Original Article

Reporting & Fate of ADEs at a Tertiary Academic Hospital setting: Cross-Sectional Study

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Abstract

Background and Objectives: Adverse Drug Events (ADEs) are a global problem for healthcare professionals. This study aimed to investigate the fate and actions that have been taken by various healthcare providers after each incident of an ADE, including medication errors (ME) or adverse drug reactions (ADR) in tertiary academic hospitals in Saudi Arabia. **Methods**: A retrospective cross-sectional study was conducted between January and September 2017. A total of 5453 events were checked manually to determine the action taken. **Results**: Out of 5453 ADE reports among the included patients, only 34 reports (0.62%) were ADR, while most of the reports were related to medication errors (99.38%). Internal medicine, general surgery, and general pediatrics (20%, 15%, and 13%, respectively) were the most errors reporting specialties. Regarding Fate, 1631 (30%) of MEs (medication errors) were omission followed by 1627 (30.8%) by adjusting the dose, 850 (15.7%) had medication restrictions, 630 (11.6%) medication discontinuation and 240 (4.4%) had no action. **Conclusions:** Most of the ADEs were related to MEs. However wrong dose, unauthorized prescription, and wrong patient were the most common conditions attributed to MEs. Informed physician, adjustments, and medication discontinuation were the most actions taken to control ME, while ADRs were by rescue therapy as an immediate action. Awareness about ADRs reporting is needed among healthcare professionals in the current settings to ensure an effective ADRs reporting process.

Keywords: Medication errors, Adverse drug reaction, reporting, Fate

Introduction

Adverse Drug Events (ADEs) are a global problem for healthcare professionals, patients, and healthcare stakeholders. It is known that ADEs are associated with an increase in morbidity, mortality, and encumbrance of illness for patients and higher costs of hospital treatment [1, 2].

Medications are essential in healthcare delivery, and when used properly, they can help in treating diseases [3-5], alleviate symptoms, and lessen patient suffering [6]. Medication errors (ME) could occur in both developed and developing countries. The rate of ME in seven developed countries was ranged from 5.2% to 8%. [7]. A study in the United States found that the rate of ADE was 138/1000 people, and 11% of them were preventable [8]. In developing countries, the rate of medication errors is varied. A systematic review found that the prescribing errors ranged from 7.1% to 90.1%, and the rate of administration errors was from 9.4 to 80% [9]. In Saudi Arabia, a study that included about four thousand patients found that there were about 1531 incidents of ADE, and only 10% of those incidents were not preventable [10].

It is known that reporting of ADEs can help in decreasing a significant number of ADE cases, as well as helping them in improving the quality of care in the health system [11, 12]. Most of the previous studies focused on under-reporting of ADEs, and factors that encourage or discourage health care providers to report errors such as professional commitment, accountability, anonymous reporting system, availability of reporting systems, inadequate time and the concept of blaming culture that might prevent them from reporting such errors [13-16]. However, no study discussed the fate of ADEs after reporting. Such a study will have a huge impact on improving the reporting system. It will help also in improving the medication-use system, reduce cost either at patient or hospital level and encourage healthcare professionals to

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report ADRs. Therefore, this cross-sectional study was designed to describe the fate and actions that have been taken by various healthcare providers after each incidence of an ADE, including medication errors or adverse drug reactions in tertiary academic hospitals in Saudi Arabia.

METHODS

Study design:

This is a retrospective cross-sectional study using data that were extracted from Datix software in an academic tertiary hospital in Riyadh, Saudi Arabia.

Data Source:

Datix software (DatixWeb 14.0.11© Datix Ltd 2016) is incident-reporting systems (IRSs) that are used to gather information about patient safety incidents and reports of ADRs. Datix is an online clinical patient safety software designed to report and manage incidents and occurrence variance report (OVR). Incident reporting cycle on Datix includes the occurrence of an incident and take immediate action by filing a Datix incident form. The incident form will then be reviewed by a manager or by a person who is in charge and will be ended by sending feedback as well as classifying and grading the incident.

Sampling Procedure

Data regarding medication errors and ADRs reports from January 2017 to the end of September 2017 were extracted from Datix software. A total of 5453 events were checked manually to determine the action taken. Variables that were extracted from the system were the gender of the reporter, medication involved in the event, time the event happened (8 AM-3:59 PM, 4 PM- 11:59 PM, 12 AM, 7:59 AM), department, type of medication error, and action taken after the error occurred.

The medications were classified into eight types as follows: antibiotics, gastrointestinal, anticoagulants, antihypertensive, vitamins & supplements, anti-inflammatory, antidiabetic, and others (electrolytes/iv fluids, lipid-lowering agents, anticonvulsants, respiratory agents, diuretics, corticosteroids, antifungals, narcotics/anxiolytics/sedatives/hypnotics, hormones, vasodilators, antipsychotics, antihistamines, antineoplastic, antidepressants, antivirals, immune suppressant, and vasopressors).

Regarding the action taken variable, four trained Pharm D interns went over all the events (5453 events) to read the description of the actions taken after the incidents occurred. Based on that, the actions were classified into six categories. These categories are physician informed, adjustment of medications dose, medication discontinuation, monitor, others (rescue therapy for ADRs), and no action.

Statistical analysis:

A descriptive analysis was carried out to describe the ADE. Percentage and count were calculated to define the type of ADEs, the severity of ADR, and the type of medication errors. Chi-square goodness of fit and fisher exact test were used as appropriate. All the analysis was calculated using Stata/SE 13 software, TX: static Corp LP.

RESULTS:

During the study period, there were 5453 ADEs reports. Only 34 reports (0.62%) were ADRs, while most of the reports were related to medication errors (99.38%). The results showed that males reported more than females (53% vs 46%). The results showed that from the 5453 reports, there were 231 reports with no action taken, three of them in ADR, and 238 in ME (p=0.173).

The results showed that the specialties reporting the most errors were internal medicine, general surgery, and general pediatrics (20%, 15%, and 13%, respectively). Regarding classification of the medications that were reported, the results showed that antibiotic made up the highest numbers of ADEs reports followed by gastrointestinal drugs (1797 (33%) and 518 (10%), respectively).

Table 1: Characteristics of medication errors and adverse drug reaction reports

Characteristics	Report Number (%)	P-value
Gender of reporter: ¥		
• **Male**	2898 (53.15%)	P<0.0001
• **Female**	2509 (46.01%)	
Type of Adverse drug events		P<0.0001
• **Adverse Drug reactions**	34 (0.62%)	
• **Medication errors**	5419 (99.38)	
Severity of Adverse drug reaction		
• **Minor**	16 (47.06%)	
• **Moderate**	16 (47.06%)	P=00.31
• **Severe**	2 (5.88%)	
Type of Medication errors		

• **Wrong dose**	1933 (35.67%)	P<0.0001
• **Unauthorized prescription**	850 (15.69%)	
• **Duplicate therapy**	468 (8.68%)	
• **Missing information**	206 (3.8%)	
• **known allergy**	148 (2.73%)	
• **Wrong route**	73 (1.35%)	
• **Others**	1741 (32.13%)	

¥: The gender of the reporter for 47 events was missing.

Medication error:

Type:

Medication errors (MEs) comprised of 5419 (99.38%) reports. About 35% of those reports were due to the wrong dose, followed by unauthorized prescription (15.69%), and duplicate therapy (8.68%). There were very few reports (less than 1%) that were reported such as wrong label, wrong rate, expired medication, and delayed dose (Table 1).

Fate:

The results showed that the most immediate action regarding mediation error was informing the physician (46%). Adjustment of the dose of medication was the second-highest immediate action (35%). The results revealed that the fate of medication error for about 11% was medication discontinue, and about 2% of immediate action was only to monitor the patients. Interestingly, there were 228 (4.21%) medication errors were reported without any immediate action was taken (Table 2).

Adverse drug reaction:

The results showed that about half of the ADRs were considered minor (47%) and moderate (47%), while severe ADRs contributed the least with a percentage of 6%. The highest immediate action taken for ADR was rescue therapy by 47% followed by discontinuing the medication and monitor the patients (23.53% and 23.53%, respectively). There were 3 ADR reported without any immediate action. Two of these three were minor and one was moderate ADR.

Table 2: Distribution of Immediate Action Taken in ADEs

Category	Informed Physician	Adjustment	Medication Discontinue	Monitor	Other	No Action	P-value
Medication Error (5419 reports)	2497	1898	630	131	35 (variety of actions)	228	P<0.0001
Adverse Drug Reaction (34 reports)	0	0	8	7	16 (rescue therapy)	3	

Discussion

Results from this study show that the majority of the ADEs were related to MEs, interestingly only 34 cases were found related to ADRs. Promisingly among the identified ADRs, only 6% of the cases were found severe. This life-threatening surveillance is yet associated with the lack of ADR reporting in the current settings. However, our study results were still better than a previous study by Shamna et al. 2014 [17] where authors found a total of 49 cases during the period of six months. Similarly, another study from Saudi Arabia by Aljadhey et al. in 2013 [18] reported 8.5 per 100 admissions of ADRs cases. Another recent study performed in Istanbul by Öztürk et al. observed a total of 65 ADRs Cases of 14,347 hospitalized patients [19]. In developed countries such as the United States of America and Canada, the authors found 4.2-30% of ADRs cases, while in Australia it was estimated 5.7-18.8% of ADRs per admissions. It was found that ADRs not only account for life threaten and also accounted for increased healthcare costs and hospital readmissions [20-22].

The presence of ADRs in the current study revealed that lack of adequate knowledge and awareness of ADR reporting among the surveyed health care professionals might be the contributing factor. Although several previous studies conducted in both the national and international levels among the gulf region reported a lack of awareness and knowledge about national ADR reporting in the health care setting [23-26].

It is evident that the reporting of ADRs were varying depending on gender and specialties [17]. In the current study, slightly greater than half of the ADRs were reported by males. This is similar to the previous study by Shamna et al. where 53.6% of the male respondents reported ADRs cases [17]. The results showed that the specialties reporting the most errors were internal medicine, general surgery, and general pediatrics (20%, 15%, and 13%, respectively), while Shamna et al. reported more ADRs from General Medicine and Pediatric departments [17].

Regarding the classification of the drugs, antibiotics made up the highest numbers of ADEs followed by gastrointestinal drugs (1797 (33%) and 518 (10%), respectively). While the previous study by Aljadhey et al., 2013 [18], reported that anticoagulants accounted for one-third of all ADEs, followed

by antibiotics and antihypertensive. Our results were comparable to a previous study by Shamna et al. [17] who reported that antibiotics such as cephalosporins (34.6%) and quinolones (30.6%) were the significant cause for the ADEs, while in our study 33% of the ADRs cases were related to antibiotics. However previous study conducted in Ethiopia among hospitalized children, reported that antimicrobials (18.9%), electrolytes, fluids (9.9%), and analgesics were the drugs that contributed to ADRs. The dosing errors, followed by the wrong drug (21.2 %), wrong time (79; 15.4 %), and deteriorated drugs were the most common MEs [27]. There present findings suggesting that the special concerns should be taken about MEs and ADRs irrespective of age. Additionally, studies reported that the correlation between the amount of medication use and incidence of ADRs [27], number of diseases and ADRs events among Individuals [28].

In the current study, high prevalence of medication errors was 5419 (99%) observed. This is comparable to previous studies by Assiri et al. (94%) [29], Koper et al. (93.5%) [30], and Mira et al. (75%) [31]. However, in UK Guthrie et al. reported a very low prevalence of medication errors (4.4%) in the form of drug interactions [32]. In our study, 35% of those MEs were mainly due to the wrong dose followed by unauthorized prescription (15.59%), and duplicate therapy (8.58%). Similar studies published around the world including Saudi Arabia reported that inappropriate prescribing was the most common type of MEs [29, 33]. Another recent systematic review aimed to estimate the nature, prevalence, and severity of medication errors in middle east countries reported administration errors ($n = 7$, 22%), 'Prescribing errors' ($n = 6$, 18%), and transcribing errors (3%) were the most common among the findings [33]. Studies also found that multiple factors responsible for medication errors including prescription mistakes, lack of knowledge, and staffing [27, 28, 33].

In this study, most of the MEs were controlled by informing physicians only, followed by adjusting the dose, frequency rate, or a combination of these. medication discontinuation was also used as an immediate action for controlling the ME. Finally, monitoring the patient was the lowest frequent method used to control MEs. The rescue therapy as an immediate action, followed by medication discontinuation and monitoring the patient were the actions considered in the case of ADRs. The findings also revealed that 4.4% of the MEs and 9% of the ADRs were neglected with improper actions to control it. This could be attributed to unawareness of the importance of reporting complete data. Studies to compare the action taken in this study are scarce. The findings suggesting that increasing the awareness and importance of medication events reporting and accuracy of reporting among health care staff and patient is necessary. Additionally, a multidisciplinary approach is highly recommended that consisted of all phases of the medication delivery process, from the physician order through the administration of the drug to the patient and clinical progress.

Conclusions:

In conclusion, most of the ADEs were related to MEs. However, the wrong dose, unauthorized prescription, and duplicate therapy were the most common conditions attributed to MEs. In addition, only 6% of the ADRs were identified as severe ADRs. The majority of the MEs were controlled by informing physicians, adjusting the dose, for ADRs rescue therapy as immediate action was taken. Awareness about ADRs reporting is needed among healthcare professionals in the current settings to ensure an effective ADRs reporting process.

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