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Abstract

Rationale, aims and objectives: The participation of all health professionals is essential for ensuring a quality and successful national postmarketing surveillance program. The aim of this study was to assess the knowledge, attitudes, and practices (KAP) among Yemeni community pharmacists (CPs) regarding medication safety in a poor-resource setting. Methods: A survey was conducted among CPs in Aden governorate. The tool comprised of: demographic profile, knowledge-, attitude- and practice-aspects of medication safety. The survey also studied the opinion about future and benefits of ADR reporting in Yemen. The data collected from the questionnaires was analyzed using the Statistical Package for Social Science version 21.0. Descriptive statistics such as frequencies, percentages, and means (SD) were used in the analysis. Results: A total of 450 CPs were enrolled in the study. Most of the participants were males (75%) with a bachelor's degree (91.9%) and between 3-6 years of experience (28%). The majority of CPs had good knowledge regarding the perception and objectives of PV as well as ADRs. Approximately 41% of participants knew the purpose of PV as an essential system for public health and safety with regard to drug use. Additionally, the Yemeni pharmacists had a positive attitude towards the reporting system. Approximately 84% of responders admitted that PV is the responsibility of the pharmacists. The majority of the participants (80%) declared that there is no reporting form available at their workplace. According to CPs, 59% said that ADR reporting in Yemen is not widely promoted by relevant authorities, and 57% replied that lack of information provided by the patient is an obstacle in the reporting system. Approximately 89% of the CPs believed that reporting ADRs would improve patient safety. Conclusions: The CPs have a positive attitude towards PV and an acceptable degree of knowledge. However, the practice level should be upraised.

1 INTRODUCTION

Adverse drug reactions (ADRs) are a critical health matter [1]. The ADR definition according to the WHO is “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” [2].

Various publications have documented the issue of ADRs. Approximately 3.2-7% of acute hospital admissions are due to ADRs [3, 4]. ADRs result in extended hospitalization and increased morbidity, mortality [5] and hospital costs [6]. Every year, more than 770,000 people suffer or die from ADRs [7]. According to a meta-analysis carried out in the United States, ADRs accounted for the fourth and sixth most common causes of death [8]. A study from Iran indicated that approximately 11.8% of patients had suffered at least one ADR [9]. In another report from Iran, approximately 16.8% of the patients had experienced at least one ADR, and 2.9% of ADRs were fatal [10]. A study from South India reported an incidence of ADRs of 9.8%; approximately 3.4% was the reason for hospital admission, and 3.7% appeared during hospitalization [11]. A retrospective study in Saudi Arabia revealed that 54% of ADRs could be prevented. The annual incidence
ranged from 0.07% in 1993 to 0.003% in 1999 [12]. In Nepal, the occurrence of ADRs was 0.9%. Severe ADRs were reported in 0.9% of males and 10.8% of females [13].

No health setting is immune from ADRs, hence pharmacovigilance (PV) becomes a very important aspect to ensure safe use of medicines in any healthcare setting. The definition of PV according to the WHO is “the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems” [14]. The current monitoring system for ADRs was established after the tragedy of thalidomide ADRs in 1950s [15].

Therefore, the reporting of common ADRs postmarketing is of great advantage. The incidence of ADRs and other drug-associated problems varies between different countries. This might be attributed to the differences in diseases, prescribing practices, heredities, diet, and culture. Drug manufacturing procedures that have an impact on drug quality, content, distribution, usage, indications, and dosing, as well as the use of other or medicines (herbal or traditional) are considered related factors that might cause specific toxicological problems for a drug when used alone and/or in combination with other drugs [15].

Continuous monitoring and reporting of ADRs are considered the backbone for their early detection. ADR detection is the building block of PV and inclusive systems for maintaining patient safety. In poor-resource setting like Yemen, the reporting was expected to reach up to 4100 reports per 25 million individuals per year. The countries with the best reporting rates should report on at least 200 cases per 1,000,000 individuals annually, as stated by the WHO. Nevertheless, only 10% of serious ADRs are reported [16]. The reporting system in Yemen is not working properly due to insufficient coverage and knowledge about the role of ADRs and PV in the improvement of health services among several health-care professionals as well as a lack of information on how, where and to whom to report ADRs. All these obstacles have resulted in a poor situation regarding patient safety; thus, many patients could die from an ADR every year. We are not certain regarding the level of knowledge, attitude and practice of CPs towards ADR reporting and PV in Yemen. Thus, this study was carried out in Aden city to assess the Yemeni CPs’ knowledge, attitudes, and practices towards medication safety. It was intended to identify the knowledge gaps, beliefs and behavioral patterns that may indicate needs, problems and barriers to assist plan and implement interventions such education and training activities.

2 METHODS

Study design

The design of the study was a cross-sectional descriptive study. This is the most convenient for conditions in which environment, time and resources are restricted. This KAP survey was carried out to collect information on ‘what is known’, ‘what is thought’, and ‘what is done’ about medication safety, an aspect of pharmacovigilance. The study was performed among CPs in Aden governorate from April 2020 to July 2020.

Study population, sample and sampling method

The study involved health professionals who worked as CPs. Due to the security and safety issues due to conflict and Covid-19 pandemic, the study was only conducted in Aden. It has a total population of 987,904, where 550,602 people live in the city of Aden (https://populationstat.com/yemen/aden). The target respondent was CPs in-charge of a pharmacy, and the respondent was excluded if he/she showed lack of willingness to participate in the study or was on leave during the study. The study participant selection and sampling method are described below. A total of 450 CPs took part in our research. The following sampling formula was used:

where n= sample size, Z= Z statistic for a given level of confidence; at 95%, the conventional value is 1.96, P= expected prevalence or proportion (in decimal representation; e.g., for 50% prevalence, P= 0.5), and d=precision (in decimal representation; e.g., for 5% precision, d=0.05). Assuming a dropout rate of 30%, final n=450.
Convenience sampling was conducted to choose the respondents due to the difficulty of having a sampling frame. All of them resided in Aden city. Respondents with different education levels were selected for this study.

**Tools development and validation**

A KAP questionnaire was used in the study to evaluate the knowledge, attitudes, and practices of the CPs towards medication safety. It was adapted from a study by Hallit et al. (2018) [17]. The permission for using the survey tool was granted by the author. These questions were initially in English and then translated to the local language, Yemeni-Arabic. The linguistic validation process was carried out to ensure the intended meaning was maintained. Face and content validity were checked. The contents were relevant to the key questions to be answered. The questions in the local language were framed in a manner that will minimize bias and best reflect knowledge, attitudes and practices.

**Outcome measures and operational definition**

The study measures the CPs’ knowledge, attitudes, and practices regarding medication safety. The operational definitions for these terms are as follows: [18]

Knowledge: “Knowledge is a set of understandings, knowledge, and science.” It is also one’s capacity for imagining, one’s way of perceiving. Knowledge of a health behavior considered to be beneficial, however, does not automatically mean that this behavior will be followed. The degree of knowledge assessed by the survey helps to locate areas where information and education efforts remain to be exerted.

Attitude: Attitude is a way of being, a position, but sometimes involves leanings or “tendencies”. Attitude is an intermediate variable between the situation and the response to the situation. It helps explain how among the possible practices for a subject submitted to a stimulus, that subject adopts one practice and not another. Attitudes are not directly observable in practice; thus, it is a good idea to assess them. Interestingly, numerous studies have often shown a low and sometimes no connection between attitude and practices.

Practice: Practices or behaviors are the observable actions of an individual in response to a stimulus. This is something that addresses the concrete with actions. For practices related to health, one collects information on consumption of tobacco or alcohol, the practice of screening, vaccination practices, sporting activities, sexuality, etc.

**Data collection**

The data were collected by hand-distributing of a structured, standardized paper questionnaire to the respondents in different areas of Aden. The pharmacy students helped in collecting the responses from the CPs. Types of data that were collected were dependent of the survey objectives and questions to be answered.

**Data analysis**

The data collected from the questionnaires were analyzed using the Statistical Package for Social Science (SPSS®) version 21.0. Frequency counts were checked for all the variables. Due to explorative nature of the study, descriptive statistics such as frequencies, percentages, and means (SD) were used in the analysis of the data.

**Ethical consideration**

The study protocol was endorsed by the Ethics Research Committee of the Faculty of Medicine and Health Sciences, University of Aden. Written informed consent was obtained from all participants who were willing to participate in the study after the objectives, importance and benefits of the
research and voluntary participation were described. They were assured that all the data gathered will be handled with full confidentiality and would be used only for research purposes.

3 RESULTS

Sociodemographic and socioeconomic characteristics of the participants

Approximately 75% of the participants were male (n=339). The largest age group of the CPs was 20-30 years (66%, n=298), followed by 31-40 years (29%, n=132). The working experience as community pharmacist was high between 1-3 years (28%, n=115) and 3-6 years (30%, n=125). Most of the CPs were employees (76%, n=340). Most of the CPs (98%, n=441) practiced in pharmacies that were located in the urban area. Approximately 84% (n=377) worked in independent pharmacies. The highest number of patients seen per day was between 10-50 (48%, n=214). Additionally, most CPs worked more than 40 hours per week (60%, n=270). The other characteristics are summarized in Table 1.

Knowledge concerning PV

The information obtained about knowledge of PV from the CPs is represented in Table 2. The results regarding the definition of PV indicated slightly higher percentages reporting definition of PV as “detection, assessment, understanding, and prevention” (36%, n=151). Approximately 41% of participants (n=187) knew the purpose of PV was to improve public health and safety in regard to drug use. Additionally, an ADR was defined as “The noxious, unintended response to a drug” (35%, n=155), “The serious side effect of a medicinal product” by 33% of the respondents (n=151), and only 10% indicated that an ARD was “The adverse event of a drug due to its use outside the terms of marketing authorization”. Nearly 50% of the pharmacists thought that ADRs appear due to the use of OTC drugs, and 39% believed they could be caused by all mentioned drugs. Sixty-eight percent of the participants (n=308) thought that ADRs could be due to drug-drug interactions.

Attitude towards PV

The results on the attitude of the CPs towards PV is outlined in Table 3. The majority of the pharmacists stated that they have come across ADRs throughout their work at the pharmacy (62%, n=284). Most of the workers (87%, n=393) declared that the pharmacists are in charge of reporting ADRs, and approximately 87% (n=389) insisted that this activity must be compulsory. Approximately 84% of the participants (n=377) admitted that the responsibility belonged to the pharmacists, and approximately 65% (n=293) felt that physicians should also be responsible. Slightly more than half of the pharmacists (63%, n=285) depended on the drug information leaflets to obtain the corresponding ADR information, 53% of the CPs (n=239) used the drug website, and 41% of them (n=184) used books. Regarding the answers concerning the challenges encountered during the reporting the ADRs, approximately 53% (n=237) reported the need for training and lectures to better define ADRs. Approximately 43% (n=193) are challenged by time constraints/workplace pressure and have difficulty judging the occurrence of ADRs, and 36% (n=161) do not know how to report an ADR. Most of the pharmacists (80%, n=360) admitted that the Supreme Board of Drug and Medical Appliance (SBDMA) should promote pharmacovigilance, whereas 61% (n=274) stated that this was the responsibility of the Ministry of Public Health.

ADR reporting in the workplace (practice)

Concerning whether the respondents had observed any cases of ADR in their practice, nearly 49% (n=222) responded with yes, and approximately 37% (n=166) said no. Only 25% of the CPs (n=55) reported the ADRs to the HOD of their institute, and 13% (n=28) to the SBMDA. The majority of the participants (84%, n=377) declared that there was no reporting form available at their workplace. Most of them (69%,
n=309) responded with no when asked if their workplace provides information regarding the reporting procedure. Meanwhile, 57% of them (n=254) felt that they did not have enough training in ADR reporting. Regarding whether the workplace encouraged the reporting of ADRs, the responses of the participants were distributed nearly equally between yes and no. Regarding the problems encountered while reporting ADRs in the workplace, 59% (n=266) answered that ADRs reporting in Yemen is not widely promoted by the relevant authorities, and 57% (n=256) replied that a lack of information provided by the patient is an obstacle in the reporting system. The detail findings on practice can be found in Table 4.

Patient safety and response to mistakes

To recognize the relationship between the response to mistakes and patient safety, seven questions were directed to the pharmacists. Sixty-four percent (n=290) of the participants reported that they had attempted to determine what problems in the work process led to the mistake. Fifty-four percent (n=244) indicated that the pharmacy helps staff learn from their mistakes, while 46% (n=207) declared when the same mistake keeps happening, they change the way they do things. More information is shown in Table 5.

The future of ADR reporting in Yemen

Regarding the future of the ADR reporting system in Yemen (see Table 6), 57% of the CPs (n=257) supported the direct reporting by the patients instead of healthcare professionals. The majority of the participants (80%, n=346) envisaged the role of information technology in facilitating ADR reporting as well as maintaining an online program or website for reporting ADRs. Around 81% (n=364) of the CPs believed that the relevant authority in Yemen should maintain an online program or website like other countries bearing records of the ADRs reported throughout the nation. Approximately 52% (n=232) thought that the online program/website should be freely accessible to everyone. About 75% of the participants (n=338) believed that the information related to the procedure of reporting ADRs should be provided compulsorily to pharmacists at their workplace.

Benefits of reporting ADRs

The benefit of reporting ADRs was also evaluated in this study (see Table 7). The majority of pharmacists (66%, n=299) believed that reporting ADRs did not cause inconveniences in the working environment. Similarly, 89% (n=401) believed that reporting ADRs would improve patient safety. Additionally, 77% of the participants (n=346) trusted that the reporting of ADRs was an effort by health institutions to indicate the provision of quality care to the patients.

4 DISCUSSION

This study was conducted to evaluate the KAP of CPs, which is considered an essential step to creating awareness about the safety of drugs, the hazard of dispensing banned medicine, the reporting of ADRs, and the importance of PV. Majority of our respondents were male, young age, an employee who is practicing in an independent pharmacy, having a working experience in a community pharmacy between 1 to 6 years and acquired a bachelor degree in pharmacy. The extent of the knowledge and attitude of the CPs reflected the practical aspects. In brief, the findings indicated a positive attitude towards PV with a reasonable knowledge level; however, the practical role of CPs should be encouraged and upraised. Generally, in developing countries and specifically in Yemen, pharmacists are considered health-care consultants who can be easily assessed and without payment. Most patients prefer to consult CPs about health-related problems, including ADRs. Therefore, there is a demand to involve CPs in the PV system.
The profiles of the CPs e.g. age, employment status, experience, degree, indicated that they have an adequate level of education and practice. Thus, it is supposed that they might have acceptable knowledge suitable for this study. The study also indicated that most of the CPs had good knowledge about the concept of PV and its purpose as well as the definition of ADRs and the medical products that may be the main cause of ADRs. The response rate was comparable with that in a study carried out in Lebanon [19]. Several studies have indicated that pharmacists are considered the health care professionals who have the most comprehensive knowledge of the pharmacological aspects of the drugs, so they should play an essential role in the identification, detection, prevention, and management of ADRs [20-23]. Continuous awareness campaigns should be conducted to install, enhance and increase knowledge among pharmacists. A meta-analysis study in India indicated that approximately 81% of Indian pharmacists were unaware of the PV system in their country [24] (See Table 2).

Regarding the attitude towards PV, about two-third of the pharmacists had encountered ADRs. The majority of the participants had a positive attitude about being the health-care professional who was responsible for the reporting of ADRs, and more than fourth-fifth believed that reporting should be compulsory process. In addition, close to fourth-fifth of the participants considered reporting ADRs as one of their duties. The result is similar to that from studies in India [25], Korea [26] and other Arab countries [19, 27-31]. One study in India revealed that the CPs believed that ADR reporting was the physician’s duty [32]. However, a negative attitude was detected among pharmacists in New Zealand [22]. Some studies reported that pharmacists believe that reporting disrupted drug dispensing and not was included among their main duties [33, 34]. The positive result in the current study might be due to incomplete knowledge on the ADR reporting procedure, as there is no active applied PV system in Aden. This study only reflects attitudes towards PV and ADR reporting, not the real reporting practice. However, the participants revealed that they had many challenges that made accessing the reporting system difficult, such as a lack of knowledge about ADR reporting procedures and judgments, the need for training to effectively detect ADRs and time restrictions in addition to work pressure. Similar challenges have been stated previously; several studies have revealed a positive relationship between knowledge level and reporting behavior (35-40). Furthermore, a study in Portugal showed that educational courses increased the number of ADR reports 10-fold [40]. Most of the pharmacists depended on drug leaflets to obtain ADR information, followed by the internet and books. However, the drug leaflets provide information on the most common ADRs, and some of the rarer and more serious ADRs are usually not mentioned. Additionally, obtaining information from the internet is not a good idea because not all websites are trustworthy (See Table 3).

Regarding ADR reporting practices, approximately half of the pharmacists reported having observed ADRs. They reported them to different authorities, as shown in Table 4. The outcomes also indicated the unavailability of the reporting system according to around fourth-fifth of the CPs, with slightly more than two-third of the CPs indicating that no information is provided regarding the reporting of ADRs. Most of the pharmacists felt that they did not have sufficient training, while nearly half of the CPs encouraged the reporting system and around half did not. Several problems were mentioned during the reporting procedures, including the lack of governmental reporting system and the lack of information from the patient. Additionally, some pharmacists revealed that work pressure prevents proper reporting, which is in line with the outcomes from studies in India [32, 41]. Meanwhile, the fear of legal repercussions was one of the problems that faces the reporting system in the community pharmacies in Yemen; similar results have been reported in other studies [245, 32, 41-43]. Patient safety was the prime concern of most participants. The majority of the pharmacists had a considerable awareness of the mistakes that may occur during their duties, and they learned from these mistakes to improve the quality of CP services.

Regarding the future of ADR reporting in Yemen, slight more than half of the participants encouraged the idea of self-reporting by the patients. This finding is comparable to those of previous studies in India [25], the UK [44] and the Netherlands [45]. Subsequently, the activation of a “spontaneous reporting system” might be an essential factor in the future. Approximately fourth-fifth of the participants encouraged the role of information technology in facilitating ADR reporting in the country. An identical result was found in a study carried out in India [46]. Concerning patient access to an online ADR program/website, nearly half
had positive responses. Approximately three-fourth of the CPs believed that reporting procedures should be compulsory.

According to this study, more than fourth-fifth of the pharmacists believed that reporting ADRs will improve patient safety. A similar finding was reported in other studies [32, 41]. When asked if ADR reporting causes inconvenience in the working environment, around two-third of the participants responded no; some of the CPs also believed that reporting ADRs is an effort by health institutions to indicate the provision of quality care to the patients, which is a positive indication of the acceptance of the ADR reporting concept.

Based on the observation from this study, there are a few recommendations for improving ADR reporting in Yemen:

1. Every governmental or private hospital should create a PV center for reporting ADRs and save associated data in the database;
2. PV workshops should be carried out to guide pharmacists and other healthcare professionals in distinguishing and reporting ADRs;
3. Self-reporting by the patients should also be encouraged alongside reporting by healthcare professionals;
4. National PV programs should be initiated, and PV specialists should help healthcare professionals;
5. Continuous seminars and training programs should be arranged by PV professionals to enhance the reporting system;
6. There should be a periodic gathering of ADR data from health centers;
7. New technology should be incorporated to facilitate ADR reporting;
8. PV education should be introduced in pharmacy and other health-related facility curricula;
9. Pharmacists should not be subjected to legal repercussions if a mistake is made;
10. ADR reporting should be made compulsory for all pharmaceutical companies and healthcare professionals; and
11. CPs should be able to obtain the required ADR data from the hospital database.

Study limitations

The study was not able to be conducted in a wider geographical area with larger sample due to the safety and security reasons mentioned above. Thus, we are not able to generalize to the whole populations of CPs in the country, even though we believe the findings will be similar. Secondly, due the nature of a cross-sectional study of KAP, the study might experience social desirability bias.

Study implications

The study highlights the awareness and attitudes of CPs towards ADR reporting guidelines and how their behavior could affect the rate of ADR reporting. This study provides health care policymakers and planners with useful data to explore the current ADR reporting status and barriers among CPs. It provides baseline data that can be used in future evaluation or reconstruction plans for the current PV system. The study can be followed up to further evaluate the factors that could affect ADR reporting among healthcare professionals and CPs in particular. The study will determine the actual interventions required to improve ADR reporting by verifying the possible factors leading to underreporting. Information about ADR reporting, such as CPs’ basic knowledge, attitudes, perceptions, and barriers, must be assessed, and the needs associated with these factors must be identified.

5 CONCLUSION

In summary, this observational study indicated that Yemeni community pharmacists have a positive attitude and that the degree of knowledge is acceptable, but still requires improvement. Despite the positive attitude
and the degree of knowledge, several obstacles prevent the proper application of PV and ADR reporting systems in Yemen. This shortcoming can be overcome by education intervention, training, and promoting the PV program. The Ministry of Health and Population alongside the academic sector should start applications for education programs to help CPs as well as pharmacy students acquire the essential concepts and practice regarding PV and reporting systems. Promotion of the role of CPs in future PV systems will help improve patient’s healthcare and safety.

Declaration:

Conflict of interest: None to declare

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