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RESEARCH ARTICLE

Healthcare personnel's experience of reporting adverse drug reactions in Baghdad city: cross-sectional study

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Abstract

Background Adverse drug reactions (ADRs) are undesirable effects to drugs at doses normally used in the clinical setting for diagnosis, treatment or prophylaxis of diseases. Spontaneous ADR reporting is currently considered as a critical part of ADRs detection. *Objective* The study aims to assess the knowledge, attitude, and practice of healthcare providers towards adverse drug reaction reporting in public and private settings within the Baghdad area. *Method* We follow a quantitative cross-sectional study design, using a self-administered questionnaire to collect data from the healthcare providers regarding their reporting practice. *Main outcome* The outcome measures include the experiences of reporting of adverse drug reactions and the available systems, in addition to the expected benefits to clinical practice. *Results* Among 485 respondents, 114 were able to differentiate ADRs from side effects. About half of them (47.6%) recognized the availability of reporting systems and 43.3% knew how to report adverse drug reactions. 43.7% of the respondents mentioned that ADRs should be reported only when they are life-threatening. Among the 188 respondents who encountered ADRs, 145 reported the events to the accessible local authority. *Conclusion* The healthcare providers working in Baghdad healthcare institutions have a good attitude toward ADR reporting. There is a relatively below-standard reporting culture of the encountered adverse reactions. The inadequate knowledge about adverse reactions and the unavailability of reporting forms played a major role in discouraging healthcare professionals to detect and report ADRs.

Keywords ADRs reporting · Adverse drug reaction · Healthcare providers · Iraq · Pharmacovigilance

Impact on practice

- Providing reporting forms for adverse drug reactions in Iraq would stimulate adequate reporting of adverse drug reactions by healthcare professionals.
- Education of the Iraqi healthcare providers about the vital role of adverse drug reaction (ADR) reporting practice should be enhanced.

Introduction

Adverse drug reactions (ADRs) can be defined as unintended and noxious effects to health products, which occur at normally used drug doses in human beings during clinical practice [1]. They are considered as a global problem, of major concern both to the community and the healthcare system [2, 3]. The practice of ADRs reporting, also known as the pharmacovigilance, can be described as the principles and practices of the detection, evaluation, interpretation, and prevention of any expected drug use-related problems [4]. It has been reported that ADRs predispose to significant morbidity and mortality within many healthcare providing systems; they were associated with up to 6.5% of

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hospital admissions in the UK healthcare system and may be the cause behind up to 5600 hospital admissions annually [5]. Additionally, around 70% of the reported ADRs can be avoided with proper reporting and management, especially if one recognizes that around 17% of the registered cases were attributed to drug–drug interactions [6, 7]. Various types of surveillance systems were adopted to predict the suspected ADRs, including the voluntary reporting systems, record linkage schemes, and electronic local or international databases [8]. Although the role of voluntary reporting systems is critical in this regard, the narrow spectrum of reports represents one of its limitations, where < 10% of all serious ADRs were detected [9]. This may be attributed to the uncertainty that the reported ADR was exactly drug-related or considered not important to be reported, in addition to the inadequate knowledge on how and when to report an ADR [10]. Because the clinical trials rarely detected the uncommon ADRs [11], the role of the healthcare providers is still best placed to detect ADRs at the time of approval and thereafter [12]. The knowledge of the healthcare providers about ADRs reporting systems, their clinical skills, and attitude to detect and report an ADR represent the principal determinants of the ADR reporting practice. Highlighting the level of ADR reporting skills among Iraqi healthcare providers and the associated problems, and targeting their causes can help the healthcare system authority to improve awareness of ADRs reporting in Iraq; in addition to adopting practical ways for ADRs reporting to become a routine part of the professional obligation.

Aim of the study

The present study aims to evaluate the knowledge, attitude, and practice of ADRs reporting among the Iraqi healthcare providers in different healthcare settings in Baghdad city.

Ethics approval

Ethical approval was obtained from the local Research Ethics Committee for Medical Studies, Faculty of Pharmacy, Al-Rafidain University College (AEC Reference Number: 6/2166). All the enrolled healthcare providers gave verbal consent before participation in the study.

Methods

Study design and setting

This cross-sectional study was conducted in the Baghdad governorate area during the period from August 2017 to October 2018. A questionnaire-based survey was conducted which involves 550 healthcare providers (physicians, dentists, and pharmacists) working in both private and public healthcare institutions (hospitals, daily clinics, and pharmacies). The sample size was selected by non-probability convenience sampling approach and was calculated utilizing the proportional formula of OpenEpi at the confidence interval of 95% [13]. A validated structured questionnaire was delivered to each healthcare provider personally and filed after a short briefing about the content details.

Questionnaire design

Many published data regarding the knowledge, attitude, and practice of ADR reporting in various communities around the world were evaluated. Different structured surveys related to the subject around the world were also evaluated before designing the initial draft of the questionnaire [14, 15]. The questionnaire was prepared in the English language since all the participants were fluent in the English language. Validation of the questionnaire was performed by pretest the questionnaire with 50 healthcare providers and the Cronbach alpha was calculated to be 0.85 [16]. After a pilot-scale test, the survey form was distributed to the participants who accept enrolment in the study. The questionnaire includes demographic information such as age, gender, profession type and specialty whether a person is a physician, dentist or pharmacist. Additionally, the survey includes questions utilized to evaluate the knowledge of respondents related to medication-induced ADRs and their experience of ADRs reporting in the healthcare setting.

Data collection and statistical analysis

Survey of various healthcare institutions was carried out; the healthcare providers were interviewed directly in their working site and the questionnaires were distributed to them after explaining the objectives of the study. Among the 550 interviewed healthcare providers who received the questionnaires, only 485 of them returned the completely filled forms which are within the accepted sample size range. Any required clarification to understand the questionnaire contents was provided by the researcher. The healthcare providers who were agreed to participate in the study were asked to fill the questionnaire in 60 min. The data were analyzed using the statistical package for social sciences (SPSS) version 16 and GraphPad Prism software (version 5.1). Results are presented as mean ± SD for quantitative variables, and numbers with percentages or graphic presentations for categorical variables. The relationship between the position of the respondents and their general knowledge of ADRs or their in-depth knowledge of the illustrated hypothetical cases was determined by using Chi square and Fisher's exact tests when applicable at $P < 0.05$ significant level.

Results

Out of 550 circulated questionnaires to the randomly selected healthcare providers, only 485 were filled and returned back within the assigned time frame giving a response rate of 88.2%. From the 485 healthcare providers, the majority (60.5%) were pharmacists. Most of the responders (44.9%) were in the age range of 22–30 years and 262 (54.0%) were males as shown in Table 1. Moreover, the majority of responders (70.7%) have a bachelor degree qualification, while only 2.2% of them are a Ph.D. qualified medical staff (Table 1). Table 2 showed that 427 (88.1%) of the respondents recognized that not all marketed drugs are totally safe which represents a significantly higher rate compared with others. Only 326 (67.2%) of the targeted healthcare providers can differentiate ADRs from the side effects and this value was significantly greater than those who can differentiate and those who have no idea (23.5% and 9.3%, respectively). Meanwhile, only 293 (60.4%) of the respondents declared that they have an idea about the term pharmacovigilance, which was significantly higher ($P > 0.05$) compared with others. In this regard, 231 (47.6%) of the surveyed healthcare providers recognized the availability of local and international ADR reporting systems, while 40% of them have no idea about the availability of these systems. Additionally, the data presented in Table 2 showed that 210 (43.3%) of the respondents have a knowledge how to report ADRs, which is comparable to the number of those who do not know the process (42.7%; $P > 0.05$). In Table 3, out of the total healthcare providers included in the study, 212 (43.7%) of the healthcare providers mentioned that ADRs should only be reported when they are serious and life-threatening; meanwhile, 199 of them mentioned that ADRs should be reported even when they are mild and cause fewer inconveniences. However, only 74 (15.3%) of the healthcare providers believed that ADRs should be reported only when they are severe and cause disability. In Table 4, the current study showed that 408 (84.8%) of the participants recognized that reporting ADRs is beneficial to the public health, while 80.8% of them believed that this practice will improve the quality of the patient care. However, only 223 (48.1%) of the participants agreed that performing ADRs reporting

Table 1 Demographic characteristic of the surveyed healthcare providers

Demographic character	
Age (year) mean ± SD	36.3 ± 12.3
Gender *n* (%)	
Male	262 (54)
Female	223 (46)
Profession *n* (%)	
Physician	123 (25.4)
Pharmacist	294 (60.5)
Dentist	68 (14.1)
Experience (year) mean ± SD	18.6 ± 11.4
Qualification *n* (%)	
PhD	11 (2.2)
MSc	37 (7.6)
Board fellowship	52 (10.8)
Diploma	42 (8.7)
Bachelor	343 (70.7)
Age distribution of the participants (year)	
22–30	218 (44.9)
31–40	105 (21.7)
41–50	73 (15.1)
51–60	73 (15.1)
> 60	16 (3.2)

Values are mean ± SD and simple frequency and percentage

Ph.D. Doctor of Philosophy, *n* number of subjects

Table 3 Safety awareness concern of the healthcare providers about the ADRs reporting in Baghdad area (public and private settings)

ADRs severity	Response *n* (%)	*P* value
Serious and life-threatening	212 (43.7)	0.027
Mild and cause fewer inconveniences	199 (41.0)	
Severe and cause disabilities	74 (15.3)	

Values are simple frequency and percentage

ADRs adverse drug reactions, *n* number of subjects

Table 2 Knowledge of healthcare staff on ADRs reporting and monitoring in the Baghdad area (public and private settings)

Variables	Yes *n* (%)	No *n* (%)	Neutral *n* (%)	*P* value
Do you recognize all marketed medications are safe?	19 (3.8)	427 (88.1)	39 (8.1)	0.012
Do you accept that S/E is a synonym to ADR?	114 (23.5)	326 (67.2)	45 (9.3)	0.014
Do you have an idea about pharmacovigilance?	293 (60.4)	176 (36.3)	16 (3.3)	0.023
Are you familiar with the ADRs reporting form?	231 (47.6)	194 (40)	60 (12.4)	0.037
Do you know how to report ADRs?	210 (43.3)	207 (42.7)	68 (14)	0.041

Values are simple frequency and percentage

ADRs adverse drug reactions, *S/E* side effects, *n* number of subjects

Table 4 Knowledge and attitudes of healthcare providers in Baghdad city (public and private settings) toward ADRs reporting

Variables	Yes *n* (%)	No *n* (%)	Neutral *n* (%)	*P* value
Is ADRs reporting beneficial to public health?	408 (84.1)	56 (11.6)	21 (4.3)	0.011
Do you believe that ADRs reporting improves the quality of patient care?	392 (80.8)	67 (13.8)	26 (5.4)	0.001
Do you agree that ADRs reporting can make a difference?	233 (48.1)	183 (37.8)	69 (14.1)	0.022
Do you accept that ADRs reporting is a duty of healthcare providers?	363 (74.8)	64 (13.3)	58 (11.9)	0.014
Do you recommend ADRs reporting as a compulsory duty?	284 (58.6)	104 (21.4)	97 (20)	0.025
Do you agree that only ADRs that cause serious outcome should be reported?	187 (38.6)	248 (51.1)	50 (10.3)	0.02
Do you think that ADRs reporting is a waste of time with no outcome?	93 (19.2)	303 (62.5)	89 (18.3)	0.018
Do you agree that suitable training is required for proper ADRs reporting?	391 (80.7)	57 (11.7)	37 (7.6)	0.013
Do you think that you are properly trained to report ADRs?	72 (14.9)	334 (68.9)	79 (16.2)	0.021
Do you support maintaining confidentiality during ADRs reporting?	315 (64.9)	86 (17.8)	84 (17.3)	0.018
Do you worry about the legal issues of ADRs reporting?	253 (52.1)	117 (24.1)	115 (23.8)	0.02
Do you recommend the regular ADRs reporting?	385 (79.4)	42 (8.7)	58 (11.9)	0.011

Values are simple frequency and percentage

ADRs adverse drug reactions, *n* number of subjects

practice in Iraq makes a difference to their profession; this value is not significantly different with those who disagree with this idea (37.8%). The presented data indicated that 363(74.8%) of the respondents accepted the idea that ADRs reporting practice should be part of their duty, and 284(58.6%) of them agreed that this practice should be compulsory for the medical staff. Table 4 also showed that 38.6% of the respondents agreed about reporting only the ADRs that cause serious outcomes, while 19.2% of them think that ADRs reporting practice is a waste of time with no predictable outcomes. Concerning their personal experience with this practice, the majority of the participants (391 healthcare providers) agreed that suitable training is a prerequisite before practicing ADRs reporting, and only 72 (14.9%) of them declared that they are well-trained to report ADRs, while 334 (68.9%) agreed that they were not effectively and adequately trained in ADRs reporting. Moreover, the majority of the respondents (64.9%) supported maintaining confidentiality during the ADRs reporting practice. Although most of the respondents (79.4%) recommended that ADRs should be reported on regular bases, the majority of them (52.1%) are worried about the legal problems that may be associated with regular ADRs reporting practice (Table 4). Table 5 showed that only 48.7% of the healthcare providers encountered a case of ADR during the last year, and 39.2% of them observed an ADR case on the patient's clinical follow-up record. Moreover, among those who encountered ADR case during their practice, only minority of them (30.0%) reported the detected ADRs to the corresponding authorities that include the hospital reporting system (48.7%), the manufacturers' drug safety department (11.8%), pharmacy personnel (17.1%), and the reporting system of the Ministry of Health (22.4%).

Table 5 The extent of practicing ADR reporting by the healthcare providers in Baghdad city (public and private settings)

Variables	Yes *n* (%)	No *n* (%)	Neutral *n* (%)	*P* value
Have you encountered a case of ADRs through the last year?	188 (38.7)	190 (39.2)	107 (22.1)	0.037
Have you noticed ADRs case on the patient's clinical record?	190 (39.2)	290 (59.7)	5 (1.1)	0.012
Have you ever reported the detected ADRs?	145 (30.0)	330 (68.0)	10 (2)	0.014
To which authority did you report the detected ADRs?				
A. Hospital reporting system	71 (48.7)			0.032
B. Manufacturer drug safety department	17 (11.8)			
C. Pharmacy personnel	25 (17.1)			
D. Ministry of Health reporting system	32 (22.4)			

Values are simple frequency and percentage

ADRs adverse drug reactions, *n* number of subjects

Discussion

Adverse drug reactions (ADRs) are one of the consequences of medication use in the approved doses to prevent or treat diseases. The practice of ADRs monitoring was concerned with the detection, reporting, evaluation, and management of ADRs. It represents a significant interest to both the pharmaceutical industries and the clinical practice [17]. The ADRs may occur as a simple reaction, permanent damage and disability or even predispose to death [18]. The knowledge, awareness and the routine practice of healthcare providers regarding ADRs reporting are closely related to their professional roles and enable the healthcare authority to avoid the problems associated with the use of drugs and ineffectively reported ADRs. The present study is a survey-based which involved both public and private healthcare institutions of the Baghdad city. There was no previous study performed in Baghdad area regarding the ADR reporting practice; therefore, the current study was conducted to evaluate the knowledge, attitude, and practice of ADR reporting among the healthcare professionals in these settings and the also the factors which influence the ADR reporting practice. The study involves physicians, pharmacists, and dentists in public and private institutions. The results showed that the majority of the study participants (44.9%) were junior staff (up to five years of experience), which might explain their limited awareness of the ADRs reporting practice. In the present study, about 22.7% of the respondents were either unable to differentiate ADRs from side effects or have no idea about this concept. This might be attributed to a lack of adequate knowledge regarding ADR during their undergraduate studies or postgraduate training courses. In this regard, many researchers addressed the inadequate knowledge about the concept of ADRs reporting and its consequences on the healthcare system especially in developing countries that share the same conditions of the healthcare system with Iraq [19, 20]. However, in order to avoid the elevated incidence of medication-related problems, the WHO recommended the use of the term side effect for minor effects which are related to the pharmacological properties of the drug [21]. Among the 485 participants, 231 (47.6%) healthcare providers were aware of the availability of the ADR reporting system and the reporting forms. This finding was in tune with the previously reported data, where only 23.17% and 25.61% of the healthcare providers have an idea about the availability of national ADR reporting system and reporting form in Ethiopia [22]. A full awareness about the availability of the ADR reporting system and standardized reporting forms can augment the practice of ADR reporting and reduce the risks of ADRs. Good understanding of the pharmacovigilance bases and its roles is one of the markers utilized to evaluate the overall knowledge of the participants on ADR reporting [23]. Accordingly, among the total of 485 healthcare providers, only 293 (60.4%) of them declared their knowledge about the pharmacovigilance concept and the importance of ADR reporting to the healthcare system; this came in tune with a previous study where 55% of the respondents believed that reporting even a single ADR is beneficial [24]. Based on the results of a study performed in Nigeria regarding the attitude of physicians to ADR reporting, it has been shown that 40.4% of the respondents were aware of the presence of the National Pharmacovigilance Center in their country [25], indicating that healthcare providers in Iraq have more awareness of ADR reporting than their peers in Nigeria. The attitude of the medical staff toward ADR reporting is a potentially modifiable factor that effectively impacts the ADRs reporting practice, and the greater their attitude the more positive impact on the rate of practicing this duty [26]. In the present study, 363 (74.8%) of the healthcare providers realized that ADR reporting should be part of their daily clinical practice, and 284 (58.6%) supported that ADR reporting should be a compulsory practice. In contrast, 183 (37.8%) did not believe that one report of ADR can make a difference. Meanwhile, the majority of the respondents 392 (80.8%) supported the idea that ADR reporting is vital for the public and improves the quality of the patients' care. Continuous medical education programs can significantly influence medical staff reporting-related attitudes and positively impact the ADRs reporting practice. In the present study, only 14.9% of the targeted healthcare providers were educated and trained regarding ADR reporting. This result is consistent with previous findings reported in similar studies conducted in Ghana and Saudi Arabia [20, 27]. Additionally, regular education and training of the medical staff before practicing ADR reporting is an important activity that provides better outcomes regarding patients' safety, clinical benefits, and improvement of the quality of life of the patients [3, 28]. The full awareness about the incidence of ADRs during the use of mediation is very important to prevent morbidity and mortality associated with adverse effects associated with the clinical use of certain drugs. In the present study, 188 (38.7%) of the surveyed medical staff met patients with ADRs and only 145 of them reported such cases to the concerned authority. In a Turkish study, 65% of the healthcare providers met patients with ADRs, and only 7% of them reported ADR to their National Pharmacovigilance Center [29]. Detection and reporting of ADRs need proper and adequate knowledge concerning their serious outcomes. Accordingly, there should be full awareness of raising training programs regarding ADRs in order to encourage healthcare providers to detect and report ADRs. The overall knowledge level of healthcare providers in the

present study is within the average; however, inadequate training programs and the shortage of regulatory legislation might affect their experience in the official reporting of ADRs, despite their higher level of perceptions towards ADR reporting. Additionally, one needs to consider many confounding factors that may affect the validity of such comparisons, such as the use of different instruments to evaluate the outcome variable.

Limitations of the study

The self-reporting pattern of the present study relays on the exactness and trustworthiness of the respondents. Accordingly, the results may not be compatible with what really occurs in practice. The relatively small sample size may make it difficult to extrapolate conclusions from this study; however, it can give an idea about the perspectives and experiences of the surveyed healthcare providers [30]. Although the response rate is considered acceptable, around 20% of the targeted healthcare providers did not provide their filled questionnaires and many of them returned an incomplete one. This kind of response may affect the interpretation of data. Additionally, due to the uneven distribution of different healthcare providers within the studied sample, the results of this study cannot be generalized to all healthcare institutions in the whole Iraqi territories, and differences are highly expected in the practice and knowledge levels.

Conclusion

The present study indicated that healthcare providers working in Baghdad healthcare institutions have a good attitude toward ADR reporting, but there is a relatively below-standard reporting culture of the encountered ADRs. The inadequate knowledge about ADRs and unavailability of ADR reporting forms play a major role in significantly discouraging healthcare professionals to detect and report ADRs.

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