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Knowledge, attitude beliefs and practices of community pharmacy dispensers in Aden, Yemen towards adverse drug reaction reporting

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ABSTRACT

Adverse drug reactions represent a serious problem worldwide including Yemen. Spontaneous reporting of adverse drug reactions remains the cornerstone of pharmacovigilance. The survey was conducted to assess knowledge, attitude practices and beliefs of community pharmacy dispensers in Aden city towards pharmacovigilance and adverse drug reactions reporting. A cross-sectional survey was carried out with a convenient sample of community pharmacy dispensers using a pre-tested questionnaire during May through August 2014. Five hundred community pharmacy dispensers participated in the survey. Ninety one percent knew what adverse drug reactions are; 69% unaware of national pharmacovigilance program; 24% mentioned to report only serious and life threatening adverse drug reactions; 70.6% felt that adverse drug reactions reporting should be mandatory for practicing pharmacists; 64.4% had observed adverse drug reactions in their practice, only 21.8% claimed that they had reported them; and 22.3% adequately trained in adverse drug reactions reporting. Inadequate adverse drug reactions and pharmacovigilance knowledge, attitudes, practices and reporting were encountered. This emphasizes the importance of establishing continuing efforts to promote adverse drug reactions program to ensure patient and public safety. Education and training of health professionals and public will be important in increasing and maintaining adverse drug reactions reporting.

Keywords: Knowledge, attitude, practices, adverse drug reactions, pharmacovigilance, community pharmacy dispensers, Aden, Yemen.

INTRODUCTION

Adverse drug reactions (ADRs) represent a serious health problem.[1] ADRs account for 3.2-7% of acute hospital admissions.[2,3] They cause morbidity, mortality, and increased duration of hospital stay[4] and also increases hospital costs.[5] Over 770,000 people are injured or die each year due to adverse drug events.[6] A commonly quoted meta-analysis performed in the United States indicated that ADRs ranged between the fourth and sixth most common cause of death in 1997.[7] The World Health Organization (WHO) defines an ADR as 'any response to a drug that is noxious and unintended, and that occurs at doses used in humans for prophylaxis, diagnosis, or therapy, excluding failure to accomplish the intended purpose'.[8]

Several studies have been conducted on the incidence of ADRs. A prospective observational study from Iran showed that 11.75% of patients had experienced at least one ADR.[9] Another study conducted in Iran reported about 16.8% of patients had at least one ADR, and 2.9% of ADRs were identified as lethal.[10] A study in South India found that the overall incidence of ADRs was 9.8%. This

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included 3.4% ADR-related hospital admissions and 3.7% ADRs occurred during the hospital stay.[11] In Saudi Arabia, a study showed 54% of ADRs to be preventable. The prevalence of ADRs per year ranged from 0.07% in 1993 to 0.003% in 1999.[12] In Nepal, the prevalence of ADRs was 0.86% and the male to female ratio of patients experiencing ADRs was 0.85 and 10.81% of the ADRs were severe.[13]

Pharmacovigilance (PV) is defined by the WHO as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects (AEs) or any other possible drug-related problems.[14] Thalidomide was the greatest medicine related tragedy of 1961 led to the establishment of the drug regulatory mechanisms of today.[15] PV is an arm of patient care with the aim of making the best use of medicines for the treatment or prevention of diseases without undesired effects. The history of international PV goes back as far as forty years, when the 20th WHO assembly adopted a resolution to start an international system for monitoring ADRs.

In 1968 the WHO established an international PV-program that has been executed since 1978 by the international centre for PV in Uppsala, Sweden that centralizes data about AEs collected by national PV centers. Some rare AEs that occur late are often only detected after the drug is marketed. For this reason, it is necessary to report AEs to the PV center once a medicine is marketed and used under real circumstances.

Yemen is a low-income country with a high illiteracy rate. The governmental contribution on health is about $13 per capita and represents only 2% of the GDP.[16] The statistical report (2003-2004) of the Ministry of Public Health & Population (MoPH&P) showed a total of 1768 private pharmacies. The local pharmaceutical industry is evolving gradually, accounting for only around 8% of the total market share.

There are critical health challenges in Yemen, including the high incidence of both communicable and non-communicable diseases. Yemen exhibits higher prevalence of lifestyle risk factors (including chewing 'khat' a plant with amphetamine-like action and malnutrition) and lacks the necessary sanitation.[17] Also the country and public are facing with many safety problems related to drug smuggling, counterfeit drugs, importation of unnecessary drugs, irrational use of medicines, medical errors and other drug-related problems. Studies have found that 60% of all imported medicines in Yemen originated through illegal channels.[18] This results in a serious threat to the health of the public. Therefore, it is necessary to make serious steps and active regulations to ensure patient and public safety in relation to medicine use.

In developing countries generally there is limited coverage and under-reporting of ADRs. Yemen does not have a nationwide coverage of ADRs reporting systems nor a plan to monitor drug reactions and related problems. Currently, Yemen is way behind other developing countries in terms of improving the effectiveness of the ADR reporting system. A PV center was established in 2011 by the Supreme Board of Drugs and Medical Appliances (SBDMA). However, there are no official data or reports released by the SBDMA regarding the number of ADRs being reported and how they are processed. It has been suggested to establish branches for the national PV center in different areas of Yemen to extend the services to cover the whole country; and to establish a plan to implement the basic steps for establishing a PV program according to Uppsala Monitoring Centre (UMC) Guidelines.[19]

The effectiveness of PV activities in a country is directly dependent on the active participation of health professionals, patients and consumers. ADRs reported by health professionals will definitely be useful for creating a national database. Therefore, all should be briefed regarding the ADR reporting systems and encouraged to report suspected ADRs.

Community pharmacists as a member of healthcare team have an important role in monitoring and reporting of ADRs due to their ease of access for patients and chances that the patients approach them for the management of symptoms associated to ADRs. There are several reports from different countries show inappropriate knowledge, attitude beliefs and practices (KABP) towards PV and ADR reporting, as well as insufficient participation of pharmacists. Unfortunately, there are no published studies in Yemen to evaluate these important aspects. Therefore, we conducted this study to assess the KAPB among Yemeni community pharmacy dispensers (CPDs) in Aden city towards PV and ADRs reporting in Aden.

MATERIALS AND METHODS

A cross sectional descriptive study was conducted on CPDs in different areas of Aden city, the commercial capital of Yemen, from May 2014 through August 2014. CPDs participated in the study were pharmacists and pharmacy technicians working in community pharmacies. A sample of 500 respondents was chosen conveniently due to

the difficulty of having a sampling frame. CPDs not willing to participate in the study were excluded. The questionnaire was consisted of seven sections related to demographic characteristics of the participants and their knowledge, attitudes and practices. It was initially written in English and then translated to the local language, Arabic. The Arabic version of the questionnaire was pretested by administering it to 20 CPDs to identify any unclear or difficult questions and to ensure that its content and length are appropriate. After minor changes, the questionnaire was finalized and distributed to the target group. The reliability of the questionnaire was tested by calculating the Cronbach alpha of the completed questionnaires. The alpha score was 0.61 and was considered acceptable. The final questionnaire was distributed to CPDs by trained pharmacy students who also collected the responses from the respondents. The collected data from the respondents was analyzed using the SPSS® version 18.0. The data from the filled questionnaires were evaluated for various parameters. Descriptive statistics such as frequencies, percentages and means were used in the analysis of the data. ***Ethical Consideration:*** The study protocol was approved by the Ethics Research Committee of the Faculty of Medicine and Health Sciences, Aden University. Verbal consent was obtained from all participants who agreed to participate in the study after explaining the objectives, importance and benefits of the research and that the participation is voluntary. They were assured that all the collected data will be handled with full confidentiality, and will be used only for the research purpose.

RESULTS

Participants' demographic data: The total number of respondents in this study was 500 CPDs with an age ranging from 21 to 48 years. The highest percentage was males (72.4%), qualified as pharmacy technicians (54%) and with work experience between 1 to 5 years (81.4%). Details of the respondents' demographic profile are illustrated in Table 1.

Knowledge of ADR reporting and monitoring by respondents: Ninety one percent of the respondents knew what ADRs are. However, only 21% have heard about PV, 19.8% were aware about the national PV program and 64.4% knew that SBMD is the ADR monitoring organization in Yemen. On the other hand 74 (14.8%) of the respondents mentioned that ADRs associated with herbal products should not be reported. On the other hand, 61.4% indicated that only serious and life treating should be reported as shown in Table 2.

Attitudes towards ADR reporting: Table 3 shows that 82.2% of the respondents thought that reporting ADRs is a pharmacist's duty and ADRs reporting in Yemen is not widely promoted by relevant authority whereas 75.2% declared their interest in the participation in ADR reporting system. With regards to the expectation of the respondents from PV program; 83.2% expect that someone from the local PV center to coordinate with them.

Beliefs of ADR reporting: The belief that reporting ADRs will improve patient safety was reported by 98.4%. However, 28.2% believe that ADR reporting is disadvantageous as it causes inconvenience in the working environment. Other beliefs are retrieved in Table 4

Practices of ADR reporting: The percentage of CPDs who had encountered patients with ADRs in practice was 64.4%. However, 92.2% claimed that ADR reporting forms are not available at their workplace and 78.2% indicated lack of information regarding ADR reporting processes (Table 5).

Problems facing respondents while reporting ADRs in workplace: The first ranking problem facing CPDs was unawareness of the existence of a national ADRs reporting system (43%) while the least was the lack of enough time among pharmacists. Other identified problems are displayed in Table 6.

Future of ADR reporting in Yemen: The most frequently retrieved opinion was the compulsorily provision of Information regarding the procedure of reporting ADRs to pharmacists at their workplace (79.8%). However, 46.8% thought that online program/website should be freely accessible to everyone. Other opinions are shown in Table 7.

DISCUSSION

This KABP survey was conducted on a specific population to collect information on what is known, believed and done in relation to a particular topic – in this case PV. According to our knowledge, this study is the first of its kind in Yemen to investigate the KABP of pharmacists towards PV and ADR reporting.

The present study has shown gap in the knowledge of CPDs about ADRs and PV. This result is similar to previous studies in developing countries[20-24] and developed countries.[25-26] Inadequate knowledge of healthcare professionals is most probably due to the fact that drug safety is not taken seriously worldwide, particularly in developing countries, although it should be one of the top priorities in

healthcare programs. Though the drug regulatory bodies have started paying more attention towards the drug safety issues, the PV activities are still inefficient.

Despite the findings of relatively high rates of unawareness and inadequate knowledge among participants, 82% of them thought that reporting ADRs is a pharmacist's duty. The result of the study revealed that 69% of the CPDs were not aware of the existence of the national PV program run by the Yemeni government represented by SBDMA. This result yielded slightly higher percentage compared to the study in Malaysia conducted by Aziz (2007) which identified the awareness of the existence of the national PV program to be 40%[22] and lower than Bawazir's study, which conducted in Saudi Arabia (86.8%).[23] This problem does not only exist in developing countries but also in developed countries.

Previous studies have shown that while the right attitude for ADR reporting exists among most of the pharmacists and physicians, the actual practice of ADRs reporting is lacking. Studies in India have shown that prescribers have high knowledge and attitude with regards to ADRs reporting but practice it poorly.[20] Our study also found clear knowledge gap. Poor knowledge on what is to be reported, who should report, when to report, how to report where to report, together with unavailability of ADRs reporting forms at the workplace definitely influences the ADRs reporting practice among dispensers in community pharmacies. The study made clear also that 64.4% observed ADRs but no one reported them. The main problem faced national PV systems worldwide is underreporting. The main reasons for underreporting in our study ware unawareness of the existence of a national ADRs reporting system (43%) while the least was the lack of enough time among pharmacists. Patients direct reporting can add more benefits to the existing system and can overcome underreporting in Yemen.

Spontaneous reporting of ADRs remains to be the foundation of PV and is very comprehensive system for maintaining patient safety. According to the WHO standards, countries with the best reporting rates must generate over 200 reports per 1,000,000 inhabitants per year. However, reporting of serious ADRs rarely exceeds 10% [31]. For instance, Yemen with a population of about 25 million was expected to receive 4100 reports per year. Unfortunately this is not so, because there is no ADR reporting activities in Yemen due to carelessness of the government about ADR reporting, and less of knowledge about ADR and PV role in the improvement of health services among most of health-care professionals and lack of information about how, whom and where to report ADR .all these problems lead to a bad situation in respect of patients safety so, Many people could be die every year due to the ADR.

The effectiveness of PV activities in a country is directly dependent on the active participation of healthcare professionals, patients and consumers. Fortunately, all respondents in this study were in favor of the idea of setting up the ADRs reporting system in Yemen and three-quarters of them were willing to be involved in the implementation of the system. Furthermore, Reporting of ADRs by the patients is supported by about two-thirds of respondents. Healthcare professionals, particularly pharmacists are responsible for formulating the appropriate plan to improve the KAP of the consumers. They can play an important role in educating the public regarding reporting of ADRs and medicine safety. So, that the consumers will be aware about the ADRs reporting and able to report any ADRs that they experience to healthcare professionals or to the ADRs reporting center. There are studies which show the involvement of community pharmacists in Norway, Spain and many other countries. Contribution of community pharmacists can be considered as supportive measure to the existing PV system.[20,27-30]

Limitations and constraints of the study: The main limitation of our study is the sampling procedures, where the target group was chosen conveniently rather than randomly which may be quite unrepresentative of the study population. Another limitation of the study is that the findings were restricted to only CPDs working in one city only. The outcome would have been more significant and could be applied to the whole country, if the study was conducted in different geographical areas of the country.

CONCLUSION

The results of the present study demonstrate that the majority of the CPDs in Aden city have insufficient knowledge about PV practices. In addition, ADRs-related monitoring and PV attitude and practices are still poor in a country like Yemen, where drug safety problems are rampant. The study also suggests that CPDs in Aden city and perhaps all other areas of Yemen may lack in-depth understanding of the facts about the national PV system and ADR reporting process and may need more information on how ADR reporting is performed.

Since there is a demand by the CPDs, reporting and PV practice need to be well implemented in order

to improve ADR reporting. PV might play an essential role in preventing and overcoming such problems and could greatly influence the impact on patient safety. Yemen must institute a structured 'PV Program' and set up PV centers in association with SBDMA and medical, pharmacy, dentistry and nursing schools as well as higher health institutes medical in the country and implement strategies to ensure patients and public safety in relations to medicines use.

The effectiveness of PV activities in a country is directly dependent on the active participation of health professionals, patients and consumers. Therefore, an awareness program for local pharmaceutical companies, healthcare professionals, patients and public to inform them about the detection and reporting of ADRs must be designed. Also, the more information about ADRs collected will definitely be useful for creating a national database. All stakeholders should be briefed regarding the ADR reporting system and encouraged to report ADRs even suspected ones.

Educational programs and training should be the first task that must be taken up by relevant governmental agencies, schools of pharmacy and medicine as well as the pharmaceutical industry in order to improve the knowledge of healthcare professionals on ADRs and encourage them to participate in ADR reporting process. SBDMA in Yemen should make sure that healthcare professionals are qualified and knowledgeable about PV and ADR reporting. It should also facilitates the process of reporting by making the reporting forms available either electronically or on paper or both consistently, and easy to complete. Proper feedback needs to be prepared and delivered to the reporters regularly to improve ADRs reporting. An extensive study covering different geographical areas in the country is essential to generate more valuable data which would form the basis for interventions. The details of our recommendations could be as follow:

1. PV course should be incorporated in the pharmacy and medicine curriculum.
2. PV workshops and seminars should be conducted to provide guidance to healthcare providers for recognizing and reporting ADRs. Also PV researches should be supported.
3. ADR reporting by healthcare professionals, manufacturing companies as well as by patients and public should be encouraged.
4. Incentives should be provided to healthcare professionals reporting ADRs not associated with human errors.
5. ADR forms should be collected periodically from health facilities by sending representatives and/or facilitated by E-mail, fax and phone.
6. Assurance of non-involvement in legal matters, if they arise.

Table 1: Demographic characteristics of the respondents (n = 500)

Characteristics	Category	Total n (%)
Gender	Male	362 (72.4)
	Female	138 (27.6)
Age	Mean average age 21 – 48 years	
Qualification	Diploma pharmacy technician	270 (54)
	Bachelor pharmacy	230 (46)
Work experience (years)	1 - 5	407 (81.4)
	6 – 10	53 (10.6)
	> 10	40 (8)

Table 2: Knowledge of ADR reporting and monitoring by respondents (n = 500)

Identified knowledge	Responses		
	Yes n (%)	No n (%)	Not sure n (%)
Know what are ADRs	455 (91)	27 (5.4)	18 (3.6)
Aware about the national pharmacovigilance program	99 (19.8)	345 (69)	56 (11.2)
Heard the term pharmacovigilance	105 (21)	331 (66)	64 (13)
ADRs associated with herbal products should not be reported	74 (14.8)	392 (78.4)	34 (6.8)
	Responses: n (%)		
The responsible organization for collecting and monitoring ADR in the Yemen			
Pharmacy council of Yemen	41 (9.0)		
SBMDA	336 (64.4)		
Don't know	123 (26.6)		

ADRs should be reported only when they are:	
Serious and life threatening	119 (24)
Severe and cause disability	79 (15.8)
Mild and cause less inconvenience	0 (0)
All above	302 (60.2)
Types of ADRs which are usually reported	
Serious and life threatening	307 (61.4)
Severe and cause disability	93 (18.6)
Mild and cause less Inconvenience	100 (20)

Table 3: Responses of respondents to the attitude related questions (n = 500)

Identified attitudes	Responses		
	Yes n (%)	No n (%)	Not sure n (%)
Thought that reporting of ADR is a pharmacist's duty	411 (82.2)	53 (10.6)	36 (7.2)
ADR reporting in Yemen is not widely promoted by relevant authorities	411 (82.2)	53 (10.6)	36 (7.2)
Interested in participating in the ADR reporting system	376 (75.2)	102 (20.4)	22 (4.4)
Thought that serious ADRs encourage pharmacists to report it to the relevant authority	358 (71.6)	73 (14.4)	66 (7.6)
Identified attitudes	Responses: n (%)		
Expectations from the pharmacovigilance program			
Someone from the local pharmacovigilance center to coordinate with you	416 (83.2)		
Financial compensation for time and energy expended	76 (15.2)		

Table 4: Beliefs related to reporting ADRs

Identified benefits	Responses		
	Yes n (%)	No n (%)	Not sure n (%)
Believed reporting ADRs will improve patient safety	492 (98.4)	8 (1.6)	0 (0)
Believed that all drugs available in the market are safe	12 (2.4)	378 (75.6)	110 (22)
Believed that herbal products have no ADRs, i.e. they are safe	58 (11.6)	360 (72)	82 (16.4)
Believed that ADR reporting should be made mandatory for practicing pharmacists	353 (70.6)	109 (21.8)	38 (7.6)
Believed reporting ADRs is an effort by health institutions to indicate provision of quality care to the patients	408 (81.6)	34 (6.8)	58 (11.6)
Reporting ADRs causes inconvenience in the working environment (disadvantage)	141 (28.2)	301 (60.2)	58 (11.6)

Table 5: ADR reporting in respondents' workplace (practice) (n = 500)

Identified attitudes	Responses		
	Yes n (%)	No n (%)	Not sure n (%)
I have observed ADR cases in my practice	322 (64.4%)	162 (32.4%)	16 (3.2%)
ADR reporting form is available at my workplace	22 (4.4%)	461 (92.2%)	17 (3.4%)
My workplace provide information regarding the process of ADR reporting	59 (11.8%)	391 (78.2%)	50 (10%)
I am adequately trained in ADR reporting	111 (22.3%)	253 (50.6%)	136 (27.2%)
My workplace encourage me to report an ADR	78 (15.6%)	334 (66.8%)	88 (17.6%)

Table 6: Problems facing respondents while reporting ADRs in workplace (n = 500)

Problems facing respondents	Responses: n (%)
Unaware of the existence of a national ADR reporting system	219 (43.8)
Lack of information provided by the patient	95 (19)
ADR reporting in Yemen is not widely promoted by relevant authorities	72 (14.4%)
Fear of facing legal problems	42 (8.4)
Pharmacist does not have enough time	30 (6)
Unaware of the need to report an ADR	20 (4)
Others	22 (4.2)

Table 7: Respondents' pinion about the future of ADR reporting in Yemen (n = 500)

	Responses		
Identified respondents' opinion	Yes n (%)	No n (%)	Not sure n (%)
Information regarding the procedure of reporting ADRs should be provided compulsorily to pharmacists at their workplace	399 (79.8)	65 (13)	36 (7.6)
Thought the relevant authority in Yemen should maintain an online program or website like other countries bearing records of the ADRs reported throughout the nation	390 (78)	74 (14.8)	36 (7.2)
Envisaged role of information technology in facilitating ADR reporting in the country (such as use of internet, mobile service etc)	382 (76.4)	82 (16.4)	36 (7.2)
Supported "Direct ADR Reporting" by the patients instead of by healthcare professionals	313 (62.6)	169 (33.8)	18 (3.6)
Thought that online program/website should be freely accessible to everyone	234 (46.8)	204 (40.8)	62 (12.4)

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