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Letter to Editor

Reporting Adverse Drug Reactions in a Tertiary Care Hospital in İstanbul

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Dear Editor,

The World Health Organization (WHO) defines adverse drug reactions (ADR) as "response to a drug that is noxious and unintended and occurs at doses normally used in men for prophylaxis, diagnosis or therapy of disease, or for modification of physiological function" [1]. Reactions can be caused by any therapeutic agent, such as antibiotics, analgesics, blood products, vaccines or radiographic contrast media [2]. The reaction may be a well-known side effect of the drug or an undefined new reaction. Initially, many ADRs are unpredictable; they are mostly described after the post-marketing widespread usage [2]. Age, polypharmacy and additional diseases are the main risk factors for ADRs [3]. A study by Pirmohamed et al. [4] showed that patients admitted with ADRs were significantly older than patients without ADRs (76 versus 66 years). Therefore, ADRs pose a considerable burden among hospitalized patients who are more likely to be older and taking multiple medicines. ADRs are more common than expected among hospitalized patients; they may occur in up to 16.8% of patients during hospitalization, and 16% of these reactions may be fatal [5,6].

Spontaneous ADR reporting systems are used for surveillance of drug associated risks, and in many countries, the adverse drug reporting form is the standard of care for detecting the annual rate of ADRs in inpatient or outpatient settings. Additionally, a computer software and database for case report management have been designed for monitoring ADRs at some centers in Europe [2]. Questionnaires are an inexpensive and simple method for identifying new ADRs occurring in hospitals. The adverse drug reporting form can be filled by pharmacists, hospital doctors, nurses, and other healthcare professionals. However, many physicians are not aware of this form and are not reporting ADRs. According to the results of a survey, only 26% of physicians know which ADRs to report, 36% think that reporting is too bureaucratic, 22% do not know how to report and 18% are unaware of the need to report ADRs [7]. Doctors and other healthcare professionals also declare that they do not have enough time to report ADRs [7]. Nevertheless, in recent years, an increase in the proportion of reports, filled and sent by nurses and pharmacists, has been noticed [2].

At our institutions, we systematically monitor ADRs occurred during inpatient care. The ADR reporting forms are completed by our inpatient nurses immediately after an unwanted drug reaction has been detected. These forms include patients' demographic details, culprit drug, details of the reaction and the management of ADR (Figure 1) [8]. The ADR team at our hospital, which comprises a pharmacist, an allergist, a pulmonologist, and a nurse, is responsible for collecting data from the forms and organizing educational activities for improving ADR management. The allergist arranges training activities according to the needs of the staff and the pharmacist submits data to our national pharmacovigilance data system. Two training sessions are organized each year for inpatient nurses; these trains consist of updated education about drug interactions, ADRs, allergic drug reactions, and methods for appropriately filling out the ADR reporting form. Our reporting system provides valuable information to our healthcare professionals and helps them to be aware of the factors related to ADRs and prevention strategies to reduce the occurrence of unwanted drug reactions, accurate diagnosis, and effective management of ADRs, such as adrenaline use in anaphylaxis. Our computer based data collecting system will also be available in the near future and will help improve the service we provide.

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Advers Drug Reaction Reporting Form

Date and time of onset of reaction:

Name of Patient:

KOÇ UNIVERSITY HOSPITAL

Weight (kg) _____ Height (cm) _____

Room number _____ Section: _____

Dignosis _____

Allergy history:

Describe advers drug reaction

_____

_____

_____

Past advers drug reaction history: Describe details

_____

_____

_____

Other relavant history including pre-existing medical conditions (pregnancy, hepatic/renal dysfunction etc)

Seriousness of the reaction

Mild	**Life-threatening**

Outcomes

Recovered	Recovering	Continuing
Fatal	Other (specify)	

Suspected medicine (s)

Trade Name [Generic Name if Trade Name is unknown]	Dose (mg)	Dose interval	Route	Date Started/Given
1 _____	_____	_____	_____	_____
2 _____	_____	_____	_____	_____
3 _____	_____	_____	_____	_____
4 _____	_____	_____	_____	_____
5 _____	_____	_____	_____	_____

Indications of medications

_____

_____

Dose reduced after the reaction	☐ yes	☐ no	☐ drug stopped

Concomitant medicines including self medication and herbal drugs

_____

_____

_____

	Name-Surname	**Section**
Reporter (Name of the Nurse)	_____	_____
Reporter / Name of the Doctor	_____	_____
Approved by /Name of the Pharmacist	_____	_____

Figure 1. Adverse drug reaction reporting form

Adverse drug reactions are regularly recorded at our inpatient settings using ADR reporting forms, which are filled by nurses. The rate of ADR reporting has nearly quadrupled over eight years (Figure 2). Between 2016 and 2017, ADRs were observed in 65 of 14,347 hospitalized patients. The mean age of the patients was 49.2±19.4 years; 69% of all patients were female. Four of these patients were children, whereas the others were adults. There were no ADR-related deaths.

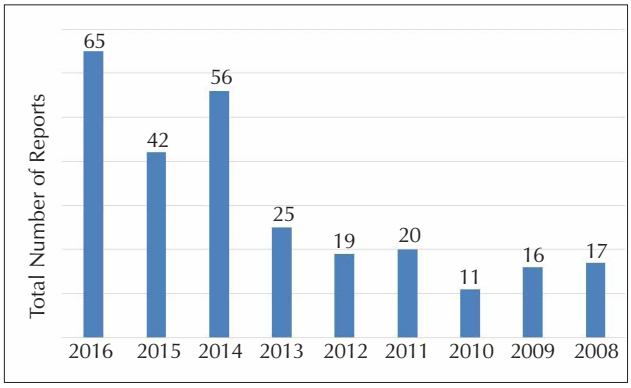

Figure 2. Total number of adverse drug reactions (ADRs) reported by inpatient nurses between 2008 and 2016

At our hospital, the ADR rate was particularly high in the elderly and patients receiving cancer treatment. The mean age of patients receiving cancer treatments was 56.1±14.6 years. Forty-seven reports were received from the adult oncology department. Seventeen of them had hematologic, 10 had urogenital, and 7 had gastrointestinal system malignancies. Eight patients had breast cancer, 3 had lung cancer, and 2 had other diseases. Nine patients had drug allergy and 2 had respiratory allergy history who reported ADRs. Chemotherapeutic and biologic administrations were mostly related to ADRs. Taxol and platinum salts were the most commonly used chemotherapeutic drugs; Rituximab was the most common among biologics. All reactions were allergic ranging from mild to severe. Five of these patients had tryptase results. After discussing the annual results of 2016–2017 at the ADR team meeting, we planned and realized two additional anaphylaxis management educations for nurses and healthcare professionals. We also discussed our results with the oncology team to provide effective management after chemotherapy and biological agent allergy, such as desensitization.

The routine use of ADR reporting forms increased the chemotherapeutic and biological drug allergy awareness at our hospital. Our inpatient nurses are now more aware of their responsibility to report ADRs and how to report them. Clinicians are now more aware of both the common occurrence of ADRs and their responsibility to manage them. We require greater use of such documentation in hospitals in Turkey. Therefore, improving reporting rates of ADRs would decrease the ADR-related mortality rates in hospitalized patients, particularly in the elderly population. This reporting system can only be successful if used more widely in hospitals. We should discover the potentials gaps for reporting ADRs in hospitals and find answers to improve the awareness of ADRs in hospital settings.

In conclusion, ADRs are common among hospitalized patients and may be severe. Older patients and the ones taking chemotherapeutic and biological drugs are more prone to ADRs. Additionally, allergic reactions occupy a significant place among all ADRs. The contribution of nurses and clinicians is essential to increase good pharmacovigilance practices. The routine use of the ADR reporting system is easy and inexpensive and may largely impact the safety and quality of patient-centered health care delivery.

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