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Establishment of a New regional Pharmacovigilance Center for South Jordan: Ten Months Experience

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ABASTACT

The Purpose of this study is to assess and evaluate the adverse drug reactions (ADRs) reports submitted to the new regional Pharmacovigilance (PV) center at Alkarak Governmental Teaching Hospital in south Jordan. ADRs forms were distributed to the hospital departments. The forms were completed and collected for assessment when suspected ADR occurred. Forty five ADRs reports were received during the first 10 months. Antibiotics and analgesics were among the most commonly drugs involved in causing ADRs. Allergic reactions and gastrointestinal symptoms were the commonest reported ADRs. According to our experience in this study, establishment of a new regional PV center increases the awareness of health care providers about PV and encourages reporting of ADRs.

Key words: Pharmacovigilance, Adverse drug reactions, Jordan.

INTRODUCTION

Pharmacovigilance (PV) is a system to monitor the safety and effectiveness of medicines. The ultimate goals of PV are to ensure the rational and safe use of medicines and to improve public health[1]. The World Health Organization (WHO) defines pharmacovigilance as '' the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems"[2]. PV is needed because the information collected during pre-marketing phase is incomplete with regard to ADRs. In addition, preclinical animal experiments are insufficient to predict safety in humans[3]. Moreover, patients recruited in clinical studies are limited in number and the duration of trials is limited[4]. Furthermore, information about rare ADRs, chronic toxicity, use in special groups such as pediatric population, elderly, pregnant women are incomplete. Therefore, PV plays a crucial role in establishing safety profile after marketing of drugs[5].

The Jordan pharmacovigilance center (JPC) was established in 2001 within the Drug Directorate/Ministry of Health in cooperation with Sweden International development Agency (SIDA)[6]. The responsibilities of JPC are to ensure the quality and safety of all marketed products, encourage health care providers to report suspected ADRs and to collect and evaluate information on pharmaceutical products in Jordan. The reporting system of ADRs is voluntary and the Yellow card is used by JPC to collect information on ADRs. All health care providers (HCPs) including physicians, dentists, pharmacists, nurses and patients and their relatives can report ADRs to JPC[7].

Countries with a long-standing experience in drug monitoring are changing their pharmacovigilance system from having one national center collecting the ADRs reports, toward a more decentralized system with establishing regional centers. Therefore, in 2002, Jordan Food and Drug Administration (JFDA) decided to set up

three regional PV centers in the north, middle and south of Jordan in order to facilitate monitoring and promote reporting of ADRs in Jordan. The PV center for south Jordan was launched officially in March 2012, and is located at Al-karak governmental teaching hospital. An ADR and drug-related problem committee was established and members of this committee included physicians, clinical pharmacists, pharmacists and nurses. The responsibilities of this committee were: to conduct lectures and workshops to increase the awareness among health care providers about PV, distribution of ADRs forms to all hospital departments, provide training to the HCPs about what, when and how to report the ADRs forms, and finally to analyze and assess the forms and provide feedback to the PV department at JFDA. In this article, our experience in setting up the first regional PV center in Jordan, results, barriers and future plans will be presented. The aims of this study were to assess and evaluate the suspected ADR reports submitted to the new PV center at Alkarak governmental hospital during 10 months period (from March to December 2012).

MATERIALAS AND METHODS

ADRs forms were distributed to all hospital departments and outpatients' clinics. The forms were completed by hospital staff when suspected ADR occurred. These forms were then collected, evaluated and analyzed.

RESULTS

Forty five ADRs reports were received from all hospital departments (Table 1). Reporting of ADRs varied within hospital departments, the gastrointestinal unit and internal medicine department recorded the highest rate of reporting (Table 2). The most common classes of drugs involved in causing the ADRs were antibiotics and analgesics (Table 3).

The most commonly drugs involved in ADRs were ceftriaxone, diclofenac, streptokinase, etoricoxib, amoxicillin and aspirin. The most common identified ADRs were allergic reactions (skin rash, fever, shortness of breath) and GI symptoms (bleeding, peptic ulcer, diarrhea, nausea, and vomiting) (Table 4).

About one third of the identified ADRs 14 (31%) was involved directly in admissions to the hospital, or prolonged the length of hospitalization or was life-threatening reaction and these reactions are classified as serious ADRs. The drugs involved in these ADRs were betamethasone, ceftriaxone, salbutamol, amoxicillin, aspirin, diclofenac, streptokinase and cefuroxime.

Regarding the frequency of identified ADRs, the majority of ADRs were common; however, rare ADRs were also identified. Examples of these ADRs are betamethasone- generalized muscle weakness, doxycycline-esophageal ulcer, and simvastatin- paresthesia.

During this study, the rate of reporting of ADRs fluctuated, the highest number of reports received during April, August and October. Regarding the profession of reporters, about 50% of ADRs were reported by nurses, 30% by physicians and 20% by pharmacists.

DISCUSSION

Since the establishment of the regional PV center at Al-karak hospital, 45 suspected ADRs reports were received during the first 10 months. These reports were received from all hospital departments and these results may indicate that the presence of PV center and dedicated staff help in establishment of PV system and stimulate the culture of reporting of ADRs among HCPs. Reporting varied in our hospital with the highest number of reports received from the GI unit. Possible explanation is that the GI unit is a referral unit for all hospitals in south region of Jordan and the majority of patients were subjected to endoscopy and all ADRs were well documented in patients' records.

According to our results, antibiotics and analgesics were the most common classes of drugs involved in causing ADRs, and allergic reactions and GI symptoms were the most commonly reported ADRs. These results are consistent with previous studies conducted in Jordan. A study by Alsbou et al showed that antibiotics and analgesics were involved in 33% and 25% of reported ADRs, respectively, and allergic reactions and GI symptoms were the most common identified ADRs[8].

Table 1: Details of ADRs reported by hospital departments

Department	Drugs	No of reports	ADRs
GI unit	Doxycycline	1	Esophageal ulcer
	Aspirin	2	Duodenal ulcer, bleeding
	Diclofenac	3	Upper GI bleeding
	Co-trimoxazole	1	Skin rash
	Ibuprofen	1	Duodenal ulcer, anemia
	Lansoprazole	1	Congestive laryngeal hypersecretion
Internal medicine	Paracetamol	1	Skin rash, fever
	Simvastatin	2	Paresthesia (perioral numbness, numbness of feet)
	Ceftriaxone	4	Fever, N & V
	Cefotaxime	1	Skin rash
	Cefuroxime	1	Tachycardia, SOB
	Iron dextran	1	SOB, tachycardia, flushing
	Metoclopramide	1	Dizziness
A & E	Betamethasone	1	Generalized muscle weakness, severe hypokalemia
	Salbutamol	1	Tachycardia, agitation, SOB
	Ranitidine	2	Skin rash, angioedema, SOB
	Fluconazole	1	Skin rash
Surgery	Ceftriaxone	1	N & V
	Metronidazole	1	N & V
	Methylcellulose	1	Corneal edema, iris inflammation
ICU	Chlorzoxazone + paracetamol	1	Skin rash, SOB, facial edema
	Pethidine	1	Tachycardia, sweating
	Streptokinase	3	Tachycardia, SOB, flushing, hypotension, vomiting
ENT	Loratidine	1	Skin rash, SOB, itching
	Desmopressin	1	Wight gain, SOB, facial edema, headache
Outpatient clinic	Ceftriaxone	1	Skin rash, redness, swelling
	Etoricoxib	1	High BP
	Erythromycin	1	Diarrhea
	Amoxicillin	1	Skin rash, fever, SOB, itching
	Tamsulosin	1	Dizziness
Pediatric	Amoxicillin + Clavulanic acid	1	Diarrhea, dehydration
	Vancomycin	1	Skin rash
Pharmacy	Gemfibrozil	1	Myalgia
	Ceftriaxone	1	seizures
	Hydroxychloroquine	1	Convulsions
	Etoricoxib	1	Facial edema
	Isotretinoin	1	Myalgia, arthralgia
	Simvastatin	1	Dizziness
Gynecology	Norethisterone	1	Jaundice

SOB: shortness of breath, N & V: nausea and vomiting

Table 2: Number of reports received from all hospital departments

GI unit	Int med	A & E	Outpatients clinic	ICU	Pharmacy	Surg	ENT	Ped	Gyn
9	8	5	5	5	5	3	2	2	1

GI: Gastrointestinal, Int med: internal medicine, A & E: accident and emergency, ICU: intensive care unit, Surg: surgery, ENT: ears-nose-throat, Ped: pediatric, Gyn: gynecology.

Table 3: Classes of drugs involved in causing ADRs

Classes of Drugs	Drugs
Antibiotics	Amoxicillin, cefotaxime, ceftriaxone, cefuroxime, co-trimoxazole, doxycycline, erythromycin, metronidazole, vancomycin
Analgesics	Aspirin, diclofenac, etoricoxib, ibuprofen, paracetamol, pethidine
Antihistamines	Loratidine, ranitidine
Antihyperlipidemics	Gemfibrozil, simvastatin
Fibrinolytics	Streptokinase
Peptic ulcer healing	Lansoprazole
Corticosteroids	Betamethasone
Adrenergic	Salbutamol, tamsulosin
Antifungals	Fluconazole
Oral contraceptives	Norethisterone
Others	Desmopressin, isotretinoin, methycellulose, metoclopramide

Table 4: The most common drugs causing ADRs

Drugs	Number of reports	ADRs
Ceftriaxone	7	Allergy (skin rash, fever, SOB), N & V
Diclofenac	3	GI bleeding, peptic ulcer
Streptokinase	3	Tachycardia, SOB, flushing, hypotension, vomiting
Etoricoxib	2	High BP
Amoxicillin	2	Allergy (skin rash, SOB, fever), itching, diarrhea
Aspirin	2	GI bleeding, peptic ulcer

SOB: shortness of breath, N & V: nausea and vomiting, BP: blood pressure

The results of a pilot study conducted at Alkarak hospital showed that antibiotics and analgesics were commonly involved in ADRs and skin rash and GI bleeding were the most frequent reactions[9].

During this study, the rate of reporting of ADRs fluctuated, with the highest number of reports received during the months of April, August and October. The possible explanation is that the educational workshops that have been held in the hospital were conducted during these months. This raises the importance of induction programs in stimulating the HCPs to report any of the suspected ADR. In addition, it appears that these induction programs should be held frequently during the year in order to keep the staff vigilant regarding reporting of ADRs.

Regarding the profession of reporters, about half of reports were submitted by nurses, 30% were reported by physicians, and pharmacists were only involved in 20% of reports. According to our

experience in this study, nurses were more welling to co-operate and spend more time in the wards with patients. In addition, they were the first to recognize any adverse effects when occurred. A study by Venulet et al. showed that 85-98 % of doctors in the UK never reported an ADR to their national authority [10]. Barry et al. reported that 25% of reports were submitted by physicians to the Canadian adverse drug reactions online database and pharmacists reported only 10%[11]. These results suggest that there is a lack of awareness regarding the importance of reporting among physicians and pharmacists, and they play an important role in prescribing and dispensing of medications, and therefore should be involved more in the process of reporting of adverse reactions.

There are several factors that play important roles in the success of establishing a new PV system. These are a full support from the hospital administration, team-working (make everyone in the hospital involved in reporting), time-resistance (creation of a new culture takes time), and finally continuity (continuous training programs for HCPs)[12].

According to our experience in this study, barriers of reporting of ADRs were lack of awareness of HCPs of the importance of reporting, low percentage of staff trained in PV, the fear that reporting may put HCPs at risk. Furthermore, some HCPs were reluctant to report ADRs because of doubts regarding the causal role of drug in causing an ADR. Therefore, HCPs should be aware that reporting of ADRs poses no risk for their profession, and dose not required a direct causal and effect relationship between the drug and the suspected ADR to be established [11].

CONCLUSION

In conclusion, establishment of regional centers facilitates the monitoring of drugs and promotes the culture of ADRs reporting and ultimately improves the health care services and patients' safety. Our future planes are to promote the concept of PV, reporting of ADRs and to conduct training to HCPs in other health care centers, community pharmacists and other hospitals in south Jordan and to have this center benchmarked throughout Jordan.

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