Pharmacovigilance in Sudan: Knowledge, Attitudes and Behaviour among Community Pharmacists

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Abstract

Background: Adverse drug reaction monitoring and reporting require a multidisciplinary approach and pharmacists have a major role to play in this matter. Under-reporting of the ADRs by the prescribers is a common problem in devolving countries.

Aim: To assess the knowledge, attitude and behaviour of community pharmacists toward pharmacovigilance in Khartoum city.

Method: Descriptive cross-sectional study among 258 community pharmacists during the period from October to November 2017 using a pre-designed questionnaire. The study was evaluated participants regarding knowledge on drug safety in routine practice, the knowledge and attitude of community pharmacists toward ADR reporting and their behaviour on ADR related aspects.

Result: Out of 325 participants, most of them were male (50.8%) with age group From 18 years to 30 years (62%) and B. Pharm (57.8%) and practice experience more than 2 years to 5 years (38.8%) and Training received in pharmacovigilance Yes (42.2%). Assessing pharmacist's knowledge showed that 74% of community pharmacists know the ADR definition and 39.5% are not know the ADR are preventable to some extent, no association between knowledge and qualification, and there is an association with practice. Assessing pharmacists knowledge toward ADR reporting, 69% of the participant are agree awareness of the national pharmacovigilance program in Sudan revealed no statistically significant association with training in pharmacovigilance, positive attitude of pharmacist toward ADR reporting, 67.8% of the pharmacists believed that the role of the pharmacist in ADR reporting was essential revealed there are statistically significant associations with training in pharmacovigilance, the behaviour of pharmacist toward ADR, 91.9%of participant agrees to ask for the allergy history of the patient before dispensing the medication revealed no statistically significant association with training in pharmacovigilance.

Conclusion: Even though most of the pharmacists had knowledge, attitude and behaviour on ADR reporting and related aspects, the number of them did not know drug safety-related aspects of specific drugs. Educational programs have to be generated awareness on how to report ADR and stimulate pharmacists' more active participation in the pharmacovigilance program. There is a true need to have training programs to improve the knowledge of pharmacists on ADR related aspects that are of benefit daily, which could greatly have an impact on patient safety.

Key Policy Messages: The result reflected pharmacists knowledge toward ADR reporting, most of the participant are agree awareness of the national pharmacovigilance program in Sudan revealed no statistically significant association with training in pharmacovigilance, positive attitude of pharmacist toward ADR reporting, most of the pharmacists believed that the role of the pharmacist in ADR reporting was essential revealed there are statistically significant associations with training in pharmacovigilance, the behaviour of pharmacist toward ADR, majority of the participant agrees to ask for the allergy history of the patient before dispensing the medication revealed no statistically significant association with training in pharmacovigilance.

Keywords: Pharmacovigilance; ADR; Marketed Drugs; Patients

Introduction and Background

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems and generally refers to the continual monitoring for unwanted effects and other safety-related aspects of marketed drugs [1].

The Royal College of Physicians in 1994: Pharmacovigilance is the process of identifying, and then responding to, safety issues about marketed drugs [2].

In their latest textbook, Mann and Andrews define pharmacovigilance as 'the Study of the safety of marketed drugs under the practical conditions of clinical Usage in large communities' [3]. But this includes more as only collecting reports of possible adverse drug reactions (ADRs) and looking for signals of new ADRs. Reasons why drug safety issues may not be identified until the post-marketing Period, The adverse reaction is rare and therefore undetectable until a large number of patients have been exposed to the drug, there is a long latency between starting the drug and development of the adverse reaction and The drug has not been studied in normal clinical practice: patients treated in clinical practice are likely to have different characteristics to a trial patient (e.g. demography, other diseases, other medication); in clinical practice, a drug is less likely to be used strictly following the recommendations by both doctors and patients, and with less monitoring [4].

In the past pharmacovigilance was repeatedly criticized because once its activities had yielded a signal of an ADR this all too often meant that the license of the drug concerned was suspended. Today it has become one of the pharmacovigilance's priorities to try and find more creative and constructive ways to deal with these signals [5].

Pharmacovigilance concerns itself with all the aspects in the circle of knowledge and practice. Besides tracing and weighing risk factors, it tries to advise doctors and pharmacists on how best to deal with these risks and provide them with tools that will enable them to apply their newly acquired knowledge to the treatment of the individual patient. This approach permits pharmacovigilance to contribute to the safe and rational use of drugs for the benefit and well-being of those patients that are dependent on pharmacotherapy. Pharmacovigilance concerns itself with all the aspects in the circle of knowledge and practice. Besides tracing and weighing risk factors, it tries to advise doctors and pharmacists on how best to deal with these risks and provide them with tools that will enable them to apply their newly acquired knowledge to the treatment of the individual patient. This approach permits pharmacovigilance

to contribute to the safe and rational use of drugs for the benefit and well-being of those patients that are dependent on pharmacotherapy [6].

The signals of adverse drug reactions derived from the experiences with patients using the drugs as reported by doctors and pharmacists lie at the heart of pharmacovigilance. Meyboom, et al. [7] defined a signal as a set of data constituting a hypothesis that is relevant to the rational and safe use of a drug in humans.

Pharmacists play an important role in the field of medicinal drugs including in the scientific field dealing with the safety of drugs - pharmacovigilance. The participation of the pharmacist in national spontaneous reporting systems for ADRs helps in improving pharmacovigilance conception. The countries that received fewer reports from pharmacists gave lower scores to their contribution.

Concerning pharmacovigilance, both sound clinical judgement of the ADR and insight into the effects of the drug are required to allow a conclusion to be drawn as to the relationship between the adverse event and the drug involved.

Currently, the role of the pharmacist in the reporting of adverse drug reactions is not appreciated everywhere. In the Scandinavian countries, for instance, pharmacists are not authorized to report ADRs [8-9]. In the United Kingdom, they have only recently been allowed to report independently [10]. By contrast, in the Netherlands 40% of the reports on ADRs are submitted by of pharmacovigilance is substantial [11]. In 1989 Fincham comments: 'Exclusion of pharmacists simply does not make sense [12]. In their 1993 article on the differences between European countries Lindquist and Edwards remark: 'Pharmacists who pharmacists and their role in the maintenance advise patients directly are the most likely to detect adverse reactions [13].

The premarketing evaluation of drug safety in phase 1-3 clinical trial provides insufficient evidence of safety. There is a lack of studies that address the knowledge, attitudes and practice toward the pharmacovigilance system and ADRs reporting. It is important to conduct comprehensive studies to explore and evaluate the roles of healthcare professionals and their contributions in the pharmacovigilance activities.

This Study Aims

To assess the knowledge, attitude and behaviour of community pharmacists toward pharmacovigilance in Khartoum city in 2017. To evaluate the knowledge of pharmacists on some of selected basic aspects of drug safety and to determine the Knowledge, attitude of community

pharmacists toward ADR reporting and their behaviour on ADR related aspects.

Materials and Methods

A descriptive cross-sectional study among community pharmacies using a structured and pilot-tested questionnaire the study was conducted in community pharmacies in Khartoum city. According to enumeration obtain from the ministry of health of Khartoum state, the total number of community pharmacies in Khartoum state is 1876. The distribution of pharmacies in Khartoum state 741; pharmacies in Khartoum (39.4%).

Study Population

Community pharmacist working in pharmacies of Khartoum city.

Inclusion Criteria

Community pharmacists working in determining pharmacies who agree to fill the questionnaire.

Exclusion Criteria

A pharmacist who refused to participate in the study or who did not fulfil inclusion criteria.

Sample Size

According to Solvin's formula.

$$n = \frac{N}{1 + N(e)^2}$$

Whereas:
n = no. of samples
N = total population
e = error margin / margin of error (0.05)
=741/1+741(0.05)2 =260
So number of pharmacists are 260.

Two pharmacists refuse to participate and thus the total of the respondent is 258.

Data Collection Procedure

A sample of 260 pharmacies was obtained from 741 pharmacies of Khartoum city by stratified random sampling. 258 pharmacies located in Khartoum city were included in the sample which represents 99% of 260 total samples. Each pharmacy in the city was given a number then systemic random sampling was performed to select the pharmacies within the city. The pharmacist was given a concise

explanation of the purpose of the study and then asked if he wants to participate in the study then the data were collected using a predesigned questionnaire.

Study Duration

This study was performed in the period from October to November 2017.

Data Analysis Plan

Data were analysed using statistical package for social science (SPSS), based on 95% confidence level as the p-value of (<0.05) was considered significant. The results were expressed in form of tables and figures using Microsoft Excel.

Ethical Consideration

Verbal consent has been obtained from each participant.

Result

Demographic Characteristics of the Study Sample

Majority of community pharmacists at Khartoum city are male (50.8%) with age group From 18 years to 30 years (62%) and B. Pharm (57.8%) and practice experience more than 2 years to 5 years (38.8%) and Training received in pharmacovigilance Yes (42.2%) as shown in Figures 1-5 respectively.
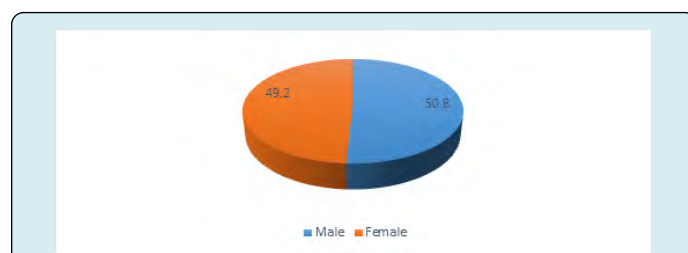
Figure 1: Distribution of community pharmacists according to gender.
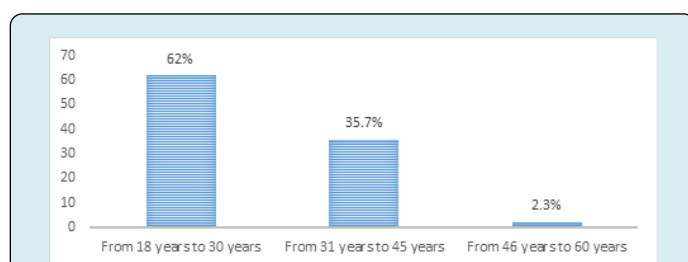
Figure 2: Distribution of community pharmacists according to age group.

Figure 3: Distribution of community pharmacists according to qualification.

Figure 4: Distribution of community pharmacists according to practice experience.

Figure 5: Distribution of community pharmacists according to Training received in pharmacovigilance.
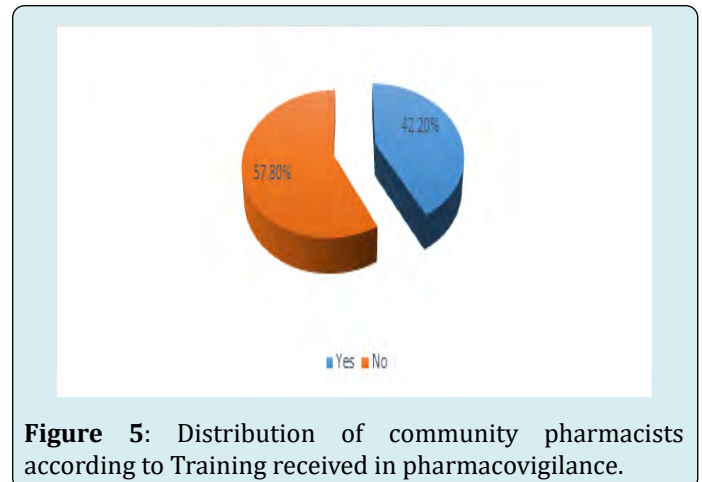
Assessment of Knowledge of Community Pharmacists on Drug Safety in Routine Practice

Only 74% of community pharmacists know the ADR definition and 39.5% are not know the ADR are preventable to some extend as illustrated in Table 1.

		Frequency	Per cent
Q1	Correct	191	74%
	wrong	67	26%
	Total	258	100%
Q2	Correct	156	60.50%
	wrong	102	39.50%
	Total	258	100%
Q3	Correct	165	64%
	wrong	93	36%
	Total	258	100%
Q4	Correct	82	31.80%
	wrong	176	68.20%
	Total	258	100%
Q5	Correct	135	52.30%
	wrong	123	47.70%
	Total	258	100%
Q6	Correct	98	38%
	wrong	160	62%
	Total	258	100%
Q7	Correct	193	74.80%
	wrong	65	25.20%

	Total	258	100%
Q8	Correct	13	5%
	wrong	245	95%
	Total	258	100%
Q9	Correct	171	66.30%
	wrong	87	33.70%
	Total	258	100%

Table 1: Frequency of assessment of knowledge among community pharmacists regarding drug safety in routine practice.

Majority of the community pharmacist (69%) agrees, awareness of the National Pharmacovigilance Program in Sudan, (38.8%) disagree Only ADRs to new drugs to be reported to the regulatory agency or drug company, (67.8%) are agree Reporting of ADRs is a professional responsibility of the pharmacists, (55.4%) disagree Reporting of ADRs adds up to unnecessary workload and (91.9%) agree Ask for the allergy history of the patient before dispensing the medication as shown in Table 2.

		Frequency	**Per cent**
Q1	Agree	178	69%
	Neutral	61	23.60%
	disagree	19	7.40%
	Total	258	100
Q2	Agree	120	46.50%
	Neutral	38	14.70%
	disagree	100	38.80%
	Total	258	100%
Q3	Agree	120	46.50%
	Neutral	38	14.70%
	disagree	100	38.80%
	Total	258	100%
Q4	Agree	231	89.50%
	Neutral	18	7%
	disagree	9	3.50%
	Total	258	100%
Q5	Agree	175	67.80%
	Neutral	63	24.40%
	disagree	20	7.80%
	Total	258	100%
Q6	Agree	81	31.40%
	Neutral	34	13.20%
	disagree	143	55.40%
	Total	258	100%
Q7	Agree	203	78.70%
	Neutral	41	15.90%
	disagree	14	5.40%
	Total	258	100%

Q8	Agree	237	91.90%
	Neutral	21	8.10%
	disagree	0	0%
	Total	258	100%
Q9	Agree	227	88%
	Neutral	23	8.90%
	disagree	8	3.10%
	Total	258	100%
Q10	Agree	232	89.90%
	Neutral	20	7.80%
	disagree	6	2.30%
	Total	258	100%

Table 2: Frequency of knowledge attitude and behaviour among community pharmacists regarding ADR.

			Answer		
Q1	Qualification	D.Pharm	20	10	30
		B.Pharm	107	42	149
		M.Pharm	64	15	79
		Total	191	67	258
		Value	3.231		
		p-value	0.199		
	Years of experience	less than 1 year	21	12	33
		1 to 2 year	45	15	60
		more than 2 years to 5 years	66	34	100
		more than 5 years to 10 years	37	4	41
		more than 10 years	22	2	24
		Total	191	67	258
		Value	14.727		
		p-value	0.005		
Q2	Qualification	D.Pharm	14	16	30
		B.Pharm	90	59	149
		M.Pharm	52	27	79
		Total	156	102	258
		Value	3.338		
		p-value	0.188		
	Years of experience	less than 1 year	24	9	33
		1 to 2 year	36	24	60
		more than 2 year to 5 years	47	53	100
		more than 5 years to 10 years	27	14	41
		more than 10 years	22	2	24
		Total	156	102	258
		Value	19.938		
		p-value	0.001		

Table 3: Association between knowledge frequency and demographic variables.

Cross tabulation and chi-square test of knowledge frequency versus demographic variables revealed no significant association (p. value >0.05) as illustrated in Table 3.

			Correct	Wrong	Total
Q1	Training in pharmacovigilance	Yes	22	86	108
		No	38	111	149
		Total	60	197	257
		Value	0.922		
		P-value	0.337		
Q2	Training in pharmacovigilance	Yes	32	76	108
		No	68	81	149
		Total	100	157	257
		Value	6.75		
		P-value	0.009		
Q5	Training in pharmacovigilance	Yes	64	45	109
		No	111	38	149
		Total	175	83	258
		Value	7.184		
		P-value	0.007		
Q6	Training in pharmacovigilance	Yes	44	65	109
		No	100	49	149
		Total	144	114	258
		Value	18.261		
		P-value	0		
Q8	Training in pharmacovigilance	Yes	99	10	109
		No	138	11	149
		Total	237	21	258
		Value	0.27		
		P-value	0.603		

Table 4: Association between knowledge attitude, behaviour frequency and demographic variables.

Cross tabulation and chi-square test of knowledge frequency versus demographic variables revealed no significant association (p. value >0.05) as illustrated in Table 4.

Discussion

Knowledge and attitude of pharmacists on drug safety-related aspects could greatly influence their behaviour and thereby contribute to patient safety [14]. No randomized studies have tested the knowledge, attitude and practice of community pharmacist towards ADR, current study attempt to assess such issue among community pharmacists in Khartoum city. The study target 260 pharmacists out of whom 258 involved with a response rate of 99%.

Among 258 participate, male predominated with the percentage of 50.8% versus 49.2% female, this is similar to Jose et al stated that majority of the participants in the study were males [15]. Age group distribution represented that, a pharmacist with age from 18 to 30 years has higher distribution are 62%, from 31 to 45 years are 35.7% and from 46 to 60 years are 2.3%. This is same with Jose et al stated that majority of the participants in the study were age from 18 to 30 years [16].

Qualification distribution revealed that pharmacist with bachelors' degree represents the vast majority group with

percentage 57.8% while remaining 30.6% with a master degree in pharmacy and 11.6% PhD holder, this is same with S Mohamed, et al. [17] stated that, majority of community pharmacists in Sudan with B. Pharm.

On other hand the predominated group found to have more than 2 year to 5 years 38.8% while pharmacists with experience less than one year represent 12.8% and one to two years is 23.3% and more than five to ten years are 15.9% and with more than 10 years are 9.3%, this may be due to the majority of pharmacists want to get the experience of two years in pharmacies then seek another chance of jobs like companies, factories or migrate aboard, this in line with Jose, et al. [18] stated that predominant practice experience in community pharmacies is from 0-5 years.

Distribution of community pharmacists according to Training received in pharmacovigilance was found to be 42.2% of pharmacist received while 57.8% of pharmacist not received. This is same with Jose et al stated that majority of the participants in the study were not received any sort of training in ADR [19].

Assessing pharmacist's knowledge showed that, 74% of the participant was defined the ADR, 39.5% are not know the ADR are preventable to some extent, 64% are Know the most common ADR with anti-tubercular drugs, 68.2% are not known amlodipine is not safe during pregnancy, 52.3% are known palpitation is the side effect of salbutamol inhaler, 62% are not known Gingival hyperplasia is more common with amlodipine, 74.8% are known metallic taste is more commonly caused by metronidazole, 95% are not known dry cough with enalapril is more likely occur in female, 66.3% are known NSAID induce ulcer in elderly, those who are taking steroids with NSAIDs and Alcoholics. We could not find published studies evaluating the knowledge of pharmacists specifically to certain drugs or reactions to make effective comparisons for these results. In my opinion, this may due to a shortage in the university curriculum regarding pharmacovigilance and lack of interest of pharmacists to read or to know what is new in world of pharmacotherapy after graduation.

Responses of pharmacist to the knowledge of community pharmacists toward ADR reporting are showed that 69% of the participant agrees on awareness of the national pharmacovigilance program in Sudan which is a good indicator of the effectiveness of the activities carried out by regulatory agencies in Sudan in raising awareness on ADR reporting. This was, same as the results obtained in the study conducted among community pharmacists in Oman, Jose et al almost all of them were aware of the National Pharmacovigilance program in Oman [20].

Responses of the attitude of pharmacists toward ADR related activities; it was encouraging to note that almost all of them were in agreement that reporting of ADR helps in adding up to existing knowledge on ADR to old and new drugs and the majority of the participants considered reporting of ADRs as a professional responsibility of the pharmacists. This was similar with the study conducted in Saudi Arabia Bawazir, et al. [21] where 97% of them considered reporting of ADRs to be an integral part of pharmaceutical care and in Turkey Toklu, et al. [19] where 89% of the pharmacists believed that the role of the pharmacist in ADR reporting was essential.

Responses of the behaviour of pharmacists toward ADR related activities, around 78.8% of the participants claimed that they report ADRs to the regulatory agency in Sudan or the Drug Company. This was similar to the study conducted in Oman Jose et al around 70% of the participants claimed that they report ADRs to the regulatory agency in Oman or the Drug Company. 91.9% of the participant agrees to ask for the allergy history of the patient before dispensing the medication and 89.9% agrees to inform patients of the methods to prevent ADRs of the dispensed medications. This same with Toklu, et al. [23] it was encouraging to note that community pharmacists reported asking for allergy history before dispensing medicines and informing patients of important side effects and methods to prevent ADRs.

31.4% of the participant are agree reporting of ADRs adds up to unnecessary workload, several factors were identified by the community pharmacist which discourage them from reporting of ADRs; lack of awareness on how to report ADRs and concern that the report may be wrong as the commonest factors. These factors have to be addressed and effectively solved during the educational/ awareness programs conducted for the pharmacists. Similarly in the study conducted among community pharmacists in Saudi Arabia Bawazir, et al. [16] several barriers were identified that prevent pharmacists from reporting ADR including, unknown address, reporting form not available, do not know how to report.

Cross-tabulation between demographic data (qualification and practice experience) and knowledge of pharmacists on the basic aspects on drug safety in routine practice revealed no statistically significant association with qualification (P-value <0.05), while there is a statistically significant association with practice experience (P-value >0.05) in the definition of ADR and the ADR is preventable to some extent, this in line with Jose et al who found that there is a significant association between knowledge and demographics data.

Cross-tabulation between the knowledge, attitude and behaviour on ADR reporting and demographic data (receiving training in pharmacovigilance), knowledge of community pharmacists toward ADR reporting is showed that 69% of the participant agrees awareness of the national pharmacovigilance program in Sudan revealed no statistically significant association (P-value <0.05) this is mean that reporting of ADR does not affect by knowledge. This is same in the study conducted in Malaysia there is no significant difference in knowledge with ADR reporting (28). The attitude of pharmacists toward ADR reporting 67.8% of the pharmacists believed that the role of the pharmacist in ADR reporting was essential revealed there are statistically significant associations (P-value >0.05) suggesting that reporting of ADR increase with attitude. The behaviour of pharmacists toward ADR reporting, 91.9% of the participant agrees to ask for the allergy history of the patient before dispensing the medication revealed no statistically significant association (P-value <0.05) this is mean that reporting of ADR did not affect by behaviour.

Conclusion

The study concluded that the majority of community pharmacist's knowledge on drug safety-related aspects define ADR and know the ADR is preventable to some extent, no significant association between knowledge and qualification but Practice showed significant association with knowledge.

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