Original Article

# Assessment of community pharmacists concerning pharmacovigilance in Iraq

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## ABSTRACT

**Objectives:** This study was designed to explore the awareness and attitude of the pharmacists working in the retail pharmacies toward the national adverse drug reactions (ADRs) system activities in Iraq.

**Methods:** A cross-sectional survey using a validated self-administered questionnaire was used in this study. The questionnaire was delivered to retail pharmacists (RPs) practicing in Baghdad during the study period (4 months).

**Results:** Of the 200, only 176 pharmacists responded to the survey (response rate of 88%). The total number of usable responses was 123 (61.5%). The survey findings revealed that 79 pharmacists (64.2%) were not aware of the Iraqi spontaneous reporting system (SRS). The restriction factors which dropping the ADRs reporting among RPs were identified. These include lack of knowledge in the way of reporting ($n = 41$; 33.3%), the unavailability of reporting forms ($n = 88$; 71.6%), and unawareness of where these reports should be sent to ($n = 88$; 71.6%).

**Conclusions:** The study showed that the RPs in Baghdad have a very positive attitude toward ADRs but unfortunately; they are not familiar with the Iraqi SRS. The study findings emphasize the serious need for special education programs to promote ADRs reporting among RPs.

Key words: Adverse drug reaction, pharmacovigilance, retail pharmacist

## INTRODUCTION

Medicines have significant benefits to our lives and lead to an obvious reduction in morbidity and mortality. It is uniformly accepted that there is no drug that is absolutely safe. Therefore, different countries have established national pharmacovigilance systems to observe adverse drug reactions (ADRs), especially after the disaster of Thalidomide in the 1960s.[1] Consequently, a new procedure to collect data concerning ADRs was developed depends on the voluntary reporting of suspected ADRs by health-care providers.[2] These reports should be analyzed and studied to identify a signal to the World Health Organization which is in overall called a spontaneous reporting system (SRS).[3]

The Ministry of Health, Iraq, charge with a responsibility of ensuring the availability of safe, effective, and good quality medicine to all peoples. In accordance with this objective, the Ministry of Health

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through the Technical Affair's Directorate (including the National Drug Regulatory Authority in Iraq) has implemented several strategies. Indeed, the Pharmacovigilance Center was developed in 2010 as a member of the safety-monitoring program.[4]

In so doing, analogously to other nations, the Iraqi Pharmacovigilance Center (IPhvC) has established the guidelines for the national safety monitoring of medicinal products system. This drug safety system is necessary for the prevention of drug related illness, early detection, and assessment of ADRs, as well as to minimize the costs associated with preventable adverse events.

Many studies have estimated that the attitude of health-care professionals has a significant impact on the rates and quality of ADRs reporting, owing that to their direct contact with the patients, as well as their expertise in medicines. However, during the past decades, safety and efficacy surveillance of medicine have not received the required attention in Iraq, indeed, there was a great lacking of national pharmacovigilance studies. In accordance, this study was designed to explore the awareness and attitude of the pharmacists working in the retail pharmacies toward the national ADRs system activities in Iraq.

## METHODS

The study was conducted over a period of 4 months. The initial survey forms were distributed to 200 retail pharmacists (RPs) in Baghdad. A cluster sampling technique was considered to cover the both parts of the capital (i.e., Karkh and Rasafa). The survey questionnaire has adopted from a previous study.[5] To distinguish the pharmacist from the administrative and/or assistant staff, before giving the questionnaire form to the respondent, the investigator asks for the pharmacist identity that it is issued by the Iraqi Syndicate of Pharmacists. The questionnaire evaluated the attitude, perception, and restrictive factors of ADRs reporting among health-care professional. The final questionnaire consisted of 53 items classified into the four categories:

1. The first part consists of 17 questions, which covers the demographic characteristics of pharmacists and verifying of the pharmacists' knowledge about the ADRs reporting system and their behavior. These questions either were multiple choices or consisted of filling in the blank
2. The second part consisted of 14 questions, exploring the pharmacists' attitude toward ADRs reporting and observing the factors that either positively or negatively affected the RPs attitude. These items were constructed as a series of statement, and the pharmacists 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)
3. The third part of the survey consisted of 15 questions, which explored the restrictive factors that hindering the ADRs reporting, these questions also used a 5-point Likert scale
4. The fourth part includes seven questions, which aimed to identify the factors that might encourage and motivate the RPs to report ADRs, these also framed in 5-point Likert scale.

### Statistical analysis

Demographics and respondents characteristics were illustrated by descriptive statistics. Percentages and frequencies were used for the categorical variables. Chi-square or Fisher's exact test was used to assess the difference or association between the categorical variables.

## RESULTS

Over a study period of 4 months, the investigators faced many interruptions during distributing and collecting the questionnaire from the RPs, some of the RPs refused to respond to the questionnaire. There was a great difficulty in dealing with them, however, of the 200, 176 (88%) pharmacist responded to the survey. The total number of usable responses was 123 (61.5%). This study included different areas in Baghdad from diversity socioeconomic backgrounds. The demographic details of the respondents are shown in Table 1. Most of the responses ($n$ = 68, 55.3%) came from employees followed by managers ($n$ = 42, 34.1%) and the owner ($n$ = 13, 10.6%). There was no statistical association between the age of the respondents and the encountered ADRs ($P$ = 0.406). Almost 60% of the respondents estimated the average number of prescription filled per day from 10 to 20. The study results revealed that there was no relationship between recognizing ADRs and length of practice, type of practice, and the average number of prescriptions handled per day ($P$ = 0.664, $P$ = 0.393, and $P$ = 0.174, respectively). Most of the respondents ($n$ = 96, 78.1%) said that ADR reporting was important to show patients that their concerns are taking seriously. Standard drug references, such as the British National Formulary, were used mostly

**Table 1: The sociodemographic characteristics of the retail pharmacists in Iraq**

| Sociodemographic | *n* (%) |
|---|---|
| Gender | |
| Male | 69 (56.1) |
| Female | 54 (43.9) |
| Age | |
| ≤30 | 83 (67.5) |
| 31-40 | 26 (21.1) |
| 41–50 | 13 (10.6) |
| ≥51 | 1 (0.8) |
| Length of practice | |
| 0-10 | 114 (92.7) |
| 11-20 | 6 (4.9) |
| 21-30 | 2 (1.6) |
| 31-40 | 1 (0.8) |
| Number prescription filled per day | |
| <10 | 30 (24.4) |
| 10-20 | 42 (34.1) |
| 21-30 | 31 (25.2) |
| >31 | 20 (16.3) |
| Participating in CPD programs per year | |
| None | 26 (21.2) |
| 1-3 | 77 (62.6) |
| 4-7 | 17 (13.8) |
| >7 | 3 (2.4) |
| Type of practicing | |
| Proprietor | 13 (10.6) |
| Manger | 42 (34.1) |
| Employee | 68 (55.3) |
| University of graduation | |
| Baghdad University | 76 (61.8) |
| Al-Mustansiriya University | 20 (16.3) |
| Baghdad University College | 11 (9) |
| Al-Yarmouk University College | 10 (8.1) |
| National Pirogov Memorial Medical University (Ukraine) | 1 (0.8) |
| Ajman University of Science and Technology (UAE) | 1 (0.8) |
| Kufa University | 1 (0.8) |
| University of Mosul | 3 (2.4) |

CPD=Continuing professional development

by the respondents (*n* = 64; 52%) as a common source of information followed by the Iraqi Drug Guide (*n* = 29, 23.6%) and Medscape (mobile application) (*n* = 17, 13.8%), with less than one-third uses Martindale (The Extra Pharmacopoeia) (*n* = 4, 3.3%).

## Knowledge and attitudes toward adverse drug reaction reporting

The study results showed that almost more than two-thirds of respondents (*n* = 79, 64.2%) were unaware of the existence of the Iraqi SRS set forward by IPhvC. Almost all of the respondents felt that it is important to report all serious ADRs which lead to life-threatening situations (*n* = 117, 95.1%), hospitalization (*n* = 114, 92.7%), congenital disorders (*n* = 113, 91.9%), and persistent disability (*n* = 108, 87.8%). A substantial number (*n* = 67, 45.5%) of respondents agreed that all reactions associated with over the counter (OTC) drugs should be reported. There was a statistically significant association between encountering ADRs and the reporting of ADRs associated with OTC medications that the higher rate of ADRs encountered resulted in a higher rate of OTC dispensing ($P < 0.001$). When the respondents were asked if any patients had claimed from any ADR to them during the 12 months before the study being conducted, about 66.7% (*n* = 82) of the pharmacists answered in the affirmative.

Although 84.6% of respondents (*n* = 104) considered ADR reporting as a part of their pharmaceutical-care duties and more than three-quarter of them (*n* = 107, 87.0%) believed in the importance of documenting ADRs, about one-third of them (*n* = 46, 37.4%) indicated that they were not motivated to report ADRs. More than half of the respondents (*n* = 69, 56.1%) agreed they would actively participate in ADR reporting if it was obligatory. However, a minority of pharmacists (*n* = 17, 13.9%) conveyed their disagreement with the statement, whereas the rest of the participants (*n* = 37, 30.1%) were neutral [Table 2].

## Barriers toward adverse drug reaction reporting

The surveyed pharmacists were asked about the reasons may hindering them from reporting an ADR. The study showed that (*n* = 41) 33.3% of the respondents felt that they did not have enough clinical knowledge to detect ADRs [Table 3]. Around two-third of the respondents (*n* = 61; 49.6%) agreed with the statement that "all serious ADRs are discovered before registration." The results illustrated that there was no major visible reason given by the surveyed pharmacists for nonreporting.

Nearly, three-quarter of the respondents (*n* = 88, 71.6%) mentioned the unavailability of the reporting form, and a similar number (*n* = 88, 71.5%) claimed that they did not recognize the address where the reporting form should be sent. As a barrier for ADR reporting, the study estimated that the unavailability of the ADR reporting form was not significantly associated with the age of the respondents ($P = 0.628$). One-third of the surveyed pharmacists (*n* = 43, 35%) was neutral with regard to whether the ADR reporting form was too complicated. Only a few of the respondents (*n* = 20, 16.3%) stated that the reporting form was not too complicated. There was a statistically significant

relationship between the perception that the reporting form was excessively complicated and the age of the respondents ($P$ = 0.03). Slightly more than one-third ($n$ = 49, 39.8%) of the respondents indicated that ADR reporting is time-consuming, whereas 43.1% of the respondents ($n$ = 53) could not report because they did not have a knowledge in ADRs reporting. There was not any statistically significant association between the number of pharmacists who believed that ADR reporting is time-consuming and their age ($P$ = 0.076). Slightly more than half of the respondent pharmacists ($n$ = 64, 52%) agreed that the centralization of the pharmacovigilance system is one of the barriers of ADRs reporting. As a reason for not reporting, only 26.1% ($n$ = 32) of the respondents were not convinced that the ADR is caused by a drug [Table 3].

**Table 2: Sociodemographic characteristics/extent of encountering of adverse drug reactions among retail pharmacists**

| Sociodemographic factors | At least one report *n* (%) | No report (%) | Total *n* (%) | *P** |
|---|---|---|---|---|
| Gender | | | | |
| Male | 36 (52.2) | 33 (47.8) | 69 (100) | 0.702 |
| Female | 30 (55.5) | 24 (44.5) | 54 (100) | |
| Age | | | | |
| ≤30 | 42 (50.7) | 41 (49.3) | 83 (100) | 0.406 |
| 31-40 | 17 (65.4) | 9 (34.6) | 26 (100) | |
| 41-50 | 7 (53.9) | 6 (46.1) | 13 (100) | |
| ≥51 | 0 (0.0) | 1 (100) | 1 (100) | |
| Type of practicing | | | | |
| Proprietor | 7 (53.9) | 6 (46.1) | 13 (100) | 0.393 |
| Manager | 26 (62.0) | 16 (38.0) | 42 (100) | |
| Employee | 33 (48.5) | 35 (51.5) | 68 (100) | |
| Average number of prescription filled per day | | | | |
| ≤10 | 11 (36.7) | 19 (63.3) | 30 (100) | 0.174 |
| 11-20 | 24 (57.1) | 18 (42.9) | 42 (100) | |
| 21-30 | 18 (58.0) | 13 (42.0) | 31 (100) | |
| ≥30 | 13 (65.0) | 7 (35.0) | 20 (100) | |
| Participation in CPD programs per year | | | | |
| None | 11 (42.3) | 15 (57.7) | 26 (100) | 0.491 |
| 1-3 | 42 (54.5) | 35 (45.5) | 77 (100) | |
| 4-7 | 11 (64.7) | 6 (35.3) | 17 (100) | |
| >7 | 2 (66.6) | 1 (33.4) | 3 (100) | |

*Chi-square test, $P$<0.05 is considered statistically significant association. CPD=Continuing professional development

## Adverse drug reactions reporting influencing factors

Although most of the surveyed pharmacists viewed ADR reporting as a pharmacist's duty, over half of them ($n$ = 69, 56.1%) agreed that making the ADR reporting mandatory would motivate them to report. Only 44.7% of the pharmacists agreed that receiving motivations would encourage them to report. Around two-thirds of the respondents ($n$ = 77, 62.6%) indicated that receiving feedback from the related authorities would be a driving factor for reporting. Although the majority of the surveyed pharmacists were not aware of the Iraqi Pharmacovigilance system, more than half ($n$ = 77, 62.6%) of them stated that simplifying the ADR reporting process would be a great inducement

**Table 3: Barriers to adverse drug reactions reporting**

| Question number | Survey question | Responses *n* (%) | | | | |
|---|---|---|---|---|---|---|
| | | Strongly agree | Agree | Neutral | Disagree | Strongly disagree |
| 1 | Reporting forms are not available | 27 (22) | 61 (49.6) | 24 (19.5) | 8 (6.5) | 3 (2.4) |
| 2 | I do not know the address where these reports should be sent | 32 (26) | 56 (45.5) | 21 (17.1) | 10 (8.1) | 4 (3.3) |
| 3 | The reporting form is too complicated to be filled | 15 (12.2) | 45 (36.6) | 43 (35) | 15 (12.2) | 5 (4.1) |
| 4 | Reporting is time-consuming | 18 (14.6) | 31 (25.2) | 35 (28.5) | 29 (23.6) | 10 (8.1) |
| 5 | All serious ADRs are detected before registration | 15 (12.2) | 46 (37.4) | 36 (29.3) | 21 (17.1) | 5 (4.1) |
| 6 | I do not report ADRs because I want to publish the case by myself | 7 (5.7) | 32 (26) | 26 (21.1) | 48 (39) | 10 (8.1) |
| 7 | I am not convinced about the confidential handling of the report | 7 (5.7) | 38 (30.9) | 43 (35) | 28 (22.8) | 7 (5.7) |
| 8 | I fear to harm the confidence of my patients | 9 (7.3) | 40 (32.5) | 33 (26.8) | 32 (26) | 9 (7.3) |
| 9 | I find it difficult to admit that the patient has been harmed | 9 (7.3) | 31 (25.2) | 44 (35.8) | 35 (28.5) | 4 (3.3) |
| 10 | I fear legal liability of the reported ADR | 7 (5.7) | 35 (28.5) | 38 (30.9) | 32 (26) | 11 (8.9) |
| 11 | I am not motivated to report | 10 (8.1) | 36 (29.3) | 42 (34.1) | 30 (24.4) | 5 (4.1) |
| 12 | I have insufficient clinical knowledge in detecting ADRs | 9 (7.3) | 32 (26) | 34 (27.6) | 37 (30.1) | 11 (8.9) |
| 13 | I do not know how to report an ADR | 16 (13) | 37 (30.1) | 31 (25.2) | 34 (27.6) | 5 (4.1) |
| 14 | Decentralization of Pharmacovigilance Center (i.e., multiple centers) would increase the rate and quality of reports among the retail pharmacists | 16 (13) | 48 (39) | 50 (40.7) | 7 (5.7) | 2 (1.6) |
| 15 | I am not convinced that the ADR is caused by the drug | 12 (9.8) | 20 (16.3) | 46 (37.4) | 30 (24.4) | 15 (12.2) |

ADRs=Adverse drug reactions

and would encourage them to actively report any encountered ADRs.

## DISCUSSION

ADRs is one of the main factors of morbidity and mortality for individuals and society. It is considered as a cause of an unreasonable burden on the resources of the health-care systems. SRS is found to be the most efficient method for producing signals to document unexpected reactions of medication.

Iraq-like other countries have had an established pharmacovigilance system since 2010.[4] This system aims to assemble data on ADRs occurring in the country. The system relies on the voluntary reporting of ADRs by health-care professionals in hospitals and retail settings. This study provides the baseline data about ADR encountering among RPs in Baghdad. Conducting another study with larger sample size would be more helpful to demonstrate a stronger conclusion. Furthermore, the findings of this study are reliable with existing previous comprehensive researches conducted globally in several countries.[6-8]

In general, the study findings demonstrated that Iraqi RPs have a good attitude toward ADR reporting. Although the majority of them had never reported any ADRs, ADR reporting was considered an essential part in the pharmaceutical duties of the RPs.[6,9] The most common reasons claimed by the respondents for not reporting ADRs were in consistent with other studies.[10-12]

An ignorance of the direction of ADRs to whom should send and an unavailability of the reporting forms were nominated as the most significant barriers prevent RPs from reporting ADRs. These indicators should impulse the regulatory authorities into action to make their addresses known in addition to working on the availability the reporting forms and accessible to the RPs to motivate them to report ADRs. However, this study also indicated that age, gender, and length of practice do not influence ADR reporting.

The results of the present study demonstrated that the majority of the RPs had insufficient knowledge about the Iraqi Pharmacovigilance System. In that way, almost all of the interviewed pharmacists were not able to define ADRs. This might be due to the lack of proper exposure during the earlier stages of their undergraduate pharmacy education and the probability of poor publicity of the concept among the respondents by the related authorities. Even though, neither the ability to define ADRs and pharmacovigilance nor familiarity with the pharmacovigilance system was associated with ADR encountering. The study results emphasize the serious need to educate and train RPs on ADR reporting. The study results showed that almost all of the surveyed pharmacists relied on the standard information resources to update themselves about drug use. 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 interpret with caution as almost all of the respondents were unfamiliar with existing pharmacovigilance systems in the country, besides the small sample size that was adopted in this reported survey. Presumably, on the whole, these attitudes, perceptions, and barriers might be altered considerably through good educational courses.[13] Nonetheless, the authors are aware of some degree of weaknesses in the study methodology as the survey depends on pharmacists' self-rated evaluation of their personal attitudes and perception, pharmacists may perhaps have felt stressed into filling the survey or may have been reluctant to disclose their practice drawbacks. Likewise, this research was a short time study which may shed imprecision on the answers objectivity and present some exaggeration in pharmacist's attitudes and perception.

## CONCLUSIONS

The study showed that the RPs in Baghdad have a very positive attitude toward ADRs, but unfortunately they are not familiar with the Iraqi SRS. The study findings emphasize the serious need for special education programs to promote ADRs reporting among RPs.

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### Conflicts of interest
There are no conflicts of interest.

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