

# Adverse Drug Reactions (ADR's) Reporting Barriers and Attitude among Pharmacists in Erbil, Kurdistan Region – Iraq

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## ABSTRACT

**Background:** There are known common adverse effects related to drugs that might lead to death. Pharmacovigilance systems are important for monitoring, safely using medicines, decreasing the number of adverse drug reactions (ADRs) and increasing awareness for reporting ADRs in health care systems. **Aim:** This study sought to investigate attitudes and barriers among Erbil pharmacists, mainly those working at hospitals and pharmacists in private pharmacy sectors about ADR reporting and the Pharmacovigilance system. **Methods:** A cross-sectional prospective pilot study was done using previously modified and developed self-administered questionnaires during a one month period from 15 February to 15 March 2017. The data were analysed using the Statistical Package for Social Sciences software (SPSS) version 20. **Results:** The majority of pharmacists (94%) said that reporting ADRs is a pharmacist's duty, with drug safety monitoring being very important (90.9%). More than 90% of pharmacists believed that it is very important to report ADRs that lead to life-threatening situations and those that lead to congenital abnormality. However, a majority were not familiar with the Iraqi Pharmacovigilance system, had never reported any ADRs, reporting forms were not available and they had insufficient clinical knowledge to detect ADRs. **Conclusions:** Under-reporting was the major problem detected by the study.

However, necessary steps should be taken to design intervention programmes to increase knowledge and awareness of pharmacists concerning the ADR reporting process.

**Key words:** ADR; Attitude; Barriers; Kurdistan

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## INTRODUCTION

Adverse drug reactions (ADRs) occur at high frequency and from time to time are considered severe adverse events when the outcome is one of the following: death; life-threatening; hospitalisation; initial or prolonged disability; significant, persistent, or permanent impairment; damage or disruption in the patient's body function/structure, physical activities or quality of life; congenital anomaly (birth defect) or requires intervention to prevent permanent impairment or damage.<sup>[1]</sup>

ADRs are responsible for 5% to 20% of hospital entrances or intensive care units. This includes the ceftriaxone allergy where many patients must be admitted and even death happens. This can be prevented by simple subcutaneous allergy test.<sup>[2,3]</sup> The majority of countries now have general Pharmacovigilance systems after the thalidomide disaster in the 1960s.<sup>[4]</sup> On 3<sup>rd</sup> November 2010, Iraq became the 102nd country to become a member of the WHO Programme for International Drug Monitoring.<sup>[5]</sup>

ADRs are seen frequently in the daily practice of pharmacies and hospitals, both private and government owned. There are many obvious morbidities and the mortality counted by them; they also cause a financial problem for the health care system. We can avoid ADRs if pharmacists and healthcare professionals pay close attention to the facts about adverse effects of the drugs administered to patients. Knowledge about ADRs can decrease the unreasonable use of an inappropriate medicine. Therefore, there is a serious need to develop awareness among pharmacists and also among doctors who prescribe drugs about ADRs and drug monitoring.<sup>[6]</sup>

Awareness of Pharmacovigilance among pharmacists is very essential. Pharmacy students need to be effectively informed on how to identify, prevent and report ADRs. The right time to improve the knowledge and awareness about Pharmacovigilance is during undergraduate education of the pharmacists.<sup>[7]</sup> On the other hand, under-reporting of ADRs by pharmacists is a problem in many countries including our country Iraq. This may be described by the deficiency of alertness and knowledge about the strategies to identify and report ADRs. Thus, this study aimed to evaluate the barriers and attitude among pharmacists in Erbil, Iraq about Pharmacovigilance.

## MATERIALS AND METHODS

A prospective cross-sectional pilot study was carried out from February 15 to March 15, 2017, using previously modified and developed questionnaires.<sup>[5,8-13]</sup> No formal sampling methods were used for the survey. The questionnaire evaluates attitude, and barriers toward ADR reporting among Erbil pharmacists. This study targeted pharmacists working at private pharmacies and government hospitals as well as academic pharmacists at Howler Medical University/College of Pharmacy. The pharmacists were invited to participate in this study and filled out the questionnaire verbally (self-administered) after explaining the aim of the study and oral consent approval. Then the data were collected manually.

The questionnaire was three pages long which included the following: the first part included 11 items about social status characteristics of the participant. The second part included 15 questions about the pharmacists' attitude about the Iraqi Pharmacovigilance system and reporting of ADRs. Pharmacists were asked to answer according to the following 5-point scale: 1='strongly agree', 2='agree', 3='neutral', 4='disagree' and 5='strongly disagree'. The third part included 15 questions to identify the barriers to reporting ADRs among Erbil pharmacists. These questions also used the 5-point scale above. The information from the returned questionnaire was coded and entered into Statistical Package for Social Sciences (SPSS) version 20 software for analysis. The social status, attitude and barriers were analysed by descriptive statistics.

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## RESULTS

### Pharmacist's characteristics

The questionnaire was delivered to 135 pharmacists in Erbil, Iraq. Only 80 pharmacists responded and fill out the survey. Others were not motivated to participate, complaining that they did not have time, interest for the subject and there was no active Pharmacovigilance system in our country so they do not get a benefit from participating; but indeed there is a Pharmacovigilance system in Iraq. However, 14 forms were not considered because of missing data (either the questionnaire was not filled out completely or not filled out at all). Therefore 66 questionnaires were considered for this investigation with a response rate of 48%. Females accounted for more than half (54.5%) of pharmacists. Most of the pharmacists were aged between 23-29 years old (66.7%); most of them did not have any post-graduate degree (83.3%), and those who had a post-graduate degree were academic pharmacists. Pharmacists were mostly graduates from Howler Medical University. Very few pharmacists knew what the term Pharmacovigilance means; most of the pharmacists had to be told what that term means [Table 1].

### Pharmacist's attitude to ADR reporting

Most of the pharmacists (90.9%) said that drug safety monitoring is very important in order to avoid undesirable effects of drugs. It is also very important to report ADRs that lead to life threatening situations (90.9%) and those that lead to congenital abnormality (92.4%). 94% of pharmacists thought that reporting ADRs should be the chief part of a pharmacist's duty. More than 89% of the pharmacists believed that it is important to consult pharmacists, physicians or academics trained in the field before reporting ADRs. 59% of the pharmacists differ with a statement that assumed ADRs and adverse drug events are the same [Table 2].

### Barriers to ADR reporting among pharmacists

Only a few pharmacists, less than 17%, thought that but were not certain that reporting forms are available and aware of the address where reporting forms should be sent. This is the reason for under-reporting of ADRs among pharmacists in general. More than one-third of the pharmacists claimed that they have insufficient clinical knowledge in detecting ADRs. Nearly half of the surveyed pharmacists were convinced that ADRs were caused by the drug, and two-thirds of the pharmacists believed that decentralisation of Pharmacovigilance centre would increase the rate and quality of reports among the pharmacists [Table 3].

## DISCUSSION

Under-reporting of ADRs is a major cause of unsuccessful Pharmacovigilance programmes even if centres are available. This highlights the need for intervention and education programmes about Pharmacovigilance in both undergraduate and graduate pharmacists.<sup>[7,14]</sup> Only a few studies have been conducted on barriers to reporting ADRs among pharmacists in Iraq.<sup>[5]</sup> Therefore, this study evaluated attitude and barriers to ADRs among pharmacists in Erbil, Iraq. The results of the current study showed that unawareness about the presence of a Pharmacovigilance system in Iraq and availability of reporting forms for ADRs was a major problem for under-reporting. However, under-reporting of ADRs is a similar problem in many other countries according to other studies,<sup>[15-17]</sup> as well as a similar study done in Iraq.<sup>[5]</sup>

Very few pharmacists knew about the presence of a reporting form and they claimed that they have never seen it; even if it is available they did not know the address where it should be sent and how to handle these reports. Especially among hospital pharmacists, they claimed

**Table 1:** Pharmacists characteristics (N=66)

Sociodemographic		N	%
<b>Gender</b>	Male	30	45.5
	Female	36	54.5
<b>Age</b>	23 – 29	44	66.7
	30 – 39	16	24.2
	>40	6	9.1
<b>Post-graduate</b>	Yes	66	100
	No	0	0
<b>Length of practice</b>	0-10	59	89
	Nov-20	5	8
	>20	2	3
<b>No. participations in scientific events</b>	None	44	66
	1-3 per year	21	32
	>3	1	2
<b>Have you ever play a role in detecting ADR</b>	Yes	27	41
	No	39	59
<b>No. of ADR observed in the last year</b>	None	45	68
	01-Feb	14	21
	>2	7	11
<b>Did you report the ADRs by a report form</b>	Yes	1	1.5
	NO	65	98.5
<b>University of graduation</b>	Hawler Medical University	53	80
	University of Baghdad	5	7
	University of Mosul	2	3
	Petra University/Jordan	1	2
	Near east University	1	2
	Syrian international university	4	6
<b>Educational Level</b>	BSc in Pharmacy	55	83
	Master	10	15
	PhD	1	2

they had insufficient clinical knowledge and information about Pharmacovigilance given fairly during undergraduate stages also after graduation.

They also believed that the syndicate of pharmacists besides participants in the Ministry of Health are also responsible for under-reporting of ADRs, because there are no education programmes and regular conferences have been held to show the importance of Pharmacovigilance and steps of reporting. Attendance at scientific conferences was very low among pharmacists (34%). A large number of those who attend such conferences were outside Iraq, but not every pharmacist has a budget to attend conferences. Another problem is a lack of patients reporting ADRs directly to the centres or drug manufacturing companies because the telephone numbers for reporting ADRs on container packages are invalid in our country, patients do not know about it (after asking patients who consume drugs regularly because of having chronic diseases) and low awareness of reporting ADRs among patients.

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**Table 2:** Pharmacist's attitude to word ADRs reporting

Survey Question	Responses n (%)				
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. Reporting of ADRs is part of a pharmacist duty.	43(65.2)	19(28.8)	4(6.1)	0	0
2. I believe that monitoring drug safety is important.	49(74.2)	11(16.7)	6(9.1)	0	0
3. It is necessary to be confirmed that an ADR is related to a particular drug before reporting.	32(48.5)	27(40.9)	7(10.6)	0	0
4. It is not necessary to report those ADRs which are related to OTC products dispensed in my pharmacy	20(30.3)	4(6)	12(18.2)	17(25.8)	13(19.7)
5. It is important to report ADRs leading to hospitalization.	42(63.6)	17(25.8)	7(10.6)	0	0
6. It is important to report ADRs leading to a life threatening situation.	54(81.8)	6(9.1)	6(9.1)	0	0
7. It is important to report ADRs leading to congenital abnormality	53(80.3)	8(12.1)	5(7.6)	0	0
8. It is important to report ADRs leading to persistence disability or in capacity.	43(65.2)	14(21.2)	9(13.6)	0	0
9. It is important to report ADRs in order to answer the questions that may arise in my practice.	35(53)	19(28.8)	11(16.7)	0	1(1.5)
10. Reporting of ADRs is important to show patients that their concerns are taken seriously.	33(50)	24(36.4)	9(13.6)	0	0
11. Consulting another pharmacist is important before reporting an ADR.	38(57.6)	23(34.8)	4(6.1)	1(5)	0
12. Moving the responsibility of Pharmacovigilance scheme to pharmaceutical industry o academy will improve ADRs reporting.	26(39.4)	19(28.8)	12(18.2)	3(4.5)	6(9.1)
13. It is important to discuss ADRs with a physician and/or an academician trained in this field	43(65.2)	16(24.2)	7(10.6)	0	0
14. Adverse drug event and ADR are same.	8(12.1)	7(10.6)	12(18.2)	23(34.8)	16(24.2)
15. ADR reporting benefits doctors and patients.	46(69.7)	17(25.8)	2(3)	0	1(1.5)

**Table 3:** Barriers to ADRs reporting

Survey Question	Responses n (%)				
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. Reporting forms are not available.	28(42.4)	21(31.8)	7(10.6)	6(9.1)	4(6.1)
2. I do not know the address where these reports should be sent.	19(28.6)	28(42.4)	8(12.1)	9(13.6)	2(3)
3. The reporting form is too complicated to be filled.	10(15.2)	14(21.2)	19(28.8)	20(30)	3(4.5)
4. Reporting is time-consuming.	6(9.1)	10(15.2)	7(10.6)	29(43.9)	14(21.2)
5. All serious ADRs are detected before registration.	13(19.7)	25(37.9)	15(22.7)	8(12.1)	5(7.6)
6. I do not report ADRs because I want to publish the case by myself.	4(6.1)	2(3)	8(12.1)	33(50)	19(28.8)
7. I am not convinced about the confidential handling of the report.	4(6.1)	18(27.3)	17(25.8)	19(28.8)	8(12.1)
8. I fear to harm the confidence of my patients.	2(3)	12(18.2)	23(34.8)	19(28.8)	10(15.2)
9. I find it difficult to admit that the patient has been harmed.	5(7.6)	11(16.7)	15(22.7)	19(28.8)	16(24.2)
10. I fear legal liability of the reported ADR.	1(1.5)	9(13.6)	24(36.4)	19(28.8)	13(19.7)
11. I am not motivated to report.	4(6.1)	12(18.2)	16(24.2)	21(31.8)	13(19.7)
12. I have insufficient clinical knowledge in detecting ADRs.	12(18.2)	14(21.2)	23(34.8)	13(19.7)	4(6.1)
13. I do not know how to report an ADR.	8(12.2)	15(22.7)	18(27.3)	18(27.3)	7(10.6)

14.	Decentralization of Pharmacovigilance center (i.e., multiple centers) would increase the rate and quality of reports among the retail pharmacists.	26(39.4)	19(28.8)	16(24.2)	3(4.5)	2(3)
15.	I am not convinced that the ADR is caused by the drug.	6(9.1)	7(10.6)	19(28.8)	18(27.3)	16(24.2)

Therefore, advance interventions are needed to solve the problem of under-reporting and its negative effect on health and financial expenditure in the community. This can be improved in many ways such as internet reporting, pharmacist/nurse reporting, and direct patient reporting as well as improved education and training of health care professionals.<sup>[18]</sup>

Nowadays there is a plan in Erbil- Iraq to establish Pharmacovigilance centres so they will be connected to each other. Pharmacists will be trained on how to report ADRs and also how to deal with ADR reporting forms received from hospitals, health centres, and pharmacies. These efforts are being made by Ministry of Health in Kurdistan regional government in Iraq. However, the exact steps of how this programme will be executed are not known, but there are efforts to make it successful. This definitely will improve under-reporting of ADRs and reporting of drugs suspected to have ADRs, which can save many lives and provide more safe and effective treatments for diseases.

Generally, any ADR reporting form should have the following essential basics: patient, drug, adverse reaction, originator/reporter of the report.<sup>[19]</sup> Most of the pharmacists (95.5%) believed that both health care professionals and patients will benefit from the process of reporting ADRs. Very few pharmacists believed that just a single centre of pharmacovigilance would increase the rate and quality of ADRs reporting. Conversely, studies showed the importance of decentralisation of pharmacovigilance that will improve under-reporting, and prevent serious ADRs for safe use of drugs.<sup>[20,21]</sup>

The Pharmacovigilance of over the counter (OTC) drugs dispensed in pharmacies by pharmacists is very important.<sup>[22,23]</sup> Less than half of pharmacists believed that it is important to report ADRs caused by OTC drugs. However, about half of the pharmacists had a good attitude toward reporting of ADRs by OTC products dispensed in their pharmacy and also believed that it is very important for pharmacists to be ready to admit and not fear legal consequences after dispensing any OTC drug that causes ADRs and show patients that their concerns are taken seriously.

ADRs and adverse drug events are not considered to be the same by more than half of pharmacists (59%). ADRs include harmful effects of drugs on humans that occur at doses that are normal for treatment, prevention, diagnosis and prophylaxis in the management of diseases and seen from the patient's point of view.<sup>[24]</sup> However, ADRs should be distinguished from adverse drug events which are defined as patient harm or injury due to a medical intervention not necessarily associated with a drug, irrespective of whether an error occurs in the medication process. This includes both those that cause hospitalisation and those that occur during hospitalisation.<sup>[25]</sup>

ADRs can occur through additives used, appropriate use of medicines such as dosing, using it when it is totally contraindicated and the risks outweigh benefits. They can also occur through inappropriate self-medication without consultation of a health care professional. About 10% of pharmacists were not convinced that ADRs are caused by drugs. Unfortunately, among all pharmacists that participated in the study, only one pharmacist reported ADRs caused by ketotifen eye drops to the manufacturing company. After investigations, it was found that this batch of the drug caused dry eye for almost everyone using it. Drug safety monitoring post-marketing is very important.<sup>[26]</sup>

The ADRs discussed above were detected mainly by pharmacists

working at hospitals, however certainly there are more important and serious ADRs that pharmacists fail to detect. This is mainly due to insufficient clinical knowledge of pharmacists to detect more complicated ADRs, as many pharmacists claimed that they have insufficient clinical knowledge in detecting ADRs and others think that they lack specialist pharmacists who are expert in that field working at hospitals. More than 80% of the pharmacists did not have a post-graduate degree, however, among those with one, about 90% of them were part of academic staff at the college of pharmacy. Thus, it is important that moving responsibility of Pharmacovigilance to academy will improve reporting as more than 65% of pharmacists in general thought that too.

ADR reporting was considered to be an essential part of a pharmacist's duty by 94% of the respondents and also pharmaceutical industry duties according to 68% of pharmacists, to improve reporting. Moving responsibility for Pharmacovigilance to the pharmaceutical industry will improve reporting especially for new drugs. According to the European Union pharmaceutical legislation, the goal and responsibilities are to ensure the safety of medicinal products in line with the main purpose to protect the community. Now other countries are moving towards the same goal of Pharmacovigilance, also involving the pharmaceutical industry besides health care professionals.<sup>[27]</sup>

## CONCLUSIONS

This study showed that Erbil pharmacists have a good attitude toward ADR reporting. Although the majority had never reported any ADRs, those that participated in the study were ready and have interest in knowing about the subject, after explaining the aim of the study. Under-reporting of ADRs was a major problem detected by the study.

## Recommendations

A study which includes a larger number of pharmacists is needed to discover knowledge, attitude, and barriers towards reporting ADRs. Future studies should also include other governors in Iraq and compare results to explore differences in undergraduates, health systems and whether knowledge of pharmacists affects the degree of reporting ADRs.

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