



## Original article

## Spontaneous adverse drug reaction reporting by community pharmacists: preparedness and barriers

Mohamed Bahlol<sup>a,b,\*</sup>, Mary Bushell<sup>c</sup>, Hani M.J. Khojah<sup>d</sup>, Rebecca Susan Dewey<sup>e</sup><sup>a</sup>Specialty of Pharmaceutical Management and Economics, Department of Pharmacy Practice and Clinical Pharmacy, Faculty of Pharmacy, Egyptian Russian University, Badr City, Cairo Governorate, Egypt<sup>b</sup>Department of Clinical Pharmacy, Faculty of Pharmacy, Jazan University, Saudi Arabia<sup>c</sup>Discipline of Pharmacy, Faculty of Health, University of Canberra, Bruce, Canberra 2617, Australia<sup>d</sup>Department of Clinical and Hospital Pharmacy, College of Pharmacy, Taibah University, P.O. Box 30051, Madinah 41477, Saudi Arabia<sup>e</sup>Sir Peter Mansfield Imaging Centre, School of Physics and Astronomy, University of Nottingham, Nottingham NG7 2RD, United Kingdom

## ARTICLE INFO

## Article history:

Received 2 December 2021

Accepted 12 April 2022

Available online 19 April 2022

## Keywords:

Egypt

Pharmacies

Drug-related side effects and adverse reactions

Surveys and questionnaires

## ABSTRACT

**Background:** Adverse drug reactions (ADRs) are undesired, unintended responses to drugs, and are significantly underreported. Pharmacists are drug experts recognized as custodians of drug safety, who are expected to be prepared for and knowledgeable about ADR reporting.

**Objectives:** To identify Egyptian community pharmacists' preparedness for and perceived barriers to spontaneous ADR reporting.

**Methods:** This cross-sectional study recruited a sample of community pharmacists across Egypt, who were invited to complete a self-administrated questionnaire during April 2020.

**Results:** A total of 923 pharmacists across Egypt responded to the questionnaire. Most pharmacists were knowledgeable about the definition of ADRs (93.9%) and indicated they felt reporting ADRs benefits the patients (82.2%). Despite recognizing their public health value, only a small percentage of participants conveyed familiarity with the reporting process for both paper (19.2%) and electronic (30.4%) forms, indeed 56.6% of participants did not remember what the ADR report form looked like. Moreover, 75.4% of respondents said they felt that community pharmacies are not the right place for reporting, with 49% suggesting that reporting was the responsibility of physicians. However, only 32.1% reported having insufficient time being a barrier to ADR reporting.

**Conclusions:** Community pharmacists in Egypt are not well prepared for spontaneous ADR reporting due to a lack of knowledge about the formal process and not acknowledging their responsibility, although time was not a major barrier. Therefore, this highlights a clear opportunity for improvement likely involving targeted education.

© 2022 The Author(s). Published by Elsevier B.V. on behalf of King Saud University. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

## 1. Introduction

In 1971, the Committee on Safety of Drugs in the UK reported that “No drug which is pharmacologically effective is entirely with-

\* Corresponding author at: Specialty of Pharmaceutical Management and Economics, Department of Pharmacy Practice and Clinical Pharmacy, Faculty of Pharmacy, Egyptian Russian University, Cairo-Suez road, Badr City, Cairo Governorate 11829, Egypt.

E-mail address: [ph\\_hossni@yahoo.com](mailto:ph_hossni@yahoo.com) (M. Bahlol).

Peer review under responsibility of King Saud University.



out hazard. The hazard may be insignificant or may be acceptable in relation to the drug's therapeutic action. Furthermore, not all hazards can be known before a drug is marketed” (Committee on Safety of Drugs 1971). Indeed, a proportion of new drugs with appropriate safety profiles during successful pre-marketing clinical trials are subjected to withdrawal after post-marketing surveillance owing to the emergence of adverse drug events (Siramshetty et al., 2016). Several factors may hinder the identification of possible adverse reactions during early clinical trials. These include the controlled conditions under which the trials are conducted, the short follow-up periods, the selective populations, the relatively small sample sizes, the limited generalizability of drug effects, and the acceptance of intermediate endpoints (Glasser et al., 2007, Ioannidis 2009).

Post-marketing surveillance is a major determinant of drug safety because it captures data on the use of drugs in real-life and also follows their long-term use by large numbers of patients across a range of patient groups. This drug-use monitoring is a cornerstone in pharmacovigilance, which can be broadly defined as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem” (World Health Organization 2020).

Most developed countries and a growing number of developing ones have pharmacovigilance systems under the control of an associated regulatory body (Alshammari et al., 2019). The Egyptian Pharmaceutical Vigilance Centre (EPVC) was established in 2009 under the Egyptian Drug Authority (The Egyptian Pharmaceutical Vigilance Centre 2020). Egypt, like 45% of Arab countries, is a member of the World Health Organization (WHO) Collaborating Center for International Drug Monitoring (Alshammari et al., 2019). The EPVC collects adverse drug reaction (ADR) reports to monitor the safety of marketed drugs and medical devices as a part of its routine tasks. There are currently five means by which ADR reports can be submitted to the EPVC: mail, online, phone call, email, and fax. Reports can be submitted directly by the patient who has experienced an ADR, or indirectly by caregivers or healthcare providers (The Egyptian Pharmaceutical Vigilance Centre 2020).

Pharmacists are healthcare professionals and experts in medications and are recognized as custodians of drugs safety. Therefore, although spontaneous ADR reporting is a voluntary process in Egypt, pharmacists are needed in this role because they are expected to be well-prepared and knowledgeable about it. However, despite Egypt being among the countries with the highest number of pharmacies worldwide (6.5 per 10,000 people) (International Pharmaceutical Federation 2012), their rate of reporting is low, and this has been reflected in the literature (Elsayed and Al-Worafi 2020). Therefore, the aim of this study is to quantify the knowledge of Egyptian community pharmacists in terms of their preparedness, self-preference, biases, and barriers related to ADR reporting.

## 2. Methods

### 2.1. Study design

A cross-sectional survey used a self-administered questionnaire to capture the views and experiences of community pharmacists during April 2020. Data collectors were recruited to visit the selected pharmacies and distribute the questionnaires as either printed forms or online links to electronic forms, according to the pharmacists' preference (see Fig. 1). This drop-and-collect technique of questionnaire distribution usually yields a higher

response rate and reduces selection bias (Walker 1976, Brown 1987). One pharmacist was asked to respond from each pharmacy visited.

### 2.2. Ethical considerations

The guidelines of the Declaration of Helsinki were followed (World Medical Association 2013) and the study protocol was approved by the Institutional Review Board of the Faculty of Pharmacy, Egyptian Russian University (no. ERUFP-PP-17-001). A confidentiality statement was included in the survey form and all participants signed to give informed consent (written or electronic according to the type of form used).

### 2.3. Data collectors

A total of 559 trained pharmacy students from the Faculty of Pharmacy, Egyptian Russian University, were recruited to distribute the forms and collect them back after completion by the pharmacists. Of these data collectors, 42 were assigned to the pilot test, and the remaining 517 each visited two pharmacies within their geographical region during the final study period. The participation of trained undergraduate students in field studies is a component of the pharmacy curriculum in Egypt, especially in courses of pharmaceutical management and pharmacoeconomics. According to the guidelines of the Egyptian Supreme Council of Universities and the National Authority for Quality Assurance and Accreditation of Education, providing professional development and connecting students with the real-life context of the labor market are among the objectives of education (Egyptian Ministry of Higher Education and Scientific Research, Egyptian National Authority for Quality Assurance and Accreditation of Education). The students were instructed to adhere to the preventive measures against COVID-19 infection during pharmacy visits (i.e., wearing facial masks, sanitizing hands before and after each visit, and observing social distancing).

### 2.4. Questionnaire development

To provide a broad and comprehensive context for the domains under investigation, as well as to minimize possible bias, the development of the questionnaire was based on an extensive review of relevant studies, globally (Ovchinnikova E. A. [Ovchinnikova E. A.] 2003, Alraie et al., 2016, Ampadu et al., 2016, Li et al., 2018, Vuković Rodríguez and Juričić 2018, Hughes and Weiss 2019). Moreover, we sought the opinions of eight highly experienced Egyptian community pharmacists to ensure face and content validity of the questionnaire. Some changes were then made according to their comments.

### 2.5. Questionnaire pilot

A pilot was performed, using both printed and electronic forms of the questionnaire, on a random sample of 42 community pharmacies from all over Egypt. In this phase we also requested feedback from the pharmacists about the structure and content of the forms, in addition to other comments, which led to finer amendments. All versions of the questionnaire were produced in the local Arabic language.

### 2.6. Questionnaire content

The questionnaire consisted of two sections with close-ended questions. The first section collected sociodemographic information, and the second section concerned the two domains under investigation, namely the preparedness of Egyptian community

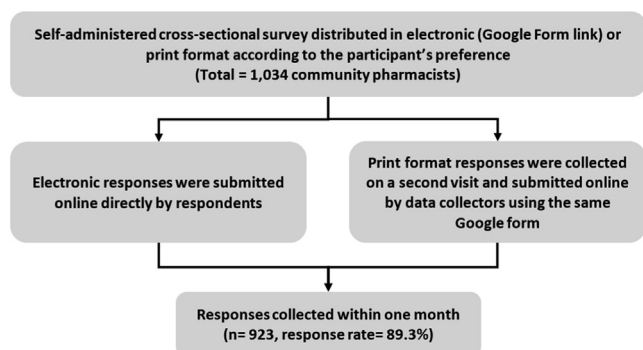


Fig. 1. Study flow chart.

pharmacists to undertake ADR reporting and their perceived barriers preventing them from reporting.

The preparedness domain contained 16 questions under three subdomains: pharmacist knowledge about ADR reporting, the reporting process, and attitudes towards reporting. The barriers domain consisted of 47 questions under four subdomains: the work environment, communication with patients and ADR identification, the reporting process, and specifying the responsibility of reporting and concerns. The questions of the survey instrument, translated into English, is given in the Supplementary material. The internal consistency of the questionnaire was measured using Cronbach's alpha = 0.824.

### 2.7. Pharmacy selection

There are around 70,000 registered community pharmacies in Egypt (Bahlol and Dewey 2021). The sample size was calculated using the formula  $X = Z^2_{\alpha/2} * p * (1-p) / MOE^2$ , where  $Z = 2.576$ , confidence level = 99%, margin of error = 5%, and sample proportion = 50% (Daniel and Cross 2018). This yielded a minimum sample size of 658. However, we were able to include 1,034 pharmacies that were selected by stratified random sampling of Egypt at a regional level based on the proportionate number of sites in each region. Egypt is divided into seven regional units across the Centre (Greater Cairo), North (Delta and Alexandria), South (North, Assiut/Centre, and South of Upper Egypt), and East (Suez Canal) of the country (General Organization for Physical Planning).

### 2.8. Data analysis

All forms were coded before analysis to keep the data analyzer blinded to the pharmacy and pharmacist responding. Analyses were conducted using the Statistical Package for the Social Sciences (SPSS) version 20. Descriptive statistics and comparative analyses between survey items were conducted using Pearson's chi-square tests, where  $p \leq 0.05$  was considered significant. For transparency and due to the presence of a small number of missing values in the data, the tabulated results show both absolute numbers of respondents and the percentage of valid responses.

## 3. Results

### 3.1. Demographics

A total of 923 community pharmacists (out of 1,034) responded to the survey with a response rate of 89.3%. Table 1 summarizes the demographics of the respondents and the basic ADR information as reported by their customers. Incomplete questionnaires were included in the analysis, where the missing data for each variable of interest ranged between 1 and 14 (mean = 4.26, mode of one missing data point per variable).

### 3.2. Pharmacists' preparedness for ADR reporting

#### 3.2.1. Clinical knowledge

It was found that 93.9% of the pharmacists correctly identified the correct definition of an ADR, and those who graduated from governmental universities or worked as senior pharmacists or pharmacy managers were significantly more knowledgeable (Table 2A). In addition, 74.6% of respondents correctly identified when ADRs should be monitored, and 94.7% understood that the causative drug must be identified when reporting an ADR.

**Table 1**  
Demographics of community pharmacists and the ADRs reported by their customers.

Information	n	Valid %
<b>A. Demographics of community pharmacists</b>		
<b>Geographic region</b>		
South	59	6.4%
East	68	7.4%
Centre	159	17.3%
North	632	68.8%
Missing	5	-
<b>Position in pharmacy</b>		
Junior	312	34.0%
Senior	202	22.0%
Manager	404	44.0%
Missing	5	-
<b>Age (years)</b>	36 <sup>a</sup>	22–72 <sup>b</sup>
Missing	10	-
<b>Experience (years)</b>	13 <sup>a</sup>	1–48 <sup>b</sup>
Missing	14	-
<b>Gender</b>		
Man	671	72.9%
Woman	249	27.1%
Missing	3	-
<b>University</b>		
Governmental	762	83.1%
Private	155	16.9%
Missing	6	-
<b>B. Customer ADR information</b>		
<b>Age category</b>		
Adults	132	14.4%
Children	33	3.6%
Both	750	82.0%
Missing	8	-
<b>Severity of reported symptoms</b>		
Mild	265	28.8%
Moderate	281	30.6%
Severe	25	2.7%
Mild and moderate	138	15.0%
Mild and severe	20	2.2%
Moderate and severe	8	0.9%
Mild, moderate, and severe	182	19.8%
Missing	4	-
<b>Types of drugs</b>		
Prescribed	251	27.3%
Over the counter	27	2.9%
Both	640	69.7%
Missing	5	-
<b>Source of drugs</b>		
Synthesized	389	42.7%
Natural	13	1.4%
Both	510	55.9%
Missing	11	-

ADR = adverse drug reaction.

<sup>a</sup> Mean.

<sup>b</sup> Range.

### 3.2.2. Knowledge about the reporting process

As shown in Table 2B, only 19.2% of pharmacists were familiar with the paper reporting process. Women, graduates of private colleges, junior pharmacists, and pharmacists working in Central Egypt reported significantly higher levels of familiarity. In addition, only 30.4% of respondents were familiar with electronic reporting, with junior pharmacists and those from Central Egypt being the most familiar. Not knowing where to report and believing that ADR reporting is a new issue were agreed with by 51.4% and 75.6% of pharmacists, respectively, and there were no significant differences between the demographics of respondents agreeing.

### 3.2.3. Attitudes towards ADR reporting

The majority of pharmacists disagreed that reporting ADRs would not benefit patients (82.2%), and that it is not necessary to report ADRs for over-the-counter, prescribed, natural, or synthetic drugs (73.3%, 87%, 75.6%, and 89.7%, respectively). Over a third

**Table 2**  
Preparedness and attitudes of community pharmacists towards ADR reporting and association with demographic factors.

Factor	n (%) <sup>a</sup>	Sex (%) <sup>b</sup>			University of graduation (%) <sup>b</sup>			Position in pharmacy (%) <sup>b</sup>				Region (%) <sup>b</sup>				
		Male	Female	P <sup>c</sup>	Government	Private	P <sup>c</sup>	Junior	Senior	Manager	P <sup>c</sup>	South	East	Center	North	P <sup>c</sup>
<i>A. Clinical knowledge</i>																
The correct definition of an ADR	852 (93.9)	93.8	94.3	NS	94.7	90.3	0.039	90.3	96.0	95.7	0.005	89.7	89.6	94.3	94.7	NS
Knowing when ADRs are monitored	684 (74.6)	74.8	73.4	NS	75.3	70.8	NS	73.0	69.8	78.2	NS	69.5	76.5	70.9	75.5	NS
Knowing that the causative drug must be identified	868 (94.7)	93.9	96.8	NS	94.9	94.2	NS	95.2	92.6	95.3	NS	91.5	97.1	93.1	95.1	NS
Familiarity with the types of ADRs	592 (64.9)	18.5	22.5	NS	64.6	67.1	NS	67.6	60.7	64.9	NS	64.4	72.1	68.4	63.5	NS
<i>B. knowledge about the reporting process</i>																
Familiarity with paper reporting	176 (19.2)	27.8	37.8	0.004	17.9	26.5	0.014	24.4	13.4	18.1	0.006	22.0	19.1	27.0	17.1	0.040
Familiarity with electronic reporting	278 (30.4)	65.5	63.7	NS	29.4	36.1	NS	34.9	31.7	26.2	0.038	25.4	26.5	43.0	28.4	0.003
Familiarity with the correct use of the reporting system	366 (40.0)	39.8	41.8	NS	39.0	45.8	NS	44.2	43.1	35.2	0.032	57.6	39.7	44.3	37.6	0.016
Not knowing where to report ADRs	470 (51.4)	51.6	50.6	NS	50.9	52.9	NS	54.7	47.0	51.1	NS	49.2	54.4	49.1	51.8	NS
Identifying and reporting ADRs is a new issue in Egypt	693 (75.6)	75.9	73.8	NS	75.7	74.0	NS	75.6	74.8	76.0	NS	72.9	67.6	75.9	76.4	NS
<i>C. Pharmacist attitudes toward ADR reporting</i>																
Reporting will not benefit the patients	163 (17.8)	18.7	15.3	NS	18.5	13.6	NS	18.0	13.4	19.8	NS	18.6	7.4	24.7	17.1	0.015
It is not necessary to report ADRs to OTC drugs	245 (26.7)	26.7	26.5	NS	26.5	27.1	NS	28.8	23.3	26.8	NS	27.1	19.1	35.2	25.4	0.037
It is not necessary to report ADRs to prescribed medications	119 (13.0)	14.5	9.2	0.035	12.8	14.8	NS	13.8	8.5	14.6	NS	5.2	9.0	17.0	13.3	NS
It is not necessary to report ADRs to natural medicines	224 (24.4)	25.2	22.1	NS	23.8	28.4	NS	28.8	22.3	22.1	NS	23.7	23.5	30.8	23.0	NS
It is not necessary to report ADRs to synthetic medicines	94 (10.3)	11.2	8.0	NS	10.0	12.3	NS	11.5	7.9	10.4	NS	8.5	10.3	10.7	10.5	NS
ADRs should only include new drugs (<3 years on the market)	361 (39.4)	39.6	39.8	NS	38.0	47.7	0.023	42.3	40.8	36.4	NS	48.3	45.6	46.5	36.2	0.029
It is not necessary to report ADRs to older drugs	459 (50.1)	50.9	48.0	NS	49.4	53.9	NS	50.6	47.0	51.2	NS	64.4	44.1	54.1	48.4	NS

**ADR**, adverse drug reaction; **NS**, non-significant; **OTC**, over the counter.

<sup>a</sup> Valid percentage of respondents who answered positively.

<sup>b</sup> Valid percentage of respondents who answered positively within the related group.

<sup>c</sup> Pearson's chi-square test. Significance at  $p \leq 0.05$ .

(39.4%) of respondents said that ADRs should only be reported for new drugs (i.e., those that came to market during the last three years). Consistent with this finding, 50.1% of pharmacists stated that it is unnecessary to report ADRs related to older drugs (Table 2C).

### 3.3. Pharmacist's perceived barriers against ADR reporting

#### 3.3.1. The work environment

As shown in Table 3A, the main barrier reported was the perception that the community pharmacy is not the right place for reporting (75.4%). In addition, 63.7% of pharmacists reported that they did not see many ADRs worth reporting (significantly more

frequent in women, graduates of private universities, and participants from Central and Northern Egypt). Conversely, a small proportion agreed that unavailability of an internet connection or sufficient time were barriers to reporting (28.1% and 32.1%, respectively).

#### 3.3.2. Communication with patients and ADR identification

Most participants reported being uncertain whether the drug was the cause, being uncertain whether the patient was harmed, and not trusting what the patient says to have been among the factors behind underreporting ADRs (80.9%, 65.4%, and 73.2%, respectively, Table 3B).

**Table 3**  
Barriers to ADR reporting and association with demographic factors.

Factor	n (%) <sup>a</sup>	Sex (%) <sup>b</sup>			University of graduation (%) <sup>b</sup>			Position in pharmacy (%) <sup>b</sup>				Region (%) <sup>b</sup>				
		Male	Female	P <sup>c</sup>	Government	Private	P <sup>c</sup>	Junior	Senior	Manager	P <sup>c</sup>	South	East	Center	North	P <sup>c</sup>
<i>A. The work environment</i>																
There is no time for reporting	293 (32.1)	32.2	31.5	NS	31.6	34.6	NS	32.7	31.0	32.1	NS	28.8	42.6	31.0	31.2	NS
The community pharmacy is not the right place for reporting	690 (75.4)	74.9	75.9	NS	74.5	80.5	NS	73.0	74.1	77.9	NS	79.7	69.1	72.3	76.3	NS
There are not many ADRs that are worth reporting	583 (63.7)	61.8	68.8	0.049	61.9	71.6	0.022	64.6	59.4	65.2	NS	45.8	58.8	64.8	65.7	0.018
Unavailability of an internet connection	258 (28.1)	27.6	29.3	NS	28.4	26.5	NS	34.4	24.8	25.0	0.010	35.6	37.3	29.6	26.1	NS
<i>B. Communication with patients and ADR identification</i>																
Uncertainty about whether the drug is the cause	742 (80.9)	81.1	79.8	NS	80.4	81.9	NS	81.7	80.7	80.4	NS	74.6	92.5	86.8	78.5	0.004
Difficulties in obtaining information from the patients	698 (76.0)	75.3	77.5	NS	77.0	71.0	NS	76.9	81.7	72.5	0.041	83.1	82.4	76.7	74.5	NS
Concerns about patient confidentiality	541 (59.0)	59.0	58.2	NS	58.3	61.9	NS	64.7	53.0	57.6	0.022	59.3	64.7	57.9	58.5	NS
Concerns about affecting the patient's trust in the pharmacist	605 (66.2)	66.5	64.5	NS	65.7	68.0	NS	69.1	59.7	67.2	NS	69.5	64.7	63.7	66.5	NS
Uncertainty about whether the patient is harmed	598 (65.4)	64.7	67.1	NS	65.7	63.9	NS	68.6	61.9	64.6	NS	76.3	61.8	67.3	64.2	NS
No contact with the patients	441 (48.1)	48.4	47.4	NS	48.7	45.8	NS	52.3	50.0	44.1	NS	52.5	37.3	53.8	47.5	NS
Patients are uncooperative	568 (62.1)	62.5	61.5	NS	62.5	59.7	NS	65.0	66.5	57.8	NS	60.3	58.8	67.7	61.3	NS
Mistrust in what the patient says	670 (73.2)	72.9	74.2	NS	71.6	81.8	0.009	77.5	75.2	68.9	0.028	71.2	79.1	78.5	71.5	NS
<i>C. The reporting process</i>																
Not knowing where the paper report form should be submitted	594 (64.9)	64.4	65.1	NS	64.8	64.5	NS	61.1	67.7	66.5	NS	67.8	64.7	54.7	67.1	0.033
The paper report form is too complicated	385 (42.3)	42.3	41.8	NS	41.2	47.1	NS	45.7	39.7	40.9	NS	39.7	39.7	41.1	43.1	NS
No access to the paper report form	736 (80.8)	80.2	82.6	NS	80.7	82.6	NS	83.5	74.8	81.5	0.036	81.0	79.4	75.9	82.1	NS
Not enough information about ADRs	322 (35.3)	33.6	39.1	NS	34.0	41.3	NS	46.0	37.6	25.9	< 0.001	45.6	49.3	40.3	31.5	0.003
Uncertainty about whether the drug is the cause	526 (57.6)	54.3	66.4	0.001	57.7	57.8	NS	64.1	56.7	53.1	0.013	62.7	65.7	62.3	54.9	NS
Not enough information about how to identify ADRs	460 (50.3)	49.0	53.0	NS	49.7	52.6	NS	55.4	53.5	44.6	0.010	64.4	51.5	51.6	48.5	NS
Reporting is time consuming	320 (35.0)	35.5	33.3	NS	33.9	40.3	NS	40.8	36.0	30.0	0.010	33.9	25.0	38.9	35.2	NS
Not knowing/remembering what the paper form looks like	518 (56.5)	57.9	51.8	NS	58.7	45.2	0.002	55.1	52.0	59.8	NS	59.3	47.1	59.1	56.4	NS
Not having the information needed for reporting	640 (70.0)	68.9	72.1	NS	70.5	67.5	NS	71.0	68.3	70.1	NS	72.9	67.6	62.3	71.8	NS
It is difficult to get copies of the paper report form	714 (78.3)	78.8	76.6	NS	78.9	75.2	NS	78.5	73.3	80.6	NS	86.4	80.9	79.1	77.0	NS
Online electronic reporting is difficult	547 (60.0)	59.9	59.8	NS	60.8	55.6	NS	56.3	54.8	65.4	0.011	62.7	55.9	56.1	61.1	NS
Unclear what ADRs are	489 (53.4)	51.7	57.5	NS	51.4	62.7	0.011	55.0	53.7	52.0	NS	47.5	52.9	55.7	53.4	NS
Not enough information about the reporting process	691 (75.4)	74.9	75.9	NS	75.7	72.9	NS	76.6	68.7	77.7	0.042	67.8	64.7	71.7	78.0	0.024
<i>D. Responsibility</i>																
I want to publish the case in my name and not just report it	209 (22.8)	23.5	20.6	NS	22.1	26.0	NS	24.4	26.9	19.6	NS	22.0	22.1	21.5	23.3	NS
Concerns about legal issues that may arise from reporting	352 (38.5)	38.8	37.5	NS	37.0	46.1	0.035	42.1	35.5	37.2	NS	39.7	23.5	39.0	39.9	NS
Reporting is the responsibility of the physician, not the pharmacist	196 (21.5)	23.8	16.5	0.017	21.1	23.9	NS	26.5	14.9	21.0	0.008	22.8	27.9	22.0	20.6	NS
Reporting is the responsibility of the hospital pharmacist, not the community pharmacist	213 (23.3)	24.8	18.9	NS	21.7	30.3	0.021	25.0	21.8	22.6	NS	28.8	16.2	27.8	22.2	NS
Reporting is the responsibility of the clinical pharmacist, not the community pharmacist	268 (29.3)	30.7	25.0	NS	28.1	35.7	NS	29.0	27.2	30.6	NS	30.5	25.4	34.8	28.1	NS
Reporting is not important	106 (11.6)	12.2	10.0	NS	12.1	9.7	NS	11.2	12.9	11.1	NS	10.2	7.5	8.8	13.0	NS
Reporting may negatively affect the pharmacist's job	135 (14.7)	15.4	12.9	NS	13.4	21.3	0.012	18.0	13.4	12.9	NS	13.8	8.8	15.7	15.1	NS
Reporting an ADR for a single case makes no difference	404 (44.3)	45.7	39.8	NS	43.8	46.4	NS	47.1	44.1	42.3	NS	33.9	30.3	48.1	45.8	0.025
Licensed medicines are safe	443 (48.5)	47.2	52.8	NS	47.9	52.3	NS	60.6	40.8	42.9	< 0.001	42.1	42.6	41.1	51.3	NS
Nothing obliges pharmacists to report or prevents them from reporting	625 (98.1)	69.3	65.1	NS	68.6	65.8	NS	66.0	64.9	71.3	NS	49.2	52.9	68.6	71.4	< 0.001
Assume the doctor will report	447 (49.0)	49.6	47.2	NS	48.7	49.7	NS	55.0	43.1	47.3	0.020	50.5	54.4	51.9	47.3	NS
Assume the nurse will report	235 (25.7)	24.0	29.4	NS	25.6	26.5	NS	31.2	25.0	21.8	0.017	19.0	30.9	32.1	24.2	NS
Assume the patients will report	388 (42.4)	41.0	45.4	NS	41.4	46.5	NS	47.7	41.6	38.6	0.049	42.4	45.6	38.2	42.9	NS
Assume someone from the patient's family will report	363 (39.5)	38.5	41.8	NS	39.0	42.6	NS	44.2	36.1	37.6	NS	37.3	39.7	37.7	40.4	NS
Difficulty communicating with the treating medical team	603 (65.8)	66.9	62.5	NS	66.5	63.2	NS	68.5	57.4	67.8	0.018	71.2	60.3	70.4	64.7	NS
Concerns about having to follow up with the patient after reporting	401 (43.8)	44.9	39.9	NS	44.2	41.2	NS	47.4	40.1	42.8	NS	45.8	42.6	43.7	43.7	NS
Reporting ADRs is not a priority	182 (19.8)	22.5	12.9	0.001	20.9	15.5	NS	19.9	13.4	23.0	0.019	22.0	16.2	20.1	19.9	NS
If the ADR is severe, the patient must be referred to the physician, who will accordingly report	591 (64.7)	66.4	59.8	NS	65.3	62.3	NS	67.5	60.9	64.4	NS	65.5	50.0	68.2	65.2	NS
Worried that I am incorrect to report	518 (56.5)	53.2	64.9	0.001	55.5	61.3	NS	65.6	55.0	50.2	<0.001	49.2	58.8	56.0	56.9	NS

Table 3 (continued)

Factor	n (%) <sup>a</sup>	Sex (%) <sup>b</sup>		University of graduation (%) <sup>b</sup>			Position in pharmacy (%) <sup>b</sup>			Region (%) <sup>b</sup>					
		Male	Female	Government	Private	P <sup>c</sup>	Junior	Senior	Manager	P <sup>c</sup>	South	East	Center	North	P <sup>c</sup>
The drug is already known to cause ADRs	680 (74.4)	73.4	77.8	74.0	76.1	NS	77.1	71.8	73.6	NS	69.5	70.1	78.0	74.4	NS
ADRs are not dangerous enough to report	535 (58.5)	57.8	60.7	61.4	45.2	< 0.001	60.0	56.2	58.4	NS	62.7	50.7	59.1	58.7	NS
Reporting is necessary only when several patients have the same reaction	595 (65.0)	64.6	66.7	65.1	63.9	NS	71.8	62.4	60.9	0.007	55.9	75.0	68.6	63.8	NS

ADR, adverse drug reaction; NS, non-significant.

<sup>a</sup> Valid percentage of respondents who answered positively.

<sup>b</sup> Valid percentage of respondents who answered positively within the related group.

<sup>c</sup> Pearson's chi-square test. Significance at p ≤ 0.05.

### 3.3.3. The reporting process

Most pharmacists (80.8%) indicated that they did not have access to the paper report form, and more than half (56.5%) did not remember what the paper form looks like, whereas 64.9% did not know where to send the ADR paper report (Table 3C).

### 3.3.4. Responsibility

More than one-fifth of the surveyed community pharmacists believed that reporting is the responsibility of physicians, hospital pharmacists, or clinical pharmacists (21.5%, 23.3%, and 29.3%, respectively, Table 3D). However, 65% of participants related reporting an ADR only when several patients complain about having the same reaction (and this was significantly more common in managers).

## 4. Discussion

Consistent with the international and regional literature, this study found that pharmacists' self-reported general knowledge on ADRs was high (Abdel-Latif and Abdel-Wahab 2015, Alsaleh et al., 2017). However, despite pharmacists having a good level of knowledge of what an ADR is and the importance of reporting ADRs for synthetic, natural, and over-the-counter drugs (see Table 1B), respondents demonstrated a startling lack of knowledge about the reporting process. This highlights a major barrier, as pharmacists' understanding of this process is fundamental to improving post-marketing surveillance, which is indeed the cornerstone of any pharmacovigilance activity. In addition, this study revealed an apparent knowledge deficit in understanding, in respondents representing all levels of pharmacist across Egypt, of where to report ADRs. There was also a lack of familiarity with, and access to, paper and electronic reporting formats. Interestingly, there were more significant barriers associated with the paper reporting process than with the electronic reporting process. Given the relatively recent introduction of the Egyptian Pharmacovigilance Centre in 2009, this finding is informative but not surprising, as it is consistent with studies conducted in other Arab countries (Said and Hussain 2017).

Given the importance of pharmacovigilance, this knowledge gap needs to be addressed. Interestingly, junior pharmacists were more familiar with both paper and electronic reporting formats than their senior colleagues. This is likely a reflection of university training and education delivered in relation to pharmacovigilance in recent years. Therefore, there is a need for a targeted pharmacovigilance training program or continuing professional development (CPD) for more senior pharmacy alumni.

Research into pharmacovigilance in developing countries has identified several practical interventions. These have included the development of easily accessible and straightforward report forms, incentives such as bonus CPD points, and further educational interventions for qualified pharmacists and pharmacy students (Elshafie et al., 2018). In addition, research conducted internationally has indicated that integrating ADR training improves students' knowledge, perceptions, and reporting rates (Zawahir et al., 2015).

In the context of existing evidence, this research has exposed a true need for educational interventions to promote the awareness of ADRs and how they are to be reported (Qassim et al., 2014, Suyagh et al., 2015, Alraie et al., 2016). An educational intervention on ADR reporting aimed at hospital pharmacists in Egypt increased knowledge, reduced barriers, and was demonstrated to be easy to use and not time-consuming (Alraie et al., 2016). Thus, there is potential value in expanding this education to community pharmacists.

The importance of spontaneous ADR reporting cannot be understated. Studies have consistently shown that improving pharma-

cists' knowledge around pharmacovigilance, together with attitudes and practice, has resulted in increased ADR reporting (Ahmad et al., 2013). This contributes to a better understanding of drug quality and safety and the incidence of adverse reactions, thereby preventing avoidable adverse reactions, which ultimately improves health outcomes (Sahu et al., 2014).

The perception that the community pharmacy is not the right place for ADR reporting was the most frequent workplace environment barrier reported by the community pharmacists in this study. Conversely, another Egyptian study that included 281 hospital pharmacists, where 96.4% of respondents indicated that ADR reporting should be the responsibility of pharmacists, and that reporting by hospital pharmacists is preferable to reporting by physicians, nurses, or patients (Alraie et al., 2016). Therefore, the findings of the present study emphasize the need for education on ADR reporting and the roles and responsibilities of community pharmacists in this regard.

Finally, this study has also highlighted that lack of time was cited as a barrier to ADR reporting by only 32.1% of Egyptian community pharmacists. This contradicts the findings of some studies conducted in the UK and Poland that identified lack of time to be a common reason for underreporting (Hughes and Weiss 2019, Kopciuch et al., 2019). As such, once other barriers have been addressed, it is not anticipated that issues of time will prevent Egyptian community pharmacists from improving spontaneous ADR reporting rates.

#### 4.1. Study limitations

This study collected data and provided insight into ADR reporting in only one low-to-middle-income country, namely Egypt, at one timepoint. As such many of these findings cannot be generalized to other high-income Arab or non-Arab countries as many of these findings will be specific to the country or socioeconomic status of the region. Conversely other findings represent universal problems that can be seen across developed and developing countries alike. Future studies observing the changes in these metrics following interventions will give insight into how modifiable the reported barriers are.

## 5. Conclusions

As drug custodians, pharmacists have an essential role in reporting ADRs to improve drug safety. This study has shown that Egyptian community pharmacists have insufficient preparedness, particularly a lack of proper knowledge about the ADR reporting process itself. In addition, the major barrier identified was not the lack of time in the workplace but the unfamiliarity with the reporting process. Therefore, this research highlights a good opportunity for improving ADR reporting by Egyptian community pharmacists. A targeted educational intervention is needed for practicing community pharmacists in this country. Finally, greater emphasis should be placed on appropriate education on pharmacovigilance and ADR reporting in pharmacy school curricula across Egypt.

## Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

## Data Availability Statement

The dataset presented in this article is available only upon reasonable request since it contains confidential information.

Requests to access the dataset should be directed to the corresponding author (ph\_hossni@yahoo.com).

## CRedit authorship contribution statement

**Mohamed Bahlol:** Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. **Mary Bushell:** Writing – original draft, Writing – review & editing. **Hani M. J. Khojah:** Formal analysis, Writing – original draft, Writing – review & editing. **Rebecca Dewey:** Writing – original draft, Writing – review & editing.

## Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

## Acknowledgment

The authors would like to thank all respondent community pharmacies for their participation, and all the undergraduate students who were trained for the interviews and data collection.

## Appendix A. Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jpsps.2022.04.006>.

## References

- Abdel-Latif, M.M.M., Abdel-Wahab, B.A., 2015. Knowledge and awareness of adverse drug reactions and pharmacovigilance practices among healthcare professionals in Al-Madinah Al-Munawwarah, Kingdom of Saudi Arabia. *Saudi Pharmaceut. J.* 23, 154–161. <https://doi.org/https://doi.org/10.1016/j.jpsps.2014.07.005>.
- Ahmad, A., Balkrishnan, R., Manna, P.K., Mohanta, G.P., Patel, I., 2013. An evaluation of knowledge, attitude and practice of Indian pharmacists towards adverse drug reaction reporting: A pilot study. *Perspect. Clin. Res.* 4 (4), 204. <https://doi.org/10.4103/2229-3485.120168>.
- Alraie, N.A., Saad, A.A., Sabry, N.A., Farid, S.F., 2016. Adverse drug reactions reporting: a questionnaire-based study on Egyptian pharmacists' attitudes following an awareness workshop. *J. Evaluation Clin. Pract.* 22 (3), 349–355.
- Alsaleh, F.M., Alzaid, S.W., Abahussain, E.A., Bayoud, T., Lemay, J., 2017. Knowledge, attitude and practices of pharmacovigilance and adverse drug reaction reporting among pharmacists working in secondary and tertiary governmental hospitals in Kuwait. *Saudi Pharmaceut. J.* 25 (6), 830–837.
- Alshammari, T.M., Mendi, N., Alenzi, K.A., Alsowaida, Y., 2019. Pharmacovigilance systems in Arab countries: overview of 22 Arab countries. *Drug Saf.* 42 (7), 849–868. <https://doi.org/10.1007/s40264-019-00807-4>.
- Ampadu, H.H., Hoekman, J., de Bruin, M.L., Pal, S.N., Olsson, S., Sartori, D., Leufkens, H.G.M., Doodoo, A.N.O., 2016. Adverse drug reaction reporting in Africa and a Comparison of Individual Case Safety Report Characteristics Between Africa and the Rest of the World: Analyses of Spontaneous Reports in VigiBase®. *Drug Saf.* 39 (4), 335–345. <https://doi.org/10.1007/s40264-015-0387-4>.
- Bahlol, M., Dewey, R.S., 2021. Pandemic preparedness of community pharmacies for COVID-19. *Res. Social Adm Pharm.* 17 (1), 1888–1896. <https://doi.org/10.1016/j.sapharm.2020.05.009>.
- Brown, S., 1987. Drop and collect surveys: A neglected research technique? *Marketing Intell. Plann.* 5, 19–23. <https://doi.org/10.1108/eb045742>.
- Committee on Safety of Drugs, 1971. Report for 1969 and 1970. HMSO, London.
- Daniel, W.W., Cross, C.L., 2018. Biostatistics: a foundation for analysis in the health sciences, Wiley, from <http://docshare02.docshare.tips/files/22448/224486444.pdf>.
- Egyptian Ministry of Higher Education and Scientific Research. Higher Education Strategy. Retrieved December 20, 2020, from [http://portal.mohe.gov.eg/ar-eg/Documents/mohe\\_strategy.pdf](http://portal.mohe.gov.eg/ar-eg/Documents/mohe_strategy.pdf).
- Egyptian National Authority for Quality Assurance and Accreditation of Education. Guidelines. Retrieved December 20, 2020, from <https://naqaae.gov.eg/guidelines>.
- Elsayed, T., Al-Worafi, Y.M., 2020. Chapter 37 – Drug safety in Egypt. *Drug Safety in Developing Countries*. Y. Al-Worafi, Academic Press: 511–523, from <https://www.sciencedirect.com/science/article/pii/B9780128198377000376>.

- Elshafie, S., Roberti, A.M., Zaghloul, I., 2018. Pharmacovigilance in developing countries (part II): a path forward. *Int. J. Clin. Pharm.* 40, 764–768. <https://doi.org/10.1007/s11096-017-0588-2>.
- General Organization for Physical Planning. Geographic Maps of Egypt. Retrieved December 20, 2020, from <http://gopp.gov.eg/eg-map/>.
- Glasser, S.P., Salas, M., Delzell, E., 2007. Importance and challenges of studying marketed drugs: what is a phase IV study? Common clinical research designs, registries, and self-reporting systems. *J. Clin. Pharmacol.* 47, 1074–1086. <https://doi.org/10.1177/0091270007304776>.
- Hughes, M.L., Weiss, M., 2019. Adverse drug reaction reporting by community pharmacists-The barriers and facilitators. *Pharmacoepidemiol. Drug Saf.* 28 (12), 1552–1559. <https://doi.org/10.1002/pds.4800>.
- International Pharmaceutical Federation, 2012. FIP Global Pharmacy Workforce Report. Retrieved December 20, 2020, from <https://www.fip.org/file/1414>.
- Ioannidis, J.P.A., 2009. Adverse events in randomized trials: neglected, restricted, distorted, and silenced. *Arch Int. Med. United States.* 169 (19), 1737. <https://doi.org/10.1001/archinternmed.2009.313>.
- Kopciuch, D., Zaprutko, T., Paczkowska, A., Ratajczak, P., Zielińska-Tomczak, Ł., Kus, K., Nowakowska, E., 2019. Safety of medicines—Pharmacists' knowledge, practice, and attitudes toward pharmacovigilance and adverse drug reactions reporting process. *Pharmacoepidemiol. Drug Saf.* 28 (12), 1543–1551.
- Li, R., Curtain, C., Bereznicki, L., Zaidi, S.T.R., 2018. Community pharmacists' knowledge and perspectives of reporting adverse drug reactions in Australia: a cross-sectional survey. *Int. J. Clin. Pharm.* 40 (4), 878–889. <https://doi.org/10.1007/s11096-018-0700-2>.
- Qassim, S., Metwaly, Z., Shamsain, M., et al., 2014. Reporting adverse drug reactions: evaluation of knowledge, attitude and practice among community pharmacists in UAE. *IOSR J. Pharm.* 22, 31–40. [https://doi.org/10.13040/IJPSR.0975-8232.5\(10\).4203-08](https://doi.org/10.13040/IJPSR.0975-8232.5(10).4203-08).
- Sahu, R.K., Yadav, R., Prasad, P., Roy, A., Chandrakar, S., 2014. Adverse drug reactions monitoring: prospects and impending challenges for pharmacovigilance. *Springerplus.* 3 (1). <https://doi.org/10.1186/2193-1801-3-695>.
- Said, A.S.A., Hussain, N., 2017. Adverse drug reaction reporting practices among United Arab Emirates pharmacists and prescribers. *Hospital Pharm.* 52 (5), 361–366. <https://doi.org/10.1177/0018578717715364>.
- Siramshetty, V.B., Nickel, J., Omieczynski, C., Gohlke, B.-O., Drwal, M.N., Preissner, R., 2016. WITHDRAWN—a resource for withdrawn and discontinued drugs. *Nucleic Acids Res.* 44 (D1), D1080–D1086. <https://doi.org/10.1093/nar/gkv1192>.
- Suyagh, M., Farah, D., Farha, R.A., 2015. Pharmacist's knowledge, practice and attitudes toward pharmacovigilance and adverse drug reactions reporting process. *Saudi Pharmaceut. J.* 23, 147–153. <https://doi.org/10.1016/j.jps.2014.07.001>.
- The Egyptian Pharmaceutical Vigilance Centre, 2020. Guidelines. Retrieved December 20, 2020, from <http://www.epvc.gov.eg/>.
- Vuković Rodríguez, J., Juričić, Ž., 2018. Perceptions and attitudes of community pharmacists toward professional ethics and ethical dilemmas in the workplace. *Res. Social Adm. Pharm.* 14 (5), 441–450. <https://doi.org/10.1016/j.sapharm.2017.05.010>.
- Walker, R.L., 1976. Social Survey Techniques: A Note on the 'Drop and Collect' Method. *Area* 8, 284–288. <https://doi.org/https://www.jstor.org/stable/20001144>.
- World Health Organization, 2020. Pharmacovigilance. Retrieved December 20, 2020, from [https://www.who.int/teams/regulation-prequalification-pharmacovigilance#:~:text=%E2%80%9CPharmacovigilance%20%E2%80%9D%20\(PV\)%20is,any%20other%20drug%20related%20problem.&text=The%20ability%20to%20review%20the,available%20requires%20functional%20pharmacovigilance%20systems](https://www.who.int/teams/regulation-prequalification-pharmacovigilance#:~:text=%E2%80%9CPharmacovigilance%20%E2%80%9D%20(PV)%20is,any%20other%20drug%20related%20problem.&text=The%20ability%20to%20review%20the,available%20requires%20functional%20pharmacovigilance%20systems).
- World Medical Association, 2013. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA* 310, 2191–2194. <https://doi.org/10.1001/jama.2013.281053>.
- Zawahir, S., Sultan, R., Asmani, M., et al., 2015. Pharmacy students' knowledge and perceptions of adverse drug reactions and reporting. *Pharmaceut. J. Sri Lanka.* 5, [https://doi.org/https://scholar.google.com/scholar?hl=en&as\\_sdt=0%2C5&q=Zawahir%2C+S.%2C+R.+Sultan%2C+M.+Asmani%2C+et+al.%2C+2015.+Pharmacy+students%E2%80%99+knowledge+and+perceptions+of+adverse+drug+reactions+and+reporting.+Pharmaceutical+Journal+of+Sri+Lanka.+5%2C++&btnG](https://doi.org/https://scholar.google.com/scholar?hl=en&as_sdt=0%2C5&q=Zawahir%2C+S.%2C+R.+Sultan%2C+M.+Asmani%2C+et+al.%2C+2015.+Pharmacy+students%E2%80%99+knowledge+and+perceptions+of+adverse+drug+reactions+and+reporting.+Pharmaceutical+Journal+of+Sri+Lanka.+5%2C++&btnG).
- Овчинникова Е. А. [Ovchinnikova E. A.], 2003. Роль мониторинга безопасности лекарственных средств в решении проблемы их рационального использования [in Russian] [The role of drug safety monitoring in solving the problem of their rational use]. *КАЧЕСТВЕННАЯ КЛИНИЧЕСКАЯ ПРАКТИКА [Good Clinical Practice]*. 4, 88–95. <https://doi.org/https://www.clinvest.ru/jour/article/view/302>.