ORIGINAL ARTICLE

Adverse Drug Reactions Reporting System: Perceptions and Awareness of Community Pharmacists in Jeddah, Saudi Arabia

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Abstract

Community pharmacists are most accessible to patients. Hence they have crucial role in ensuring drug safety by detecting and reporting adverse drug reactions (ADRs). Here we analyze community pharmacists' knowledge and perceived barriers to adverse drug reaction (ADR) reporting systems in Jeddah, Saudi Arabia. A cross-sectional study was performed between June 1st and September 15th 2017, including community pharmacies in Jeddah. A total of 202 community pharmacists were surveyed via a cluster sampling method. A self-administered, 34-item questionnaire was undertaken. The survey response rate was 71.43% (144 responses). Regarding knowledge of ADRs, very few (4.8%) pharmacists did not distinguish between the correct and incorrect definitions of what an ADR was. One-hundred-fourteen pharmacists (56.4%) were unaware of the existence of ADR reporting system in Saudi Arabia. The critical barrier to ADR reporting was a deficient professional environment. In conclusion, more than half of the community pharmacists were unaware of the existence or importance of the ADR reporting system in Saudi Arabia. Establishing a user-friendly system that incorporates the system of community pharmacies with Saudi Vigilance will enhance the reporting process.

Keywords

Adverse drug reaction, community, pharmacy, practice, side effect

Introduction

Adverse drug reactions (ADRs) remain a significant cause of morbidity and morbidity worldwide[1]. In 2002, ADRs were ranked as the sixth leading cause of mortality in developed countries like the United States of America (USA)[2]. In the United Kingdom (UK), about 6.5% of hospital admissions have previously been found to be due to an ADR[3], while in Sweden, 12% of patient admissions to internal medicine departments are due to ADRs[4]. According to the USA Institute of Medicine (IOM), an adverse drug event (ADE) is defined an injury resulting from medical intervention related to a drug, including medication errors, adverse drug reactions, allergic reactions and overdoses[5]. A high economic burden on both patients and society was reported due to the higher number of ADRs[6]. The reporting of suspected ADRs by pharmacists or patients increases the knowledge regarding the possible harmful effects of certain medicines, so even reports of small numbers

of adverse events can help the Saudi Food and Drug Authority (SFDA) and Ministry of Health (MOH) to identify safety issues to be added in their reporting system.

Analysis of adverse event reports is one way that the SFDA can monitor the safety of drugs, medical devices, and SFDA-regulated products used in Saudi Arabia. Post-market monitoring of the safety of drugs, medical devices, and SFDA-regulated products significantly add to healthcare providers' understanding of any possible adverse effects experienced by patients outside the controlled conditions of a clinical setting.

The ADR reporting system in Saudi Arabia named "Saudi Vigilance" is run by SFDA and has been launched recently. It is similar to the "MedWatch" ADR system in the USA. In 1998, the MOH set up the first initiative, which launched a reporting system to detect ADRs and measure their frequency in both hospital and community pharmacy settings[7].

Only a few studies have been published addressing Saudi community pharmacists' current knowledge and perceived barriers to ADR reporting systems[7,8]. No reports have been published regarding this issue in Jeddah. A study conducted in the Eastern region of Saudi Arabia, Alahsa highlighted that community pharmacists practicing in Alahsa were found to be unaware of the existence of the ADR reporting system in Saudi Arabia[8]. This study investigates community pharmacists' knowledge and perceived barriers to ADR reporting systems.

Methods

Study Design and Settings

A cross-sectional study was carried out among community pharmacies in Jeddah, Saudi Arabia. The study was performed between June 1st and September 15th 2017.

Questionnaire Design

This study tool was designed based on previously published literature[7]. It is a self-administered, 34-item questionnaire which is divided into three sections. Section one is designed to record demographics and pharmacy-related information (Table 1). Section two is formulated to assess the knowledge and perceptions of community pharmacists towards ADRs reporting (Table 2). The ten items were scored using the Likert scale (strongly agree, agree, neutral, disagree, strongly disagree). Section three was to document any perceived barriers that hinder ADR. Nine items were evaluated in this section using the Likert scale, as shown in Table 3. Lastly, section four focused on the factors encouraging the reporting of ADRs. Similarly, five items were evaluated via the Likert scale, as shown in (Table 4).

Content Validity and Tool Reliability

A pilot survey was completed by five academic pharmacists and five community pharmacists to re-assess the validity of the tool. Minor translation modifications were completed to clarify any vague item.

Data Analysis

Data analysis was performed using the Statistical Package for Social Science version 13. Descriptive statistics were used to calculate frequencies and percentages. A relative index (RI) ranking was used to identify the top five barriers in the ADR reporting process. The routine ranking was performed using the denominator (less than one and decreasing) RI rank.

Table 1. Record of demographics and pharmacy related information.

Demographic Variable	N (%)
Gender	
Male	202 (100)
Education level	
Bachelor of Pharmacy	187 (92.6%)
Doctor of Pharmacy	11 (5.4%)
Master	3 (1.5%)
Ph.D.	1 (0.5%)
Nationality	
Egypt	162 (80.2%)
Saudi	24 (12%)
Jordan	8 (4%)
Syrian	6 (3%)
Sudan	1 (0.5%)
Yemen	1 (0.5%)
How long have you been working as a pharmacist?	
0-5 Years	50 (24.75%)
5-10 Years	71 (35.14%)
More than 10 years	81 (40.1%)
In your current practice, how many adverse drug reaction ADR cases have you seen?	
Less than 5	172 (85.1%)
6-12	20 (10%)
More than 12	10 (4.9%)
Have you ever reported any adverse drug reaction ADR seen among your patients in last 12 months?	
Yes	20 (10%)
No	182 (90%)

Table 2. Knowledge of ADRs & their reporting

No	Statements	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1	I think it is important to report ADR.	99(49.5%)	102(50%)	1(0.5%)	0%	0%
2	I know that there is a national pharmacovigilance program for reporting ADR.	30(14.8%)	34(16.8%)	24(11.8%)	96(47.5%)	18(8.9%)
3	I think consumers should be involved in reporting ADR	44(20.7%)	139(68.8%)	11(5.4%)	9(4.4%)	1(0.5%)
4	I think the SFDA is a governmental monitoring agency for ADRs in Saudi Arabia.	33(19.3%)	71(35%)	24(11.8%)	62(30.6%)	12(6%)
5	I believe that pharmacovigilance was not well covered in the Pharmacy curriculum.	41(20.2%)	109(53%)	29(14.3)	20(10%)	3(1.5%)
6	Reporting of ADRs makes no significant contribution to the reporting system.	3(1.5%)	18(8.9%)	13(6.4%)	115(56.9%)	53(26.2%)
7	I believe serious and unexpected reactions that are not fatal during post-marketing must not be reported.	2(1%)	14(6.9%)	3(1.5%)	104(50.9%)	79(39.1%)
8	I am willing to report any ADRs in my future practice.	112(55%)	80(39.6%)	7(3.4%)	3(1.5%)	0%
9	I think that SFDA deals with my ADR report seriously.	13(6.4%)	47(23.2%)	123(61.3%)	15(7.4%)	3(1.5%)
10	It is not necessary to report those ADRs which are related to over the counter products (OTC).	4(1.6%)	18(8.9%)	5(2.4%)	109(53.9%)	66(30%)

Table 3. Barriers to ADRs reporting

No	I Do Not Report Because?	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1	I do not report because reporting forms are not available.	19(9.4%)	109(53.9%)	40(19.8%)	25(12.3%)	9(4.4%)
2	I do not report because the reporting form is too complicated to be filled.	5(2.4%)	33(16.3%)	122(60%)	38(18.8%)	4(1.9%)
3	I do not report because reporting is time-consuming.	9(4.4%)	38(18.8%)	111(54.9%)	40(19.8%)	4(1.9%)
4	I do not report because I fear legal liability of the reported ADR.	16(7.9%)	22(10.3%)	21(10.4%)	100(49%)	43(21.2%)
5	I do not report because I am not motivated to report.	35(17.3%)	101(50%)	10(4.9%)	41(20.3%)	15(7.4%)
6	I do not report because I do not know how to report.	74(36.6%)	64(31.6%)	10(10.4%)	30(14.9%)	13(6.4%)
7	I do not report because I am not confident whether it is an ADR.	4(1.2%)	42(21.8%)	39(19.3%)	95(46%)	22(11%)
8	I do not report because unavailability of a professional environment to discuss ADR.	64(31.7%)	93(46%)	24(12%)	18(9%)	3(1.5%)
9	I do not report because I believe that only safe drugs are marketed.	1(0.5%)	15(7.4%)	8(4%)	102(50.5%)	76(37.6%)

Table 4. Factors encouraging reporting of ADRs

	I Would Report If:	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1	I would report if there is an obligation to do so.	40(19.8%)	140(69.3%)	15(7.4%)	6(3%)	1(0.5%)
2	I would report if guidelines on reporting and bulletins on ADRs provided regularly.	87(43%)	104(51.5%)	8(4%)	3(1.5%)	0%
3	I would report if I receive feedback from relevant authorities.	83(41.1%)	114(56.4%)	2(1%)	3(1.5%)	0%
4	I would report if a simple method of reporting were implemented.	113(56%)	86(42.6%)	3(1.5%)	0%	0%
5	I would report if a patient request to report ADR.	46(23%)	115(57%)	29(14.5%)	7(3.47%)	5(2.5%)

Results

A total of 202 pharmacies were identified in Jeddah, and a representative sample of community pharmacists was identified. The overall survey response rate was 71.43% (144 responses). As was the case in other parts of Saudi Arabia, most community pharmacists practicing in Jeddah are Non-Saudi, (e.g., Egyptians, Syrian, Jordanian, Yemeni, and Sudanese). Some of these pharmacists hold a Bachelor Degree in pharmacy with the majority (187, 92.6%), having a Doctor Degree in pharmacy (11, 5.4%), hold a Master Degree in pharmacy (three, 1.5%), or a PhD. Degree in pharmacy (one, 0.5%). Approximately 50 (24.75%) had work experience of 0–5 years, 71 (35.14%) had 5-10 years of experience, and 81 (40.1%) had more than 10 years of experience. Approximately 172 pharmacists

(172,85.1%) stated that they had observed less than five adverse events during their practice in Saudi Arabia, while (20,10%) observed 6-12 adverse events and (10,4.9%) stated that they experienced more than 12. Moreover, most (82,90%) did not report any ADR in the last twelve months, while 20 (10%) stated that they observed an adverse event during this period. The demographics and observed adverse events are given in Table 1.

Regarding the knowledge of Saudi Vigilance System, most pharmacists (114, 56.4%) did not know that there is a national pharmacovigilance program for reporting ADR; The Saudi Vigilance System (Table 2). One hundred four pharmacists (54.3%) thought that the SFDA is a governmental monitoring agency for ADRs in Saudi Arabia. Regarding reporting adverse events, 168 (83.1%) pharmacists stated that reporting of ADRs makes a significantly contribution to the reporting system in general. However, 123 (61.3%) think that SFDA is not serious with ADR reports. Moreover, 22 (10.5%) pharmacists believed that there was no need to report any adverse event associated with using over-the-counter (OTC) drugs.

Section 3 of this questionnaire showed that the common barriers to the ADR reporting system lacked motivation, unavailability of a professional environment to discuss ADR, poor understanding of the ADR reporting process, and the majority of community pharmacists stating that it is a time-consuming process (Table 3).

Section 4 highlighted the factors that encouraged the reporting of ADRs. One-hundred-eighty (89.1%) pharmacists stated that they would only report if there is an obligation to do so, while (199,98.6%) stated that they would report if a simple method of reporting was implemented.

Discussion

This is the first survey in Jeddah that explores pharmacists' attitudes towards ADRs and their self-reporting behavior in community pharmacy settings in Saudi Arabia. The findings of this study are similar to those of previously published studies conducted in the Saudi Arabia.[7-9] The majority of community pharmacists surveyed (90%) were not even aware of The Saudi Vigilance System, as an ADR reporting system in Saudi Arabia. The primary purpose for this might be a lack of motivation, the process is time-consuming, or that the SFDA do not look up their reports. Most of the practicing pharmacists in this region are expatriates, with experience of 3–5 years. However, they have not heard about the Saudi Vigilance System and its importance in establishing a national database.

Moreover, private community pharmacies have led to a low incidence of ADR reporting. Thus, the concept of services and reporting of ADRs may be regarded as a low priority by these pharmacy entrepreneurs, which is most likely to be the case in many developing countries.[10-13] It has also been reported that pharmacists in many developed countries are unaware of the ADR reporting system in their own countries.[14-16] In addition to awareness among community pharmacists, the role of the SFDA is doubtful due to the lack of enforcement of regulations in community pharmacies in particular. Additionally, 20% thought that it was unnecessary to report any events associated with using OTC products. All pharmacists who participated in this study stated that the ADR reporting would help to advance medication safety but not the welfare of patients visiting community pharmacies. Close monitoring by the SFDA would enhance pharmacists' and patients' ADR reporting, thereby enhancing patient medication safety and help to identify any future drug-related threats to the community. Moreover, as a mandatory step before pharmacists issue their licenses, appropriate training for pharmacists regarding the ADR reporting system, would be an enormous step toward creating awareness among overseas pharmacists about the Saudi ADR reporting system. At the same time, pharmacy colleges should discuss this topic and include it in their curriculum to augment awareness among native pharmacists.

In terms of barriers, most of the pharmacists stated that the primary reason for not reporting the ADR cases is because they do not know the relative index (RI) ranking used to identify the top five barriers in the ADR reporting process is decreasing (RI = 0.84). Besides, the unavailability of the reporting form in their system, not linked to the Saudi Vigilance System, was found to be the second main barrier to the ADR reporting process (RI = 0.81), followed by the ADR reporting process being problematic (RI = 0.60), and reporting being time-consuming (RI = 0.59). These findings were similar to previous studies which reported logistic barriers as primary reasons for community pharmacies' low incidence of ADR reports.[8] However, our study found that the community pharmacists were enthused and confident to report ADRs and classify them to enhance

the welfare of patients. This finding is inconsistent with previous studies that have found poor clinical knowledge, lack of confidence, and fear of liability as the main barriers to ADR reporting among healthcare providers.[17]

The population-based estimate of the annual rate of ADR in Saudi Arabia population is 28%.[18] Effective ADR reporting systems in community pharmacies, frequent training, education, linking community pharmacies' system to the Saudi Vigilance System, and a compensation system would improve a spontaneous ADR reporting system among community pharmacies in Saudi Arabia.

Conclusion

More than half of community pharmacists practicing in Jeddah were unaware the Saudi Vigilance System, as an ADR reporting system in Saudi Arabia. The principal barriers to reporting were the community pharmacies' systems and a lack of adequate understanding of the ADR reporting system. Thus, establishing a user-friendly system incorporating pharmacies system with the Saudi Vigilance System will enhance the reporting process. Besides, enforcing community pharmacists to report (e.g., with regulations) and providing financial compensation will likely improve an ADR reporting in Saudi Arabia.

Conflict of Interest

The author declared that there is no conflict of interest that is related to this study and this article.

Disclosure

The author did not receive any type of commercial support either in the form of compensation or financial support for this case report. The author has no financial interest in any of the products, devices, or drugs mentioned in this article.

Ethical Approval

The study was approved by the Ethics Committee of the KAUH in Jeddah, Kingdom of Saudi Arabia, also known as the Institutional Review Board of Hospitals.

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نظام الإبلاغ عن التفاعلات الدوائية الضارة: تصورات وتوعية صيادلة المجتمع في جدة، المملكة العربية السعودية

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المستخلص. الهدف من هذه الدراسة هو تحليل وعي صيادلة المجتمع بخصوص أنظمة الإبلاغ عن التفاعلات الدوائية الضارة، وإدراك العوائق التي تواجههم في مدينة جدة، المملكة العربية السعودية. تم إجراء دراسة ميدانية بين ١ يونيو و١٥ سبتمبر ٢٠١٧م، استهدفت صيدليات المجتمع في جدة، حيث تم زيارة بما مجموعه ٢٠٢ من صيادلة المجتمع باستخدام طريقة العينات العنقودية. تم عمل الاستبيان المكون من ٣٤ بندًا ذاتياً، لمعرفة العوائق التي تواجه صيادلة المجتمع. كان معدل الاستجابة للمسح (٧١,٤٣٪). فيما يتعلق بمعرفة التفاعلات العكسية للدواء، عدد قليل جدًا (٨٪) من الصيادلة كانوا غير قادرين على التمييز بين التعريف الصحيح وغير الصحيح للتفاعلات الدوائية. ذكر حوالي (٥٦,٤ ٪) من الصيادلة عدم معرفتهم بنظام الإبلاغ عن التفاعلات الدوائية الضارة المستخدم في المملكة العربية السعودية. كان العائق الرئيسي أمام عملية الإبلاغ عن التفاعلات الدوائية الضارة هو ضعف البيئة المهنية. بالإضافة إلى ذلك، عدم سهولة توفر نماذج الإبلاغ عن التفاعلات الدوائية الضارة وعدم فهم عملية إعداد التقارير. في الختام، كان معظم صيادلة المجتمع غير مدركين لوجود نظام إبلاغ عن التفاعلات الدوائية الضارة وأهميته في المملكة العربية السعودية.

الكلمات المفتاحية: التفاعلات الدوائية الضارة، المجتمع، الصيدلية، نظام إبلاغ، الآثار الجانبية