



Original article

Public awareness and perception toward Adverse Drug Reactions reporting in Riyadh, Saudi Arabia

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ABSTRACT

Purpose: To assess the general public awareness and perception about Adverse Drug Reactions (ADRs) reporting and pharmacovigilance. **Method:** A cross-sectional study conducted on June 2012 during awareness campaign held in two malls in Riyadh city for two days. A self-administered questionnaire consisting of three parts was distributed to the attendees who accepted to participate in the study. **Results:** A total of 204 questionnaires were collected with a response rate of 68%. Twenty-three percent could correctly define ADRs. Only 13(15.7%) of responders were familiar with the term “Pharmacovigilance” and only 78.6% were aware about the Saudi Pharmacovigilance Center. Sixty-seventy percent indicated that their physicians or pharmacists don't actively encourage them to report ADRs that may occur when they take their medications. The majority of responders (73.2%) believed that the medical team, rather than consumers, should report ADRs. When asked why patients do not report ADRs, 19.1(48.5%) believed that patients do not know whether the ADR is from the medication or not, 18.1(46.1%) stated that the reason was because patients don't know about the Pharmacovigilance Center, 16(40.7%) think that patients don't know about the importance of ADRs reporting, and 14(36.3%) responded that patients probably don't know how to report ADRs. **Conclusion:** The general public in Saudi Arabia are not aware about ADRs reporting and the pharmacovigilance system. The Saudi Food and Drug Authorities (FDA) need to put more efforts to increasing public awareness about the importance of ADRs reporting process and the importance of pharmacovigilance system in promoting patient safety.

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1. Introduction

Although one of the primary objectives of pharmacovigilance was to detect, assess, understand and prevent adverse effects to safeguard the general public, and patient self-reporting of ADRs was previously an under-exploited asset. The European Directive on pharmacovigilance commended the inclusion of patient report-

ing and it has been concluded that reports from consumers have many distinguishing characteristics and benefits. They are uninfluenced by the prescriber's interpretation and provide useful information on causality; many reports explicitly mention the effects on the person's life, family, and career; they report different drugs and types of reactions in contrast to the reports of professionals; they make patients active participants, and reporting can improve health literacy (Herxheimer and Alves, 2010; Avery et al., 2011; Directive 2010/84/EU of the European Parliament and of the Council, 2010). Although many countries, such as the US, Canada, Australia, and New Zealand, have allowed patients to report ADRs directly since the conception of their pharmacovigilance schemes, there still remain several countries with deficient or non-existent methods for direct patient ADR reporting.

In Saudi Arabia, the National Pharmacovigilance Center (NPC) was established in March 2009 with “encouraging rational and safe use of drugs and the early detection of ADRs” among its primary objectives (SFDA, 2015). They have been active in promoting the reporting system via educational campaigns and distribution of materials, such as brochures. The NPC accepts reports from

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healthcare professionals, drug manufacturing companies, patients and consumers. Despite the emphasis upon mass educational efforts, in the period from 2009 to 2012, very few reports have come from the general population (Saeed, 2014). This is in stark contrast to the United States Food and Drug Administration (FDA) which was established in 1969. Since 2007, consumers have submitted more reports than physicians and pharmacists combined (FDA, 2015).

The high percentage of reports submitted by the public in the United States is the exception, not the rule. For instance, in the United Kingdom, the majority of patients are oblivious to the fact that they have the ability to report ADRs (Fortnum et al., 2012). In other countries, there may be organizational circumstances, such as the absence of sufficient resources to promote the reporting systems or handle a large volume of reports from patients, or there could be a general lack of knowledge of medication and ADRs that may deter patients from reporting (Van Hunsel et al., 2012).

In light of the suboptimal participation of the general public in the efforts of the Saudi NPC, we decided to consult with the Saudi population to determine their awareness and knowledge regarding pharmacovigilance and ADRs, and sought to obtain information that may determine the causes behind their inactivity. This is a new service offered to the public by the Saudi NPC and these questions have not previously been investigated. We developed a public survey to assess the perception of the Saudi community toward ADRs reporting and pharmacovigilance.

2. Methods

This was a cross-sectional study conducted on June 2012 for two days during awareness campaign for the public held in two shopping malls in Riyadh, Saudi Arabia. The Medication Safety Research Chair organized an awareness campaign in two malls for two days. The participants were selected randomly during the campaign and requested to participate in the study. The chosen malls are known to serve the middle and low social classes that represent the majority of the society.

The study was conducted using a validated, self-administered questionnaire adapted from similar surveys translated from the English language to the Arabic language (Belton et al., 1995; Belton, 1997; Green et al., 1999, 2001; Sweis and Wong, 2000; Backstrom et al., 2004; Vallano et al., 2005; Sullivan and Spooner, 2008; Ali, 2009; Elkalmi et al., 2009, 2011; Mahmoud et al., 2014). Pharmacy students, who supervised the campaign, received training by one of the study investigators on each section of the questionnaire. Before the participants' start filling the questionnaire, the students explained the purpose of the study and assisted them by clarifying any questions.

The questionnaire consisted of three parts to assess the knowledge and perceptions of the Saudi public about pharmacovigilance and ADRs reporting. The first part collected demographic data, the second part consisted of questions about pharmacovigilance, and the third part was related to ADRs reporting. The questions were further classified into one of the following categories: pharmacovigilance and the Saudi NPC, the definition of ADRs and their implications, personal responsibility, ADRs reporting and evaluation, and public participation and education. This study was approved by the Research Ethics Committee at the College of Pharmacy of King Saud University.

Descriptive statistics was conducted and continuous variables are represented as mean \pm SD and categorical variables as counts and percentages. Chi-Square test was performed to evaluate the influence of gender on participants' responses. If the participant did not respond to a question, this was counted as a missing and did not contribute to the percentages of the specific question. Some

questions have multiple choices and participants were able to select more than one choice if applicable. The analysis was carried out using the Statistical Package for Social Science (SPSS) version 22.

3. Results

Out of 300 surveys distributed to the public, a total of 204 (68%) questionnaires were completed. The majorities of the participants were female (63.7%) and were students, unemployed, or held positions within the governmental sector. The complete details of the participant demographics can be found in Table 1.

3.1. Pharmacovigilance and the Saudi National Pharmacovigilance Center (NPC)

The participants were asked whether they had ever heard of the term "Pharmacovigilance". Only 15.7% of responders were familiar with this terminology. When asked if they were aware of the Saudi NPC, a mere 8.6% acknowledged previous knowledge of the center (Table 2).

3.2. Adverse Drug Reactions (ADRs): Definition and implications

For the purposes of the survey, we defined an ADR as, "An unexpected and noxious reaction after taking the normal dose [of a medication]." Most participants (30.6%) selected the definition, "Any effect from a medication". Almost equal proportions of the responders selected, "The expected reaction after taking the normal dose" (26.2%) and the correct definition (25.7%). While the majority of participants believed that all ages could be harmed from ADRs (67%), 50.5% think that ADRs are "somewhat serious". Although 92.6% believed that it is important to gather any information related to ADRs, 91.3% believed that reporting ADRs are for the benefit of the community, and that the major advantage of ADRs reporting system is to increase medication safety (66.7%), and 39.1% stated that they would not report a non-serious ADR (Table 2). However, females were more motivated about the importance of gathering ADRs information ($P < 0.05$).

3.3. Personal responsibility

Close to sixty-one percent (60.7%) of the responders ask their healthcare providers about their medications' ADRs and the majority of them use their physicians (61.8%) or pharmacists (36.8%) as resources to educate themselves about ADRs; however, 70.5% indicated that their physicians or pharmacists don't actively encourage them to report any ADRs that may occur when they take their medications. In comparison with their male counterparts, a significantly higher number of female participants indicated that healthcare providers failed to direct them to report any ADRs ($P < 0.05$). If the participants decided to report an ADR, they prefer to report by

Table 1
Patients' demographic characteristics.

Variable		Frequency (%)
Gender	Male	74 (36.3)
	Female	130 (63.7)
Average age (mean \pm SD)		29 (11.5)
Job	Not working	48 (23.5)
	Retired	4 (2)
	Student	79 (38.7)
	Freelancers	6 (2.9)
	Governmental job	44 (21.6)
	Private job	19 (9.3)

Table 2
Public perception toward ADRs reporting.

Pharmacovigilance and the Saudi National Pharmacovigilance Center		Frequency (%)
Have you heard about the term Pharmacovigilance?	Yes	28 (15.1)
	No	157 (84.9)
Have you heard about the Saudi National Pharmacovigilance Center?	Yes	16 (8.6)
	No	170 (91.4)
<i>Adverse Drug Reactions: definition and implications</i>		
What does – Adverse Drug Reaction – mean?	Any effect from the medication	56 (30.6)
	Unexpected reaction after taking the normal dose	47 (25.7)
	Expected reaction after taking the normal dose	48 (26.2)
	I do not know	32 (17.5)
Which age can be harmed from Adverse Drug Reaction?	Children	34 (18.1)
	Adult	5 (2.7)
	Elderly	17 (9)
	All ages	126 (67)
	I do not know	6 (3.2)
Do you think that an ADR is harmful?	Very harmful	53 (28.1)
	Somewhat serious	95 (50.5)
	Not harmful	11 (5.8)
	I do not know	29 (15.4)
Is it important to gather any information related to ADR?	Yes	176 (92.6)
	No	14 (7.3)
If you were suffered from a non-serious ADR, would you report that?	Yes	114 (60.9)
	No	73 (39.1)
Do you think that our community will benefit from ADR reporting?	Yes	168 (91.3)
	No	16 (8.7)
Is it important to educate patients about ADR and how to report one?	Yes	172 (93.5)
	No	12 (6.5)
<i>Personal responsibility</i>		
Do you ask about your medication's ADR	Yes	116 (60.7)
	No	75 (39.3)
Which of the following resources do you use to search about an ADR? (Select any if applicable)	Asking your physician who prescribed the medication to you	126 (61.8)
	Asking the pharmacist who dispensed the medication	75 (36.8)
	From books or magazines	13 (6.4)
	From Internet	38 (18.6)
	From the leaflet that comes with the medication	11 (5.4)
Does your physician or pharmacist ask you to report any ADR that may happen to you?	Yes	56 (29.5)
	No	134 (70.5)
Which of the following ways do you prefer to report ADRs? (Select any if applicable)	By phone	113 (55.4)
	Fill a specific form and send it manually	31 (15.2)
	By using the internet	75 (36.8)
	Using an specific application on smartphones	72 (35.3)
<i>ADR reporting and evaluation</i>		
Who should be notified about any serious ADR? (Select any if applicable)	Physician	169 (82.8)
	Pharmacist	161 (79)
	Nurses	134 (65.2)
	Pharmacovigilance Center	114 (55.8)
What agency should evaluate the ADRs reports? (Select any if applicable)	World Health organization	118 (57.8)
	Pharmacovigilance center	97 (47.5)
	Ministry of Health	132 (64.7)
Who is responsible to report any possible ADR to PVC?	Medical team	131 (73.2)
	Consumers (patients)	48 (26.8)
<i>Public participation and education</i>		
How to motivate the consumers to report any ADR? (Select any if applicable)	Make the reporting processes easier	104 (50.1)
	Increase the awareness about ADR reporting system	97 (47.5)
	Make it mandatory for patients	40 (19.6)
	Provide a 7/24 phone number to receive patients calls to report any ADR	92 (45.1)
	Increase the awareness about the importance of ADR report	86 (42.1)
	Security of reporting process and only authorized employee can access it	33 (16.2)
How can we educate our community about the importance of ADR reporting? (Select any if applicable)	Pharmacist should explain to the patient the importance of reporting any ADR	124 (60.8)
	Write slogans or few words on the medication's package to show the importance of ADR reporting	73 (35.8)
	Publish any reports that received from patients in newspapers	45 (22)
	Awareness campaign	86 (42.1)
Why patients do not report ADRs? (Select any if applicable)	Does not know if it is from the medication or not	99 (48.5)
	The ADR is not serious	71 (34.8)
	Common ADR	44 (21.5)

Table 2 (continued)

Pharmacovigilance and the Saudi National Pharmacovigilance Center	Frequency (%)	
	Does not know about Pharmacovigilance center	94 (46.1)
	Does not know about the importance of ADR reporting	83 (40.7)
	Does not know how to report	74 (36.3)
	Bureaucracy of reporting process	38 (18.6)
	Does not have time to report	15 (2.9)
Which of the following resources do you use to search about an ADR? (Select any if applicable)	Asking your physician who prescribed the medication to you	126 (61.8)
	Asking the pharmacist who dispensed the medication	75 (36.8)
	From books or magazines	13 (6.4)
	From Internet	38 (18.6)
	From the leaflet that comes with the medication	11 (5.4)
What advantages the community can get from the ADR reporting system? (Select any if applicable)	Increase the medication safety	136 (66.7)
	Increase the awareness of ADR among the community	78 (38.2)
	Improve our quality life	48 (23.5)
	A solution for the low reporting issue	18 (8.8)
	Strengthening and protecting the human's rights	45 (22)

phone (55.4%), electronically (36.8%), or by using a smartphone application (35.3%).

3.4. ADRs reporting and evaluation

Participants were undecided as to which profession/organization (physicians, pharmacists, nurses, Pharmacovigilance Center) should receive ADRs reports and which agency should evaluate the reports (World Health Organization, Pharmacovigilance Center, Ministry of Health). However, the majority of responders (73.2%) believed that the medical team, rather than consumers, should report ADRs (Table 2).

3.5. Public participation and education

When asked why patients do not report ADRs, 48.5% believed that patients do not know whether the reaction is from the medication or not, 46.1% stated that the reason was because patients don't know about the Pharmacovigilance Center, 40.7% think that patients don't know about the importance of ADRs reporting, and 36.6% responded that patients probably don't know how to report ADRs (Table 2).

While the majority of responders believed that it is important to educate patients about ADRs and how to report them (93.5%), they differed in the approach toward achieving this goal. Around thirty-eight percent (60.8%) stated that the pharmacist should emphasize the importance of reporting ADRs, 42.1% recommended awareness campaigns, and 35.8% believed that statements and reminders should be placed on each patient's medication packages and containers (Table 2).

4. Discussion

The results of this study indicate that, while the public is inclined to acquire information about ADRs and realize the benefits of reporting ADRs, their understanding of their essential role in reporting ADRs is insufficient. In addition, their knowledge of the potential magnitude of harm that may occur from ADRs is deficient.

It has been reported by the United Nations Children's Fund (UNICEF) that the adult literacy rate in Saudi Arabia is 87% (UNICEF, 2015). Further, a study by Alamari and colleagues assessing the health literacy among visitors to a primary healthcare clinic in Jeddah, Saudi Arabia, concluded that 83.9% of the survey partic-

ipants were categorized as having adequate literacy (Alamari, 2010). Despite these achievements and the efforts of the Saudi NPC in promoting the ADRs reporting system, patient reporting remains discouragingly low.

The overwhelming majority of survey participants were unfamiliar with the term "pharmacovigilance". However, it was more disturbing the fact that less than 10% of the participants had ever heard of the Saudi NPC. Although the center is relatively new, there obviously needs to be a greater emphasis in promoting the center, its activities, and the importance of public participation.

Participants were somewhat confused regarding the correct definition of an ADR. They acknowledged the importance of reporting ADRs for the general safety of the community and for monitoring purposes; however, their perceptions of the potential harms of ADRs are likely related to their misunderstanding of the definition of an ADR. Likewise, the fact that many stated that they would not report a non-serious ADR also indicates a lack of knowledge regarding the purpose and desired goals of monitoring ADRs.

Participant negligence toward reporting may possibly be influenced by the relative inattention placed on reporting ADRs by healthcare professionals themselves. Although participants indicated that they proactively request information about their medications from their healthcare providers and use them as a source of reference regarding ADRs, most physicians and pharmacists do not actively encourage their patients and customers to submit ADR reports. While the vast majority of healthcare professionals acknowledge the importance of ADRs reporting, their knowledge of the reporting system in Saudi Arabia and their actual reporting of ADRs are suboptimal. Al-Hamzi and Naylor reported that 47.1% of healthcare workers were aware of ADRs reporting (Al-Hazmi, 2013); however, 59.1% were not aware of the existence of the Saudi NPC. In addition, 47.1% professionals had come across ADR within the past month, 33.2% submitted an ADR to Ministry of Health, and 21.65% submitted to one of the pharmaceutical companies. Mahmoud and colleagues reported that only 22.1% of community pharmacists were familiar with the ADR reporting process and only 13.5% had ever reported an ADR (Mahmoud et al., 2014). Bawazir conducted a similar survey among community pharmacists and found that only 13.2% had previous knowledge of the ADR reporting system in Saudi Arabia and four percent had submitted ADR reports to the Ministry of Health and 6.3% had submitted reports to one of the pharmaceutical companies (Bawazir, 2006). These studies imply that healthcare professionals should lead by example in pharmacovigilance activities and ADR reporting, especially since the majority of patients believe that the

medical team should report ADRs. In a recent qualitative study, healthcare professionals have identified several challenges to pharmacovigilance practice in Saudi Arabia. Recommendations to improve pharmacovigilance included communication, stronger regulatory role, strengthening of research to support pharmacovigilance decisions and continuous education and training (Aljadhey et al., 2015). When asked about reporting and evaluating ADRs, participants did not agree as to which profession should report ADRs or which organization should evaluate such incidents. This should not be surprising since they are unaware of the precise definition of an ADR or Pharmacovigilance. Many responders were also oblivious to the fact that the Saudi NPC existed. This indicates the importance of educating patients of what constitutes an ADR and the implications of these events and the reporting of such incidences.

Speculation behind the reasons why patients do not report ADRs closely varied among those who believed that patients do not know whether the reaction is from the medication or not, those who are unaware of the Saudi NPC, those who think that patients don't know about the importance of ADR reporting, and those that think that patients probably don't know how to report ADRs. This supports the belief of healthcare professionals that medication education is essential to the success of direct-patient ADR (Alshakka et al., 2013).

Participants in this study considered it important to educate patients about ADRs and how to report them. They offered multiple recommendations on the means of disseminating this knowledge. Some agreed that the pharmacist should take the leading role in providing this information, others recommended awareness campaigns, and a large proportion of responders insisted that statements and reminders should be a mandatory component of medication container and vial labels. Other means of disseminating this information may be to use various media outlets such as the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK (Fortnum et al., 2012). This may include commercial advertisements, instructional videos on the Web site, and other advertising campaigns.

Although females were more inclined to gather information related to ADRs, they lack information on how to report ADRs. As they reported, neither physicians nor pharmacist are educating them on how to report. This health disparity could be attributed to social differences between males and females in the country.

With 204 responders, it is difficult to generalize the results to the entire population. In addition, this was a random sample of the population; therefore, certain characteristics such as the level of education of the participants and their access to technology and medical information were not accessed. However, Riyadh includes the some of the most prestigious universities in the country. In addition, the residents of Riyadh, Jeddah, and Dammam are considered to be more educated than the rest of cities. Therefore, the results could underestimate the actual percentage of the population who lack any information about ADRs, pharmacovigilance, or the Saudi NPC.

This study highlights that the public in Saudi Arabia are not aware about ADRs and the recently implemented reporting system. Further, they are not aware of how and to whom they should report ADRs. Future intervention studies should focus on educating public about medication ADRs and how to report ADRs, and the perception of health professionals in Saudi Arabia toward patient-reported ADRs.

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