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Original article

Knowledge, attitudes & practices of healthcare professionals in hospitals towards the reporting of adverse drug reactions in Saudi Arabia: A multi-centre cross sectional study

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ABSTRACT

Introduction: Adverse drug reactions (ADRs) are a major global clinical problem, causing substantial mortality and morbidity especially in hospitals. Healthcare professionals (HCPs) knowledges', attitude and practices are crucial points to evaluate the hospital safety environment. Objective of the study was to investigate the knowledge, attitudes, and practices of HCPs regarding the ADRs reporting system.
Methods: A cross-sectional survey was conducted between January and February of 2013 in nine tertiary care hospitals (governmental and private) that provide highly specialized medical services in Riyadh, Qassim, and the Eastern region of the Kingdom of Saudi Arabia. A validated questionnaire was used to assess the knowledge, attitudes, and practices of HCPs regarding the ADR reporting system. All statistical analyses were performed using SAS version 9.2.
Results: In total, 480 questionnaires were distributed, and the response rate was 70% (n = 336). Only 33% of the participants were aware of the National Pharmacovigilance Centre (NPC). Of those HCPs who were familiar with the NPC and their responsibility to report ADRs, most (50%) were pharmacists, followed by physicians (24%) and nurses (16%), and these differences were statistically significant ($p < 0.01$). Twenty-seven percent of the participants were involved in reporting ADRs; among these HCPs, 62% were pharmacists, 26% were nurses, and 6% were physicians. Most participants (95%) favoured reporting ADRs caused by antibiotics and new/old drugs. The prominent factors discouraging ADR reporting included fear that the report might be incorrect (46%) and lack of time (44%).
Conclusions: A significant lack of knowledge, positive attitudes, and practices regarding ADRs and reporting was observed in hospital HCPs. This finding represents an international concern, and urgent action is needed to promote drug safety and pharmacovigilance in this region.

1. Introduction

The World Health Organization (WHO) defines adverse drug reactions (ADRs) as "any response to a drug that is noxious and unintended and occurs at doses normally used in man for prophylaxis, diagnosis or therapy of diseases" (World Health Organization, 2016). ADRs constitute a major global clinical problem, causing substantial mortality and morbidity (Bouvy et al., 2015). ADRs are not caused by a single factor and involve several components, including factors related to the patients, drugs, healthcare professionals (HCPs), and society (Alomar, 2014).

According to an analysis of data from developed nations, the rates of in-hospital ADRs are 5.6% in the United States (US), 4.8% in Germany and 3.2% in the United Kingdom (UK) (Stausberg, 2014). The most serious ADRs lead to hospitalization, and hospital stays can lead to further ADRs. Hence, HCPs and hospitals can play a significant role in minimizing ADR-related morbidity and mortality (Bouvy et al., 2015). HCPs can play multiple roles by carefully reviewing the full patient history, particularly the drug allergy

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and drug-drug interaction history, to avoid any unwanted ADRs. In addition, reporting ADRs to the responsible office at their hospital or the regulatory authority is a pharmacovigilance approach that can be used to minimize ADRs because reporting ADRs can increase HCPs' awareness of reactions, which could result in the avoidance of particular drugs, thus reducing the harm associated with reactions to particular drugs. Additionally, reporting ADRs increases HCPs' vigilance of the effects of a drug or a drug class/group if the members of the group share the mechanism causing the ADRs. Several drugs have been withdrawn from the market as a result of HCPs reporting ADRs. In the US, a meta analyses included studies in the period between 1966 and 1996 found that ADRs are between the fourth and sixth leading causes of death, and ADRs and in 1994, fatal ADRs occurred in 6.7% and 0.32% of hospitalized patients, respectively (Lazarou et al., 1998). Moreover, in 2000, 7.5% of Canadian hospital admissions were for ADRs; of these ADRs, 36.9% were considered preventable, and 20.8% of the admitted patients died from the ADRs (Baker et al., 2004). Furthermore, hospital admissions caused by ADRs among children ranged from 0.4% to 10.3%, and 0.6% to 16.8% of children staying in hospitals suffer from ADRs (Smyth et al., 2012).

However, ADR reporting alone might not be enough to measure the overall harms from drugs because the reports might have low-quality information, and studies have shown that an incident reporting system alone might not be sufficient to detect ADRs. Nevertheless, combining pharmacovigilance tools (e.g., periodic safety update reports and data mining) is a good method for improving the detection of ADRs. Furthermore, several methods can be used to detect ADRs, and these include the reporting of ADRs by HCPs, consumers or pharmaceutical companies as recommended by the WHO. As previously mentioned, ADR reporting by HCPs has led to the detection of several ADRs and consequently to the withdrawal of these medications due to their harmful effect. Other tools, such as risk management plans, are used to detect known and unknown ADRs, prompting both HCPs and pharmaceutical companies to search for new safety signals from the medications (World Health Organization, 2017). However, understanding the knowledge and practice of HCPs regarding ADR reporting is very important for enhancing the reporting of ADRs (Alshammari et al., 2017; Vincent, 2007; Vincent et al., 2013).

The Saudi Food & Drug Authority (SFDA) established the National Pharmacovigilance Centre in 2009 primarily to enhance ADR reporting by HCPs. The SFDA allows all HCPs and consumers to submit ADR reports. Furthermore, the SFDA facilitates reporting by providing several reporting methods, such as an ADR online reporting system and allowing reports to be submitted by e-mail, fax, telephone and mail. Based on the latest available information in 2014, only 2856 reports were submitted by HCPs, which accounted for 3.7% of all ADR reports received by the SFDA because the SFDA also received reports from pharmaceutical companies (Alshammari et al., 2017). Notably, it is mandatory for pharmaceutical companies to submit ADR reports regarding their drugs to the SFDA. Reporting ADRs to the SFDA is of the utmost importance for improving patient safety in Saudi Arabia and promoting enhancement of the healthcare system's performance by healthcare professionals (HCPs) (Alshammari et al., 2015). These reports are useful because they are stored in the SFDA pharmacovigilance database and are used to detect any suspicious signals; once a signal is detected, a full safety review is conducted to assess the relationship between the drug and the suspected reaction. In addition, because the SDFA is a member of the WHO Uppsala Monitoring Centre, the SFDA is required to submit local reports. Therefore, knowledge and attitudes regarding ADR reporting are essential factors that reflect the healthcare services provided to patients. Although the National Pharmacovigilance and Drug Safety Centre (NPC) of Saudi Arabia is one of the centres supervised by the SFDA to facilitate ADR reporting through the Saudi Vigilance reporting system, no previous studies have examined the knowledge, attitudes and practices of hospital HCPs regarding ADR reporting in Saudi Arabia; therefore, there is a great need to assess and evaluate these factors.

The aim of this study was to determine the knowledge, attitudes, and practices of hospital HCPs regarding ADR reporting and compare these attributes among HCPs.

2. Methods

2.1. Study area/setting

This study was conducted between January and February of 2013 at nine tertiary care hospitals with bed capacities ranging from 300 to 1000 at each hospital. The hospitals were randomly selected using a simple ballot at certain regions in the cities where the study was conducted. The hospitals included teaching, governmental, private, and specialist hospitals that provide highly specialized medical services in three different regions of the Kingdom of Saudi Arabia, including Riyadh, Qassim, and the Eastern regions. Different regions in Saudi Arabia and different types of hospitals were selected to provide more precise results reflecting the variety and different standards of healthcare services among the regions and hospitals. This study was approved by the ethical committee of the medication safety research chair at King Saud University.

2.2. Design and study population

A cross-sectional questionnaire-based study involving physicians, pharmacists, and nurses was conducted at the hospitals. The participants were randomly selected. The questionnaires were adapted from questionnaires used in previous studies assessing the attitudes and perceptions of HCPs regarding ADR reporting in the United Kingdom and Nigeria (Bateman et al., 1992; Belton et al., 1997; Belton et al., 1995; Green et al., 2001; Oshikoya & Awobusuyi, 2009), further validation was performed, and the questionnaire was piloted with 12 healthcare professionals who have both clinical and research backgrounds. Only slight modifications to the language of the survey were performed. However, the questionnaire was amended to be suitable for hospitals in Saudi Arabia. The questionnaires consisted of four parts (A, B, C, and D). Part A contained questions related to the demographic characteristics of the HCPs, including their age, gender, years of service (practice), experience, and the nature of the services they provide. Part B addressed the HCPs' knowledge of the ADR reporting system. Part C assessed the attitudes of the HCPs towards reporting ADRs. Part D included questions pertaining to education and training related to improving ADR reporting.

The study population included HCPs, such as physicians, pharmacists, nurses, and others, who were full-time employees at hospitals and/or healthcare centres and were willing to participate in the survey.

2.3. Data collection

A self-administered questionnaire was used to assess the knowledge and attitudes regarding ADR reporting among HCPs. The questionnaire was validated by performing a pilot survey with ten randomly selected HCPs who had research expertise. The questionnaire was hand distributed to HCPs and department heads at each hospital. After three days, the hospitals were visited to collect the completed questionnaires. After ten days, another attempt to collect the questionnaires was performed. After these two

attempts, the HCPs who did not return the questionnaires were considered non-respondents. Completing the questionnaires and participation in the study were voluntary, and completed and returned questionnaires were considered as providing consent to participate.

2.4. Statistical analyses

The data were entered and coded, and descriptive statistics were calculated for all survey items. All statistical analyses were conducted using SAS version 9.2. The results are expressed as percentages and presented in graphs. In addition, the associations between the variables were determined by performing chi-square tests. A p-value < 0.05 was considered significant in all analyses.

3. Results

3.1. Demographic data

In total, 480 questionnaires were distributed during the study period, and the response rate was 70%. Of all participating HCPs, 16% were physicians, 41% were pharmacists, and 33% were nurses (Table 1), and there were more female (56%) than male participants. Most respondents (84%) were between 20 and 40 years of age. Over half of the respondents had up to five years of experience, whereas only 10% of the respondents had more than 15 years of experience.

3.2. Knowledge of the ADR reporting system

Only 34% of the participants reported that all HCPs were qualified to report ADRs. Of these participants, 48% were pharmacists, and only 18% were physicians; this difference was statistically significant (p < 0.01). Most participants believed that physicians (80%) and pharmacists (74%) were the only HCPs qualified to report ADRs.

Approximately two-thirds (67%) of the HCPs were not aware of the existence of the National Pharmacovigilance Centre (NPC), which is the department within the regulatory body (SFDA) in Saudi Arabia responsible for receiving all ADR reports. Among the HCPs (33%) who were familiar with the existence of the NPC and its responsibility to receive ADRs, 50% were pharmacists, 24% were physicians, and 16% were nurses; these differences were statistically significant (p = 0.01). Nevertheless, only 22% of those aware of the NPC had proper knowledge of the exact location of the NPC (e.g., within the SFDA). Approximately two-thirds (77%) of these HCPs were pharmacists, and the lowest percentage were nurses (8%). Most nurses and physicians thought that the NPC was located within the Ministry of Health. Although a high percentage (73%) of HCPs were aware of the ADR reporting system at their hospitals, the practice of reporting ADRs was uncommon, and only 27% of the HCPs participated in ADR reporting. Approximately two thirds (62%) of these participants were pharmacists, followed by nurses (26%) and physicians (6%).

Most HCPs (95%) stated that ADRs should be reported for both new and old marketed agents. Regarding the types of ADRs that should be reported, 75% of the respondents believed that all reactions should be reported, whereas 16% stated that only serious reactions should be reported. The physicians and pharmacists had nearly identical responses (80%) in stating that all reactions should be reported. However, the nurses (20%) believed that serious ADRs should be reported for more than one type of reaction, which was in contrast to the views of the physicians (10%) and pharmacists (15%).

ADRs associated with antibiotics were the most likely type of medication-associated ADRs (95%) to be reported by the participants, whereas ADRs associated with herbal medicines (59%) were the least likely to be reported. Furthermore, 87% of the participants stated that they would report ADRs related to vaccines (Fig. 1).

The HCPs' level of knowledge regarding the specific ADRs associated with five drugs—furosemide, isosorbide-dinitrate, enalapril, heparin, and diclofenac-sodium—was examined. Knowledge regarding specific ADRs associated with particular drugs was higher for certain medications, such as thrombocytopenia associated with heparin (59%) and GI bleeding associated with diclofenac sodium (60%), followed by jaundice associated with furosemide (54%), headaches associated with isosorbide-dinitrate (38%), and hiccups associated with enalapril (36%) (Table 2).

3.3. Attitudes towards the ADR reporting system

Regarding the HCPs' attitudes towards the ADR reporting system, many participants (64%) were motivated to report an ADR if it was a serious reaction (Fig. 2). However, the most frequent factors that prevented the reporting of ADRs were the HCP's perception that the report might be incorrect (46%) and lack of time to report ADRs (44%) (Fig. 3).

Most HCPs (86%) believed that ADR reporting is a professional obligation. Moreover, 55% of the respondents realized that even a single ADR report could make a significant contribution to the reporting system database. Forty-three percent of the participants who shared this perspective were pharmacists, followed by nurses (35%) and physicians (14%). Approximately 26% of the respondents did not know how to submit an ADR report. In total, 61% of the respondents believed that the ADR reporting form was too complex. Over half of the respondents (58%) believed that ADR reporting should be compulsory. Among these HCPs, 40% were nurses, followed by pharmacists (35%), and physicians (15%) (p = 0.01).

3.4. Education and training to improve ADR reporting

A low percentage (25%) of the respondents was trained in ADR reporting and the appropriate reporting procedure, whereas most respondents had not received training either in school or their professional settings. However, 34% of the HCPs suggested that improvements could be made in ADR reporting by increasing awareness among HCPs via symposiums and conferences that provide education and training regarding ADR reporting in medical, pharmaceutical and nursing schools and residency programs and implementing compulsory training for new HCP staff in hospitals and other health institutions.

Table 1
Demographic characteristics of the study participants (n = 336).

Characteristic	Number (N)	Percentage (%)
Age (years)		
20–40	282	84
41–61	54	16
Gender		
Male	147	44
Female	189	56
Professionals		
Physicians	55	16
Pharmacists	138	41
Nurses	110	33
Intern students	33	10
Years of experience		
Less than 1 year	60	18
1–5 years	121	36
6–10 years	77	23
11–15 years	44	13
16–20 years	20	06
More than 20 years	14	04

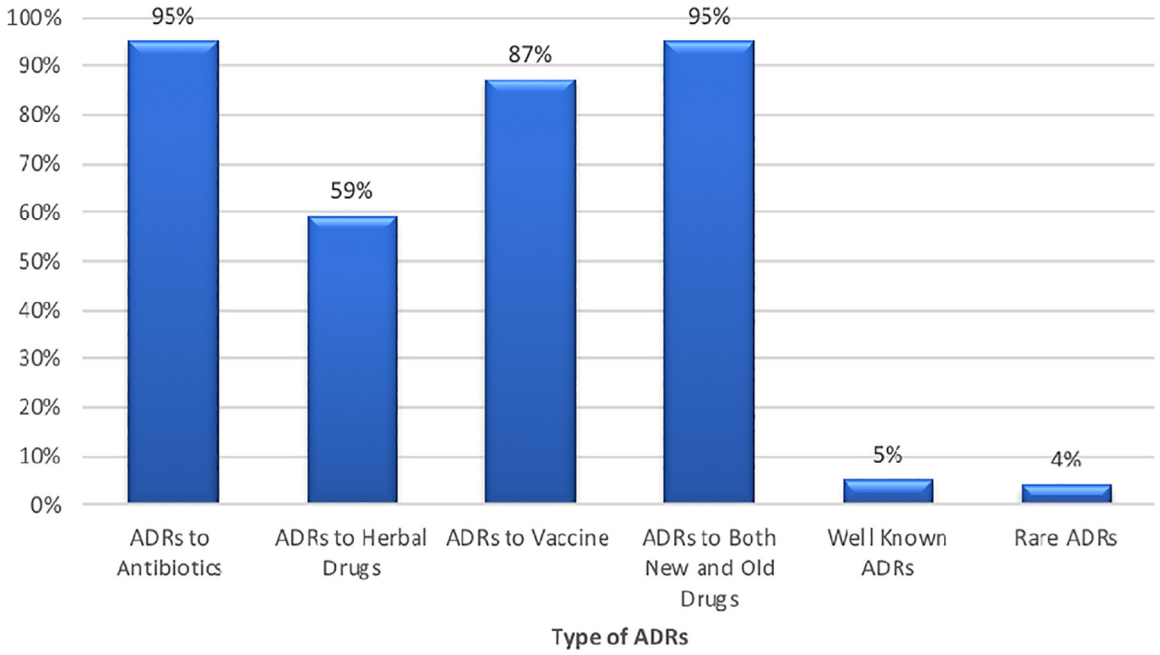

Fig. 1. Healthcare professionals' knowledge of the types of ADRs to be reported.

Table 2
Knowledge of HCPs regarding the reporting of suspected ADRs associated with furosemide, isosorbide dinitrate, enalapril, heparin and diclofenac sodium.

Suspected ADR	Yes N (%)	No N (%)	Do not know N (%)
Jaundice following the use of furosemide	182 (54)	51 (15)	103 (31)
Headache following the use of isosorbide dinitrate	128 (38)	134 (40)	74 (22)
Hiccups following the use of enalapril	121 (36)	102 (30)	113 (34)
Thrombocytopenia following the use of heparin	198 (59)	90 (27)	48 (14)
Gastrointestinal bleeding following the use of diclofenac sodium	202 (60)	90 (27)	44 (13)

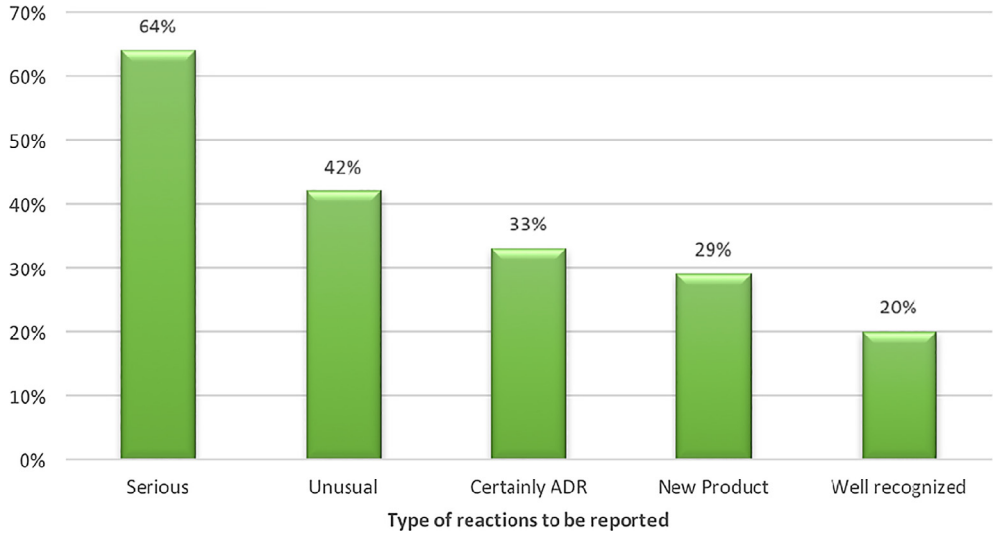

Fig. 2. Factors that motivate healthcare professional to report ADRs.

4. Discussion

ADRs are considered relevant causes of morbidity and mortality globally. Approximately 6% of hospital admissions are due to drug-related problems, and approximately 6–15% of inpatients have experienced serious ADRs (Jose and Rao, 2006). Therefore, this study aimed to investigate the knowledge and attitudes of hospital HCPs regarding ADR reporting.

In this study, the response rate (70%) was higher than that observed in similar studies performed by Khan et al. (63%), Fadare et al. (59%), Nahar et al. (34%), and Alshakka et al. (18%) in India, Nigeria, Bangladesh and Malaysia, respectively (Alshakka et al.,

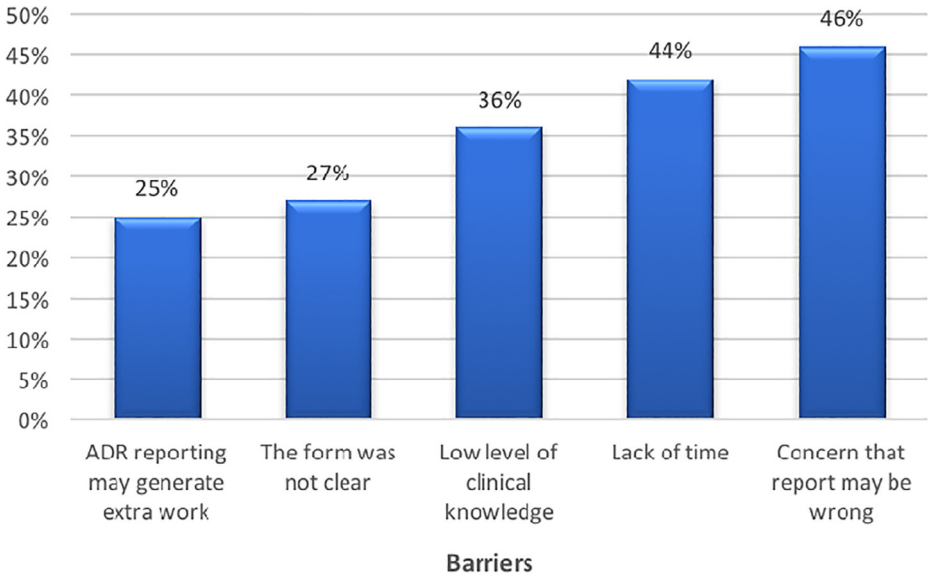

Fig. 3. Barriers that discourage healthcare professional from reporting ADRs.

2013; Fadare et al., 2011; Khan et al., 2013; Nahar et al., 2011). However, studies conducted in Nepal and Nigeria had better response rates of 74% and 82%, respectively (Oshikoya and Awobusuyi, 2009; Santosh et al., 2013). Therefore, the response rates in studies investigating ADRs are variable among different countries. Eighty-four percent of the participants were between 20 and 40 years of age, which is similar to studies conducted in other countries (Iffat et al., 2014). Therefore, young HCPs are likely more enthusiastic about ADR reporting systems. Similarly, women were found to be more interested in participating in surveys investigating drug safety issues (Iffat et al., 2014; Palaian et al., 2011).

More than half (54%) of the study participants were at the early stages of their professional careers (up to five years of experience), which might explain the limited knowledge and awareness of the ADR reporting system. However, many participants had more years of experience, and these participants had more knowledge regarding the ADR reporting system.

National pharmacovigilance centres exist in various countries worldwide, including Saudi Arabia, and these countries are also members of the WHO Uppsala Monitoring Centre in Sweden. Certain hospitals in each country have centres that are responsible for ADR reporting and recording medication errors; these centres report to the national pharmacovigilance centre, which, in turn, reports to the Uppsala Monitoring Centre (World Health Organization (WHO) & Uppsala Monitoring Centre). In our study, only one-third of the participating HCPs were aware that the NPC was the national centre to which ADRs should be reported. Furthermore, only 22% of the participants were aware that the NPC was located at the SFDA. However, this lack of knowledge is not a major concern because HCPs can report ADRs online or via e-mail, postal mail, fax or phone, and all of these routes are accepted by the NPC as reporting methods (Saudi Food and Drug Authority, 2013). These results illustrate that the participants lacked knowledge regarding a major issue that should have been known to avoid potentially jeopardizing patient safety. In contrast, Nigerian physicians have been found to have a higher level of knowledge regarding the existence of the NPC and its location in Nigeria (Oshikoya and Awobusuyi, 2009). Thus, Nigeria and Nigerian healthcare providers place more emphasis on their pharmacovigilance program. Similarly, clinicians from India (59%) and the UAE were more aware of their NPCs (Hardeep et al., 2013; John et al., 2012).

Furthermore, different healthcare professions were compared in this study, and pharmacists (77%) were found to be better informed regarding the NPC's location; most physicians and nurses thought the NPC existed within the Ministry of Health. Knowledge, awareness, and practice are interrelated but might not always be reciprocal. In our study, a quite encouraging percentage (73%) of HCPs were aware of the ADR reporting system at their workplace; however, only 27% of the HCPs were able to report ADRs. Furthermore, only 6% of the physicians indicated that they have reported ADRs. The practice of underreporting is a challenging issue, mainly in developing countries (Belton et al., 1995; Eland et al., 1999; Oshikoya and Awobusuyi, 2009). In Saudi Arabia, pharmacists were found to be in a superior position compared with physicians and nurses regarding their awareness and reporting of ADRs.

In this study, 95% of the participants responded that they would report ADR reactions for both old and newly marketed agents. This result is similar to that obtained in a study conducted by John et al., who found that 88% of participants would report ADRs for both types of agents; however, another study showed that 92% of participants would report serious reactions to newly marketed agents, and 88% would report serious reactions to older marketed agents (Bateman et al., 1992; Gavaza et al., 2011; John et al., 2012; Oshikoya and Awobusuyi, 2009). Three-fourths of the respondents believed that all reactions should be reported. This finding illustrates that HCPs have a very positive attitude towards ADR reporting, regardless of the cause and type of reaction. Nurses believed that reactions of a serious nature require more attention and should thus be reported more often than other types of reactions (Karlsson et al., 2015).

Although ADRs (in response to any drugs) are important to report, the study participants highlighted reporting certain categories of drugs, including antibiotics, new/old drugs, and vaccines. Similar results have been reported in previous studies (John et al., 2012; Ndagije, 2010; Oshikoya and Awobusuyi, 2009). This emphasis on antibiotics can be associated with the fact that antibiotics are the most widely used drugs and are a leading cause of death caused by ADRs, mainly among children (Weiss et al., 2002). Similarly, new drugs are not well studied and therefore need to be monitored closely. In addition, vaccines are gaining popularity among people to prevent the occurrence of various life threatening viral infections.

We examined the level of knowledge among HCPs regarding specific ADRs to five drugs—furosemide, isosorbide-dinitrate, enalapril, heparin, and diclofenac-sodium. The knowledge of ADRs, such as jaundice associated with furosemide (54%), headaches associated with isosorbide-dinitrate (38%), and hiccups associated with enalapril (36%), in this study was similar to that observed in a similar study conducted in Nigeria. However, our HCPs were more familiar with other ADRs, such as thrombocytopenia associated with heparin (59%) and GI bleeding associated with diclofenac-sodium (60%), than the HCPs in the Nigerian study, in which only 40% and 36%, respectively, of healthcare workers had knowledge regarding these ADRs (Oshikoya and Awobusuyi, 2009).

In this study, 64% of the HCPs were found to share the perspective that only serious drug reactions followed by unusual reactions (42%) should be reported, which is likely due to the perception that usual reactions or side effects are inevitable and acceptable, do not cause much harm, and thus do not need to be reported. However, serious and unusual reactions endanger lives and must be reported (Ekman and Bäckström, 2009).

An analysis of the factors discouraging HCPs from reporting ADRs showed that the HCPs feared that the report may be incorrect (46%), that they lacked the time to make reports (44%) and that they had an insufficient level of clinical knowledge (36%). The fear of submitting an inaccurate report as a discouraging factor is consistent with findings in Malaysian and Spanish studies (Agarwal et al., 2013; Vallano et al., 2005). Other barriers to ADR reporting in Asia include varied geographical, cultural, and medical practices in this region because some countries have good medical practice while others do not. In contrast, several advancements (e.g., establishing guidance, databases, reporting ADR via gateway, etc.) have been implemented in Western countries to improve pharmacovigilance and ADR reporting (Biswas, 2013).

Although ADRs are a well-known problem and a leading cause of morbidity and mortality in hospitals worldwide, healthcare providers, such as physicians, pharmacists, and nurses, have a variety of attitudes towards the importance of ADR reporting. Of the respondents (55%) who believed that reporting even a single ADR is worthwhile, 43% were pharmacists, followed by nurses (35%) and physicians (14%). Thus, pharmacists are in a better position to report ADRs than other HCPs. A significant percentage of respondents (86%) considered ADR reporting a duty of HCPs. However, considering the actual practice of reporting ADRs, only 58% of the HCPs favored making ADR reporting mandatory. Therefore, knowledge and awareness of ADR reporting alone is not sufficient, and an emphasis on the practical involvement of HCPs in ADR reporting is required (Su et al., 2010). Approximately three-fourths of the respondents were familiar with where to report ADRs, and approximately two-thirds (61%) of the respondents found the ADR reporting form to be too complex. The perception that the reporting form is complex might be one of the factors contributing to the low level of reporting.

In this study, only 25% of the HCPs received education and training regarding ADR reporting. This finding is consistent with the survey results reported in a similar study conducted in Ghana by Sabblah et al., who reported a training and education rate of 27% (Sabblah et al., 2014). Furthermore, training professionals with prior exposure to pharmacovigilance practices could result in better outcomes (Ahmad et al., 2013). Strengthening the regular education and training of HCPs about pharmacovigilance and ADR reporting is a very important step towards improving the safety and quality of life of patients (Alshammari et al., 2015; Sabblah et al., 2014).

The study has several limitations. The response rate is considered an acceptable rate however, approximately 30% of the HCPs did not return the questionnaire, and several returned an incomplete questionnaire (Fincham, 2008). These completion rates might affect the interpretation of the results because different conclusions might have been obtained if the missing questionnaires and/or questions were completed. Moreover, the results of this study might not be generalizable to other hospitals in Saudi Arabia because there might be differences in the practice and level of knowledge in other hospitals in other cities.

4.1. Recommendations

Based on this study, there is a need to enhance drug safety knowledge and provide ADR-related education and training. Specifically, (1) campaigns should be launched at hospitals and other health institutions to promote drug safety, pharmacovigilance and ADR reporting, (2) hands-on training and workshops on how to address ADRs and assess the events associated with medications should be provided, (3) participation in conferences and meetings about ADR reporting and pharmacovigilance should be promoted, (4) health colleges at universities should be encouraged to incorporate ADR reporting and pharmacovigilance into the curriculum, (5) collaboration between regulatory authorities and pharmaceutical companies should be increased to apply pharmacovigilance and ADR reporting regulations, and (6) medication safety officers responsible for all activities related to drug safety, including ADR reporting, should be employed at all hospitals.

5. Conclusions

Our study illustrates that hospital HCPs have minimal knowledge regarding ADR reporting and the appropriate practices. This lack of knowledge of HCPs regarding ADRs, which is supported by the previous studies discussed above, is an international concern. Therefore, there is an urgent need to promote drug safety and provide ADR-related education and training in healthcare centres with a special emphasis on training HCPs working at hospitals.

Conflicts of interest

The authors declare that they have no conflicts of interest.

Financial disclosure statement

The authors declare that they have no conflict of interests and no financial support that might affect the study.

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