



Contents lists available at ScienceDirect

Saudi Pharmaceutical Journal

journal homepage: www.sciencedirect.com



Original article

Knowledge, attitude and practices of pharmacovigilance and adverse drug reaction reporting among pharmacists working in secondary and tertiary governmental hospitals in Kuwait



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ARTICLE INFO

Article history:

Received 29 June 2016

Accepted 11 December 2016

Available online 26 December 2016

Keywords:

Pharmacovigilance
Adverse drug reactions
Pharmacists
Hospitals

ABSTRACT

Introduction: Pharmacovigilance (PV) is essential to detect and prevent adverse drug reactions (ADR) after a drug is marketed. However, ADRs are significantly underreported worldwide. **Objective:** The aims of this study were to document the knowledge, attitude and practices (KAP) of pharmacists toward PV and ADR reporting and to explore the barriers to implementing a fully functional PV program in Kuwait. **Material and methods:** Pharmacists working at governmental hospitals were asked to complete a paper-based 25-item questionnaire. **Results:** A total of 414 pharmacists received the questionnaire and 342 agreed to participate, giving a response rate of 82.6%. Most pharmacists were knowledgeable about the concepts of PV (61.5%) and ADRs (72.6%) and the majority (88.6%) was willing to implement ADR reporting in their clinical practice. Despite this positive attitude, only 26.8% of participants had previously reported an ADR and the main reason for underreporting was stated as not knowing how to report (68.9%). Barriers that hinder the implementation of a PV center included lack of cooperation and communication by healthcare professionals and patients ($n = 62$), lack of time and proper management ($n = 57$), lack of awareness of staff and patients ($n = 48$) and no qualified person to report ADRs ($n = 35$). **Conclusions:** Overall this study shows that hospital pharmacists in Kuwait had good knowledge and positive attitude toward PV and ADRs reporting. However, the majority of them have never reported ADRs. These results suggest that targeted educational interventions and a well-defined policy for ADR reporting may help increase ADR reporting and support the implementation of a fully functional independent PV center in Kuwait.

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1. Introduction

The World Health Organization (WHO) defines pharmacovigilance (PV) as “the science and activities relating to the detection,

assessment, understanding and prevention of adverse effects or any other drug-related problem”. PV aims at enhancing patient safety by assessing the risk-benefit profile of medicines (WHO, 2002a). As such, adverse drug reaction (ADR) reporting is the foundation of any PV system and the timely identification and reporting of ADRs to the regional or national drug-regulating authorities are critical. WHO defines ADRs as ‘a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function’ (WHO, 2002b). ADRs have increasingly drawn worldwide attention accounting for significant morbidity and mortality and associated with increased health costs (Pirmohamed et al., 1998, 2004). Recent estimates suggest that ADRs are the sixth leading cause of death in the United States of America (USA) (WHO, 2002b). In other developed countries such as the United Kingdom (UK), France and Sweden, they are responsible for 6.5%, 3.2% and 12%

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Peer review under responsibility of King Saud University.



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hospital admissions, respectively (Mjörndal et al., 2002; Pirmohamed et al., 2004).

On the other hand, ADRs are underreported and undisclosed in developing countries due to lack of medication monitoring and prioritization of medication safety or even lack of an ADR reporting system (Wilson et al., 2012). In South India region only, the overall incidence of the ADRs was 9.8% (Arulmani et al., 2007), while in Iran, a study documented that among 16.8% of patients, at least one had an incidence of ADRs (Gholami and Shalviri, 1999). In the Middle East region, limited data are available on the incidence and prevalence of ADRs. However, a multicenter study in Morocco showed an incidence of ADRs of 11.5 per 100 admissions in medical and surgical units (Benkirane et al., 2009). In the Kingdom of Saudi Arabia (KSA), the annual ADR reports were estimated to range from 0.07% in 1993 to 0.003% in 1999 (Al-Malaq et al., 2008).

Although ADRs data from other countries are essential to undertake medication safety decisions by a local regulatory authority and the drug manufacturer, several factors are known to influence ADRs, such as local population traditions, diets and complementary and alternative medicines (CAM) (Alshami et al., 2014). Therefore, it is crucial for every country to develop its own national PV program (WHO, 2002a). A recent survey showed that many countries in the Middle East region (e.g. KSA, Qatar, Bahrain, Oman, Yemen, Jordan, Egypt, Lebanon) are members of the WHO Programme for International Drug Monitoring; however, the existing PV programs in most of these countries are still in their infancy with limited regional collaboration (Wilbur, 2013a). Recently, important steps have been undertaken by the Kuwait Drug and Food Control (KDFC) to establish a national PV center. Although an appropriately designed online ADR reporting form is available for healthcare professionals (HCP) (KDFC, 2016), very few reports over the last two years have been received. Importantly, a functional PV center requires ongoing support from the political stakeholders for its full development and ongoing operations.

The importance of reporting ADRs cannot be understated. Studies have shown that optimizing knowledge, attitude and practices (KAP) with regard to PV is important in formulating strategies to encourage ADR reporting (Ahmad et al., 2013). In this context, there is an extensive body of literature examining KAP toward ADR reporting among pharmacists working in hospitals or community, and exploring causes of underreporting, which shows that lack of clinical knowledge and unfamiliarity of the reporting system were major discouraging factors for reporting ADRs (Sweis and Wong, 2000; Subish et al., 2008; Toklu and Uysal, 2008; Nichols et al., 2009; Vessal et al., 2009; Gavaza et al., 2010; Su et al., 2010; Elkalmi et al., 2011; Fadare et al., 2011; Palaian et al., 2011; Pérez García and Figueras, 2011; Rajesh et al., 2011; Chinenye and Michael, 2012; Ahmad et al., 2013; Irujo et al., 2013; Okeshukuwu et al., 2013; Wilbur, 2013b; Abdel-Latif and Abdel-Wahab, 2014; Afifi et al., 2014; Jose et al., 2014; Mahmoud et al., 2014; Mulatu and Worku, 2014; Varallo et al., 2014; Gupta et al., 2015; Suyagh et al., 2015). Some of these studies were conducted in the Arabic Gulf region, such as Oman, Qatar and KSA (Wilbur, 2013b; Jose et al., 2014; Mahmoud et al., 2014; Suyagh et al., 2015). However, there are no published data from Kuwait. Therefore, the objective of this study was to document KAP among pharmacists working in the government hospitals in Kuwait and to explore barriers of establishing PV activities.

2. Material and methods

A cross-sectional study was conducted among pharmacists working in the secondary and tertiary governmental hospitals in Kuwait: Al-Jahra Hospital, Al-Farwaneya Hospital, Al-Amiri

Hospital, Mubarak Al-Kabeer Hospital, Al-Adan Hospital, Al-Sabah Hospital and Al-Sabah Specialized Hospitals.¹

2.1. Sampling strategy

The sample size included the entire population of pharmacists who work in the governmental hospitals across the different Governorates in Kuwait. Preliminary fieldwork showed that there are a total of 502 pharmacists working in the secondary and tertiary hospitals. However, to ensure the study objectives were met, the following pharmacists were excluded from the study sample: pharmacists with minimal patient contact or no medication dispensing duties [e.g. those working in the total parenteral nutrition (TPN) unit, medical storage, or pharmacy laboratory ($n = 57$)]. Hence only pharmacists who manage drug distribution and dispensing on a daily basis were included in the study ($n = 445$).

2.2. Study tool

A self-administered 25-item questionnaire was used to understand pharmacists' familiarity with regard to PV and whether they were undertaking any ADR reporting practices, and to explore barriers to implementing a fully functional national PV center in Kuwait. The questionnaire consisted of questions included in previous local and international studies that examined the KAP of HCP, including pharmacists (Toklu and Uysal, 2008; Palaian et al., 2011; Rajesh et al., 2011; Chinenye and Michael, 2012; Ahmad et al., 2013; Isfahani et al., 2013; Khan, 2013; Santosh et al., 2013; Abidi et al., 2014; Jose et al., 2014; Mahmoud et al., 2014; Khan et al., 2015; Suyagh et al., 2015). The questionnaire was composed of five sections. The first section consisted of five questions to document the knowledge and awareness of PV and ADRs. The second part consisted of six questions to assess pharmacists' perception and attitude toward ADR reporting. The third part of the questionnaire had three questions, which identified practices regarding the reporting of an identified ADR. Two open-ended questions formed the fourth part of the questionnaire to investigate the barriers that exist in Kuwait toward having a PV center and any further recommendations or suggestions from the study participants. The last part of the questionnaire focused on the pharmacists' demographics. The questionnaire was distributed in English.

2.3. Validity and reliability of the study tool

The questionnaire consisted of questions that were pre-tested for reliability in previous studies (Palaian et al., 2011; Isfahani et al., 2013; Khan, 2013; Santosh et al., 2013; Khan et al., 2015). For the current study, two researchers reviewed the questionnaire and checked the questions' consistencies, clarity and relevance. Moreover, a pilot study was initially done among 10 pharmacists working in two general hospitals ($n = 5$ from Mubarak Al-Kabeer Hospital and $n = 5$ from Al-Amiri Hospital) to assess the content and face validity of the tool and whether data collection procedures were feasible or not. Slight modifications were recommended in order to clarify some of the questions without

¹ Al-Sabah Specialized Hospitals comprise 21 hospitals: Al-Razi Hospital, Kuwait Center for Mental Health, NBK Hospital, Zain Hospital, Natural Medicine & Rehabilitation Hospital, Infectious Diseases Hospital, Maternity Hospital, Chest Diseases Hospital, Pulmonary Rehabilitation Center, Ibn-Sina Hospital, Sheikhan Al-Farsi Center for rheumatic diseases, Al-Rashid Allergy Center, Islamic Medicine Center, Kuwait Cancer Control Center that include both Shaikha Badriya Al-Ahmad for oncology and stem cell transplant and Hussain Makki Juma Center for specialised surgery, Asaad Al-Hamad Dermatology Center, Khaled Al-Nafisi Center for dialysis, Center of Hamed Al-Essa for organ transplants, Al-Bahar Eye Center, Al-Babtain Center for burns and plastic surgery, and Sabah Al-Ahmad Hospital for urology.

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