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ORIGINAL ARTICLE

Pharmacist's knowledge, practice and attitudes toward pharmacovigilance and adverse drug reactions reporting process

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KEYWORDS

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Abstract *Background:* Adverse drug reactions (ADRs) are a major cause of drug related morbidity and mortality. Pharmacovigilance is the science that plays an essential role in the reduction of ADRs, thus the evolution and growth of this science are critical for effective and safe clinical practice.

Objectives: This study is considered the first study in the region to evaluate pharmacist's knowledge, practice and attitudes toward ADRs reporting after establishing the national ADRs reporting center in Jordan.

Method: A cross sectional study was used to evaluate pharmacist knowledge and attitude toward ADRs reporting. A structured validated questionnaire was developed for this purpose and a total of 208 pharmacists were recruited to participate in this study.

Results: The majority of pharmacists have insufficient awareness and lack of knowledge about pharmacovigilance and ADRs reporting. Also the rate of reporting of ADRs was extremely poor. Several factors were found to discourage pharmacists from reporting ADRs, which include inadequate information available from the patient, unavailability of pharmacist ADRs form when needed, unawareness of the existence of the national ADRs reporting system. Also pharmacists think that ADRs are unimportant or they did not know how to report them.

Conclusion: The results of this study suggest that pharmacists have insufficient knowledge about the concept of pharmacovigilance and spontaneous ADRs reporting. On the other hand, pharmacists had positive attitudes toward pharmacovigilance, despite their little experience with ADRs reporting. Educational programs are needed to increase pharmacist's role in the reporting process, and thus to have a positive impact on the overall patient caring process.

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1. Introduction

Adverse drug reactions (ADRs) are a major cause of patient related morbidity and mortality (Lee and Thomas, 2007), and they are associated with a high prevalence of hospital

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admission reaching about 6.5% as well as a considerable economic burden; in which around £466 million was reported as an annual total cost for drug related admissions in the united kingdom (Pirmohamed et al., 2004). Thus reporting of ADRs is considered to be an important step in maintaining and achieving a safe drug therapy use.

Most countries developed their national pharmacovigilance systems after the thalidomide disaster in 1960s (Rawlins, 1995). World Health Organization (WHO) has established the definition of pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems" (WHO, 2002). Pharmacovigilance plays an essential role in the reduction of ADRs, thus the evolution and growth of this science are critical for effective and safe clinical practice. ADRs spontaneous reporting systems are the basic components for the comprehensive post-marketing surveillance of drug-induced risks (Stricker and Psaty, 2004). These systems are inexpensive and simple to operate and they enable the generation of signals indicating potential problems, allowing the identification of new and rare ADRs, but also enable continuous monitoring of all drugs used in real life situations from the time they are first marketed. However, their strength is tightly connected to the actual reporting rate by health care professionals (Wiholm et al., 2002).

All sectors of the healthcare system would need to be involved in the reporting process, such as public and private hospitals, general practitioners, nurses, retail dispensaries, and pharmacists. Wherever medicines are being used, there should be a readiness to observe and report unwanted adverse events (both expected and unexpected) (WHO, 2002, 2004). Pharmacists were found to have an important role in ADRs reporting, and constitute a potentially valuable source for spontaneous ADRs reports (Kaboli et al., 2006; van Grootheest et al., 2004). However, under-reporting of ADRs is a main intrinsic problem, in which reporting of serious ADRs rarely exceeds 10% (Granas et al., 2007; Su et al., 2010; Toklu and Uysal, 2008; Vessal et al., 2009). It was found that the main reasons for poor reporting rate were either due to legislative restrictions or because of lack of tradition (van Grootheest and de Jong-van den Berg, 2005; van Grootheest et al., 2004).

The Jordanian Pharmacovigilance Center (JPC) was established in January 2001 in cooperation with Sweden International Development Agency (SIDA) and the Higher Council for Science and Technology (Yadav, 2008). Since that time, no studies have assessed pharmacists' knowledge and attitudes toward ADRs reporting in the hospital and community settings in Jordan. Our study was in the unique position to study pharmacist's attitudes toward ADRs reporting after the initiation of the national ADRs reporting center and their understanding and knowledge of the yellow card spontaneous ADRs reporting scheme.

2. Methodology

2.1. Study design, settings and study subjects

This is a cross-sectional study that was conducted in two of the largest cities in Jordan; Amman and Zarqa. The study commenced in July-2012 and continued for two months. Two hundred and eight pharmacists (both community and hospital pharmacists) were included in the study with a response rate of 96.7%. Each pharmacist was asked to fill a validated structured questionnaire delivered by hand. The participated pharmacists were from independent and chain pharmacies as well as from different hospitals (public and private hospitals). Sixteen hospitals in Amman and Zarqa were covered, while the community pharmacies coverage represented about 5.2 % of the total number of pharmacies in Jordan.

2.2. Questionnaire

Content validity was assessed by distributing the questionnaire to 10 pharmacists recruited to complete the validation process. The initial draft of questionnaire was hand delivered to those pharmacists to help review the structured questionnaire and perform any amendments needed.

The final form of the questionnaire consisted of pharmacist demographic data, and a total of 20 questions that covered three main areas of interest. These areas included: (1) assessment of pharmacist knowledge regarding pharmacovigilance and ADRs reporting, (2) pharmacist's attitude and practice toward ADRs reporting process and (3) pharmacists' recommendations and suggestion to improve the drawback in the system.

2.3. Statistical analysis

Data were analyzed using statistical package for social science version 17 (SPSS, Inc., Chicago, IL, USA). The descriptive analysis was done using mean and SD for continuous variables and percentage for qualitative variables. Pearson Chi- Square was used to calculate p-values for categorical variables.

3. Results

3.1. Demographics

The demographic details of the pharmacists included in the study are shown in Table 1. The mean age of pharmacist was approximately 32 years, and the average year of experience was 7.83 years. In this study, 62.5% of pharmacists were community pharmacists while 37.5 % were hospital pharmacists. Females accounted for 63.9% of pharmacists.

3.2. Pharmacist knowledge regarding pharmacovigilance and ADR reporting

This questionnaire contained two open-ended questions in which the pharmacists were asked to define the terms 'pharmacovigilance' and 'adverse drug reaction'. Of the responding pharmacists, only 25.5 % defined 'pharmacovigilance' correctly while 69.7% defined ADR correctly. Hospital pharmacists showed better awareness of the concept of pharmacovigilance compared with the community pharmacists (p-value less than 0.05), while there is no significant difference found between the two groups for the definition of ADR. Only 8.2% had attended a workshop regarding how to report an ADR.

Most of pharmacists were not aware of the presence of legal provisions in the medicines act that provide for