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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.

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 reporting 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 ± 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 mediations' 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 ± 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)