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Knowledge, Attitude and Practice on Adverse Drug Reactions Reporting among Pharmacists in Aden

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Abstract

Introduction: Once a medicine is registered and marketed, healthcare systems rely heavily on spontaneous reporting of adverse drug reactions (ADRs) to monitor the safety of drugs. ADRs reporting is considered a cornerstone of pharmacovigilance (PV) system. Underreporting has been a major obstacle and poses a great challenge to PV activities that negatively influence public health. Therefore, this study aimed to assess pharmacists' knowledge, attitude and practice toward ADRs reporting in Aden City - Yemen.

Methods: A comparative cross-sectional study was conducted during November and December 2022 in Aden city. A self-administered, pretested questionnaire- comprised of sections on pharmacists' characteristics, knowledge of PV concepts and ADR reporting process, attitudes towards ADR reporting and practice of ADR reporting- was administered to selected community and hospital pharmacists. Data were summarized using descriptive statistics and the Pearson's Chi-square test was used to examine the differences between both groups of pharmacists.

Results: Four hundred pharmacists participated in the study. Three quarters of them were males. About half of them correctly identified PV definition and purposes as well as ADR definition, but 38.5% and 37.8% were heard about national ADR scheme/guideline and aware of the existence of an ADR system in Yemen respectively. Only 29.3% and 10.8% showed adequate knowledge of PV concepts and ADRs reporting process respectively. The majority showed positive attitude towards PV and ADR reporting, 97.8% agreed that reporting process can benefit the public health, 94.3% contributes to drug safety and 87.3% agreed that PV should be taught in detail to health care professionals. However, in practice, 48.3% and 41.5% of pharmacists had ever diagnosed an ADR and encountered one or more ADRs in their daily practice respectively and only 12.3% of them had ever reported an ADR. The differences between community and hospital pharmacists by their overall knowledge, attitude scores and in ADR reporting practice were statistically insignificant.

Conclusion: The majority of community and hospital pharmacists had inadequate knowledge and poor practice, with a positive attitude towards ADRs reporting. Therefore, strategies to improve knowledge and practices regarding ADR reporting should be implemented. Regular mandatory education and continuous in job training should be provided to all pharmacists and others health care professionals.

Keywords: Pharmacovigilance, Awareness, Drug safety, Community pharmacists, Yemen

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المعارف والمواقف والممارسات حول الإبلاغ عن الآثار الضارة للدواء بين أوساط الصيادلة في عدن

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ملخص الدراسة

المقدمة: بمجرد تسجيل الدواء وتسويقه، تعتمد أنظمة الرعاية الصحية بشكل كبير على الإبلاغ التلقائي والطوعي للآثار الضارة للدواء (ADRs) لمراقبة سلامة الأدوية. يعتبر الإبلاغ عن الآثار الضارة للدواء حجر الزاوية في نظام التيقظ الدوائي (PV). ويعتبر عدم أو نقص الإبلاغ عقبة رئيسية وتحديًا كبيرًا لأنشطة نظام التيقظ الدوائي والتي تؤثر سلبًا على الصحة العامة. لذلك، هدفت هذه الدراسة إلى تقييم معارف ومواقف وممارسات الصيادلة حول الإبلاغ عن الآثار الضارة للدواء في مدينة عدن - اليمن.

المنهجية: أجريت دراسة مقطعية مقارنة خلال شهري نوفمبر وديسمبر 2022 في مدينة عدن. وتم تقديم استبيان معد مسبقاً- يتألف من أقسام عدة حول خصائص الصيادلة، ومعارفهم حول مفاهيم نظام التيقظ الدوائي وعملية الإبلاغ عن الآثار الضارة للدواء، والمواقف والممارسة نحو الإبلاغ عن الآثار الضارة للدواء - إلى العينة التي تم اختيارها من الصيادلة. وتم تلخيص البيانات باستخدام الإحصاء الوصفي واستخدام اختبار بيرسون كاي سكوير لفحص الاختلافات بين مجموعتي الصيادلة.

النتائج: شارك في الدراسة أربعمائة صيدلاني، ثلاثة أرباعهم من الذكور. حوالي النصف كانت إجاباتهم لتعريف وأغراض التيقظ الدوائي والإبلاغ عن الآثار الضارة للدواء صحيحة، بينما 38.5% و37.8% منهم سمعوا عن البرنامج/الدليل الوطني للإبلاغ عن الآثار الضارة للدواء وكانوا على دراية بوجود نظام الإبلاغ عن الآثار الضارة للدواء في اليمن على التوالي. وجد أن 29.3% و10.8% فقط من الصيادلة لديه معرفة كافية بمفاهيم التيقظ الدوائي وعملية الإبلاغ عن الآثار الضارة للدواء على التوالي. وأظهرت أغلبيتهم موقفاً إيجابياً تجاه عملية الإبلاغ عن الآثار الضارة للدواء، حيث وافق 97.8% على أن عملية الإبلاغ يمكن أن تفيد الصحة العامة، و94.3% على أنها ستساهم في سلامة الأدوية، ووافق 87.3% منهم على أنه ينبغي تدريس التيقظ الدوائي بالتفصيل إلى مقدمي الرعاية الصحية. ومع ذلك، من الناحية العملية، فإن 48.3% و41.5% من الصيادلة قد قاموا بتشخيص الآثار الضارة للدواء وواجهوا الآثار الضارة للدواء في ممارساتهم اليومية على التوالي، ولكن 12.3% منهم فقط أبلغوا عن الآثار الضارة للدواء. لم تكن هناك فروق ذات دلالة إحصائية بين صيادلة المجتمع والمستشفيات في المعارف والمواقف والممارسات المتعلقة بالإبلاغ عن الآثار الضارة للدواء.

الخلاصة: غالبية صيادلة المجتمع والمستشفيات لديهم معارف غير كافية ومستوى ممارسة متدني، مع موقف إيجابي تجاه الإبلاغ عن الآثار الضارة للدواء. لذلك، ينبغي تنفيذ استراتيجيات لتحسين المعارف والممارسات المتعلقة بالإبلاغ عن الآثار الضارة للدواء. كما يجب توفير تعليم إلزامي منتظم والتدريب المستمر أثناء العمل لجميع الصيادلة وغيرهم من مقدمي الرعاية الصحية.

كلمات مفتاحية: التيقظ الدوائي، التوعية، سلامة الدواء، صيادلة المجتمع، اليمن

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Introduction

Drugs play an essential role in day-to-day life. However, they are not free from adverse drug reactions (ADRs).[1] ADRs are a major cause of morbidity and mortality and contribute to the occurrence of adverse events, leading to increased healthcare costs.[2] ADRs have become a major public health problem in developing countries. [3]

Quality, safety, and efficacy-assured medicines are essential for patient health. Even before marketing, clinical and preclinical studies are done to validate its safety and efficacy. It has been found that the information collected during this pre-marketing phase of drug development is inevitably incomplete concerning possible ADRs.[4] Therefore, post-marketing surveillance is important to allow detection of less common, but sometimes very serious ADRs. Once a drug is registered and marketed, the healthcare system relies heavily on spontaneous ADRs reporting to monitor drug safety throughout the population during actual use. [5,6] A spontaneous reporting system of ADRs is fundamental to effectively discover new adverse reactions but under-reporting is its major limitations [7,8].

Health professionals are responsible for identifying, documenting and ADRs reporting. Their contribution to the early detection and reporting of ADR is essential[9]. Globally, the pharmacists represent the third largest health professional groups outnumbered only by physicians and nurses [10]. and the most accessible for the patients more than the others. [11] Thus, pharmacists are well placed for timely collection and spontaneous reporting of ADRs.

The knowledge and attitudes of pharmacists are strongly related to ADRs reporting. [8,12] and it is very important to understand the knowledge and practice of pharmacists related to ADR reporting to improve reporting practices. [13] Therefore, the aim of this study was to assess the knowledge, attitude and practice of pharmacovigilance and ADRs reporting among community and hospital pharmacists in Aden.

Methods

Study design and setting

A comparative cross-sectional study was conducted in Aden city.

Target population

The target population consists of the pharmacists working in Aden city. The term "pharmacists" in this study include both pharmacists and pharmacy technicians.

Sampling

The sample size was calculated using the following formula [14]:

$$n = \frac{Z^2 P(1-P)}{d^2}$$

Where:
n= required sample size
Z= standard of 1.96 at 95% certainty
p= the prevalence of (50%)
d= precision or error allowable, which was in our study is 0.10
By the above equation, the calculated sample size was 400 pharmacists divided between Aden districts according to proportional allocation technique of pharmacies in each district.

Sampling technique

A convenience sampling strategy was used within each district to reach the required sample size. Pharmacists who are dealing with medications on a daily basis were invited to participate in the study.

Data collection

To fulfill the study objectives, data were collected through a self-administered, pretested questionnaire of four sections with close-ended questions. First section consisted of questions related to personal characteristics of pharmacists and the second one consisted of 18 questions, 7 to measure the knowledge of pharmacists, related to PV basic concepts and 11 for ADRs reporting process. The third section consisted of 8 questions, which assessed pharmacists' attitudes towards ADR reporting, while the fourth section is about the practice of ADR reporting. The questionnaire was formulated based on previous studies [15-17] and little modification was done to fit with the local environment. The questionnaire was originally in English then translated into Arabic, and back translated to English to ensure that the translation preserved the meaning captured by the original English version. The survey tool was used in Arabic text. The questionnaires were distributed by the researcher and well-trained pharmacists.

Statistical analysis

The coded data were systematically verified and checked for errors and entered into the Statistical Package for Social Sciences (SPSS), version 23.0 for analysis. For quantitative variables (age, years of experience, No. of patients seen per day) the arithmetic mean and standard deviation (SD) were used to express numerical data, while for qualitative variables (gender, level of education, sitting of practice, city of practice) absolute frequencies and relative frequencies (percentages) were used.

For knowledge score; each correct answer had a score of 1 and each wrong answer had a score of 0. Thus, the total score ranged from 0 to 18 points and $\geq$ 70% of the maximum points considered as an adequate knowledge level. Regarding participants' attitudes, the 'positive' responses received a score of 2, 'neutral' a score of 1 and 'negative' a score of 0. Therefore, the maximum possible attitude score was 16 and those with $\geq$ 70% of the maximum points were considered as with a positive attitude score.

The Chi-square test was used to explore the potential relation of the different variables on ADR reporting practice, significance level of $P < 0.05$ was used, where the test was relevant.

Ethical consideration

This study was approved by the Ethics Research Committee of the Faculty of Medicine and Health Sciences, University of Aden. Participants were briefed about the objectives and the significance of research and written consent was taken from them prior the data collection. Participation in the study was voluntary and the responses were dealt with high level of confidentiality and anonymity.

Results

Personal characteristics of the pharmacists

A total of 400 pharmacists were encountered and consented to participate in the study. Of them, 81.0% were community pharmacists, 24.3% were female and 75.3% hold Bachelor or higher degree of qualification. Their mean age was 28.9±5.6 years and the mean years of experience was 5.8±4.6.

Table 1: Personal Characteristics of the Pharmacists

Characteristics		Community pharmacists (n= 323)		Hospital pharmacists (n=77)		Total pharmacist (n=400)		*P*
		No.	%	No.	%	No.	%	
Gender	Male	251	77.7	52	67.5	303	75.8	0.045
	Female	72	22.3	25	32.5	97	24.3	
Age (years)	20 – 30	232	71.8	54	70.1	286	71.5	0.3
	31 – 40	83	25.7	18	23.4	101	25.3	
	41 – 50	7	2.2	4	5.2	11	2.8	
	≥ 51	1	0.3	1	1.3	2	0.5	
	Mean (SD)	28.8 (±5.4)		29.3 ± (6.6)		28.9 (±5.6)		
Work Experience (years)	1 – 5	192	59.4	52	67.5	244	61	0.080
	6 – 10	102	31.6	15	19.5	117	29.3	
	11 – 15	18	5.6	5	6.5	23	5.8	
	16 – 20	10	3.1	3	3.9	13	3.3	
	≥ 21 years	1	0.3	2	2.6	3	0.8	
	Mean (SD)	5.7 (±4)		6 (±6.5)		5.8 (±4.6)		
Educational qualification	Diploma	153	47.4	19	24.7	172	43	0.000
	Bachelor or higher	170	52.6	58	75.3	228	57	

Knowledge of the pharmacists

Overall, only 29.3% of the pharmacists had an adequate knowledge score about all PV concept related statements and the difference regarding these statements between community and hospital pharmacists was statistically insignificant.

Table 2 also shows a statistically significant difference between community and hospital pharmacists regarding PV definition (*P*= 0.002) and the types of ADRs that the PV center wants HCs to report (*P*= 0.015) with more community pharmacist aware about PV definition whereas more hospital pharmacists know he ADR that the PV center wants healthcare professionals to report.

Table 2: Knowledge of Pharmacists about PV Basic Concepts

Statements	Correct Response						*P*
	Community pharmacists (n= 323)		Hospital pharmacists (n=77)		Total pharmacists (n=400)		
	No.	%	No.	%	No.	%	
Definition of PV	192	59.4	31	40.3	223	55.8	0.002
Purpose of PV	167	51.7	38	49.4	205	51.2	0.403
Definition of ADR	172	53.3	49	63.6	221	55.3	0.064
The ADR that the PV center wants healthcare professionals to report	172	53.3	52	67.5	224	56	0.015
PV center accepts ADRs reports from	203	62.8	46	59.7	249	62.3	0.352
Most ADRs information collected during which phase	150	46.4	36	46.8	186	46.5	0.530
The minimum required data for reporting	95	29.4	20	26.0	115	28.7	0.327
Adequate knowledge score	97	30.0	20	26.0	117	29.3	0.289

Concerning the pharmacists' knowledge about ADRs reporting, Table 3 reveals that only 10.8% of the pharmacists had an adequate knowledge score about ADRs reporting process and there are no significant differences between community and hospital pharmacists present in this score.

Table 3: Knowledge of Pharmacists about ADRs Reporting Process

Statements	Positive Response						*P*
	Community pharmacists (n= 323)		Hospital pharmacists (n=77)		Total Pharmacists (n=400)		
	No.	%	No.	%	No.	%	
Identified ADR reporting channels	194	60.1	49	63.6	243	60.8	0.329
You would make contact for spontaneous reporting of ADR	187	57.9	47	61	234	58.5	0.356
ADR reporting system in Yemen is through ADR reporting form	115	35.6	27	35.1	142	35.5	0.521
Heard about national Adverse drug reaction reporting scheme/guideline	128	39.6	26	33.8	154	38.5	0.207
Aware about the national PV system in Yemen	125	38.7	26	33.8	151	37.8	0.252
Knwo how to report ADR	78	24.1	15	19.5	138	34.5	0.238
Had seen ADR reporting form	114	35.3	24	31.2	93	23.3	0.293
Know the nearest PV center located from your working place	88	27.2	26	33.8	114	28.5	0.159
Received training about drug safety or ADR reporting	64	19.8	19	24.7	83	20.8	0.213
Adequate Knowledge Score	36	11.1	7	9.1	43	10.8	0.387

Attitudes of pharmacists towards ADRs reporting

As shown in Table 4, there were eight questions assessing attitudes of ADRs. The majority of pharmacists (ranged from 97.8% to 73.0%) had a positive attitude regarding all the statements except only in their responses to the question of, is herbal products have no ADRs? as only 39.0% had a positive attitude. Overall, 89.0% of pharmacists showed a positive attitude and there is no statistically significant difference between community and hospital pharmacists present in the overall attitude score.

Table 4: Attitudes of Respondents towards ADRs Reporting

Statements	Positive Responses						*P*
	Community pharmacists (n=323)		Hospital pharmacists (n=77)		Total pharmacists (n=400)		
	No.	%	No.	%	No.	%	
Reporting of ADRs can benefit the public health	314	97.2	77	100	391	97.8	0.155
One report can make a difference.	279	86.4	65	84.4	344	86.0	0.565
ADR reporting contributes to drug safety	302	93.5	75	97.4	377	94.3	0.001
PV should be taught in detail to HCP	277	85.8	72	93.5	349	87.3	0.052
ADRs reporting should be voluntary	234	72.4	58	75.3	292	73.0	0.707
It is necessary to confirm that an ADR is related to particular drug before reporting it	274	84.8	68	88.3	342	85.5	0.451
All drugs Available in the market are safe (Dis agree is +ve attitude)	229	70.9	63	81.8	292	73.0	0.049
Herbal products have no ADR, i.e. they are safe? (Dis agree is +ve attitude)	122	37.8	34	44.2	156	39.0	0.254
Positive attitude Score	286	88.5	70	90.9	356	89	0.358

Practices of pharmacists about ADRs reporting

Of the 400 pharmacists, 48.3% had ever diagnosed ADR, 12.3% had ever reported ADR to any reporting center, 59.3% had ever counseled patients about ADR and 41.5% of them encountered ADR in the last 12 months of their practice. Table 5 also shows that a statistically significant higher percentages of hospital (63.6%, 45.5% and 76.6%) than community pharmacists (44.6%, 41.6% and 54.8% had ever diagnosed ADR (*P*=0.002), had ever encountered ADRs in the last 12 months of their practice (*P*=0.004) and had ever read an article related to ADR in the last 12 months (*P*=0.000) respectively.

Table 5: Practices of Pharmacists about ADRs Reporting

Statements	Positive Response						*P*
	Community pharmacists (n=323)		Hospital pharmacists (n=77)		Total Pharmacists (n=400)		
	No.	%	No.	%	No.	%	
Have you ever diagnosed an ADR	144	44.6	49	63.6	193	48.3	0.002
Have you ever reported an ADR to any reporting center	41	12.7	8	10.4	49	12.3	0.369
Have you ever-counseled patient regarding ADR in the last 12 months	190	58.8	47	61	237	59.3	0.412
ADRs ever encountered	131	41.6	35	45.5	166	41.5	0.004
Is your department informing you about the process of spontaneous reporting of adverse drug reaction	91	28.2	21	27.3	112	28.0	0.498
Have you ever read an article related to ADRs in the last 12 months	177	54.8	59	76.6	236	59.0	0.000

Discussion

Pharmacists have a central role in drug safety by contributing to the prevention, identification, documentation, and reporting of ADRs.[18] Pharmacists cannot effectively participate in the reporting of ADRs without sufficient knowledge of the ADR and its reporting process. One of the main goals of this study was to assess the knowledge of pharmacists towards PV and ADRs reporting. Unfortunately, only 29.3% and 10.8% of the pharmacists had an adequate knowledge score about all PV concept and ADRs reporting related statements respectively, similar to the reports seen in Al-Worafi *et al* study[19], in Sana'a-Yemen but slightly higher than

the findings reported by Zawiah *et al* study[20], in five governorates of Yemen. Higher than this study findings seen in a national survey among Saudi community pharmacists [21], and Turkey[22]. Lack of information and awareness of healthcare professionals including pharmacists about the authority responsible for monitoring ADRs in the country may contribute largely to underreporting. The present study showed that only 37.8% of the pharmacists aware of the existence of an ADR system in Yemen. This meant that most of the participants did not have information about the authority responsible for monitoring ADRs in Yemen. Similarly, lack of knowledge about the national ADR reporting system was also reported in Sana'a [19] and another study conducted in five governorates in Yemen[20]. Similarly, a substantial proportion of the pharmacists in the study performed at Alkarak, Jordan lacked knowledge on the presence of PV centers[23]. Responses to questions exploring the pharmacists' attitudes toward PV and ADRs reporting, the majority of pharmacists in this study agreed that reporting process can benefit the public health (97.8%), contributes to drug safety (94.3%) and the overall positive attitude among them was 89.0%. This result confirmed what was reported among the pharmacists at Alkarak, Jordan[23], and among the pharmacists working in the government hospitals in Najran city of Saudi Arabia[24]. Spontaneous reporting of ADRs considered as an indication of PV awareness and knowledge and good PV practice and ADRs reporting will be reflected positively on public health through promoting rational use of drugs and ensuring patient safety [4]. Another important finding in this study was that ADRs reporting practices among pharmacists were very poor. Although 48.3% and 41.5% of pharmacists had ever diagnosed an ADR and encountered one or more ADRs in their daily practice respectively, only 12.3% of them had ever reported an ADR. Higher figures of ADRs reporting practice were reported in other studies conducted in five Yemeni governorates (38.3%)[20], United Arab Emirates (71.1%)[25] and Najran city of Saudi Arabia (71.3%)[24].

Conclusion

The majority of community and hospital pharmacists had inadequate knowledge and poor practice, with a positive attitude towards ADRs reporting. Therefore, strategies to improve knowledge and practices regarding ADR reporting should be implemented. Regular mandatory education and continuous in job training should be provided to all pharmacists and others health care professionals.

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