



Pharmacovigilance Study: Exploring the Role of Community Pharmacists in Adverse Drug Reactions Reporting in Alkharj City, Saudi Arabia

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SUMMARY. Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems. Spontaneous adverse drug reaction (ADR) reporting is the foundation stone of pharmacovigilance activity. A cross sectional survey was carried out from September 2013 to January 2014 to evaluate the role of community pharmacists in ADRs reporting, by using a pre-assessed questionnaire with structured face-to-face interviews with community pharmacists from randomly selected private community pharmacies in Alkharj, Kingdom of Saudi Arabia. A total of 53 community pharmacists participated in the study, Results of this study reflected lack of adequate knowledge regarding ADRs reporting among community pharmacists. Regulatory authorities and professional pharmaceutical organizations in Saudi Arabia need to raise concern and educate pharmacists on the system of pharmacovigilance.

RESUMEN. La farmacovigilancia es la ciencia y las actividades relacionadas con la detección, evaluación, comprensión y prevención de los efectos adversos o cualquier otro problema de la droga. La notificación espontánea de reacciones adversas a medicamentos (RAM) es la piedra fundamental de la actividad de farmacovigilancia. Un estudio transversal se llevó a cabo de septiembre de 2013 a enero de 2014 para evaluar el papel de los farmacéuticos comunitarios en RAMs de informes, mediante un cuestionario pre-evaluados con entrevistas estructuradas cara a cara con los farmacéuticos de las farmacias privadas seleccionados al azar en Alkharj, Reino de Arabia Saudita. Un total de 53 farmacéuticos comunitarios participaron en el estudio; los resultados reflejan falta de conocimientos adecuados en relación con información sobre ADRs entre los farmacéuticos comunitarios. Las autoridades regulatorias y las organizaciones profesionales de farmacéuticos en Arabia Saudita deben preocuparse por educar a los farmacéuticos en el sistema de farmacovigilancia.

INTRODUCTION

According to World Health Organization (WHO), Pharmacovigilance is defined as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems^{1,2}. The main scope of pharmacovigilance is to improve the safe and rational use of medicines, thereby improving patient care and public health.

In 1961, thalidomide disaster occurred and in response to this WHO established its Program for International Drug Monitoring. Most countries in the world have their own established adverse drug reactions (ADRs) reporting systems³. However, ADRs remain a major cause of both

morbidity and mortality⁴⁻⁷. Moreover, ADRs are one of the major factors for hospital admissions and it varies worldwide⁸. In developed countries such as United States of America (USA), ADRs ranked as the six leading cause of mortality², and shown to be responsible for 3%-6% hospital admission of patients of all ages⁹. It has been reported that ADRs cause 7% of all hospital admissions in the United Kingdom (UK)¹⁰, while in Sweden 13% of patients admission to the internal wards were result of ADRs¹¹. The scope of pharmacovigilance is to promote patient safety in relation to the use of drugs; and to support public health programs by providing reliable, balanced information for the ef-

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fective assessment of the risk-benefit profile of medications.

Community pharmacists play an important role in post marketing surveillance activities, which are vital in providing important safety information that cannot realistically be collected before approval of a drug¹². To prevent or reduce harm to patients, procedures to evaluate and monitor the safety of drugs are extremely important. Such procedures form the core of pharmacovigilance programs, however, many challenges face health care providers in achieving success following these procedures, especially, reporting systems.

Pharmacists play a vital role in enhancing individual's health care, advancing the body of knowledge about medications and ensuring safe and effective use of drugs¹³. As part of this responsibility, pharmacists should proactively communicate feedback information regarding safety of medications with regulatory authorities. As front-line easily accessible health care providers, pharmacists are most likely to receive ADRs reports from consumers. In Saudi Arabia the National Pharmacovigilance Center of the Saudi Food and Drug Authority (SFDA) is actively involved in receiving ADRs reports from pharmacists and other health care professionals in Saudi Arabia. ADRs reporting forms are available (http://www.sfda.gov.sa/en/drug/about/sector_departments/national_pharmacovigilance_center/Pages/reporting_forms.aspx).

Community pharmacists can play an important role in patient counseling and should be able to give basic drug information in terms of appropriate drug use, administration, dosage, side effects, storage and drug-drug and drug-food interactions¹⁴. A number of studies have been conducted in the Kingdom of Saudi Arabia on various aspects of pharmacy practice in both hospital and community pharmacy settings¹⁵⁻²⁰. Among these studies, three addressed in detail the issue of ADRs reporting in Saudi Arabia^{15,19,20}. However, to our knowledge, none of previously published reports found to address any aspect of pharmacy practice or pharmacovigilance in Alkharj city. Alkharj city is located in the central region of Kingdom of Saudi Arabia with a population of around 235000 according to the Central Department of Statistics and Information of Kingdom of Saudi Arabia in 2010²¹.

The main aim of this study was to evaluate knowledge, attitude, behavior and perception of ADRs reporting among community pharmacists in Alkharj city in Saudi Arabia.

MATERIAL AND METHODS

A cross sectional study was carried out from September 2013 to January 2014, involving randomly selected 65 community pharmacists in Alkharj city in Kingdom of Saudi Arabia. A self administered, validated, 37-item questionnaire was used to assess community pharmacists knowledge and attitude towards adverse drug reactions and barriers to their reporting. The questionnaire was primarily adapted from previously published literature¹⁵, with some modification. In brief, the questionnaire was comprised of five sections.

First section consisted of questions regarding the demographics and pharmacy related information. Second section, was used to assess general knowledge of ADR reporting and monitoring. Nine questions were listed in this section using a nominal scale (yes/no), *i.e.*, Do you know pharmacovigilance system?, Do you know the common terms used in the ADR reporting system?, Do you know where to report the ADR?, Have ever come across the ADR reporting form?, if you want to report, where to find the ADR reporting form?, Awareness of laws guiding ADRs reporting?, Have you ever observed a suspected ADRs?, Have you ever reported a suspected ADRs?, and Do you obtain regular information on ADRs?.

Third Section, was used to assess the attitudes and behaviors of pharmacists towards ADRs reporting and comprised of twelve items, *i.e.* Reporting ADRs is part of the professional role of a pharmacist, Need to discuss the suspected ADR with the prescriber before reporting, I had reported an ADR to either the drug control authorities or SFDA?, I had come across any ADRs in daily practice within the previous year, I believe that the science of monitoring drug safety (pharmacovigilance) is important, I want to be sure the ADR is related to the drug before reporting, I do not report ADRs of Over The Counter (OTC) products supplied by my pharmacy, I report to get more insight into ADR questions that I come across in my practice, I report to show the patient that their concern is being taken seriously, I always report ADRs because it is part of pharmaceutical care, ADRs reporting should be compulsory, ADRs reporting should be voluntary.

Fourth section was used to discover barriers to ADRs reporting. Fourteen items listed in this section, *i.e.* No reporting forms available, Reporting address unknown, Reporting form too complicated, Reporting ADRs is time consum-

ing, All ADRs are known, Want to publish myself, Confidentiality, Patient confidence, Fear of liability, No motivation, Insufficient clinical, knowledge, Do not know how to report, Causality uncertain, One report makes no difference.

This study was approved by the ethical committee of college of pharmacy of Prince Sattam Bin Abdulaziz University and fund was granted by the deanship of scientific research. Verbal consent was obtained from all study participants before their participation in this study. Any information that discloses the responder's identity was excluded from the data collected. Only, the name of community pharmacies were written in coded form to differentiate the pharmacies such as chain and independent pharmacies.

Statistical analysis

Data from questionnaires were analyzed using Statistical Package for the Social Sciences (SPSS) version 20.0.

RESULTS

The sample under investigation consisted of 65 community pharmacists who were invited to participate in this study by filling the questionnaires, and answering oral questions. 53 filled questionnaires were obtained giving a response rate of 81%, one pharmacist refused to fill the questionnaire (1.5%) and 11 (17%) pharmacists were not able to fill the questionnaires due to lack of time.

Community pharmacist demographic characteristics

Vast majority of responders were of young age with 98% younger than 40 years of age. Fur-

Demographics	Frequency	(%)
Age group (in years)	24-30	39
	31-40	13
	41-50	1
Country of graduation	Egypt	51
	Sudan	2
Duration of practice experience (in years)	1-5	20
	6-10	18
	>10	15
For how long have been a registered pharmacist (in years)	1-5	25
	6-10	15
	>10	13

Table 1. Demographic Characteristics of Community Pharmacists.

thermore, community pharmacists in our sample were predominantly graduated from Egypt ($n=51$, 96%) and most of them ($n = 51$, 96%) had bachelorette degree in pharmacy. Demographic characteristics of study participants including those related to professional experience are shown in Table 1.

Community pharmacists knowledge of ADR reporting and pharmacovigilance

Only 25% ($n = 13$) of the respondents knew pharmacovigilance system. 34% ($n = 18$) said that they know the common terms used in the ADRs reporting system. Among respondents who were aware of reporting system, when they were asked where to report the ADRs, 21% ($n = 11$) knew where to report the ADRs. However, 81% ($n=43$) never came across ADRs. Questions regarding the knowledge of community pharmacists along with responses are presented in Table 2.

Questions	NA	Yes	No
	Count (%)	Count (%)	Count (%)
Do you know pharmacovigilance system?	3 (6%)	13 (25%)	37 (70%)
Do you know the common terms used in the ADR reporting system?	3 (6%)	18 (34%)	32 (60%)
Do you know where to report the ADR?	3 (6%)	11 (21%)	39 (74%)
Have ever come across the ADR reporting form?	4 (7%)	6 (11%)	43 (81%)
If you want to report, where to find the ADR reporting form?	6 (11%)	10 (19%)	37 (70%)
Awareness of laws guiding ADRs reporting?	2 (4%)	16 (30%)	35 (66%)
Have you ever observed a suspected ADR?	2 (4%)	18 (34%)	33 (62%)
Have you ever reported a suspected ADR?	2 (4%)	9 (17%)	42 (79%)
Do you obtain regular information on ADRs?	2 (4%)	23 (43%)	28 (53%)

Table 2. Community pharmacists knowledge regarding ADR reporting and pharmacovigilance. NA: not answered.

Community Pharmacists attitudes and behaviors toward ADRs reporting

85% (n = 45) of the participating pharmacists agreed that reporting ADRs is part of the professional role of a pharmacist. However, only 19% (n = 10) of participants reported that there is no need to discuss the suspected ADRs with the prescriber before reporting. 49% (n = 26) of pharmacists had noticed an ADR in a patient in daily practice within the previous year, while 83% (n = 44) had ever reported an ADR to either the drug control authorities or Saudi Food and Drug Authority (SFDA), and importantly, 96% (n = 51) believed that the science of monitoring drug safety (pharmacovigilance) is important.

Out of 53 respondent's data, 79% (n = 42) believed that they always report ADRs because it

is part of pharmaceutical care, while only 38% (n = 20) mentioned that they do not report ADRs of OTC products supplied by their pharmacy. About 72% of those surveyed thought that ADR reporting should be compulsory, while 70% thought that it should be voluntary (Table 3).

Community pharmacists' barriers contributing to non-reporting of ADRs

Among the barriers contributing to non-reporting 91% (n = 48) of responders agreed that reporting forms are not available, 70% (n = 37) reporting address unknown, and 79% (n = 42) agreed that non-reporting is due to confidentiality. Interestingly, 51% (n = 27) agreed that all ADRs are known. Table 4 represents pharmacists' answers regarding barriers to ADR reporting.

Questions	NA	Agree	Disagree
	Count (%)	Count (%)	Count (%)
Reporting ADRs is part of the professional role of a pharmacist	1 (2%)	45 (85%)	7 (13%)
Need to discuss the suspected ADR with the prescriber before reporting?	1 (2%)	42 (79%)	10 (19%)
I had reported an ADR to either the drug control authorities or SFDA?	3 (6%)	44 (83%)	6 (11%)
I had come across any ADRs in daily practice within the previous year.	1 (2%)	26 (49%)	26 (49%)
I believe that the science of monitoring drug safety (pharmacovigilance) is important	2 (4%)	51 (96%)	0 (0%)
I want to be sure the ADR is related to the drug before reporting	2 (4%)	46 (87%)	5 (9%)
I do not report ADRs of OTC products supplied by my pharmacy	2 (4%)	20 (38%)	31 (58%)
I report to get more insight into ADR questions that I come across in my practice	3 (6%)	44 (83%)	6 (11%)
I report to show the patient that their concern is being taken seriously.	3 (6%)	47 (89%)	3 (6%)
I always report ADRs because it is part of pharmaceutical care	3 (6%)	42 (79%)	8 (15%)
ADRs reporting should be compulsory	2 (4%)	38 (72%)	13 (25%)
ADRs reporting should be voluntary	2 (4%)	37 (70%)	14 (26%)

Table 3. Community pharmacists attitudes and behaviors toward ADR reporting. NA: not answered.

Questions	NA	Agree	Disagree
	Count (%)	Count (%)	Count (%)
No reporting forms available	1 (2%)	48 (91%)	4 (8%)
Reporting address unknown	2 (4%)	37 (70%)	14 (26%)
Reporting form too complicated	2 (4%)	16 (30%)	35 (66%)
Reporting ADRs is time consuming	2 (4%)	22 (42%)	29 (55%)
All ADRs are known	3 (6%)	27 (51%)	23 (43%)
Want to publish myself	3 (6%)	24 (45%)	26 (49%)
Confidentiality	2 (4%)	42 (79%)	9 (17%)
Patient confidence	2 (4%)	37 (70%)	14 (26%)
Fear of liability	4 (8%)	29 (55%)	20 (38%)
No motivation	4 (8%)	32 (60%)	17 (32%)
Insufficient clinical knowledge	3 (6%)	20 (38%)	30 (57%)
Do not know how to report	4 (8%)	29 (55%)	20 (38%)
Causality uncertain	4 (8%)	39 (74%)	10 (19%)
One report makes no difference	4 (8%)	23 (43%)	26 (49%)

Table 4. Community pharmacists' barriers contributing to non-reporting of ADR. NA: Not answered.

DISCUSSION

The present study is the first study of this type of issue in Alkharij city which tried to assess the knowledge, attitudes and behavior of community pharmacists toward spontaneous ADRs reporting and pharmacovigilance. According to our findings, response rate was good (81%) and improved as compared to the report obtained by Bawazir (71.7%)¹⁵. All the community Pharmacists were Arabic speakers (From Egypt and Sudan) and almost similar findings were established in previous study¹⁵. This is due to lack of Saudi pharmacists and also most of the qualified pharmacy graduates like to join the government sector because of better salary and other adornment benefits. However, our findings, regarding Saudi pharmacists appointments in community setting found to be contrasting to the expectation given by Bawazir, 2006¹⁵. There are several reports from different countries which emphasized the problem of the ADRs under-reporting among pharmacists²²⁻²⁶.

Various studies previously published in Asia, Europe, America, and Africa have shown scarce knowledge among healthcare professionals regarding pharmacovigilance and ADRs reporting²⁷⁻³¹. In a Malaysian study, it was established that majority of community pharmacists were found to be unaware of the existence of the national reporting system³². Other studies have also exposed that ADRs under-reporting by health professionals is commonly attributed to reasons such as ADR is not serious, ADR is well known, uncertainty about causal relationship and lack of time³³. In accord with these studies, our study also established lack of sufficient knowledge among the community pharmacists with regard to ADRs reporting system in Saudi Arabia and where to report the ADRs. Our findings is little bit lower than the results reported previously in Saudi Arabia by Bawazir¹⁵ and for Hong Kong Pharmacists by Lee *et al.*³⁴ and higher than facts reported from Holland (1%)³⁵ and United Kingdom (7%)³⁶ where community pharmacists were not aware of the ADRs reporting program in their countries.

In this study, participants claimed good attitudes and behaviors on pharmacovigilance and related aspects. The majority of community pharmacists in our study had reported an ADR (83%) and most of them claimed that they had submitted ADRs to either the drug control authorities or SFDA. In the previous study by Bawazir¹⁵, the majority of pharmacists surveyed

claimed that they had submitted ADRs to the pharmaceutical company as well as the Ministry of Health¹⁵. The fact that 85% of our study participants believed that reporting ADRs is part of the professional role of a pharmacist indicating an appropriate education concerning this subject, comparable findings were listed by Vessel *et al.*³⁷.

In our study, 79% of participants reported that ADRs reporting is part of pharmaceutical care while on an average 71% demonstrated that ADRs reporting should be compulsory or voluntary. However, in a study previously conducted in Saudi Arabia 97% of pharmacists considered ADRs reporting to be an integral part of pharmaceutical care¹⁵. In addition, according to a Turkish study, 89% of pharmacists believed that the role of pharmacists in ADR reporting is essential²⁵.

In this study, one of the most serious barriers reported by participants is no reporting forms available, whereas 42% felt that ADRs reporting is time consuming and a reason for not reporting. Although, there is an ADRs reporting system in Saudi Arabia available in paper as well as electronic format, the majority of community pharmacists in our study are not aware of where and how to report ADRs. Several studies emphasized that the lack of time was a common factor in preventing ADRs reporting^{23,26,30}. In a study performed in Netherlands over 35% of medical practitioners recorded that reporting was time consuming and too bureaucratic³⁸. In a study performed in UK, 40% of hospital pharmacists quoted a lack of time to complete ADRs reports²².

CONCLUSION

Community pharmacists play a major role in pharmacovigilance and their spontaneous reporting of suspected ADRs are of crucial importance to patient safety. Present study showed that the knowledge of pharmacists concerning pharmacovigilance and ADR reporting is poor. The role of pharmacists in ADR reporting was not clear to majority of pharmacists under investigation, and the process of ADR reporting in terms of "How to report? and Where to report?" is also unknown. However, positive attitudes were noticed in vast majority of pharmacists involved in this study towards the importance of pharmacovigilance.

The regulatory authorities need to raise concern and educate pharmacists on the system of

pharmacovigilance. Also, there is a greater need of awareness to promote the reporting of ADRs by community pharmacists of the kingdom. These approaches can greatly influence in bringing reporting culture in community pharmacists and may lead to improve reporting rates of ADRs. The major limitation of our study is that the findings could not be applied to the wider community pharmacist's of the kingdom as study was restricted to Alkharj city only. Therefore, our recommendation is that several studies of similar kind especially in community pharmacist's setup throughout the kingdom need to be conducted to know the knowledge, attitude and behavior of community pharmacists towards ADRs reporting system in Kingdom of Saudi Arabia.

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