

## Assessment of Community Pharmacist Awareness about Adverse Drug Reaction and Pharmacovigilance Reporting System in Khartoum Locality, 2020

### Abstract:

### Introduction:

Adverse drug reactions were harmful or unpleasant reaction resulting from the use of a medicinal product. Pharmacovigilance is associated with collection, detection, assessment, monitoring and prevention of adverse effects of the pharmaceuticals product after marketing. The aim of the study were to recognise the awareness of pharmacist 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 randomisation. The data were collected by direct interview using self-administrated Questionnaire and analysed by SPSS version 23.

**Results:** 57.4% 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 centre. 79% from pharmacists in the study were not aware about existence of pharmacovigilance program in Sudan. 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.

### Conclusion and recommendations:

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, Reporting, Pharmacovigilance

**Conflict of interest:** There is no conflict of interest

## **Introduction**

### **Adverse Drug Reactions:**

There is no therapy devoid from adverse effects. <sup>(1)</sup> The significance of safety measures for drugs based on experiences related to ADRs. New drugs are approved based on a benefit-risk assessment but in post marketing survey, unexpected, rare and serious ADRs have been detected. <sup>(2)</sup> The adverse drug reactions are harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product. Adverse drug reactions can be considered a form of toxicity. Incidence and severity of adverse drug reactions vary according to patient demographics (e.g. age, sex, ethnicity, coexisting of disorders, genetic or geographic factors) and by drug factors (e.g. type of drug, administration route, treatment duration, dosage, bioavailability). The incidence of adverse drug reactions is usually higher in advanced age patients and polypharmacy. <sup>(3)</sup>

### **Pharmacovigilance:**

Pharmacovigilance is essential part of healthcare systems worldwide associated with collection, detection, assessment, monitoring and prevention of adverse effects of the pharmaceuticals product after marketing <sup>(4)</sup>. Most countries 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 national pharmacovigilance systems.

The objective of pharmacovigilance is safe use of drugs, patient safety, and ultimately, safeguarding public health. To achieve this goal, 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. However, the number of reported ADRs is far below the number of ADRs that actually occur. Hence, statistics available through the UMC only show data on ADRs reported but not all actual events. <sup>(5)</sup>

### **Adverse event reporting:**

1. **Individual Case Safety Report (ICSR).**
2. **Coding of adverse events**
3. **Seriousness determination** <sup>(6), (7)</sup>
4. **Expedited reporting**
5. **Clinical trial reporting**

## 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. <sup>(8)</sup>

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. <sup>(9, 10)</sup>

## 7. 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.

## 8. 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 programmes 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. <sup>(11)</sup>

### Literature review:

Hale. M. k. et al found (17.2%) of pharmacists had knowledge about pharmacovigilance. (21%) had report of adverse drug reaction to the concern organization in the previous 12 months. And 7% report to national pharmacovigilance centre. <sup>(12)</sup>

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. <sup>(13)</sup>

55 % of community pharmacies in Lagos state have ever heard of the word 'Pharmacovigilance' out of which less than half (representing only 18% of all respondents) could define the term 'Pharmacovigilance'. Only 3% of respondents actually reported an ADR to the National Pharmacovigilance Centre. The most important reason for poor reporting was lack of knowledge about how to report ADRs (44.6%), 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. <sup>(14)</sup> 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. <sup>(15)</sup>

Maysa Suyagh stated that majority of pharmacists have insufficient awareness and lack of knowledge about pharmacovigilance and ADRs reporting. Also pharmacists think that ADRs are unimportant or they did not know how to report them. <sup>(16)</sup>

Jimmy j. K. M. et al concluded that good number of community pharmacist had no enough knowledge about adverse drug reaction reporting and thus they need to have a training course to improve their knowledge and attitude about adverse drug reaction reporting system. <sup>(17)</sup>

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. <sup>(18)</sup>

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. <sup>(19)</sup>

Yasser M. W. Y. 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. <sup>(20)</sup>

M.Elmusbah and H.Elkheir found that there are poor knowledge of health care professionals about pharmacovigilance. <sup>(21)</sup>

### **Justification:**

This study aimed to recognise the awareness of community pharmacist regarding pharmacovigilance and adverse drug reactions reporting, assess the knowledge of community

pharmacist about reporting system regarding (to who will report, international centre and reporting form of adverse drug reaction) and assess the attitude of community pharmacist regarding pharmacovigilance and to assess the barrier of adverse drug reaction reporting Pharmacist play crucial roles in health systems in maintaining the rational and safe use of medicines while pharmacovigilance mainly targets safety of medicine who are specifically trained in this field. Effective use of pharmacist's workforce (patient counselling) will improve the outcome of the pharmacotherapy, increase patient safety, improve quality of life and decrease medication cost in Sudan.

Sudan became an official member of WHO for drug monitoring, in Uppsala 2008, so to promote the role of pharmacovigilance the community pharmacist should also play an important role.

### **Methodology:**

Descriptive cross-sectional study conducted to 237 pharmacists working in Khartoum's locality pharmacies from August 2019 to March 2020 selected by simple randomisation. The data were collected by direct interview using self-administrated Questionnaire and analysed by SPSS version 23 (IKM SPSSInc., Chicago, IL) and STATA 11.

### **Results**

The demographic characteristics of participants, 43% were male and 57% were female. 68% were fell in the age less than 30 years, 24% were fell in the age range 30-40 years and 8% more than 40 years. The educational level of the participants, 73% where bachelor holders, 24% master holders while 3% where PhD holder in pharmacy.

In the area of years of experience more than half (51.5%) from the pharmacists in the study have experience range from 2- 5 years, 22.4% 6-10 years, 11.4% , more than 10 years and 14.8% less than 2 years of experience.

In area of practice of adverse drug reactions pharmacists, 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 adverse drug reactions reporting form, 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.

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.

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. 79% from pharmacists in the study were not aware about existence of pharmacovigilance program in Sudan represented in figure 3.

62.9% from respondents didn't know where the international center for monitoring adverse drug reactions represented in figure 4.

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. 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.

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.

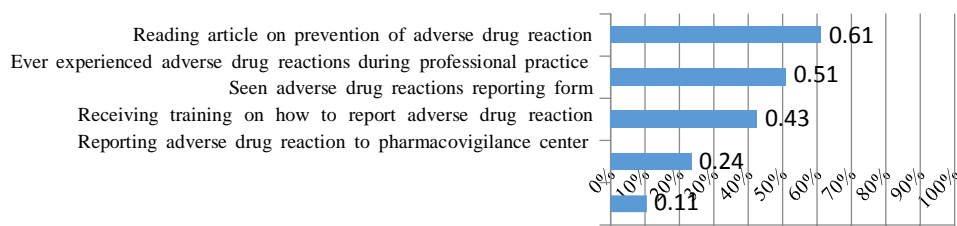
98.8% of respondents strongly agree that reporting adverse drug reactions is necessary, 91.7% of respondent thought that pharmacovigilance should be taught in details to all under graduate medical students, this competency is very important, so the graduates can serve an important role not only for patient 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.

In our study we found 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

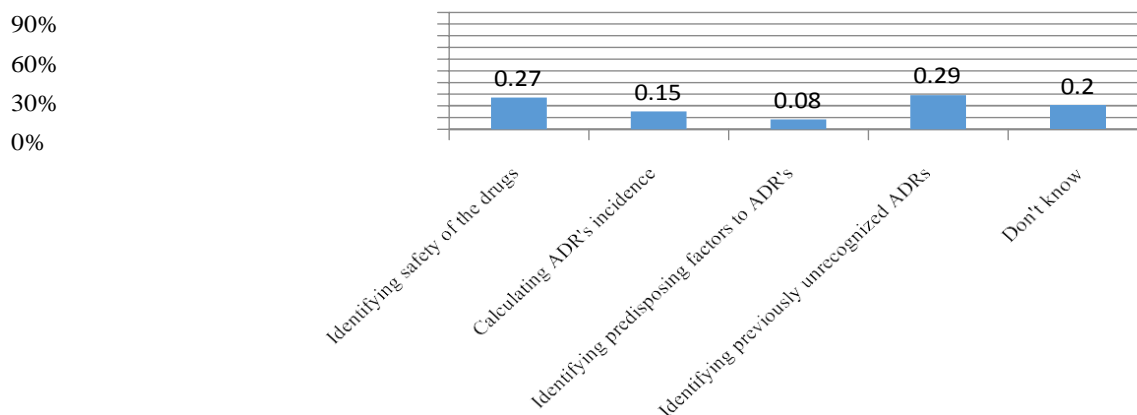


**Figure 1:** Represent the practice of the pharmacists towards adverse drug reactions

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%

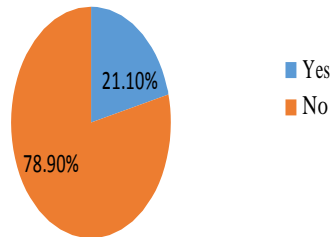
**Table 1:** Pharmacovigilance definition

### Most important goals of Pharmacovigilance



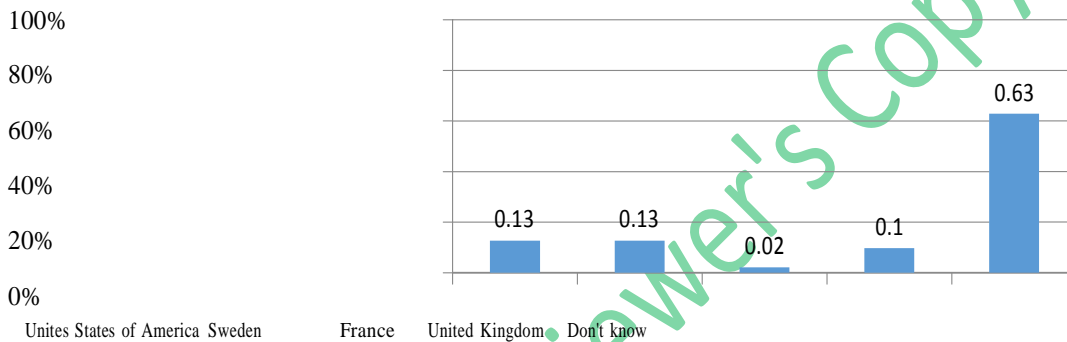
**Figure 2:** Most important goals of pharmacovigilance

Knowledge regarding existence of pharmacovigilance program in Sudan



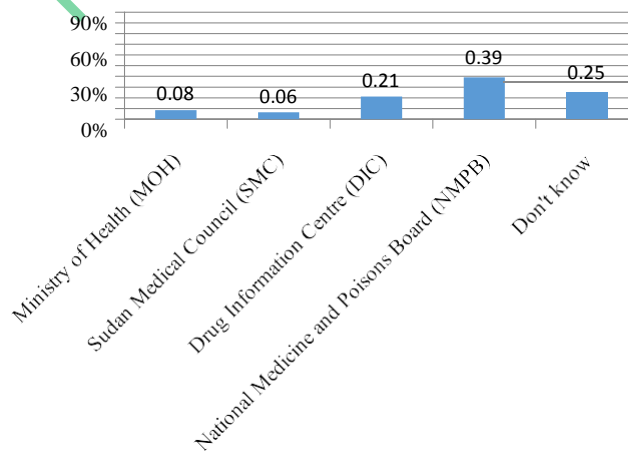
**Figure 3:** Knowledge regarding existence of pharmacovigilance program in Sudan

Location of international centre for monitoring adverse drug reactions



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

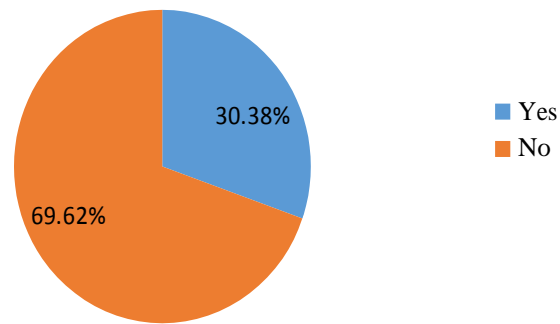
Regulatory body in Sudan is responsible for monitoring adverse drug reactions



**Figure 5:** Represent the regulatory body In Sudan responsible for monitoring adverse drug reactions

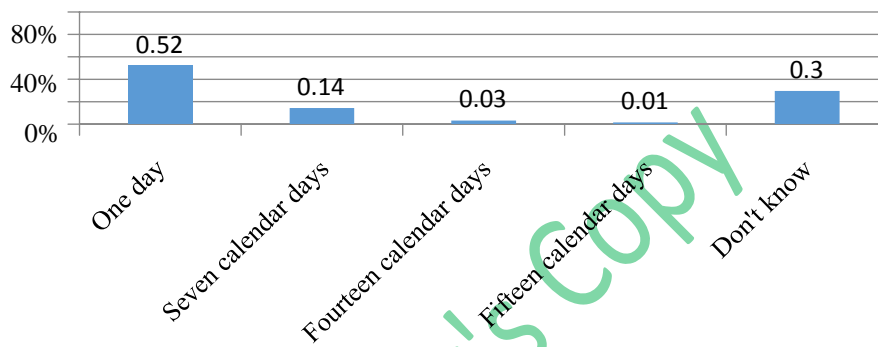


Knowledge about filling an adverse drug reaction report form



**Figure 6:** Represent the Knowledge about filling an adverse drug reaction report form

Duration of reporting serious adverse event in Sudan



**Figure 7:** Represent the duration of reporting serious adverse event in Sudan

<i>Knowledge variables</i>	<i>Correct</i>	<i>Incorrect</i>	<i>Percent of Correct</i>
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%

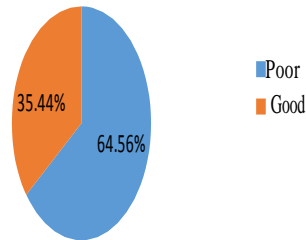
In Sudan which regulatory body is responsible for monitoring adverse drug reactions	93	144	39.2%
Duration of reporting serious adverse event in Sudan	34	203	14.3%

Reviewer's Copy

n=237

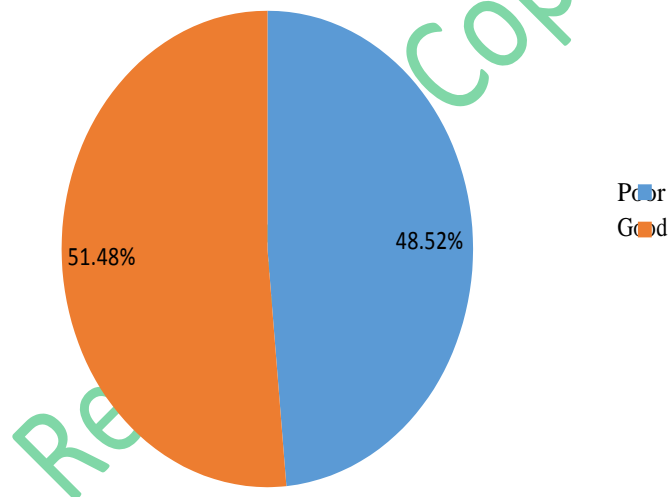
Table 2: Represent the knowledge score about adverse drug reactions and pharmacovigilance system in Sudan

Knowledge score about adverse drug reaction and pharmacovigilance reporting system



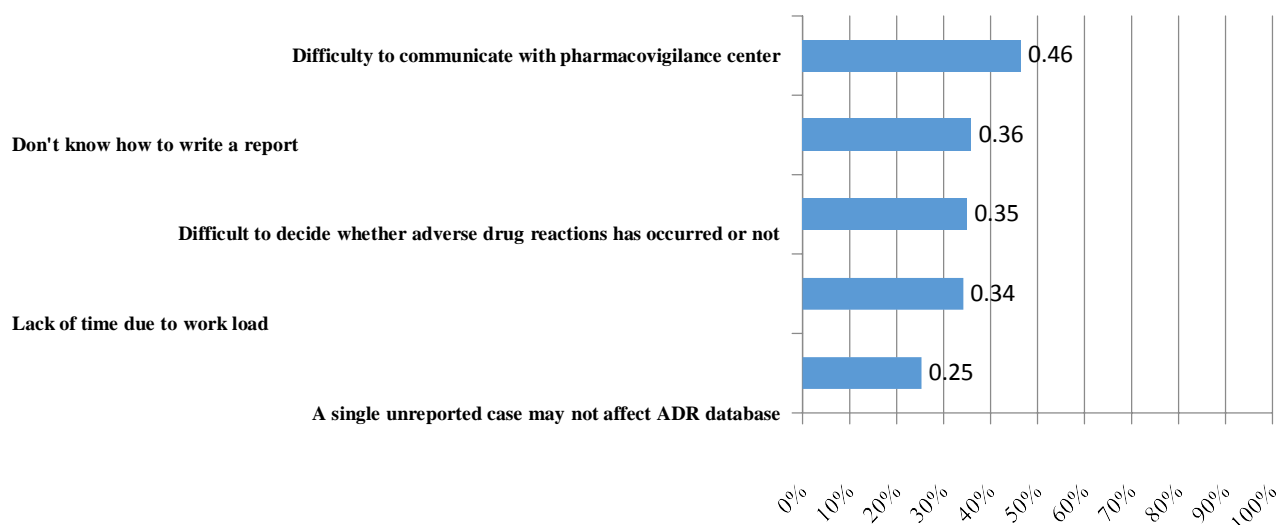
**Figure 8:** Knowledge score about adverse drug reaction and pharmacovigilance reporting system

Attitude score about adverse drug reaction and pharmacovigilance reporting system



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

Most important factor that discourages pharmacist from reporting adverse drug reactions monitoring



**Figure 10:** Represent the most important factors discourages pharmacists from reporting drug reactions monitoring

Variables		Knowledge score about adverse drug reaction and pharmacovigilance reporting system		Chi square P value	Fisher's exact test P value
		Poor	Good		
Gender	Male	61.40%	38.60%	0.379*	0.412*
	Female	66.9 %	33.1%		
Age groups	Less than 30 years	70.80%	29.20%	0.014**	0.014**
	30 – 40 years	50.90%	49.10%		
	More than 40 years	52.60%	47.40%		
Educational level	Kachelor	67.40%	32.60%	0.320*	0.275*
	Master	56.90%	43.10%		
	PhD	57.10%	42.90%		
Years of experience	Less than 2 years	62.90%	37.10%	0.064*	0.060*
	2 – 5 years	72.10%	27.90%		
	6 -10 years	54.70%	45.30%		
	More than 10 years	51.90%	48.10%		
Reading article on prevention of adverse drug reaction	Yes	57.90%	42.10%	0.007**	0.008**
	No	75.00%	25.00%		
Seen adverse drug reactions reporting form	Yes	52.50%	47.50%	0.001**	0.001**
	No	73.50%	26.50%		
Reporting adverse drug reaction to pharmacovigilance center	Yes	64.00%	36.00%	0.951*	0.999*
	No	64.6%	35.4%		
Receiving training on how to report adverse drug reaction	Yes	51.80%	48.20%	0.022**	0.026**
	No	68.50%	31.50%		
Ever experienced adverse drug reactions during professional practice	Yes	61.20%	38.80%	0.264*	0.280*
	No	68.10%	31.90%		

- \*\*.P value<0.05that's considered as statistically significant.
- \*.P value>0.05that's considered as statistically insignificant.

Table 3: Relationship between different variables and Knowledge score about adverse drug reaction and pharmacovigilance reporting system

## Discussion:

237 pharmacists responded to the study, 57% were females, while 43% were males. Most of them were young (those less than 30 years old were 67.9%), those may think community pharmacy is the suitable way to apply both business and pharmacotherapy knowledge, together with the opportunities to grow as a leader and be responsible for multiple pharmacies. 72.6% of them with a bachelor degree.

In terms of knowledge, 33.8% of pharmacists define the pharmacovigilance as: The detection, assessment, understanding and prevention of adverse effects, which complying with the WHO definition of pharmacovigilance. This is similar to the results of a study conducted in Saudi Arabia which found that the majority of pharmacists knew the correct definition of pharmacovigilance (PV), that might be because of the continuing education activities conducted by the top hospital management and supervised and monitored by the Saudi Food and Drug Authority. (Dhfer Alshayban, Mansour Adam Mahmoud, Md Ashraf Islam, Shouq Alshammari, Duaa Alsulaiman, Pharmacovigilance Perception and Knowledge Among Pharmacists and Interns in Saudi Arabia)

29.1% of community pharmacists thought that 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. (Mohammed Zawiah, Ramzi Mukred, Sayida Al-Jamei, Taha Kadi, Abdulrhman Al-Kaidani, Rana Abu Farha, Pharmacists' knowledge and perceptions about pharmacovigilance and barriers towards adverse drug reactions reporting in Yemen).

Results provide an indicator to that most of respondents did not know where is the international centre for monitoring adverse drug reactions (62.9%), which may put a responsibility on the regulatory authority in Sudan to hold training programs for community pharmacist about pharmacovigilance. Although most of them know that the responsible body in Sudan is The National Medicines and Poisons Koard.

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. (Maysa Suyagh, Doaa g Farah,

Rana Abu Farha, Pharmacist's Knowledge, Practice and Attitudes toward Pharmacovigilance and Adverse Drug Reactions Reporting Process).

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. (Hadi MA, Neoh CF, Zin RM, Elrggal ME, Cheema E. Pharmacovigilance: pharmacists' perspective on spontaneous adverse drug reaction reporting).

From the previous results it is clear that the knowledge score about adverse drug reactions and pharmacovigilance system in Sudan was poor, only 35% of participants had a good knowledge, that need planned and clear interventions from the regulatory authority. The use of SMS as a reinforcement tool appeared to have positively impacted on the knowledge and practice of pharmacovigilance in a study in Nigeria, while continuous medical education may be required to effect long-lasting changes.( Abimbola O. Opadeyi, Annie Fourrier-Réglat, and Ambrose O. Isah. Educational intervention to improve the knowledge, attitude and practice of healthcare professionals regarding pharmacovigilance in South-South Nigeria)

In our study we found 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).

Regarding the attitude of respondents about adverse drug reactions and pharmacovigilance, most of them (62%) strongly agree that adverse drug reactions reporting is professional obligation,

Most of the respondent strongly agree 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.

98.8% of respondents strongly agree that reporting adverse drug reactions is necessary, that to protect patient's lives from serious adverse drug reactions,

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.

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.

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.

When respondents answered the question about the factors discourage them from reporting of adverse drug reactions, 46.4% of them thought that there is a difficulty in communicating with pharmacovigilance centre in Sudan, this result show that the centre need 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. 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.

### **Conclusion:**

The results of this study suggest that community pharmacists have insufficient knowledge about the concept of pharmacovigilance and spontaneous ADRs reporting. On the other hand, pharmacists had positive attitudes toward pharmacovigilance, despite their little experience with ADRs reporting.

The study determined many Factors those discourage adverse drug reactions reporting could be managed.

### **Recommendations:**

- Pharmacovigilance knowledge, and attitude of community pharmacist can be strengthened by educational trainings and workshops.
- Establishing relationship between the regulatory authority (National Medicines and Poisons Koard, General Directorate of Pharmacy) and community pharmacists in form of continuous professional education programs, and online training
- Link those training programs with credit points required for renewing permanent registration in Sudan Medical Council.
- Further researches should be conducting in other parts of Sudan

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