

Physicians' knowledge about pharmacovigilance in Iraq

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Abstract

Background: Pharmacovigilance plays an essential role in the reduction of adverse drugs reaction (ADRs), thus the evolution and growth of this science are critical for effective and safe clinical practice.

Aim: This study will evaluate doctors' attitudes, barriers and factors encouraging toward ADRs reporting.

Methods: A cross-sectional prospective study has been conducted. It was a psychometric evaluation assessment using a previously modified questionnaire.

Results: The majority of the surveyed doctors (78%) believed that reporting adverse drug reactions (ADRs) is part of their duty, and monitoring drug safety is also important (96%). The study findings revealed that about 68% of the doctors felt that they did not have sufficient clinical knowledge to detect ADRs. Nearly two-third of the doctor's agreed that they are not convinced that the ADRs are caused by the drug. This study show that an association between doctors knowledge about ADRs detection and the number of patient seen by day, as the number of patient increased the doctors knowledge about ADRs improved.

Recommendations: Special and direct educational programs, along with continued promotion, could help to enhance the involvement of physicians in ADR reporting and pharmacovigilance activities and help to reduce misconceptions and other logistic barriers to ADR reporting. Further studies with large populations are needed for a better understanding of the actual deterrents which prevent private clinic doctors from reporting ADRs.

Keywords: Pharmacovigilance; Iraq; Physician; Attitude; Knowledge; Barriers; ADRs

Introduction

Adverse drug reactions (ADRs) are a major cause of patient related morbidity and mortality [1], and they are associated with a high prevalence of hospital admission reaching about 6.5% as well as a considerable economic burden; in which around £466 million was reported as an annual total cost for drug related admissions in the United Kingdom [2]. Thus reporting of ADRs is considered to be an important step in maintaining and achieving a safe drug therapy use. Most countries developed their national pharmacovigilance systems after the thalidomide disaster in 1960s [3].

The World Health Organization (WHO) has established the definition of pharmacovigilance as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems” [4]. Pharmacovigilance plays an essential role in the reduction of ADRs, thus the evolution and growth of this science are critical for effective and safe clinical practice.

However, their strength is tightly connected to the actual reporting rate by health care professionals [5]. All sectors of the healthcare system would need to be involved in the reporting process, such as public and private hospitals, general practitioners, nurses, retail dispensaries, and pharmacists. In the general use of medicine, practitioners should take the responsibility to have adequate knowledge and to report unwanted adverse events (both expected and unexpected) [6].

Doctors were found to have an important role in ADRs detection, and constitute a potentially valuable source for spontaneous ADRs reports [7]. However, sometimes the spontaneous reporting system may experience several hinders resulting in under-reporting of ADRs. The low reporting rate of ADRs is a main intrinsic problem.

In a big step forward, on 3rd November 2010, Iraq became the 102nd country to become a full member of the WHO Program for International Drug Monitoring, after fulfilling all the required conditions [8]. Since that time, no studies have assessed doctor's knowledge and attitudes toward ADRs reporting at the hospital and community settings in Iraq. Our study was in the unique position to study doctors' attitudes, barriers and factors encouraging toward ADRs reporting after the initiation of the national ADRs reporting center.

Methods

A cross-sectional prospective study has been conducted. It was a psychometric evaluation assessment using a previously modified and developed questionnaire [9-13]. The researchers have done some amendments on the mentioned tool to fit the actual physician practice in private out-patient clinics in Baghdad. The questionnaire examined the attitudes, perception, and barriers to ADR reporting among health-care professionals. Cluster sampling method was conducted in this study, the investigators have targeted private clinics in several districts in Baghdad with different socioeconomic levels including (Harithiya, Birut square, Sader city, Adamiya, and Nafaq shurta). The final

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Received: June 13, 2016; Accepted: June 20, 2016; Published: June 28, 2016

Citation: Muhannad RMS, Arwa YA, Omer QBA, Ramadan ME, Kurmanji JM (2016) Psychometric Evaluation of Physician toward Pharmacovigilance Practice in Iraq. J Pharmacovigilance 4: 214. doi:10.4172/2329-6887.1000214

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questionnaire was 6 pages in length classified into the following areas: the first part consisted of 15 items, which covered the demographic characteristics of the respondents. It does include general questions to verify the extent of the doctors' knowledge about the Iraqi ADR reporting system and the doctors' behavior. The second part comprises of 14 items exploring the doctors' attitude to ADRs reporting. It is looking at the factors that either positively or negatively affected the doctors' attitude. These items were constructed as a series of statements and the doctors were asked to indicate their agreement or disagreement using a 5-point Likert scale format (1="strongly agree," 2="agree," 3 = "neutral," 4 = "disagree," and 5 = "strongly disagree).

The third part of the survey contained 15 items, which explored the barriers to report an ADR. These questions also used a 5-point Likert scale. The fourth part of the questionnaire consisted of 7 items, which aimed to identify the factors that might encourage and motivate doctors to report ADRs. Similar to the above stated parts, these items were also framed in a 5-point Likert rating scale.

Results

Respondent's characteristics

Over the study period (two months; February and March 2016), the surveyed questionnaire were delivered to 120 out-patient clinics, only 70 doctors filled the questionnaire. However, 20 forms were neglected for missing data. Therefore, merely 50 questionnaires were considered for this investigation with a useful response rate of 41%. Males accounted for 78% (39) of respondents. More than one-third of surveyed doctors don't hold any post-graduate degree. Nearly two-third of the doctors considers the British National Formulary (BNF) as the main source of drug information.

A considerable proportion of the respondents (11; 22%) claimed that they know what the term "pharmacovigilance" is stand for. Nevertheless, around 81% (9) of them were unable to give a correct definition (Table 1).

Attitude and behaviors

78% of doctors believed that reporting adverse drug reactions (ADRs) is part of their duty, and monitoring drug safety is also important 96% (48).

More than 90% of the physicians think that they should only report ADRs leading to hospitalizations, life threatening conditions, congenital abnormalities, persistent disability or incapacity.

A large percentage (92%) of the respondents reflects that it's important to discuss ADRs with the pharmacist and/or an academician trained in this field (Table 2).

Barriers to ADRs reporting

Around three-quarter of the respondents stated that the unavailability of the reporting form and the unawareness of the address where the reporting form should be sent are reasons for under-reporting.

The study findings revealed that about 68% of the doctors felt that they did not have sufficient clinical knowledge to detect ADRs. Nearly two-third of the doctor's agreed that they are not convinced that the ADRs are caused by the drug (Table 3).

This study show that an association between doctors knowledge about ADRs detection and the number of patient seen by day, as the number of patient increased the doctors knowledge about ADRs improved (Table 4).

Sociodemographic	N	%
Gender		
Male	39	78
Female	11	22
Age		
31 – 40	13	26
41 – 50	20	40
≥ 51	17	34
Post-graduate		
Yes	38	76
No	12	24
Length of practice		
0-10	14	28
11-20	19	38
21-30	11	22
31-40	5	10
40<	1	2
No. patients per days		
0-10	26	52
11-20	19	38
20<	5	9
No. participations in scientific events per year		
None	2	4
1-3 per year	34	68
4-7 per year	7	14
>7 per year	7	14
No. of ADR reported in the last year		
Never	43	86
One	1	2
Two	3	6
Three	3	6
University of graduation		
University of Baghdad	21	42
Al-Mustansiriya University	14	28
University of Mosul	6	12
University of Tikrit	2	4
University of Anbar	2	4
University of Basrah	4	8
Al-Nahrain University	1	2

Table 1: Physician's characteristics (N=50).

Factors encouraging reporting of ADRs

Only 28% of the doctors disagreed that receiving incentives would encourage them to report. Approximately three-quarter (74%) of respondents indicated that receiving feedback from the relevant authorities would be an important factor, which would motivate them to report ADRs.

More two-third (70%) of them claimed that simplifying the ADR reporting process would be a great encouragement to actively participate in ADR reporting. (44%) of physician think that they would report if there is an obligation to do so. Seeing their colleagues doing so would encourage them to report (42%) of them agreed. The doctors think Publication such as in the medical journal will give them more attention about pharmacovigilance system (66%)

Discussion

Underreporting of ADRs is a major threat to the success of pharmacovigilance program. Various factors have been found to be responsible for underreporting of ADRs by doctors. These factors are

	Survey Question	Responses n (%)				
		Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1.	Reporting of ADRs is part of a doctor duty.	8 (16)	31 (62)	6 (13)	4(8)	1 (2)
2.	I believe that monitoring drug safety is important.	24 (48)	24 (48)	2 (4)	0	0
3.	It is necessary to be confirmed that an ADR is related to a particular drug before reporting.	9 (18)	31 (62)	6 (12)	4 (8)	0
4.	It is not necessary to report those ADRs which are related to OTC products dispensed in my pharmacy	1 (2)	8 (16)	12 (24)	23 (46)	6 (12)
5.	It is important to report ADRs leading to hospitalization.	23 (46)	22 (44)	3 (6)	2 (4)	0
6.	It is important to report ADRs leading to a life threatening situation.	32 (64)	17 (34)	0	1 (2)	0
7.	It is important to report ADRs leading to congenital abnormality	35 (70)	14 (28)	0	1 (2)	0
8.	It is important to report ADRs leading to persistence disability or in capacity.	31 (62)	3 (6)	3 (6)	1 (2)	0
9.	It is important to report ADRs in order to answer the questions that may arise in my practice.	14 (28)	27 (54)	6 (12)	3 (6)	0
10.	Reporting of ADRs is important to show patients that their concerns are taken seriously.	9 (18)	31 (62)	7 (14)	2 (4)	1 (2)
11.	I feel annual reports issued by MADRAC concerning monitoring and reporting of ADRs are useful.	4 (8)	27 (54)	13 (26)	4 (8)	2 (4)
12.	Consulting the physician is important before reporting an ADR.	5 (10)	38 (76)	5 (10)	1 (2)	1 (2)
13.	Moving the responsibility of Pharmacovigilance scheme to pharmaceutical industry o academy will improve ADRs reporting.	6 (12)	22 (44)	12 (24)	7 (14)	3 (6)
14.	It is important to discuss ADRs with a physician and/or an academicians trained in this field	8 (16)	38 (76)	1 (2)	2 (4)	1 (2)

Table 2: Respond of Attitudes toward ADRs reporting.

	Survey Question	Responses n (%)				
		Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1.	Reporting forms are not available.	31 (62)	8 (16)	5 (10)	2 (4)	4 (8)
2.	I do not know the address where these reports should be sent.	28 (56)	8 (16)	3 (6)	2 (4)	9 (18)
3.	The reporting form is too complicated to be filled.	13 (26)	5 (10)	13 (26)	4 (8)	15 (30)
4.	Reporting is time-consuming.	14 (28)	5 (10)	6 (12)	8 (16)	17 (34)
5.	All serious ADRs are detected before registration.	13 (26)	6 (12)	11 (22)	5 (10)	15 (30)
6.	I do not report ADRs because I want to publish the case by myself.	4 (8)	1 (2)	5 (10)	12 (24)	28 (56)
7.	I am not convinced about the confidential handling of the report.	9 (18)	3 (6)	10 (20)	8 (16)	20 (40)
8.	I fear to harm the confidence of my patients.	1 (2)	11 (22)	10 (20)	10 (20)	18 (36)
9.	I find it difficult to admit that the patient has been harmed.	8 (16)	2 (4)	7 (14)	10 (20)	23 (46)
10.	I fear legal liability of the reported ADR.	13 (26)	3 (6)	8 (16)	6 (12)	20 (40)
11.	I am not motivated to report.	9 (18)	7 (14)	6 (12)	6 (12)	22 (44)
12.	I have insufficient clinical knowledge in detecting ADRs.	4 (8)	4 (8)	8 (16)	7 (14)	27 (54)
13.	I do not know how to report an ADR.	11 (22)	5 (10)	7 (14)	6 (12)	21 (42)
14.	Decentralization of Pharmacovigilance center (i.e. multiple centers) would increase the rate and quality of reports among the retail pharmacists.	20 (40)	6 (12)	14 (28)	5 (10)	5 (10)
15.	I am not convinced that the ADR is caused by the drug.	4 (8)	6 (12)	10 (20)	30 (60)	30 (60)

Table 3: Barrier to ADRs reporting.

Variables	Physician's n (%)			P
	≤10 patient/day	11-21 patient/day	>20 patient/day	
	26 (52)	19 (38)	5 (10)	
I have insufficient clinical knowledge in detecting ADR				
Disagree	13 (50)	17 (89.5)	4 (80)	0.020
Neutral	8 (30.8)	0 (0.0)	0 (0.0)	
Agree	5 (19.2)	2 (10.5)	1(20)	

Table 4: Association between the number of patients seen by the respondent physicians and some barriers to report adverse drug reaction (N = 50).

mainly related with the barriers and attitudes [14]. Very few studies have been conducted to find out these factors in Iraqi doctors. Therefore, the present study was performed to investigate the knowledge and attitudes of doctors to ADR reporting in outpatient clinics. The results reflect upon the lack of awareness of participant doctors about the existence of ADR reporting system, which would ultimately affect the reporting. Similar observations were also reported in other studies [15,16]. The deficits in the spontaneous reporting system can be meaningfully reduced if the doctors are aware of the importance of reporting ADRs. Although majority of the doctors felt that ADR reporting is a professional obligation, they are more motivated to report serious

ADRs [15]. Personal discussions and awareness programs will help to remove misconceptions and modify the attitudes of doctors, whereby ADR reporting is perceived as an integral part of clinical practice.

There was an obvious underestimation for the magnitude of ADRs related to OTC products among the Iraqi physicians. Indeed, the pharmacovigilance concepts encourage the reporting of all suspected, even non-serious and common ADRs related to all type of medicines including OTC products [17].

Marketing approval is given to a product after phase III clinical trial. Many times, serious and unusual ADRs are not identified during phase III trial, but are detected later on when the drug is available for use to general population. Inability of the respondents to identify the serious risk of newly marketed drug is an alarming situation and needs to be addressed urgently. As the Iraqi market is flooded with the arrival of newer and newer drugs, delayed detection of serious ADR may prove to be disastrous to the patients and the society at large. The findings of our study are indicative of the inadequate risk for newly marketed drugs as well as OTC products. Probably, this may be attributed to the absence of pharmacovigilance papers in the undergraduate curriculum for medical school in Iraq. Thirty eight percent of the doctors think that ADRs reporting is time consuming process. This may negatively affect the reporting rate among Iraqi doctors. Fearing legal liability and financial incentives had a little influence on the respondents. These findings suggest that underreporting of ADRs is related to obvious gaps in knowledge and negative perception, which is also pointed out in other studies [17-19]. Interestingly, fear is a discouraging factor for majority of the doctors to report an ADR.

Ignorance of the address where the ADR report should be sent and unavailability of the reporting form were nominated as the most significant barriers prevent doctors from reporting ADRs. These indicators should push the regulatory authorities into action to make their addresses identified as well as to enhance the availability of the form. The inability to define the concept of pharmacovigilance among the vast majority of respondents might be attributed to a lack of proper exposure during the earlier stages of their undergraduate medical education and the likelihood of poor publicity of the concept among the respondents by the relevant authorities.

Although a substantial number of the respondents considered decentralization of the pharmacovigilance center as a significant facilitator of the ADR reporting process. These findings should be interpreted with caution as almost all of the respondents were unfamiliar with existing pharmacovigilance systems in the country. The literature reported that the decentralization of the pharmacovigilance system has been adopted in some developed countries [20,21] A previous study carried out by Eland et al in 1999 showed that the number of reports from healthcare professionals increased by approximately 75% after the decentralization of the reporting system [21].

Conclusion

The study has generated important data about the characteristics, attitudes, barrier and factors of doctors in Iraq, which could be useful to further support the development and successful implementation of strategies to improve the involvement in private clinic doctors in ADR reporting activities. As the study findings demonstrate, Continuous medical Education is one of the possible and successful ways to motivate and encourage doctors to be involved in ADR reporting and pharmacovigilance activities. Special and direct educational

programs, along with continued promotion, could help to enhance the involvement of physicians in ADR reporting and pharmacovigilance activities and help to reduce misconceptions and other logistic barriers to ADR reporting. Further studies with large populations are needed for a better understanding of the actual deterrents which prevent private clinic doctors from reporting ADRs.

Recommendation

In order to enhance the pharmacovigilance responsiveness and simplify the reporting process, we recommend making awareness conference for the doctors, that supported by the Iraqi pharmacovigilance center and ministry of health. Improve the reporting process by simplify the delivering of the forms to the doctors and extracting the form from them by special representatives or more easy by email, mobile number and mobile application. Expansion in social media is important to reach the maximum possible number, unfortunately the Facebook page of IPHC we found was ignored and lack updating for a long time ago.

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