**Reviewer’s Comments**



Assessment of Community Pharmacist Awareness onAdverse DrugReactionandPharmacovigilanceReportingSysteminKhartoumLocality,2020

## Abstract:

**Introduction:**

Adverse drug reactions were harmful or unpleasant reaction resulting from the use of amedicinal product. Pharmacovigilance is associated with collection, detection, assessment,monitoring and prevention of adverse effects of pharmaceuticals product after marketing.The aim of the study were to recognize the awareness of pharmacist regardingpharmacovigilance and adversedrugreactionsreporting.

## Methodology:

Descriptive cross-sectional study conducted to 237 pharmacists working in Khartoum’slocality pharmacies from August 2019 to March 2020 selected by simple randomisation. Thedata were collected by direct interview using self-administrated Questionnaire and analysedbySPSS version23.

**Results:** 57.4% never seen adverse drug reactions reporting form, 76.4% never receivetraining on how to report it and only 10.5% from the pharmacists in the study report it topharmacovigilancecentre.79%frompharmacistsinthestudywerenotawareaboutexistenceof pharmacovigilance program in Sudan. 51.5 % from pharmacists have good attitude aboutadversedrugreactionsandpharmacovigilanceinSudanwhile 48.5%hadpoorattitude.

Difficulty in communicating with pharmacovigilance centre in Sudan and how to write thereportwerethe factorsdiscouragepharmacistsfromreportingofadversedrugreactions.

## Conclusionandrecommendations:

Communitypharmacistshaveinsufficientknowledgeabouttheconceptofpharmacovigilance and spontaneous ADRs reporting while they had positive attitudes towardpharmacovigilance,despitetheirlittleexperiencewithADRsreporting,thiscanbestrengthened by educationaltrainingsand workshops.

**Keywords:**Assessment,Reporting,Pharmacovigilance

Conflictofinterest:Thereisnoconflictofinterest

**Introduction**

**AdverseDrugReactions:**

There is no therapy devoid from adverse effects. (1) The significance of safety measures fordrugs based on experiences related to ADRs. New drugs are approved based on a benefit-riskassessment but in post marketing survey, unexpected, rare and serious ADRs have beendetected. (2) The adverse drug reactions are harmful or unpleasant reaction, resulting from anintervention related to the use of a medicinal product, which predicts hazard from futureadministration and warrants prevention or specific treatment, or alteration of the dosageregimen, or withdrawal of the product. Adverse drug reactions can be considered a form oftoxicity. Incidence and severity of adverse drug reactions vary according to patientdemographics (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 agepatientsandpolypharmacy.(3)

## Pharmacovigilance:

Pharmacovigilance is essential part of healthcare systems worldwideassociated withcollection, detection, assessment, monitoring and prevention of adverse effects of thepharmaceuticals product after marketing (4). Most countries operate nationalpharmacovigilance systems as part of their public health and healthcare policies. The WorldHealth Organization international drug monitoring program through the Uppsala MonitoringCentre(UMC)aimstofacilitatethecollaborationofnationalpharmacovigilancesystems.

The objective of pharmacovigilance is safe use of drugs, patient safety, and ultimately,safeguarding public health. To achieve this goal, national regulators and internationalorganizations rely on the reporting of adverse drug reactions (ADRs). National, regional, andglobal data on ADRs are working to inform regulators, healthcare professionals, and thepublic about safety concerns with pharmaceutical products. However, the number of reportedADRs is far below the number of ADRs that actually occur. Hence, statistics availablethroughtheUMConlyshowdata onADRsreported butnotallactualevents. (5)

**Adverseeventreporting:**

1. **IndividualCaseSafetyReport(ICSR).**
2. **Codingofadverseevents**
3. **Seriousnessdetermination**(6),(7)
4. **Expeditedreporting**
5. **Clinicaltrialreporting**
6. **Spontaneous reporting**

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

One of the major weaknesses of spontaneous reporting is that of under-reporting, where,unlikeinclinicaltrials,lessthan100%ofthoseadverseeventsoccurringarereported.

In view of this, medical personnel may not always see reporting as a priority, especially if thesymptomsarenotserious.(9,10)

## Aggregatereporting

Aggregate reporting, also known as periodic reporting, plays a key role in the safetyassessment of drugs. Aggregate reporting involves the compilation of safety data for a drugover 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 itprovidesabroader viewof thesafety profileof adrug.

## Otherreportingmethod:

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 controversialdrugs, or on the prescribing habits of groups of doctors, or involving pharmacists inreporting. All of these generate potentially useful information. Such intensive schemes,however, tend to be the exception. A number of countries have reporting requirements orreporting systemsspecific to vaccine-related events.(11)

## Literaturereview:

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 12months.And7%reporttonationalpharmacovigilancecentre.(12)

Ghazal Vessel. Z. M. et al found that the Iranian pharmacists have little knowledge regardingtheoperation,purposes,andusefulnessofadversedrugreactionreportingsystem.(13)

55%of communitypharmaciesin Lagosstatehaveeverheardoftheword‘Pharmacovigilance’ out of which less than half (representing only 18% of all respondents)could define the term ‘Pharmacovigilance’.Only 3% of respondents actually reported anADR to the National Pharmacovigilance Centre. The most important reason for poorreporting was lack of knowledge about how to report ADRs (44.6%), meanwhile, 90% ofrespondents believed that the role of the pharmacists in ADR reporting was important. Mostcommunity 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 inIndia.Pharmacistshavepoorknowledge,goodperceptionandnegligibly lowreportingrates.

(15)

MaysaSuyagh stated that majority of pharmacists have insufficient awareness and lack ofknowledge about pharmacovigilance and ADRs reporting. Also pharmacists think that ADRsare unimportantorthey didnot knowhowtoreportthem.(16)

Jimmy j. K. M. et al concluded that good number of community pharmacist had no enoughknowledge about adverse drug reaction reporting and thus they need to have a training courseto improve their knowledge and attitude about adverse drug reaction reporting system. (17)Mansour Adam. Y. T. et al stated thatmajority of a community pharmacist in Riyadh have apoor knowledge about ADR reporting system and need for interventional program to improveit.(18)

A study conducted in India stated that few pharmacists knew about Central Drugs StandardControl Organization (CDSCO) as a centre for reporting ADRs. Majority of pharmacistswould direct the patients to the physician, in case of occurrences of ADR. According to26.67% of the pharmacists in the study, busy schedule is considered as a vital factor forunder-reportinganADR.(19)

Yasser M. W. Y. et alfound that Pharmacists had a better knowledge than pharmacytechnicians regarding pharmacovigilance. So, educational interventions and training is veryimportant for community pharmacists and pharmacy technicians to increase their awarenessand participationinadverse drugreactionreporting.(20)

M.ElmusbahandH.Elkheirfoundthattherearepoorknowledgeofhealthcareprofessionalsaboutpharmacovigilance.(21)

## Justification:

This study aimed to recognise the awareness of community pharmacist regardingpharmacovigilanceandadversedrugreactionsreporting,assesstheknowledgeofcommunity

pharmacist about reporting system regarding (to who will report, international centre andreporting form of adverse drug reaction) and assess the attitude of community pharmacistregarding pharmacovigilance and to assess the barrier of adverse drug reaction reportingPharmacist play crucial roles in health systems in maintaining the rational and safe use ofmedicines while pharmacovigilance mainly targets safety of medicine who are specificallytrained in this field. Effective use of pharmacist’s workforce (patient counselling) willimprove the outcome of the pharmacotherapy, increase patient safety, improve quality of lifeand decreasemedicationcostin Sudan.

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

## Methodology:

Descriptive cross-sectional study conducted to 237 pharmacists working in Khartoum’slocality pharmacies from August 2019 to March 2020 selected by simple randomisation. Thedata were collected by direct interview using self-administrated Questionnaire and analysedbySPSSversion23 (IKM SPSSInc., Chicago, IL) andSTATA 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%masterholders while 3% wherePhD holderin pharmacy.

In the area of years of experience more than half (51.5%) from the pharmacists in the studyhave experience range from 2- 5 years, 22.4% 6-10 years, 11.4% , more than 10 years and14.8%less than2 years of experience.

In area of practice of adverse drug reactions pharmacists, 61.2% from pharmacists readingarticles on prevention of adverse drug reaction, 51.5% ever experienced adverse drugreactions during professional practice, 57.4% never seen adverse drug reactions reportingform, 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 aspresented in figure1.

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 sciencedetecting the type and incidence of adverse drug reactions (ADR) after drug is marketedwhile 23.6%don’tknowthedefinition ofpharmacovigilanceaspresented intable 1.

29.1% from pharmacists stated that the goal of pharmacovigilance is identifying previouslyunrecognizedADRs, 27%stated thegoal is identifying safetyof thedrugswhile 20.3%didn’t know the goal of pharmacovigilance as presented in figure 2. 79% from pharmacists inthestudy werenotawareaboutexistenceofpharmacovigilanceprogramin Sudanrepresented infigure3.

62.9% from respondents didn’t know where the international center for monitoring adversedrugreactionsrepresentedinfigure4.

24.9% from the respondent didn’t know the regulatory body responsible for monitoringadverse drug reactions, 39.2% know that the responsible body in Sudan is the NationalMedicine and Poisons Koard (NMPK) as presented in figure 5. 69.6% from the respondentshad 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 respondentsagreed that the reporting should be within one day, 29.5% don’t know while 14.3% statedthat should bewithinsevencalendardays aspresentedin figure7.

From the previous results, 64.6% from the respondents in the study had poor knowledgescore about adverse drug reactions and pharmacovigilance system in Sudan as presented infigure8.

Regarding the attitude of respondents about adverse drug reactions and pharmacovigilance,62% strongly agree that adverse drug reactions reporting is professional obligation, most ofthe respondentstrongly agreethat pharmacistcanreport adversedrugreactions.

98.8%ofrespondentsstronglyagreethatreportingadversedrugreactionsisnecessary,91.7%ofrespondentthoughtthatpharmacovigilanceshouldbetaughtindetailstoallundergraduatemedicalstudents,thiscompetencyisveryimportant,sothegraduatescanserveanimportantrolenotonlyforpatientsafetyinindividualpatientcarebutalsofordrugsafetymonitoringatapopulationlevelandthemajorityofrespondentsthoughtthatitisnecessarytoestablishadversedrugreactionmonitoringcentreineveryhospital.Fromthepreviousresultsitisclearthattheattitudescoreaboutadversedrugreactionsandpharmacovigilancesystem inSudanwasgood51.5%while 48.5%hadpoorattitudeaspresented infigure 9.

About the factors discourage pharmacists from reporting of adverse drug reactions, 46.4% ofthem thought that there is a difficulty in communicating with pharmacovigilance centre inSudan, 35.9% of respondents said they did not know how to write the report, while 35% saidthey could not decide whether the adverse drug reaction occurred or not, 34.2% ofrespondentsmentionedthattheyhadnotimetoreportadversedrugreactions duetoworkload

while 25.3% stated that a single unreported case may not affect ADR database as presented infigure10.

In our study we found a significant relationship between poor knowledge score about adversedrug reaction and pharmacovigilance reporting system and the following factors: pharmacistsaged above 40 years old, reading articles on prevention of adverse drug reaction, seeing theadverse drug reactions reporting form and training received on how to report adverse drug (Pvalue<0.05) as presented intable3.

**Practicevariables**

Readingarticle onpreventionof adversedrug reactionEverexperiencedadversedrugreactionsduringprofessionalpractice

0.61

0.51

0.43

0.24

0.11

SeenadversedrugreactionsreportingformReceivingtrainingonhow toreport adverse drugreactionReportingadversedrugreactiontopharmacovigilancecenter

**Figure1:**Representthepracticeofthepharmacists towardsadversedrugreactions

|  |  |  |
| --- | --- | --- |
| **Pharmacovigilancedefinition** | **Number** | **Percent** |
| Thesciencedetectingthetypeandincidence ofadversedrugreactions  (ADR)afterdrugismarketed | 75 | 31.6% |
| ThesciencethatmonitorsADR'soccurrenceinhospitals | 14 | 5.9% |
| Theprocessofimproving drugsafety | 12 | 5.1% |
| Thedetection,assessment,understandingandpreventionofadverse  effects | 80 | 33.8% |
| Don'tknow | 56 | 23.6% |
| Total | 237 | 100% |

**Table1:**Pharmacovigilancedefinition

**MostimportantgoalsofPharmacovigilance**

90%

0.27

0.15

0.29

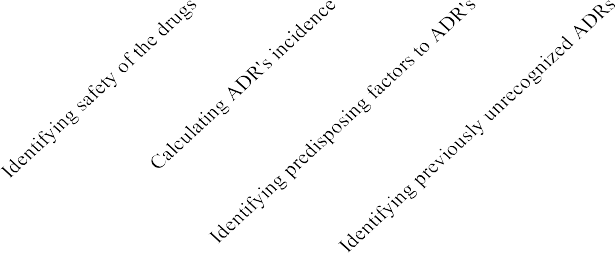
0.08

0.2

60%

30%

0%



**Figure2:**Mostimportantgoalsofpharmacovigilance

**Knowledgeregardingexistenceof pharmacovigilanceprograminSudan**

YesNo

21.10%

78.90%

**Figure3:**KnowledgeregardingexistenceofpharmacovigilanceprograminSudan

# Locationofinternationalcentreformonitoringadversedrugreactions

100%

0.63

0.13

0.13

0.02

0.1

80%

60%

40%

20%

0%

UnitesStatesofAmericaSweden France UnitedKingdomDon'tknow

**Figure4:**Location ofinternationalCentreformonitoringadversedrugreactions

RegulatorybodyinSudanisresponsibleformonitoringadversedrugreactions

90%

0.08

0.21

0.39 0.25

0.06

60%

30%

0%

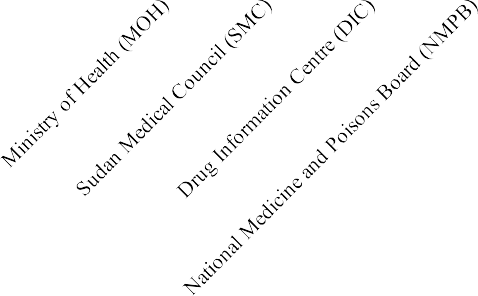


Figure 5: Represent the regulatory body In Sudan responsible for monitoring adverse drugreactions

Knowledgeaboutfillinganadversedrugreactionreportform

YesNo

30.38%

69.62%

**Figure6:**RepresenttheKnowledgeaboutfillinganadversedrugreactionreportform

# Durationof reportingseriousadverse eventinSudan

80%

0.52

0.14

0.3

0.03

0.01

40%

0%

**Figure7:**Representtheduration ofreportingseriousadverseeventinSudan

|  |  |  |  |
| --- | --- | --- | --- |
| ***Knowledgevariables*** | ***Correct*** | ***Incorrect*** | ***Percentof***  ***Correct*** |
| Locationinternational Centreformonitoringadversedrug  reactions | 30 | 207 | 12.7% |
| Knowledgeregardingexistenceofpharmacovigilance  programin Sudan | 50 | 187 | 21.1% |
| MostimportantgoalsofPharmacovigilance | 64 | 173 | 27% |
| Knowledgeaboutfillinganadversedrugreactionreportform | 72 | 165 | 30.4% |
| Pharmacovigilancedefinition | 80 | 157 | 33.8% |
| InSudanwhichregulatorybodyisresponsibleformonitoring  adversedrugreactions | 93 | 144 | 39.2% |
| DurationofreportingseriousadverseeventinSudan | 34 | 203 | 14.3% |

n=237

Table2:Representtheknowledgescoreaboutadversedrugreactions andpharmacovigilance

systeminSudan

Knowledgescoreaboutadversedrugreactionandpharmacovigilancereportingsystem

PoorGood

35.44%

64.56%

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

Attitudescoreaboutadversedrugreactionandpharmacovigilancereportingsystem

PoorGood

51.48%

48.52%

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

Mostimportantfactorthatdiscouragespharmacistfromreportingadversedrugreactionsmonitoring

**Difficultytocommunicatewithpharmacovigilancecenter**

0.46

0.36

0.35

0.34

0.25

**Don't know howtowriteareport**

**Difficulttodecidewhetheradversedrugreactions has occurredornot**

**Lackoftimeduetoworkload**

**AsingleunreportedcasemaynotaffectADRdatabase**



**Figure 10:** Represent the most important factors discourages pharmacists from reportingdrugreactionsmonitoring

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Variables | | Knowledgescoreabout  adversedrugreactionand  pharmacovigilancereportingsystem | | Chi square Pvalue | Fisher'sexacttestP  value |
| Poor | Good |
| Gender | Male | 61.40% | 38.60% | 0.379\* | 0.412\* |
| Female | 66.9% | 33.1% |
| Agegroups | Lessthan30years | 70.80% | 29.20% | 0.014\*\* | 0.014\*\* |
| 30– 40years | 50.90% | 49.10% |
| Morethan40years | 52.60% | 47.40% | 0.320\* | 0.275\* |
| Educationallevel | Kachelor | 67.40% | 32.60% |
| Master | 56.90% | 43.10% |
| PhD | 57.10% | 42.90% |
| Yearsofexperience | Lessthan2years | 62.90% | 37.10% | 0.064\* | 0.060\* |
| 2– 5years | 72.10% | 27.90% |
| 6-10years | 54.70% | 45.30% |
| Morethan10years | 51.90% | 48.10% |
| Readingarticleonpreventionofadversedrug  reaction | Yes | 57.90% | 42.10% | 0.007\*\* | 0.008\*\* |
| No | 75.00% | 25.00% |
| Seenadversedrugreactionsreportingform | Yes | 52.50% | 47.50% | 0.001\*\* | 0.001\*\* |
| No | 73.50% | 26.50% |
| Reportingadversedrugreactionto  pharmacovigilancecenter | Yes | 64.00% | 36.00% | 0.951\* | 0.999\* |
| No | 64.6% | 35.4% |
| Receivingtrainingonhowtoreportadverse  drugreaction | Yes | 51.80% | 48.20% | 0.022\*\* | 0.026\*\* |
| No | 68.50% | 31.50% |
| Everexperiencedadversedrugreactions  duringprofessionalpractice | Yes | 61.20% | 38.80% | 0.264\* | 0.280\* |
| No | 68.10% | 31.90% |

* \*\*.Pvalue<0.05that’sconsideredasstatisticallysignificant.
* \*.Pvalue>0.05that’sconsideredasstatisticallyinsignificant.

Table 3: Relationship between different variables and Knowledge score about adverse drugreactionand pharmacovigilancereporting system

**Discussion:**

237 pharmacists responded to the study, 57% were females, while 43% were males. Most ofthem were young (those less than 30 years old were 67.9%), those may think communitypharmacyisthesuitablewaytoapplybothbusinessandpharmacotherapyknowledge,togetherwiththeopportunitiestogrowasaleaderandberesponsibleformultiplepharmacies.72.6% of themwithabachelordegree.

Intermsofknowledge,33.8%ofpharmacistsdefinethepharmacovigilanceas:Thedetection,assessment,understandingandpreventionofadverseeffects,whichcomplyingwith the WHO definition of pharmacovigilance. This is similar to the results of a studyconducted in Saudi Arabia which found that the majority of pharmacists knew the correctdeﬁnition of pharmacovigilance (PV), that might be because of the continuing educationactivities conducted by the top hospital management and supervised and monitored by theSaudi Food and Drug Authority.( DhferAlshayban, Mansour Adam Mahmoud, Md AshrafulIslam, ShouqAlshammari, DuaaAlsulaiman, Pharmacovigilance Perception and KnowledgeAmongPharmacistsand Internsin SaudiArabia)

29.1% of community pharmacists thought that the important goal of pharmacovigilancesystem is identifying previously unrecognized ADRs, which is a good thing in Sudan formonitoring and improving the local pharmaceutical manufacturers. Regarding the knowledgeof existing pharmacovigilance program in Sudan only 79% of respondents were not aware ofthe existence of ADRs reporting system in Sudan, which is a superior result comparing to astudy done in Yemen, 96.3% were not aware of the existence of ADRs reporting system inYemen. (Mohammed Zawiah, Ramzi Mukred, Sayida Al‐Jamei, Taha Kadi, AbdulrhmanAl‐Kaidani,RanaAbuFarha,Pharmacists’knowledgeandperceptionsaboutpharmacovigilanceandbarrierstowardsadversedrugreactions reporting in Yemen).

Resultsprovideanindicatortothatmostofrespondentsdidnotknowwhereistheinternationalcentreformonitoringadversedrugreactions(62.9%),whichmayputaresponsibility on the regulatory authority in Sudan to hold training programs for communitypharmacist about pharmacovigilance. Although most of them know that the responsible bodyin SudanisTheNational MedicinesandPoisons Koard.

69.6%fromrespondentshadnoknowledgeaboutfillinganadversedrugreactionreportform, that is similar to a study conducted in Jordan found that pharmacists think that ADRsareunimportant,andtheydidnotknowhowtoreportthem.(MaysaSuyagh,DoaagFarah,

Rana Abu Farha, Pharmacist’s Knowledge, Practice and Attitudes toward Pharmacovigilanceand AdverseDrug ReactionsReporting Process).

The study lead to a good result regarding the duration of reporting serious adverse event, thatrespondents (51.9%) agreed with that the reporting should be within one day, this is in linewith a result of many previous studies insisted that prompt ADR reporting is crucial inensuringdrugsafety.(HadiMA,NeohCF,ZinRM,ElrggalME,CheemaE.Pharmacovigilance:pharmacists’perspectiveonspontaneousadversedrugreactionreporting).

Fromthepreviousresultsitisclearthattheknowledgescoreaboutadversedrugreactionsand pharmacovigilance system in Sudan was poor, only 35% of participants had a goodknowledge, that need planned and clear interventions from the regulatory authority. The useof SMS as a reinforcement tool appeared to have positively impacted on the knowledge andpractice of pharmacovigilance in a study in Nigeria, while continuous medical education mayberequiredtoeffectlong-lastingchanges.(AbimbolaO.Opadeyi,AnnieFourrier-Réglat,andAmbroseO.Isah.Educationalinterventiontoimprovetheknowledge,attitudeandpractice ofhealthcareprofessionalsregardingpharmacovigilanceinSouth-SouthNigeria)

In our study we found a significant relationship between poor knowledge score about adversedrug reaction and pharmacovigilance reporting system and the following factors: pharmacistsaged above 40 years old, reading articles on prevention of adverse drug reaction, seeing theadverse drug reactions reporting form and training received on how to report adverse drug (Pvalue<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 professionalobligation,

Most of the respondent strongly agree that pharmacist can report adverse drug reactions, andthat is clear, because the role of the pharmacist expanded from traditional dispenser towardpharmaceutical careprovider.

98.8%ofrespondentsstronglyagreethatreportingadversedrugreactionsisnecessary,thatto protectpatient'slives fromseriousadversedrug reactions,

91.7% of respondent thought that pharmacovigilance should be taught in details to all undergraduate medical students, this competency is very important, so the graduates can serve animportant role not only for patient safety in individual patient care but also for drug safetymonitoringatapopulationlevel.

92.9% strongly agree about establishing adverse drug reactions monitoring centre in everyhospital,thisisusefulforinitiatingacultureofADRreportingamonghealthcareprofessionals,andimprovecommunicationbetweenthephysiciansandnurseswiththepharmacovigilance centreinthehospital.

From the previous results it is clear that the attitude score about adverse drug reactions andpharmacovigilance system inSudan was good51.5%while 48.5%hadpoorattitude.

When respondents answered the question about the factors discourage them from reporting ofadversedrugreactions,46.4%ofthemthoughtthatthereisadifficultyincommunicatingwith pharmacovigilance centre in Sudan, this result show that the centre need to promote itswork, and should do some awareness campaigns targeting community pharmacies. 35.9% ofrespondents said they did not know how to write the report, while 35% said they could notdecide whether the adverse drug reaction occurred or not, this may be due to lack of trainingof community pharmacists. 34.2% of respondents mentioned that they had no time to reportadverse drug reactions due to workload. These finding were similar to the results of a study inJordan which include no enough information available from the patient, unavailability ofpharmacists ADRs form when needed, unawareness of the existence of a national ADRsreporting system,the ADRistoo trivial to reportandthey didnot knowhowtoreport.

## Conclusion:

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

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

## Recommendations:

* Pharmacovigilanceknowledge,andattitudeofcommunitypharmacistcanbestrengthened by educationaltrainingsandworkshops.
* Establishingrelationshipbetweentheregulatoryauthority(NationalMedicinesand

PoisonsKoard,GeneralDirectorateofPharmacy)andcommunitypharmacistsinformofcontinuous professional education programs, and online training

* Linkthosetrainingprogramswithcreditpointsrequiredforrenewingpermanent

registrationinSudanMedicalCouncil.

* FurtherresearchesshouldbeconductinginotherpartsofSudan

**Author’s Contribution**

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