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Original Article

# KNOWLEDGE, ATTITUDE AND PRACTICE OF YEMENI PHYSICIANS TOWARD PHARMACOVIGILANCE: A MIXED METHOD STUDY

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**ABSTRACT**

**Objective:** The objective of the current study was to investigate the physician's knowledge, attitude and practice towards pharmacovigilance.

**Methods:** A mixed qualitative and quantitative method was conducted in this study using a face to face questionnaire among the physicians in the capital Sana'a, Yemen.

**Results:** Of the 105 respondents (79 %) were male. Participants age mean was 35.55±4.45 y. Majority of physicians (73.3 %) had a moderate knowledge towards pharmacovigilance; (15.2 %) had a good knowledge and (11.4 %) had a poor knowledge. 35 (33.3 %) physicians were seen adverse drug reactions (ADRs) happened to their patients. Allergy was the most common ADRs. However, no ADR was reported. 66.7 % of physicians had a positive attitude towards pharmacovigilance. The most barriers reported by physicians were: lack of motivation and lack of knowledge about reporting system. Reported factors to encourage ADRs reporting were: attend courses or workshops; educational materials and simplification of reporting procedures.

**Conclusion:** Majority of physicians in Sana'a, Yemen had moderate knowledge and postitive attitude towards pharmacovigilance. Educational and training programmes are the cornerstone of improving ADRs reporting in Yemen.

**Keywords:** Pharmacovigilance, Knowledge, Attitude, Physicians and Yemen


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## INTRODUCTION

Pharmacovigilance science and activities are necessary for the safety and effcacy of medications [1]. Pharmacovigilance activities worldwide play very important role to ensure the rationality as well as safety of medicines and herbal medications which improve the cost-effectiveness [1-4]. One of the most important activities of pharmacovigilance is adverse drug reactions (ADRs) reporting [2].9 Pharmacovigilance defined by World Health Organization (WHO) decades ago as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems" [1] ADRs defined by WHO as "any noxious, unintended, and undesired effect drug that occurs as a result of treatment with drug at a normal doses used in man for diagnosis, prophylaxis, and treatment" [5]. ADRs reported as an important cause of patient's morbidity and mortality, admissions to the hospitals and increase the length of hospitalization as well as the cost of management [6-10]. Yemeni Pharmacovigilance Center (YPVC) was established on the capital Sana'a in early 2011 with the following aims and objectives; "early detection of adverse drug reactions (ADRs); detection of increase in frequency of (known) adverse reaction; identification of risk factors and possible mechanisms underlying adverse reactions; estimation of quantitative aspects of benefit/risk analysis and dissemination of information needed to improve drug prescribing and regulation; prevention of adverse drug reactions; drug quality surveillance; encouraging rational and safe use of drugs and communication with international institutions working in pharmacovigilance" [11, 12] The role of physicians is very important in reporting ADRs [13, 14]. Therefore, the aim of this study was to investigate the knowledge, attitude and barriers of Yemeni physicians towards pharmacovigilance, ADRs and ADRs reporting.

## MATERIALS AND METHODS

### Study design and study duration

A cross-sectional study was conducted over a period of four months (1st August to 30th November 2016) among Physicians in Sana'a, Yemen.

### Sample size

According to the annual reports of the Ministry of Public Health and Population 2014 the numbers of physicians are 1732 in the capital Sana'a [15]. Based on this statistics 315 physicians were selected conveniently from each region in the capital Sana'a to have an estimate of precision at the 95% confidence interval (CI), with an $\alpha = 0.05$.

### Study tools

A mixed qualitative and quantitative method was conducted in this study using a face to face questionnaire. The questionnaire was developed based on the information from the literature [16-18]. The questionnairewas pilot tested on a convenience sample of ten physicians in Ibb city to test the validity of the survey form. The final questionnaire was composed of six sections. Scoring system was used in this study to assess the knowledge and attitude of physcians in Yemen towards pharmacovigilance, ADRs and ADRs reporting. A score of 1 and 0 was given for each correct and wrong answer respectively, the answer was considered correct if the participant answered correctly or nearly to the correct answer. Total scores were calculated for each participant. A maximum 10 score were for evaluation the knowledge. A score equal to and greater than 6 was considered as good knowledge, scores 5 and 4 was considered as moderate knowledge, score less than 4 were considered as poor knowledge.

Four levels Likert scaling (A: agree. SA: strongly agree. D: disagree and SD: strongly disagree.)

Was used to explore the attitude, barriers and factors will encourage physicians in Yemen to report ADRs. A maximum 10 score were for evaluation the attitude. A score of 1 and 0 was given for each positive and negative answer respectively. Total scores were calculated for each participant. A score greater than or equal to 6 was considered as positive attitude, score less than 6 were considered as negative attitude. Tow trained pharmacists were conducted this study by visiting physicians at their clinics or working hospitals.

**Ethical approval**

This study was approved from University of Science and Technology, Yemen. Furthermore, written consent was also taken from the respondents. Questions that may related the personal information were avoided.

**Statistical analysis**

Data were entered and analysed using SPSS version 21 (SPSS Statistics for Windows, version 21.0, IBM Corp., USA). Differences in proportional were tested with Chi-square test or Fisher's exact test. Differences test in the means were test with the student t-test. All reported *p*-values are two tailed, and the result is significant if *P*-value is ≤ 0.05.

**RESULTS**

A total of 400 physicians were interviewed. However only 105 questionnaires were completed and analyzed. The mean age of the respondents was found to be 35.55±4.54 y. The characteristics of the study sample are presented in table 1.

**Table 1: Sociodemographic characteristics of the physicians**

| Variable | Frequency (%) |
|---|---|
| **Gender** | |
| Male | 83 (79 %) |
| Female | 22 (21 %) |
| **Qualifications** | |
| Bachelor | 4 (3.8 %) |
| Higher | 101 (96.2 %) |
| **Workplace** | |
| Hospital | 26 (24.8 %) |
| Clinic | 79 (75.2 %) |
| **Rank** | |
| General practitioner | 4 (3.8 %) |
| Specialist | 83 (79 %) |
| Consultant | 18 (17 %) |
| **Experience years** | |
| less than 5 | 10 (9.5 %) |
| 5-10 | 64 (61 %) |
| 11-20 | 25 (23.8 %) |
| More than 20 | 6 (5.7 %) |
| **Graduation country** | |
| Yemen | 26 (24.8 %) |
| Others | 79 (75.2 %) |

**Table 2: Knowledge related questions (correct answers)**

| Statement | Frequency (%) |
|---|---|
| What is Pharmacovigilance? | 94 (89.5 %) |
| What is an Adverse Drug Reaction (ADR)? | 95 (90 %) |
| How does an ADR differ from a side effect? | 89 (84.8 %) |
| What are the types of ADRs? | 11 (10.5 %) |
| Why is pharmacovigilance important? | 93 (88.6 %) |
| Who should report ADRs? | 17 (16.2%) |
| How the report an adverse drug reaction can be done? | 17 (16.2%) |
| When the pharmacovigilance centre in Yemen was established? | 3 (2.9 %) |
| Where is the location of pharmacovigilance Centre in Yemen? | 3 (2.9 %) |
| What is the objectives of pharmacovigilance centre in Yemen? | 1 (1%) |
| Total scores: mean±(SD) | 4.03±(1.60) |
| Knowldge | |
| Good knowledge | 16 (15.2 %) |
| Moderate knowledge | 77 (73.3 %) |
| Poor knowledge | 12 (11.4%) |

**Knowledge of physicians about pharmacovigilance, ADRs and ADRs reporting in Yemen**

The finding of this study showed that there were no significant association between the good knowledge and other factors (*P*-value>0.05).

Table 2 shows the knowledge of physicians towards pharmacovigilance, ADRs and ADRs reporting.

**Experience of yemeni physicians with adverse drug reactions (ADRs) and its reporting**

The finding of this study showed that there were 35 (33.3 %) physicians were detected and seen ADRs in their practice. The most common ADRs they detected were allergy. However they didn't report any ADR.

**Attitude of Yemeni physicians towards pharmacovigilance and adverse drug reactions (ADRs) reporting**

The finding of this study showed that there were no significant association between the positive attitude and other factors (*P*-value>0.05).

Table 3 shows the attitude of physicians towards pharmacovigilance, ADRs and ADRs reporting.

**Barriers of adverse drug reactions (ADRs) reporting**

Table 4 shows the barriers of ADRs reporting

**Table 3: Attitude related questions (Positive attitude)**

| Statement | Frequency (%) |
|---|---|
| I believe that pharmacovigilance is important | 101 (96.2 %) |
| Reporting ADRs is part of the professional role | 86 (81.9 %) |
| I want to be sure the ADR is related to the drug before reporting | 63 (60 %) |
| I report an ADR that causes: | |
| a. hospitalisation | 69 (65.7 %) |
| b. a life threatening situation | 69 (65.7 %) |
| c. a congenital anomaly | 69 (65.7 %) |
| d. persistent disability or incapacity | 72 (68.6 %) |
| e. death of the patient | 43 (41 %) |
| I report to get more insight into ADR questions that I come across in my practice | 8 (7.6 %) |
| I report to show the patient that their concern is being taken seriously | 45 (42.9 %) |
| Total scores: mean±(SD) | 5.95±(3.23) |
| Positive attitude | 70 (66.7 %) |

**Table 4: Barriers of adverse drug reactions (ADRs) reporting**

| Barrier | Frequency (%) |
|---|---|
| I don't report ADR because reporting form not available | 15 (14.3 %) |
| I don't report ADR because I don't know the address where these reports should be sent | 16 (15.2 %) |
| The reporting form too complicated | 17 (16.2 %) |
| Reporting ADRs is time consuming | 14 (13.3 %) |
| All serious ADRs are detected before registration | 5 (4.8 %) |
| I don't report ADR because I want to publish about them myself | 2 (1.9 %) |
| I don't report ADR because I am not convinced about the confidential handling of the reports | 9 (8.6 %) |
| I don't report ADR because I fear it may harm the confidence of my patients | 20 (19 %) |
| I don't report because I find it difficult to admit that the patients has been harmed | 3 (2.9 %) |
| I don't report because reporting may give the impression that I am ignorant concerning ADRs | 3 (2.9 %) |
| I don't report because I fear legal liability for the reported ADRs | 4 (3.8 %) |
| I am not motivated to report | 105 (100 %) |
| I don't report because I have insufficient clinical knowledge | 4 (3.8 %) |
| I don't report because I don't know how to report ADR | 86 (66.7 %) |
| I don't report because I am not convinced the ADR is caused by the drug | 70 (38.1 %) |

**Table 5: Factors encourage adverse drug reactions (ADRs) reporting**

| Factors | Frequency (%) |
|---|---|
| I will report if: | |
| 1. attend course or workshops to understand the reporting process | 68 (64.2 %) |
| 2. receive materials to understand the reporting process | 77 (72.6 %) |
| 3. More attention to ADR reporting in university curriculum | 88 (83 %) |
| 4. simplification of reporting procedure | 69 (65.1 %) |
| 5. promoting reporting as a part of professional duty | 13 (12.3%) |
| 6. there is a fee | 89 (84 %) |
| 7. I receive more feedback through mailings | 39 (36.8 %) |
| 8. compulsory reporting | 43 (40.6 %) |

**Factors encourage adverse drug reactions (ADRs) reporting**

Table 5 shows the factors encourage ADRs reporting.

**DISCUSSION**

This study aimed to explore the knowledge, attitude, practice and barriers of physicians toward pharmacovigilance, ADRs and ADR reporting in Yemen. This issue is very important to research in order to identify the required interventions to improve the ADRs reporting. The concept of pharmacovigilance in Yemen is new as the Yemeni Pharmacovigilance Center (YPVC) was established in early 2011 [11, 12].

Majority of physicians (73.3 %) had a moder knowledge towards pharmacovigilance, ADRs and ADRs reporting; (15.2 %) had a good knowledge and (11.4 %) had a poor knowledge. Majority of physicians couldn't have answered the questions related to ADRs reporting system and Yemeni pharmacovigilance system, while they answerd correctly questions related to the pharmacovigilance and ADRs. There is a difference between the findings of this study and the previous studies in terms of knowledge [19-23].

This is could be due to that Yemeni Pharmacovigilance Center (YPVC) was established on the capital Sana'a in early 2011 and faced challenges in reporting and marketing its activities [11, 12, 24].

The finding of this study showed that there were 35 (33.3 %) physicians were detected and seen ADRs in their practice. The most common ADRs they detected were allergy. However they didn't report any ADR. There was a difference between this study and the previous studies [19-23] in terms of experience of reporting ADRs. This is could be due to that Yemeni Pharmacovigilance Center (YPVC) was established on the capital Sana'a in early 2011 and faced challenges in reporting and marketing its activities [11, 12, 24].

The finding of this study showed that (66.7 %) of physicians had a positive attitude towards pharmacovigilance and ADRs reporting. There was a similarity between the findings of this study and the previous studies [19-23].

The most barriers reported by physicians were: lack of motivation and lack of knowledge about reporting system. Several studies done previously reported that lack of sufficient knowledge among physicians about ADR reporting considered as a major factor for not reporting ADRs [19-23]. The finding of this study showed that the factors to encourage ADRs reporting were: attend course or workshops; educational materials and simplification of reporting procedure. ADRs could harm the patients and could be minimized by increasing the awareness of health care professionals about it [25].

## CONCLUSION

The present study showed that the majority of physicians in Sana'a, Yemen had moderate knowledge about pharmacovigilance, ADRs and its reporting. They had a poor knowledge towards ADRs reporting. Physicians should take their responsibility towards pharmacovigilance. Education and training are the cornerstone of improving ADRs reporting in Yemen. The current study hasd several limitations: This study was conducted in the capital Sana'a only therefore; the findings cannot be generalized to other cities.

## RECOMMENDATIONS

Future studies in other cities are highly recommended. Increase the awareness about pharmacovigilance and ADRs reporting among physicians as well as other health care professionals are highly recommended. Training and educational programmes are highly recommended to improve the ADRs reporting.

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## CONFLICT OF INTERESTS

There is no conflict of interest

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