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Original Article

Kerman Health System Workers Knowledge and Attitudes Regarding the Spontaneous Reporting System for Adverse Drug Reactions

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Abstract

Adverse drug reaction (ADR) is one of the most life threatening problems, and the economic burden of ADR is considerable. The main objective of this study was to assess the attitude of the Kerman health system staff, to evaluate their knowledge of the spontaneous reporting system and to identify the reasons for low reporting rate. In this descriptive study, a Persian translated questioner was used based on standard European pharmacovigilance research group. Among 800 distributed questionnaires, 78% were filled and returned. Returned questioner (82%) indicated to have already suspected an ADR but only 4% reported it to Iranian ADR centre. The 4 major reasons for not reporting were: a) reporting process was unknown (65%), b) Iranian pharmacovigilance centre was unknown for the staff (45%), c) the yellow cards for reporting ADR were not available (30%), and d) ADR were not important (22%). We concluded that our medical staff's knowledge about ADR is little. Appropriate teaching and acceptable effort is needed to strengthen the current system and to prevent other serious ADRs.

Key words: Adverse drug reaction; Attitude; Knowledge.
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1. Introduction

Any substance that is capable of producing a therapeutic effect can also produce unwanted adverse effects. WHO definition of adverse drug reaction (ADR) is a response to a drug that is noxious and unintended and occurs at doses normally used in man for prophylaxis, diagnosis or therapy of a disease [1]. Some ADRs are life- threatening, however, the majority subside without squeal [2]. It is reported that ADRs have been responsible for about 9% of hospital admission of patients [3]. It is estimated that 3% of hospitals mortality rates are because of ADRs [4]. ADRs occur 2 to 3 times more frequently in elderly people (ages of 60) [5]. We have to consider the indirect costs of ADRs including morbidity and mortality [6, 7]. A meta-analysis showed that 106000 deaths occurred from ADRs in US in 1994 [8]. Australia is among the countries

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Table 1. Demographic profile of the samples

Demographic parameter		*p* Value
Age (Years±SD)	33±8	$p<0.05$
Sex		
Men	370 (59%)	
Women	252 (41%)	
Experience		
≤5 Years	250 (40%)	
> 5 Years	372 (60%)	
Job title		
Specialist physician	30 (5%)	$p<0.05$
General physician	228 (37%)	
Pharmacist	135 (22%)	
Dentist	65 (10%)	
Nurse	164 (26%)	

in which ADRs are reported regularly, and about 12000 ADRs are reported each year despite its small population [9]. This reporting rate is 210000 per year for France [10]. It seems that only 5% of happened ADRs is report to the pharmacovigilance centers worldwide [6]. Clinical trial studies can not detect all of adverse drug events and post marketing surveillance studies and spontaneous reporting systems are very important for detecting ADRs [11].

In Iran, pharmacovigilance centre was established in 1997. Although the yellow card ADRs reporting system has existed for about 11 years in our country, there were no data about the attitudes and knowledge of health providers about the ADRs. Then we decided to do it and to identify the reasons for low reporting rates.

2. Materials and methods

Eight hundred questionnaires were distributed in the meetings or posted by mail to the health system staffs (general practitioners and specialist physicians, pharmacists, dentists, nurses). The questionnaire used, was based on the attitudinal survey II questionnaire of the European pharmacovigilance research group. The questionnaire sought information regarding: Demographic factors, personal history of reporting ADR, knowledge of the spontaneous reporting system, attitudes towards reporting, quantitative understanding of various frequency terms and incentive to improve reporting. The data were analyzed using SPSS version 13. 'T' test and X^{2-} tests were used. p value <0.05 were considered as significant.

3. Results

The response rate was 78% (n=622). For socio-demographic characteristics of questionnaires see Table 1.

Reports in 82% of the questionnaires indicated that the reporters have already suspected an adverse drug reaction, however, only 4% of them reported it to a pharmacoviglance center. The most important reasons for non-reporting were: a) reporting process was unknown to them (65%); b) pharmacovigilance centers were unknown to them (45%); c) ADRs reporting yellow cards were not available; d) the occurred ADRs were very well known and did not need reporting (30%); and finally ADRs are too trivial to be reported (22%).

To find out whether there are special characteristics of a suspected ADR that make a report more likely, 5 questions were presented (Table 2). Textbooks and patient information leaflets often use some terms to describe the incidence of ADRs (common, occasional, rare, very rare). The questionnaires asked to link these terms with incidence estimates

Table 2. Characteristics of a suspected ADR that make a report more likely.

Type of ADR	% of questionnaires who will report it
Serious and well-known ADR of a new drug	65%
Serious and un-known ADR of an old drug	85%
Serious and un-known ADR of a new drug	98%
Serious and well-known ADR of an old drug	30%
Non serious of an old drug	7%

Table 3. Interpretation of the official terminology for risk quantification by the questionnaires (n=620). For example 47.1% of the questionnaires think that a rare ADR occurs in 1:1000-1:10000 patients.

Very rare ADR<1:1000	Rare 1:100-1:1000	Occasional 1:10-1:100	Common ADR>1:10	Official terminology
Health staff incidence estimate				
0	0	12.3	35.1	ADR>1:10
0.8	5.3	16.1	30	1:10-1:100
4.3	23.4	29.8	11	1:100-1:1000
31	47.1	4.6	0	1:1000-1:10000
43	11.1	1.8	0	ADR<1:1000
20.9	13.1	35.4	23.9	Missing

(Table 3).

The final part of the questionnaire looked for starting to increase detected ADRs. For method of reporting, 91% of people choose phone, 3% fax, 4.3% e-mail and 12% said that mail is the best way for reporting ADRs.

4. Discussion

Countries with best ADR reporting rate have 200 reports per 1000000 inhabitants per year and for Iran, we must have about 14000 reported ADRs each year. But Iranian pharmacovigilance center received only 16000 reports over 11 years [12, 13]. Therefore, we still have to do a lot of work to improve under reporting rates.

In Germany, 68% of the physician indicated to have already suspected an adverse drug event without reporting it. The 3 major reasons for not reporting were: a) ADRs are already well known (75%); b) ADRs are too trival to report (71%); and c) uncertainly concerning definite causality (66%) [14]. We found that, 82% of our medical staff have already suspected an ADR without reporting it, however, this rate was 68% for German physicians. The most important causes of low reporting rates in Iran were: a) unknown reporting process; and b) unknown pharmacovigilance center.

As in other studies [15, 16], the possibility to report adverse drug events by phone was mentioned by many of our health staff.

We concluded that despite improvement of ADR reporting systems in Iran, we still have to do lots of works to improve ADR reporting rate in Iran. For example medical staff must be informed about spontaneous reporting system. Yellow cards must be distributed in medical offices, drugstores, hospitals and any other health provider system. Performing workshops with continues medical education score will increase motivation for better learning about ADRs. Unfortunately, pharmacology courses for medical students in Iran are basic and we need to teach also clinical pharmacology. General and clinical pharmacists can have important roles for detection, prevention and reporting ADRs specifically at hospitals for improving pharmacotherapy.

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