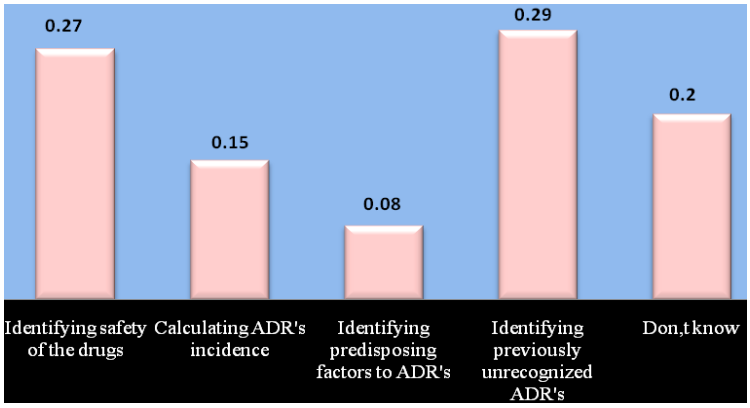

Figure 2: Most important goals of pharmacovigilance.

Table 2: Knowledge of definition of Pharmacovigilance.

Pharmacovigilance definition	Number	Percent
The science detecting the type and incidence of adverse drug reactions (ADR) after drug is marketed.	75	31.6%
The science that monitors ADR's occurrence in hospitals	14	5.9%
The process of improving drug safety	12	5.1%
The detection, assessment, understanding and prevention of adverse effects	80	33.8%
Don't know	56	23.6%
Total	237	100%

Regarding the attitude of respondents about adverse drug reactions and pharmacovigilance, 62% strongly agree that adverse drug reactions reporting is professional obligation, most of the respondent strongly agree that pharmacist can report adverse drug reactions.

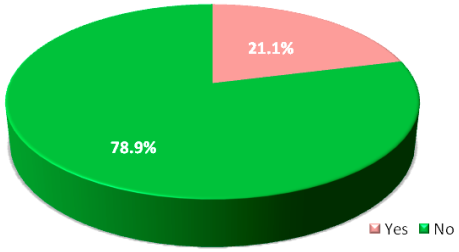

Figure 3: Knowledge regarding existence of pharmacovigilance program in Sudan.

Total 98.8% of respondents strongly agree that reporting adverse drug reactions is necessary, 91.7% of respondent thought that pharmacovigilance should be taught in details to all under graduate medical students, this competency is very important, so the graduates can serve an important role not only for patient safety in individual patient care but also for drug safety monitoring at a population level and the majority of respondents thought that it is necessary to establish adverse drug reaction monitoring centre in every hospital. From the previous results it is clear that the attitude score about adverse drug reactions and pharmacovigilance system in Sudan was good 51.5% while 48.5% had poor attitude as presented in Figure 9. About the factors discourage pharmacists from reporting of adverse drug reactions, 46.4% of them thought that there is a difficulty in communicating with pharmacovigilance centre in Sudan, 35.9% of respondents said they did not know how to write the report, while 35% said they could not decide whether the adverse drug reaction occurred or not, 34.2% of respondents mentioned that they had no time to report adverse drug reactions due to workload while 25.3% stated that a single unreported case may not affect ADR database as presented in Figure 10.

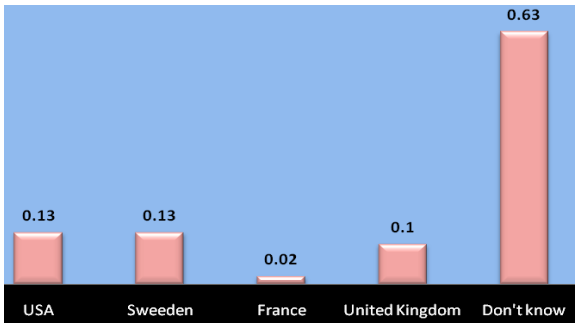

Figure 4: Location of international Centre for monitoring adverse drug reactions.

In current study it was found that a significant relationship between poor knowledge score about adverse drug reaction and pharmacovigilance reporting system and the following factors: pharmacists aged above 40 years old, reading articles on prevention of adverse drug reaction, seeing the adverse drug reactions reporting form and training received on how to report adverse drug (p value<0.05) as presented in Table 3.

Practice variables

Reading article on prevention of adverse drug reaction Ever experienced adverse drug reactions during professional practice seen adverse drug reactions reporting form Receiving training on how to report

adverse drug reaction Reporting adverse drug reaction to pharmacovigliance center.

RESULTS AND DISCUSSION

In knowledge area, 33.8% of pharmacists define the pharmacovigilance as: The detection, assessment, understanding and prevention of adverse effects, which complying with the WHO definition, which is similar to Saudi Arabia study (18) which found that the majority of pharmacists knew the correct definition of pharmacovigilance (PV) that might be due to the continuing education activities conducted by the top hospital management and supervised and monitored by the Saudi Food and Drug Authority. Total 29.1% of participants thought the important goal of pharmacovigilance system is identifying previously unrecognized ADRs, which is a good thing in Sudan for monitoring and improving the local pharmaceutical manufacturers. Regarding the knowledge of existing pharmacovigilance program in Sudan only 79% of respondents were not aware of the existence of ADRs reporting system in Sudan, which is a superior result comparing to a study done in Yemen, 96.3% were not aware of the existence of ADRs reporting system in Yemen[20].

Table 3: Knowledge score about adverse drug reactions and pharmacovigilance System in Sudan (N=237).

Knowledge variables	Correct	Incorrect	Correct (%)
Location international Centre for monitoring adverse drug reactions	30	207	12.7
Knowledge regarding existence of pharmacovigilance Program in Sudan	50	187	21.1
Most important goals of Pharmacovigilance	64	173	27
Knowledge about filling an adverse drug reaction report form	72	165	30.4
Pharmacovigilance definition	80	157	33.8
In Sudan which regulatory body is responsible for monitoring Adverse drug reactions	93	144	39.2
Duration of reporting serious adverse event in Sudan	34	203	14.3

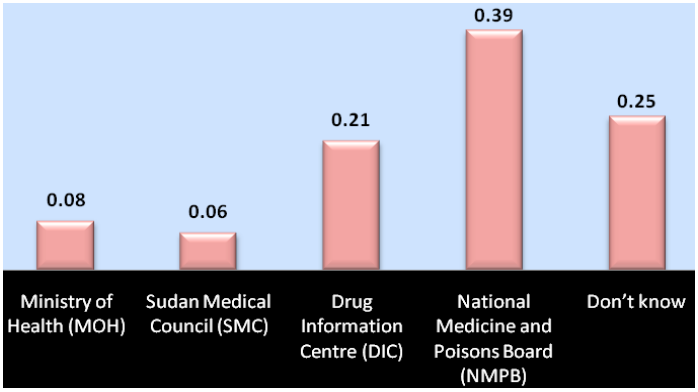

Figure 5: Regulatory body in Sudan responsible for monitoring adverse drug reactions.

Most of respondents did not know where is the international center for monitoring adverse drug reactions (62.9%) and most of them know that the responsible body in Sudan is The National Medicines and Poisons Board, which may put a responsibility on the regulatory authority in Sudan to hold training programs for community pharmacist about pharmacovigilance. The study lead to a good result regarding the duration of reporting serious adverse event, that respondents (51.9%) agreed with that the reporting should be within one day, this is in line with a result of many previous studies insisted that prompt ADR reporting is crucial in ensuring drug safety[16]. Knowledge score about adverse drug reactions and pharmacovigilance system in Sudan was poor which is clear from previous results, only 35% of participants had a good knowledge, that need planned and clear interventions from the regulatory authority.

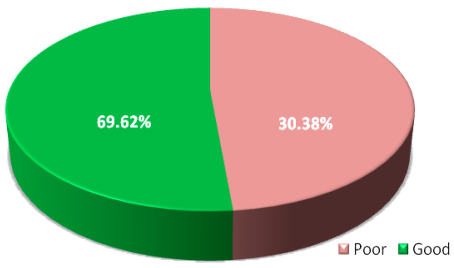

Figure 6: Knowledge about filling an adverse drug reaction report form.

In Nigeria, the use of SMS as a reinforcement tool appeared to have positively impacted on the knowledge and practice of pharmacovigilance, while continuous medical education may be required to effect long-lasting changes[14]. Total 69.6% from respondents had no knowledge about filling an adverse drug reaction report form, that is similar to a study conducted in Jordan found that pharmacists think that ADRs are unimportant, and they did not know how to report them[16]. Significant relationship was found between poor knowledge score about adverse drug reaction and pharmacovigilance reporting system and the following factors: pharmacists aged above 40 years old, reading articles on prevention of adverse drug reaction, seeing the adverse drug reactions reporting form and training received on how to report adverse drug (p value<0.05).

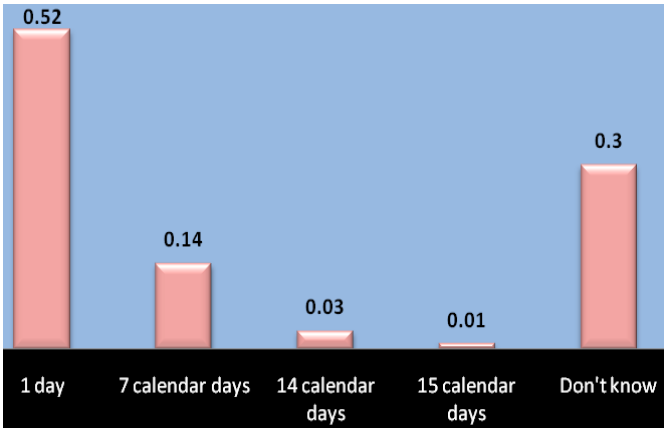

Figure 7: Duration of reporting serious adverse event in Sudan.

In area of attitude of respondents about adverse drug reactions and pharmacovigilance, most of participants (62%) strongly agree that adverse drug reactions reporting is professional obligation. Most of the respondent strongly agrees that pharmacist can report adverse drug reactions, and that is clear, because the role of the pharmacist expanded from traditional dispenser toward pharmaceutical care provider.

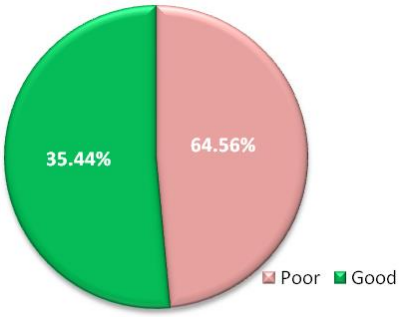

Figure 8: Knowledge score about adverse drug reaction and pharmacovigilance reporting system.

Total 98.8% of respondents strongly agree that reporting adverse drug reactions is necessary, that to protect patient's lives from serious adverse drug reactions, Majority of respondent (91.7%) thought that pharmacovigilance should be taught in details to all under graduate medical students, so the graduates can serve an important role not only for patient safety in individual patient care but also for drug safety monitoring at a population level.

Majority (92.9%) strongly agree about establishing adverse drug reactions monitoring centre in every hospital, this is useful for initiating a culture of ADR reporting among healthcare professionals, and improve communication between the physicians and nurses with the pharmacovigilance centre in the hospital. The attitude score about adverse drug reactions and pharmacovigilance system in Sudan from previous studies was good (51.5%) while 48.5% had poor attitude.

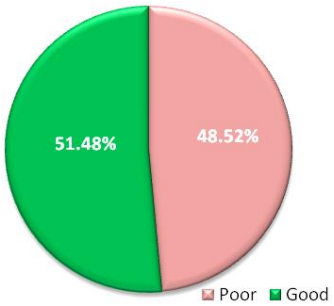

Figure 9: Represent attitude score about adverse drug reaction and pharmacovigilance reporting system.

In area of factors discourage participants from reporting adverse drug reactions, 46.4% thought there is a difficulty in communicating with pharmaco-vigilance center in Sudan, so there is need from center to promote its work, and should do some awareness campaigns targeting community pharmacies. 35.9% of respondents said they did not know how to write the report, while 35% said they could not decide whether the adverse drug reaction occurred or not, this may be due to lack of training of community pharmacists. Total 34.2% of respondents mentioned that they had no time to report adverse drug reactions due to workload. These finding were similar to the results of a study in Jordan which include no enough information available from the patient, unavailability of pharmacists ADRs form when needed, unawareness of the existence of a national ADRs reporting system, the ADR is too trivial to report and they did not know how to report.

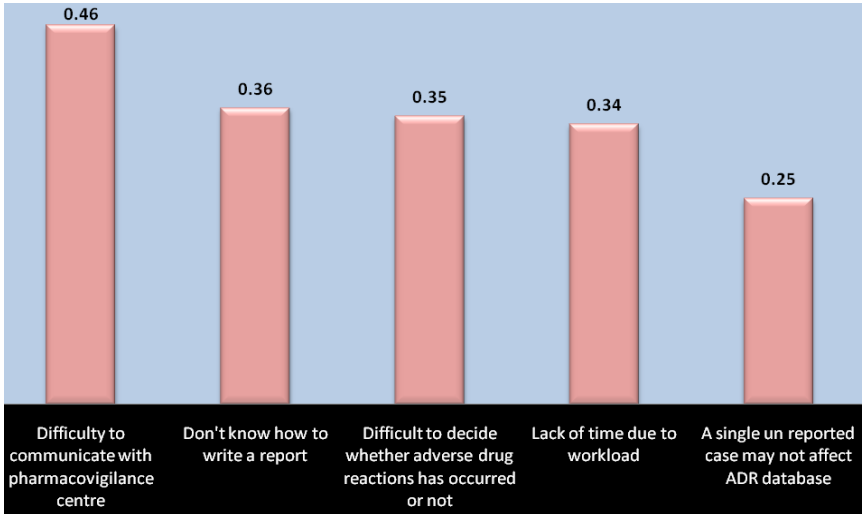

Figure 10: Represent the most important factors discourage pharmacists from reporting drug reactions monitoring.

Table 4: Relationship between different variables and knowledge score about adverse drug reaction and pharmacovigilance reporting system.

Variables		Knowledge score about adverse drug reaction and pharmacovigilance reporting system		Chi square *p* value
		Poor (%)	Good (%)	
Gender	Male	61.40	38.60	0.379*
	Female	66.9	33.1	
Age groups	Less than 30years	70.80	29.20	0.014**
	30– 40years	50.90	49.10	
	More than 40years	52.60	47.40	
Educational level	Kachelor	67.40	32.60	0.320*
	Master	56.90	43.10	
	PhD	57.10	42.90	
Years of experience	Less than 2 years	62.90	37.10	0.064*
	2– 5 years	72.10	27.90	
	6-10 years	54.70	45.30	
	More than 10years	51.90	48.10	
Reading article on prevention of adverse drug reaction	Yes	57.90	42.10	0.007**
	No	75.00	25.00	
Seen adverse drug reactions reporting form	Yes	52.50	47.50	0.001**
	No	73.50	26.50	
Reporting adverse drug reaction to Pharmacovigilance center	Yes	64.00	36.00	0.951*
	No	64.6	35.4	
Receiving training on how to report adverse Drug reaction	Yes	51.80	48.20	0.022**
	No	68.50	31.50	
Ever experienced adverse drug reactions during practice	Yes	61.20	38.80	0.264*
	No	68.10	31.90	

***p* value<0.05 that's considered as statistically significant; **p* value>0.05 that's considered as statistically insignificant.

CONCLUSION

Insufficient knowledge of community pharmacists about pharmacovigilance concept and spontaneous ADRs reporting. On other hand, pharmacists had positive attitudes toward pharmacovigilance, despite their little experience with ADRs reporting. Many factors discourage adverse drug reactions reporting could be managed.

RECOMMENDATIONS

Community pharmacist knowledge and attitude toward pharmacovigilance in Khartoum locality, Sudan can be strengthened by educational trainings and workshops, establishing relationship between the regulatory authority (National Medicines and Poisons Board, General Directorate of Pharmacy). Continuous professional education programs and online training for pharmacovigliance can be linked with credit points required for renewing permanent registration in Sudan Medical Council.

AUTHOR'S CONTRIBUTIONS

Saeed AA: writing original draft, revision. **Umballi O:** collection of the data, research writing. **Ahmed N:** investigation, data interpretation. **Ali S:** data curation, investigation. **Alfaki A:** critical review, supervision.

The final manuscript was read and approved by all authors.

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DATA AVAILABILITY

The data supporting the findings of this study are not currently available in a public repository but can be made available upon request to the corresponding author.

CONFLICT OF INTEREST

None to declare.

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